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TABLE OF CONTENTS

INVITED PAPERS

T.Bajd , A.Kralj, M.Štefančič, N.Lavrač (Ljubljana, Slovenia): FES ASSISTED WALKING IN INCOMPLETE SCI SUBJECTS: AN OVERVIEW	1
H.Kern , Ch.Hofer, M.Strohhofer, W.Mayr, W. Richter, H. Stöhr (Vienna, Austria): STANDING-UP WITH DENERVATED MUSCLES IN HUMAN USING FES	11
S.Salmons (Liverpool, U.K.): PERMANENT CARDIAC ASSISTANCE FROM SKELETAL MUSCLE: A PROSPEKT FOR THE NEW MILLENIUM	19

SESSION 1 ASPECTS OF LONG-TERM STIMULATION

A.Shah , V.Nagao, V.Sahgal, H.Singh (Cleveland, OH, USA): EFFECT OF NERVE STIMULATION ON RAT SKELETAL MUSCLE. A STUDY OF PLASMA MEMBRANE	29
A.Shah , V.Sahgal, M.Marzocchi, R.Brouillette (Cleveland, OH, USA): EFFECTS OF DIAPHRAGMATIC PACING ON IMMATURE CANINE DIAPHRAGM	33
E.D.H.Zonnevijlle , N.N.Somia, G.P.Abadia, R.W.Stremel, C.Maldonado, P.M.N.Werker, M.Kon, J.H.Barker (Nieuwegein, The Netherlands): THREE PARAMETERS OPTIMIZING CLOSED LOOP CONTROL IN SEQUENTIAL SEGMENTAL NEUROMUSCULAR STIMULATION	37

SESSION 2 LATISSIMUS DORSI, CARDIAC ASSISTANCE

U.Carraro , G.Docali, M.Barbiero, K.Gealow, D.Casarotto, C.Muneretto (Padova, Italy): NEW NON-INVASIVE MONITORING AND LIGHTER DEMAND STIMULATION OF LD WRAP IN DYNAMIC CARDIOMYOPLASTY: RATIONALE OF THE IMPROVED CLINICAL RESULTS	41
W.Haslik , L.P.Kamolz, W.Girsch, R.Koller, M.Rab, H.G.Stöhr, H.Gruber (Vienna, Austria): FUNCTIONAL AND MORPHOLOGICAL TRANSFORMATION OF THE LATISSIMUS DORSI MUSCLE DURING MUSCLE CONDITIONING BY MULTICHANNEL STIMULATION	45
L.P.Kamolz , W.Haslik, W.Girsch, H.Lanmüller, M.Rab, R.Koller, H.Gruber (Vienna, Austria): DAMAGE OF THE LATISSIMUS DORSI MUSCLE DUE TO VASCULAR DELAY TECHNIQUE AND PRECONDITIONING FOR THE USE AS AN ASSISTING SKELETAL MUSCLE: FIRST RESULTS OF AN HISTOMORPHOLOGICAL ANALYSIS	49
M.Rab , W.Girsch, R.Koller, R.Seitelberger, H.Lanmüller, W.Haslik, L.P.Kamolz, U.Windberger, H.Schima, H.G.Stöhr, M.Frey (Vienna, Austria): ELECTRICALLY STIMULATED BIOLOGICAL NEO-VENTRICLE FOR AORTIC COUNTERPULSATION: AN ANIMAL EXPERIMENT IN SHEEP	53

TABLE OF CONTENTS

G.Wipplinger , M.Rab, W.Girsch, R.Koller, W.Haslik, L.P.Kamolz, S.Sauermann, H.Lanmüller, H.Schima (Vienna, Austria): A COMPUTER-MODEL FOR THE EVALUATION OF THE HEMODYNAMIC EFFICACY OF A SKELETAL MUSCLE VENTRICLE IN COUNTERPULSATION MODE	57
J.C.Jarvis , D.M.Pullan, A.P.Shortland, S.Salmons (Liverpool, U.K.): NUMERICAL PREDICTION AND EXPERIMENTAL MEASUREMENT OF CARDIAC ASSISTANCE FROM SKELETAL MUSCLE VENTRICLES	61

SESSION 3 *TECHNOLOGY AND APPLICATIONS 1*

W.Baumgartner , W.Gstöttner, K.Ehrenberger (Vienna, Austria): 1978-1998 TWENTY YEARS COCHLEAR IMPLANTS IN VIENNA: „FROM EPOXY SINGLE TO CIS FAST STIMULATORS“	63
F.Rattay , P.Lutter, V.Stüger (Vienna, Austria): MAN VERSUS CAT: THE MORPHOLOGICAL DIFFERENCES IN THEIR COCHLEAR NEURONS LEAD TO ESSENTIAL DIFFERENCES IN FIRING PATTERN	65
M.-A.Crampon , M.Sawan, V.Brailovski, F.Trochu (Montreal, Qc, Canada): NEW EASY TO INSTALL NERVE CUFF ELECTRODE USING SHAPE MEMORY ALLOY ARMATURE	69
M.S.Rahal , J.T.Taylor, N.de N.Donaldson (London,UK.): MINIMISATION OF INTERFERENCE IN ENG RECORDING USING CUFF ELECTRODES	73

SESSION 4 *TECHNOLOGY AND APPLICATIONS 2*

O.Scholz , D.Marin, J.Parramon, T.Stieglitz, W.Eberle, J.U.Meyer, E.Valderrama (St.Ingbert, Germany): EVALUATION AND EXAMINATION OF WIRELESS COMMUNICATIONS FOR NEURAL PROSTHESES	77
D.Marin , O.Scholz, J.Parramon, T.Oses, J.-U.Meyer, E.Valderrama (Bellaterra, Spain): FAST PROTOTYPING OF IMPLANTABLE SYSTEMS FOR STIMULATION AND RECORDING BASED ON A BI-DIRECTIONAL AND RF POWERED TELEMETRY INTEGRATED CIRCUIT	81
S.Sauermann , A.Inmann, E.Unger, H.Lanmüller (Vienna, Austria): AN EFFICIENT, MISALIGNMENT-TOLERANT 0.6W INDUCTIVE POWER TRANSMISSION LINK FOR IMPLANTABLE FES DEVICES	85
S.Pourmehdi , P.Strojnjk, H.Peckham, J.Buckett, B.Smith (Cleveland, OH, USA): A CUSTOM-DESIGNED CHIP TO CONTROL AN IMPLANTABLE STIMULATOR AND TELEMETRY SYSTEM FOR CONTROL OF PARALYZED MUSCLES	89
P.Strojnjk , S.Pourmehdi, H.Peckham (Cleveland, OH,USA): INCORPORATING FES CONTROL SOURCES INTO IMPLANTABLE STIMULATORS	93
M.Schwarz , L.Ewe, R.Hauschild, B.J.Hosticka, J.Huppertz, T.Kneip, S.Kolnsberg, W.Mokwa, H.K.Trieu (Duisburg, Germany): DEVELOPMENT OF A RETINA IMPLANT FOR EPIRETINAL GANGLION CELL STIMULATION FOR PATIENTS SUFFERING FROM RETINITIS PIGMENTOSA	97

TABLE OF CONTENTS

A.Uranga , N.Barniol (Bellaterra, Spain): IMPLANTABLE ELECTRICAL STIMULATOR FOR BLADDER CONTROL	101
---	-----

H.Lanmüller , S. Sauermann, E.Unger, G.Schnetz, W.Mayr, M.Bijak, D.Rafolt, W.Girsch (Vienna, Austria): BATTERY-POWERED IMPLANTABLE NERVE STIMULATOR FOR CHRONIC ACTIVATION OF TWO SKELETAL MUSCLES USING MULTICHANNEL TECHNIQUES	105
--	-----

SESSION 5 *LOWER EXTREMITIES 1*

D.J.Maxwell , M.H.Granat, G.Baardman, H.J.Hermens (Glasgow, U.K.): DEMAND FOR AND USE OF FES SYSTEMS AND CONVENTIONAL ORTHOSES IN THE SPINAL LESIONED COMMUNITY OF THE UK	109
---	-----

F.Palazzo , J.Quintern, R.Riener, M.Ferrarin, T.Edrich, C.Frigo (Milano, Italy): FES CONTROL STRATEGIES FOR SINGLE JOINT MOVEMENT: SIMULATION AND EXPERIMENTS IN PARAPLEGICS	113
--	-----

SESSION 6 *LOWER EXTREMITIES 2, STANDING-UP AND STANDING*

R.Riener , T.Fuhr, M.Ferrarin, C.Frigo (Milano, Italy and Munich, Germany): PATIENT-DRIVEN CONTROL OF FES-INDUCED STANDING-UP AND SITTING-DOWN SUPPORTED BY A MECHANICAL SYSTEM: A SIMULATION STUDY	117
---	-----

M.Ferrarin , R.Spadone, R.Cardini (Milano, Italy): PILOT APPLICATION OF A CLOSED-LOOP FES SYSTEM FOR THE STANDING UP TRAINING OF PARAPLEGIC PATIENTS	121
--	-----

R.Kamnik , T.Bajd, A.Kralj, H.Benko, P.Obreza (Ljubljana, Slovenia): JOINT TORQUES DURING FES AND ARM SUPPORTED SIT-TO-STAND OF PARAPLEGIC PATIENTS	125
---	-----

M.Mihelj , Z. Matjačić, T.Bajd (Ljubljana, Slovenia): ASSESSMENT OF INTACT SUBJECT'S BALANCING STRATEGY	129
---	-----

Z. Matjačić , B.Petrič, T.Bajd (Ljubljana, Slovenia): EMULATION OF POSTURAL ACTIVITY IN UNDERACTUATED VIRTUAL BALANCING IN ARM FREE PARAPLEGIC STANDING	133
---	-----

D.E.Wood , V.J.Harper, F.M.D.Barr, P.N.Taylor, G.F.Phillips, D.J.Ewins (Salisbury, U.K.): EXPERIENCE IN USING KNEE ANGLES AS PART OF A CLOSED-LOOP ALGORITHM TO CONTROL FES-ASSISTED PARAPLEGIC STANDING	137
--	-----

T.Houdayer , R.Davis, B.Andrews (Augusta, ME, USA): PROLONGED STANDING IN PARAPLEGIA BY MEANS OF FUNCTIONAL ELECTRICAL STIMULATION AND ANDREWS ANKLE-FOOT ORTHOSIS	141
--	-----

TABLE OF CONTENTS

SESSION 7 LOWER EXTREMITIES 3, GAIT

T.Karčnik , A.Kralj (Ljubljana, Slovenia): STABILITY AND VELOCITY IN INCOMPLETE SCI SUBJECTS GAIT	145
M. Bijak , C.Hofer, H.Lanmüller, W.Mayr, S.Sauermann, E.Unger, H.Kern (Vienna, Austria): PC SUPPORTED EIGHT CHANNEL SURFACE STIMULATOR FOR PARAPLEGIC WALKING - FIRST RESULTS	149
M.R.Popovic , T.Keller, S.Ibrahim, G.v.Bueren, M.Morari (Zürich, Switzerland): GAIT IDENTIFICATION AND RECOGNITION SENSOR	153
J.R.Henty , D.J.Ewins (Guildford, Surrey, U.K.): APPLICATIONS OF GYROSCOPIC ANGULAR VELOCITY SENSORS IN FES SYSTEMS	157
K.T.Kalveram , C.Kirtley (Düsseldorf, Germany and Hong Kong, China): HUMAN WALKING: A CONTROL-THEORETICAL MODEL AND ITS EVALUATION BY EMPIRICAL DATA	161
K.Y.Tong , M.H.Granat (Glasgow, U.K.): USING NEURAL NETWORKS TO GENERATE OPTIMUM FES GAIT CONTROLLERS	165
F.Sepulveda , M.H.Granat, A.Cliquet Jr (Campinas, Brazil): AN AUTOMATIC ON-LINE LEARNING NMES SYSTEM FOR GAIT SWING RESTORATION	169

SESSION 8 LOWER EXTREMITIES 4, MUSCLE TRAINING AND MEASUREMENT TECHNIQUES

M.Gföhler , T.Angeli, T.Eberharter, P.Lugner, L.Rinder (Vienna, Austria): MEASUREMENTS OF PEDALING BY FES	173
V.Valenčič , N.Godina (Ljubljana, Slovenia): INFLUENCE OF ACUTE PHYSICAL EXERCISE IN TWITCH RESPONSE ELICITED BY STIMULATION OF SKELETAL MUSCLES IN MAN	177
S.Djordjevič , V.Valenčič, N.Godina, B.Jurčič-Zlobec (Ljubljana, Slovenia): THE COMPARISON OF DYNAMIC CHARACTERISTICS OF SKELETAL MUSCLES IN TWO GROUPS OF SPORTSMEN - SPRINTERS AND CYCLISTS	181
W.Mayr , M.Bijak, W.Girsch, C.Hofer, H.Lanmüller, D.Rafolt, M.Rakoš, S.Sauermann, C.Schmutterer, G.Schnetz, E.Unger, G.Freilinger (Vienna, Austria): ELECTROMYOSTIMULATION TO PREVENT MUSCLE ATROPHY IN MICROGRAVITY AND BED- REST: PRELIMINARY REPORT	185

TABLE OF CONTENTS

SESSION 9 *LOWER EXTREMITIES 5, FOOT DROP CORRECTION*

P.Taylor , J.Burridge, A.Dunkerley, J.Norton, D.Wood, C.Singleton, I.Swain (Salisbury, Wilts, U.K.): LONG TERM FOLLOW UP OF 160 USERS OF THE ODESTOCK DROPPED FOOT STIMULATOR	189
E.Ott , M.Munih, H.Benko, A.Kralj (Ljubljana, Slovenia): COMPARISON OF FOOT-SWITCH AND HAND-SWITCH TRIGGERED FES CORRECTION OF FOOT DROP	193
A.Kostov , M.Hansen, M.Haugland, T.Sinkjaer (Edmonton, AB, Canada): ADAPTIVE RESTRICTION RULES PROVIDE FUNCTIONAL AND SAFE STIMULATION PATTERN FOR FOOT-DROP CORRECTION	197
J.A.F.Lopes , L.A.Okai, H.T.Moriya, J.C.T.B.Moraes, R.L.Battistella (Sao Paulo-S.P., Brazil): EVALUATION OF A PORTABLE TELEMETRIC FNS DEVICE IN A 3-D MOTION ASSESSMENT SYSTEM	201
R.C.Junqueira , A.P.C.Fonseca (Belo Horizonte/MG, Brazil): THE UTILIZATION OF THE FUNCTIONAL ELECTRICAL ORTHESIS - KM 25 IN REHABILITATION OF HEMIPARETIC PATIENTS	205

SESSION 10 *DENERVATED MUSCLE*

M.Reichel , W.Mayr, F.Rattay (Vienna, Austria): COMPUTER SIMULATION OF FIELD DISTRIBUTION AND EXCITATION OF DENERVATED MUSCLE FIBERS CAUSED BY SURFACE ELECTRODES	209
A.H.Woodcock , P.Taylor, D.J.Ewins (Guildford, Surrey, UK): LONG PULSE BIPHASIC ELECTRICAL STIMULATION OF DENERVATED MUSCLE	213

SESSION 11 *VARIOUS APPLICATIONS*

L.G.Y.Claeys (Vienna, Austria): SPINAL CORD STIMULATION (SCS) FOR PERIPHERAL VASCULAR DISEASE: A CRITICAL REVIEW OF THE EUROPEAN EXPERIENCE	217
S.I.Reger , A.Hyodo, S.Negami, H.Kambic, V.Sahgal (Cleveland, OH, USA): EXPERIMENTAL WOUND HEALING WITH ELECTRICAL STIMULATION	221
J.Rozman , B.Zorko, A.Seliškar (Ljubljana, Slovenia): REGENERATION OF THE RADIAL NERVE IN THE DOG INFLUENCED BY ELECTRICAL STIMULATION	225
S.W.J.Seager , D.V.C. and L.S.Halstead (Washington, USA): THE USE OF ELECTROEJACULATION FOR THE TREATMENT OF ANEJACULATION	229

TABLE OF CONTENTS

B.Kralj (Ljubljana, Slovenia): DEVELOPMENT, ACTUAL STATUS AND THE FUTURE OF EXTERNAL FUNCTIONAL ELECTROSTIMULATION IN TREATMENT OF FEMALE URINARY INCONTINENCE	231
C.L.Ludlow , C.Hang, S.Bielamowicz, P.Choyke, V.Hampshire, W.S.Selbie (Bethesda, MD, USA): THREE DIMENSIONAL CHANGES IN THE UPPER AIRWAY DURING NEUROMUSCULAR STIMULATION OF LARYNGEAL MUSCLES	235
J.Jeraj , U.Stanič, F.Kandare, R.J.Jaeger (Ljubljana, Slovenia): FOUR-CHANNEL STIMULATOR FOR EXPIRATORY SUPPORTED VENTILATION	239
K.M.Blossfield , R.Jaeger, W.E.Langbein (Schaumburg, Illinois, USA): PRECISELY TIMED FUNCTIONAL ELECTRICAL STIMULATION FOR COUGH ASSISTANCE IN PERSONS WITH SPINAL CORD INJURY	243

SESSION 12 *UPPER EXTREMITIES, EMG-CONTROL*

D.Popović , M.Popović, A.Stojanović, A.Pjanović, S.Radosavljević, D.Vulović (Belgrade, Yugoslavia): CLINICAL EVALUATION OF THE BELGRADE GRASPING SYSTEM	247
R.H.Nathan , H.P.Weingarden, A.Dar, C.Macaspac (Beer Sheva, Israel): RESTORATION OF FUNCTIONAL ACTIVITIES WITH THE HANDMASTER NMS1	251
Y.Muraoka , S.Miyajima, Y.Tomita, S.Honda, N.Tanaka, Y.Okajima (Keio, Japan): EMG-CONTROLLED HAND OPENING SYSTEM FOR HEMIPLEGIA	255
M.Rakoš , B.Freudenschuß, W.Girsch, C.Hofer, J.Kaus, T.Meiners, T.Paternostro, W.Mayr (Vienna, Austria): EMG-CONTROLLED FES FOR TREATMENT OF THE PARALYZED UPPER EXTREMITY	259
R.Thorsen , M.Ferrarin, R.Spadone, C.Frigo (Milano, Italy): AN APPROACH USING WRIST EXTENSION AS CONTROL OF FES FOR RESTORATION OF HAND FUNCTION IN TETRAPLEGICS	263
D.M.Tepavac , E.Medri (Miami, FL, USA): PROGRAMABLE FUNCTIONAL ELECTRICAL STIMULATOR WITH EMG FEEDBACK	267

TABLE OF CONTENTS

POSTERS

B.Andrews , R.Davoodi, R.Kamnik, T.Bajd (Alberta, Canada): BEHAVIORAL CLONING FOR FES CONTROL AND BIOMECHANICAL MODELING	271
I.Axenovich (Eger, Hungary): THE USE OF ORIGINAL ELECTRODES IN LONG-TERM, CONSTANT, EXTERNAL ELECTRIC STIMULATION OF MUSCLES	275
M.Bunc , J.Rozman, D.Šuput (Ljubljana, Slovenia): FORCE TRANSDUCER FOR MEASUREMENT OF GILL MOVEMENTS IN FISH	279
P.Chiarelli , P.Ragni, D.de Rossi, S.Donato (Pisa, Italy): A THERMO-REVERSIBLE GEL ACTUATOR FOR AN ARTIFICIAL URETHRAL PROSTHESIS	283
L.G.Y.Claeys (Vienna, Austria): IMPROVEMENT OF MICROCIRCULATORY SKIN BLOOD FLOW UNDER SPINAL CORD STIMULATION (SCS) IN PATIENTS WITH ISCHEMIC PAIN	287
P.M.Dall , B.Müller, I.Stallard, J.Edwards, M.H.Granat (Glasgow, U.K.): MEASUREMENT OF THE FORCES IN THE CABLE OF A RECIPROCATING GAIT ORTHOSIS (RGO) DURING PARAPLEGIC WALKING	291
H.Egger , M.Bijak, W.Mayr, C.Hofer, H.Kern, A.Scholtz (Vienna, Austria): GAIT IMPROVEMENT BY PERONEAL NERVE STIMULATION WITH SURFACE ELECTRODES - A CASE STUDY	295
D.Escorza , R.Mavri, H.Benko, R.Savrin, A.Stefanovska (Ljubljana, Slovenia): THE EFFECT OF ELECTRIC STIMULATION ON THE BLOOD FLOW DYNAMICS IN THE VICINITY OF A PRESSURE SORE	299
M.Gföhler , M.Loicht, P.Lugner (Vienna, Austria): CYCLING DEVICE FOR PARAPLEGICS USING FES	303
V.L.Ionescu (Weiterstadt, Germany): A μ CONTROLLER - BASED RECORDER TO CATCH FAST EVOKED-BIOPOTENTIALS	307
M.Munih , M.Ponikvar, Z. Matjačić (Ljubljana, Slovenia): STANDING BALANCING WITH ARMS RELEASED AND LOADED	311
M.Quittan , A.Sochor, G.F.Wiesinger, J.Kollmitzer, B.Sturm, R.Pacher, W.Mayr (Vienna, Austria): STRENGTH IMPROVEMENT OF KNEE EXTENSOR MUSCLES IN PATIENTS WITH CHRONIC HEART FAILURE BY NEUROMUSCULAR ELECTRICAL STIMULATION	315
M.Rakoš , T.Paternostro, W.Mayr, C.Hofer (Vienna, Austria): FUNCTIONAL RECOVERY DUE TO EMG-TRIGGERED FES IN CHRONIC BRACHIAL PLEXUS PALSY - A CASE REPORT	319
F.Sepulveda , M.H.Granat, A.Cliquet Jr (Campinas, Brazil): AN ADAPTATION STRATEGY FOR ON-LINE LEARNING IN ARTIFICIAL NEURAL CONTROL OF GAIT GENERATION BY MEANS OF NMES	321
E.Unger , H.Lanmüller, W.Mayr, S.Sauermann, G.Schnetz, M.Zrunek (Vienna, Austria): BATTERY - POWERED MINIATURE IMPLANT FOR NERVE STIMULATION	325
L.Zhou , M.Munih, M.K.Haugland, T.A.Perkins, N.de N.Donaldson (London, U.K.): AN IMPLANTABLE TELEMETER FOR E.N.G. SIGNALS	327

FES ASSISTED WALKING IN INCOMPLETE SCI SUBJECTS: AN OVERVIEW

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SUMMARY

A therapeutic electrical stimulation in incomplete spinal cord injury patients can be initiated after testing if there are no contraindications for low frequency electrotherapy; only patients with upper motor neuron type lesion are candidates for this program. Three groups of patients were identified: those in whom an improvement of both voluntary and stimulated muscle force was observed, those with an increase in stimulation response only, and patients in whom no effect of electrical stimulation training could be recorded. As it is difficult to predict the outcome of the electrical stimulation rehabilitation process, a diagnostic procedure was developed predicting soon after the accident which incomplete SCI patients are candidates for a permanent use of FES orthotic aid. Based on data about 31 incomplete SCI patients, a classification tree was developed using a machine learning approach. The induced classification tree indicates that the candidates for chronic use of FES are patients with weak ankle dorsiflexors and sufficiently strong knee extensors. These patients are equipped with a single-channel peroneal stimulator augmenting dorsiflexion, and knee and hip flexion in a total lower limb flexion response. By applying the FES to ankle plantar flexors, the swing phase of walking can be significantly shortened and faster walking obtained.

STATE OF THE ART

In the last decades advances in traffic control and motor vehicle engineering together with more efficient first aid and improved transport to the emergency center have resulted in a reduction in the number of complete spinal cord injured (SCI) patients. As a consequence, more incomplete cases are arriving in spinal units. There are more incomplete tetraplegic than paraplegic cases. About one-half of the incomplete SCI patients recover and need no orthotic aid. In these patients functional electrical stimulation (FES) can be used as therapeutic treatment in the early post-trauma phase. The other incomplete SCI patients are candidates for functional chronic use of FES rehabilitative aids.

Incomplete lesions of the spinal cord are characterized by three different kinds of muscles: normal, centrally denervated (spastic) and peripherally denervated (flaccid). All three kinds of muscles can be found, not only in the lower extremity of an incomplete SCI patient but also in a single muscle group. This makes the FES rehabilitative approach rather difficult. It is difficult to predict the outcome of the FES rehabilitation process when patients are admitted to the spinal unit soon after the accident. Similarly, it is not possible to decide what rehabilitation aid the patient will need after recovering from a spinal cord injury.

It was found that early recovery of quadriceps muscle strength post spinal injury is a useful predictor of future ambulation [4]. Motor incomplete spinal cord injured patients who recovered to a quadriceps strength greater than 3/5 by two months post injury had an excellent prognosis for subsequent ambulation by half a year post injury. No relationship was found between age and ambulatory status. Also, no relationship between the level

of injury and recovery of ambulation was observed. This is in accordance with the data presented in [11] where no significant differences in motor recovery were related to the type of injury and type of spinal fracture. In another study [6] all subjects with an early quadriceps muscle grade greater than 0/5 ambulated. The same examiners also noticed that somatosensory evoked potentials did not offer any additional prognostic value over that provided by the clinical examination. However, the prognostic value of preserved sensation was proven in the study. The preservation of pinprick sensation between the level of the injury and the sacral dermatomes was the best prognostic indicator for useful motor recovery with the patients regaining the ability to walk [7]. The relationship between neurocontrol patterns evoked by lower limb movement in the supine position and the assistive device used for ambulation in chronic incomplete SCI patients was also evaluated [10]. Marked decreases in motor unit output and/or loss of motor organization were found in the nonambulatory group of patients. Coactivation of proximal muscles, poor timing of muscle activity and radiation of activity into contralateral muscles were also noted in subjects who required a walker or crutches.

The aim of the present investigation was primarily to develop a diagnostic procedure which will soon after the accident predict which incomplete SCI patients are candidates for permanent use of FES orthotic aid. In this overview presentation it is also our goal to discuss the importance of knee extensors, peroneal nerve, and ankle plantar flexors stimulation after incomplete SCI.

KNEE EXTENSORS STIMULATION

The therapeutic electrical stimulation program consisted of cyclic stimulation of partially paralyzed knee extensor muscles where stimulation trains of 4 seconds and pauses of equally 4 seconds alternately followed one another. The electrical stimulation was applied through large (6x4 cm) sheet-metal electrodes covered with water-soaked gauze. The electrical pulses used were rectangular and monophasic. A stimulation frequency of 20 Hz, a pulse duration of 0.3 ms, and a stimulation amplitude of sufficient intensity to bring the legs into full extension were used. During the training, the patients were positioned supine with both lower extremities semiflexed to approximately 30 degrees by a pillow under the knees. The FES session lasted for half-hour a day [1].

The effects of muscle strengthening program were tested and assessed through isometric knee-joint torque measurement. The isometric knee joint torque was assessed once every week in each incomplete SCI patient. The training program lasted for about two months. Both voluntary and electrically provoked knee joint torques were assessed in a group of seven incomplete SCI patients and are presented in Fig. 1.

In the first subject the incomplete T-11 spinal cord lesion resulted from a motorbike accident. The stimulation was delivered to him eight months after the injury. No improvement was observed in voluntary and stimulated response. The second subject had a C-6,7 incomplete SCI lesion after a car accident. He came to the spinal unit for the electrical stimulation training purposes two years after the accident. It is evident that no effect was achieved by daily stimulation of his knee extensors. Because of rather strong pain sensation, the voluntary responses are stronger than FES induced. The patient remained confined to the wheel-chair. The third patient suffered C-3,4 incomplete spinal cord lesion from a car accident. Electrical stimulation training program started eight months after the injury. Both stimulated and voluntary joint torque had quite low values at the beginning of the program. The voluntary isometric torque remained at this initial value for the rest of the program. In contrary, the stimulated isometric knee joint torque was noticeably increased. After the rehabilitation program the patient was able to walk by the help of walker and bilateral m. quadriceps and n. peroneus stimulation on short distances only.

In the following four patients considerable improvement in voluntary knee joint torque was observed. The fourth patient had an incomplete C-5,6 lesion after stab wound. The improvements in maximal stimulated and

voluntary torques are similar. The final result of the strengthening program was 50 Nm of voluntary knee joint torque. This was sufficient for unassisted standing. The patient was able to walk for short distances by the help of two crutches and two peroneal stimulators. She was occasionally using wheel-chair. Subject no. 5 suffered C-5,6 incomplete spinal cord lesion from motor vehicle accident eight months before being admitted to the rehabilitation center from neurological clinic. Both stimulated and voluntary joint torque had quite low values at the beginning of the program and increased to about 30 Nm towards the end of the training process. The voluntary torque achieved was not enough to provide solid support. The patient was using wheel-chair to a considerable extent. Similar results were obtained also in patient no. 6 suffering from a tumor at C-2 spinal cord level. She came to rehabilitation center six years after surgical intervention. In spite of an increase in both voluntary and stimulated muscle force she was unable to stand unassisted. The seventh patient had incomplete C-7 spinal cord lesion after fall. When the electrical stimulation training started, he was two months after injury. An increase to about 50 Nm was observed when comparing the initial and final results obtained both during electrically stimulated and voluntary muscle contraction. The voluntary knee joint torque increased from almost zero to about 50 Nm what was found sufficient for unassisted walking with the help of two crutches. Patient was not using wheel-chair after leaving rehabilitation center.

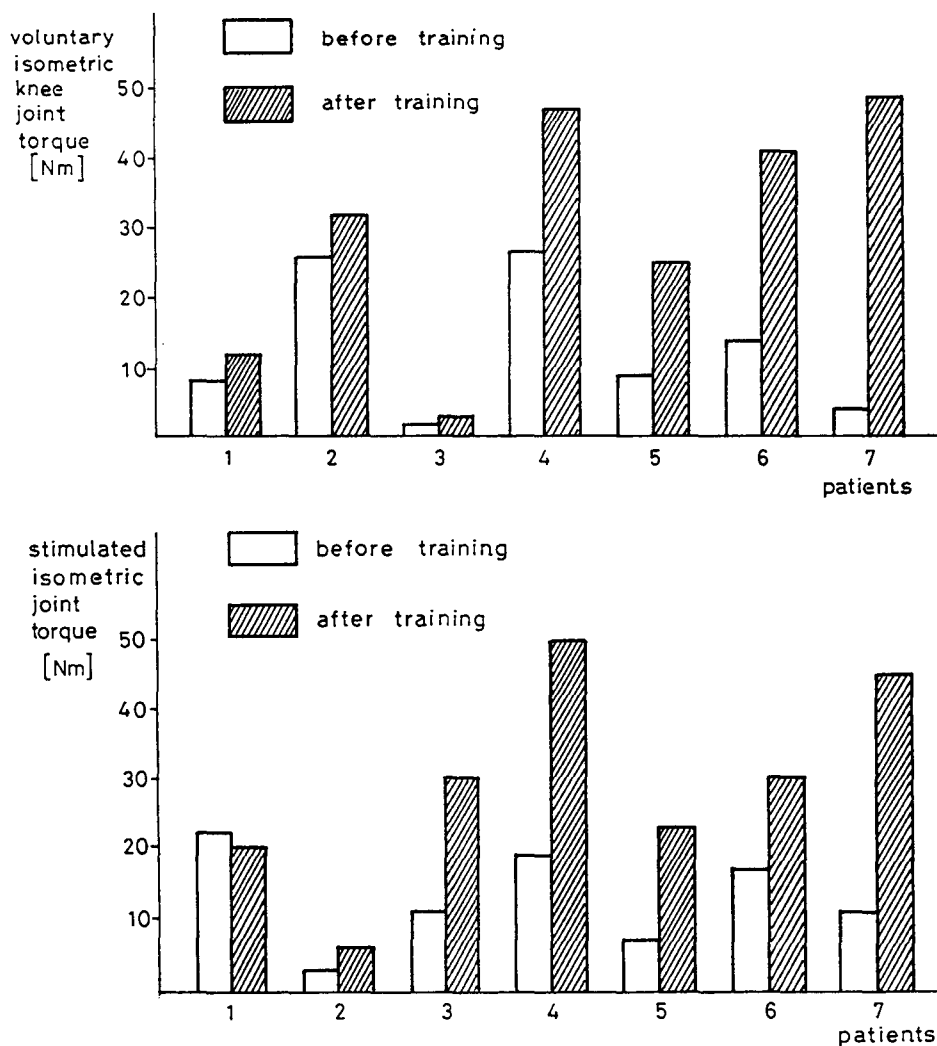


Fig.1. Maximal voluntary and stimulated knee joint torques assessed before and after FES muscle training program.

PERONEAL NERVE STIMULATION

With every incomplete SCI patient several simple clinical tests were performed by physiotherapists at the arrival of the patient to the rehabilitation unit. First, the manual muscle test was carried out. The muscle groups governing the hip movement (extensors, flexors, and abductors), knee movement (extensors and flexors), and ankle joint movement (dorsal and plantar flexors) were evaluated. In the manual muscle test the responses to voluntary control were estimated by nine grades (0, 1 -2, 2, -3, 3, -4, 4, 5). It was observed that both hip and ankle antagonists were rather severely affected in most of the subjects. The strongest muscle group was knee extensors. The presence of superficial and deep sensation was also tested in patient's paralyzed lower extremities. The presence of sensations was indicated by a yes/no answer. The spasticity in the major muscle groups of the lower extremities was estimated by four grades. Significant nonsymmetry between the neuromuscular properties of the right and left paralyzed leg was often observed in the group of incomplete SCI persons. The data appertaining to the severely handicapped extremity were taken into consideration for further computer analysis. General patient's data have been gathered: year of birth, sex, date of accident, level of spinal cord lesion and cause of accident or disease. 31 incomplete SCI patients with central (thoracic or cervical) SCI were included into the present study. Only the patients who were unable to walk on the day of examination were taken into account.

Apart from regular therapeutic treatment, cyclic electrical stimulation for restrengthening of disuse atrophied muscles was delivered to the patients during several months of their stay in the rehabilitation center. In some patients FES for standing and walking was also applied [1]. At the release from the rehabilitation center the patients were divided into four different classes regarding their locomotor capabilities:

- wheelchair users (19 patients)
- users of FES and crutches (4 patients)
- users of mechanical brace and crutches (2 patients)
- no orthotic aid (6 patients)

One-channel electrical stimulators were given to the patients for chronic use after release from the rehabilitation center. One channel FES was delivered to the peroneal nerve resulting in flexion response of the lower extremity [9]. In this way simultaneous hip and knee flexion and ankle dorsiflexion were obtained unilaterally and bilaterally enabling swing phase of walking. Here, it must be noted that electrical stimulators were given also to ten wheelchair users for gait exercise.

Machine learning tools have been applied in a variety of real-world domains. These tools enable the induction of knowledge in different forms, for example, the form of rules or decision trees. In supervised machine learning, a set of examples with known classification is given. An example is described by an outcome (class) and the values of a fixed collection of parameters (attributes). Each attribute can either have a finite set of values (discrete attribute) or to take real numbers as values (continuous attribute).

In this study, the program CART [3] as implemented in the S-Plus package was used to construct decision trees. This tree induction algorithm belongs to the ID3 family of systems for top-down induction of decision trees. The program recursively builds binary decision tree. The nodes of the tree correspond to attributes, arcs correspond to values or sets/intervals of values of attributes, and leaves (terminal nodes) correspond to predicted classes. In each recursive step of decision tree construction, an attribute is selected and a subtree is built. Standardly, the recursion stops when all examples belong to the same class, meaning that generated leaf is labeled with the class of examples.

To classify a new case, a path from the root of the tree is selected on the basis of values of attributes of the new example to be classified. In this way, for a given example, the path leads to a leaf which assigns a class that labels the leaf. The selected path may be viewed as a generalization of the specific example for which the

prediction is being determined. If a leaf is labeled with more than one class, each with the probability of class prediction, then the class with the highest probability is selected for the classification of a new case.

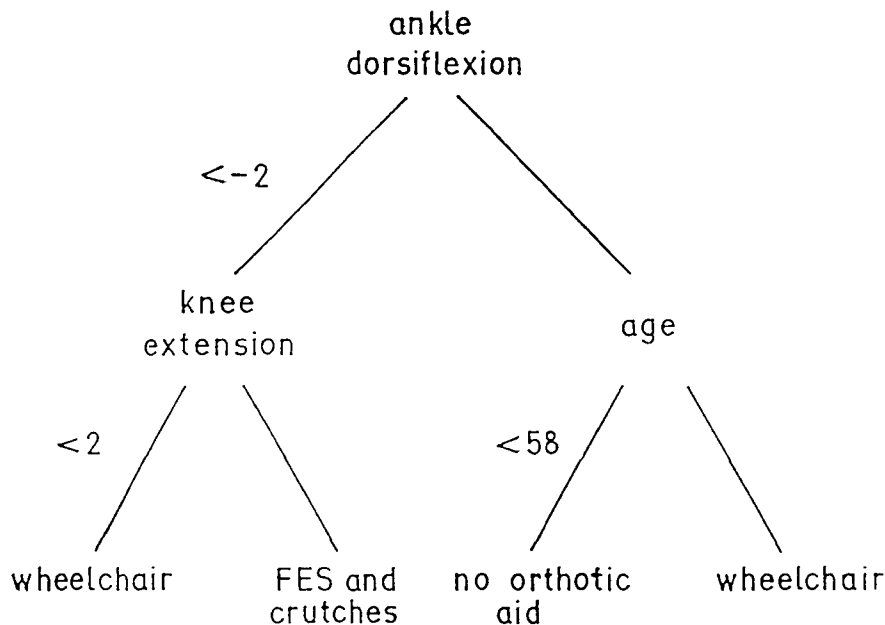


Fig.2. Decision tree prognosing the ambulation abilities of incomplete SCI subjects.

The decision tree prognosing the ambulation abilities of incomplete SCI persons, as obtained through the machine learning approach, is shown in Fig.2. At the root of the tree the strength of the ankle dorsiflexors is tested. This is quite in accordance with the FES rehabilitative method as peroneal stimulation predominantly results in improved ankle dorsiflexion. In patients with inadequate voluntary ankle dorsiflexion (lesser than 2), the strength of the knee extensors must be evaluated. This finding is in agreement with the observation of other authors [4,6]. Patients with sufficiently strong knee extensors (over 2) are candidates for the use of peroneal electrical stimulator and crutches. These patients can be considered as community walkers. They can use electrical stimulator for several hours per day during their daily activities. Patients with weak knee extensors are bound to the wheelchair. It is interesting to note that in patients with adequate ankle dorsiflexion (above -2), the voluntary strength of the knee extensors contraction has not to be tested. These patients are divided on the basis of their age. Older patients are wheelchair users, while younger can walk without any orthotic aid.

In our study of prediction of walking abilities in incomplete SCI persons the data on sensation and spasticity were not found relevant what is not quite in accordance with some authors [7,10]. In further computer analysis of the data gathered, the group of the wheelchair users was divided into patients using FES and wheelchair and those making use of wheelchair only. No sensible decision tree was obtained in this case. This outcome can be considered as an indication that FES is not really necessary in incomplete SCI patients who are bound to the

wheelchair. These patients can only be treated as exercise walkers using FES for about half an hour per day for therapeutic purposes.

ANKLE PLANTAR FLEXORS STIMULATION

The effectiveness of FES delivered during gait to the ankle plantar flexors in order to obtain an improved swing phase of walking was experimentally evaluated. It was hypothesized that FES of ankle plantar flexors may provide lifting of the heel, upward propulsion to the swinging leg and flexion of the knee. Electrical stimulation was delivered to the ankle plantar flexors unilaterally during crutch-assisted walking of a group of five incomplete SCI patients. One of the patients had thoracic, while the rest had cervical lesion of the spinal cord. All patients were selected from a group of SCI subjects who had one leg almost completely paralyzed and the other leg under satisfactory voluntary control.

Two stimulation sequences were investigated. Within the first stimulation sequence only the peroneal nerve was stimulated. The sequence was controlled by hand-triggered push-button built into the handle of a crutch. In this stimulation strategy, the flexion response was elicited with 50Hz. In the second stimulation sequence, FES of the ankle plantar flexors was applied. To obtain strong and fast propulsion, a stimulation frequency of 50 Hz was used to stimulate the calf muscles. In both examples of stimulation sequences, the same amplitudes and pulse durations of stimuli were used [2].

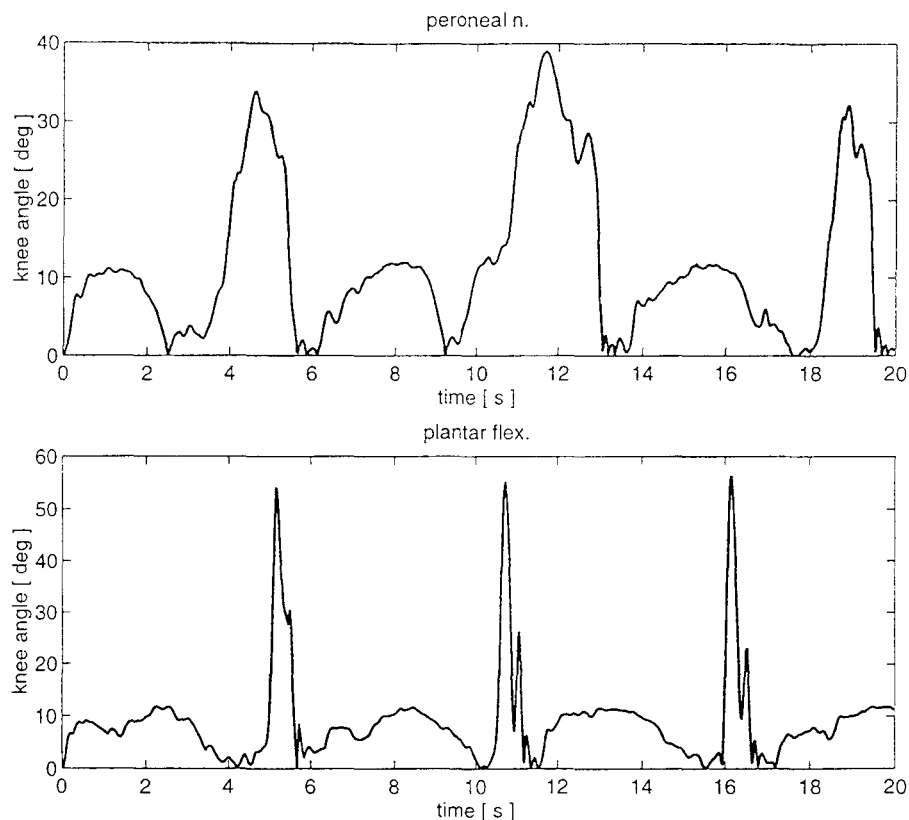


Fig. 3. Knee goniograms during walking with peroneal nerve stimulation (upper trace) and with stimulation delivered to ankle plantar flexors.

The movements of the swinging leg were assessed by an optical measuring system OPTOTRAK. Four markers were placed on the estimated anatomical positions of the hip, knee, ankle and metatarsal joints in the sagittal plane. Here, we are presenting the knee goniograms as assessed during three consecutive steps of a tetraparetic subject when walking by the use of both stimulation sequences (Fig. 3). The maximal swings were increased when stimulation was applied to the ankle plantar flexors. However, the most significant difference between the two gait patterns is evident from the swing time duration, which decreased by almost 50% when FES of calf muscles was used. A shorter swing phase may result in faster walking by incomplete SCI subjects. A decrease in the walking cycle time for about 15% can also be observed from Fig. 3.

In this study, we have observed that, in incomplete SCI subjects, stimulation with electrodes positioned on the posterior side of the calf over the triceps surae muscle can also provoke the flexion response of the whole limb. Electromyographic recordings showed that surface electrical stimulation over the belly of the ankle plantar flexors results in afferent stimulation and efferent stimulation of the same muscle. By EMG examination, bursts of flexion reflex activity have been observed in the thigh muscles. Thus, the surface electrical stimulation of the calf muscles results in complex movements, consisting of a combination of the efferently provoked ankle plantar flexion and knee flexion, and also the afferently evoked flexion withdrawal response [2].

We demonstrated that FES of ankle plantar flexors results in a significantly shorter swing phase, which may provide a higher gait speed in incomplete SCI patients. It appears that electrical stimulation of ankle plantar flexors delivered during the toe-off phase has a similar effect as hip extension produced by the treadmill movement. Hip extension at the end of the stance phase is often inducing involuntary hip flexion initiating the swing phase of walking [12]. Adding the stimulation of ankle plantar flexors is also essential when producing a high step for a paralyzed extremity. This may be required when walking over rough, uneven terrain, when overcoming obstacles such as pavements and when climbing stairs.

CONCLUSIONS

The following conclusions can be redrawn from this review presentation:

- FES training of the knee extensors was found effective in large number of incomplete SCI subjects. It remains to be determined whether cyclical FES of quadriceps muscles represents sufficient training or an early walking exercise may yield improved benefits.
- The voluntary response in knee extensors improved in majority of the patients who were unable to walk in the beginning of the training program. Only rare incomplete SCI patients are candidates for application of FES to their quadriceps muscles.
- A diagnostic procedure was developed predicting soon after the accident which incomplete SCI patients are candidates for a permanent use of a FES orthotic aid.
- Peroneal nerve stimulation was found useful in at least 10% of incomplete SCI patients in order to augment dorsiflexion, knee, and hip flexion in a total lower limb reflex pattern.
- Stimulation of ankle plantar flexors results in a significantly shorter swing phase, which may provide a higher gait speed.
- The stimulation of ankle plantar flexors is essential when producing a high step for a paralyzed extremity. This may be required when walking over rough, uneven terrain, when overcoming obstacles such as pavements and when climbing stairs.

We can talk about two possible applications of FES to incomplete SCI patients:

- Short-term therapeutic treatment in the clinical environment.
- Permanent orthotic use of FES rehabilitative system.

In the beginning of therapeutic FES treatment, cyclical electrical stimulation can be used with the aim of restrengthening the atrophied muscles, increasing the range of motion and reducing spasticity [5]. Electrical stimulation can also be used to predict the extent to which an incomplete SCI patient could improve, as well as to foresee the period within which the patients will increase their strength to a useful level. The comparison of voluntary and electrically elicited responses soon after an injury yields additional information for prognosis. Here, it should be stressed that FES represents one of the rare rehabilitative approaches for the incompletely paralyzed subjects soon after the accident, not only returning them to a vertical position, but also restoring their walking pattern [8].

When recovering at this early therapeutic FES phase is not sufficient, the incomplete SCI patient is a candidate for the life-long application of an FES orthotic system. Owing to greater preserved exteroception and proprioception, most of these patients are excellent candidates for implanted FES systems which can turn them into community walkers, effectively using the stimulator throughout the day.

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STANDING-UP WITH DENERVATED MUSCLES IN HUMAN USING FES

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SUMMARY

The use of electrical stimulation for denervated muscles is still being considered to be a controversial issue by many rehabilitation facilities and medical professionals, since prior clinical experience has shown that to treat denervated muscle tissue using exponential current over a long time period constitutes an impossible task.

In spite of this fact, we managed to evoke tetanic contractions in denervated muscle using a long duration stimulation with anatomically - shaped electrodes and sufficiently high amplitudes. The pulse amplitudes, which were being used for this purpose, exceeded by far the MED - GV and EC - regulations. For this reason, an application has recently been submitted to have the EC - regulations changed accordingly.

It takes a tetanic contraction to achieve the desired muscle fibre tension, constituting a hypertrophic stimulus. It is also an appropriate means of exercise which is able to create the metabolic and structural conditions needed (e.g. increase of mitochondric cells, capillary growth) to obtain satisfactory muscle performance.

With patients suffering from a complete spinal cord injury at level Th12 / L1, having motor and sensory loss in both lower extremities, we were able to train denervated muscle using long-duration stimulation, evoking single muscle contractions at first, soon followed by tetanic contractions against gravity.

To increase the efficacy of this FES strengthening program we used ankle weights and ended up producing torques between 16 and 38 Nm in the M. quadriceps. With daily FES training over a period of 1 - 2 years, denervated muscle was exercised until standing up from a sitting position in parallel bars was made possible.

Our results show that denervated muscle in humans is indeed trainable and can perform functional activities with FES. Furthermore this method of stimulation can assist in the decubitus prevention and significantly improve mobility of paraplegics.

STATE OF THE ART

Permanently damaged denervated muscle is normally not being treated with exponential current. In physical therapy exponential current is most commonly used for temporary lesions such as plexus paresis, peripheral nerve damage with or without surgical reconstruction, in order to facilitate the postsynaptic membranes and their thresholds. A standard treatment program for outpatients usually consists of an electrical stimulation with a pulse duration of 200 ms (100 – 500 ms), 2000 ms off-time, applied 3 times per week for 15 min. In most cases small surface electrodes (20 - 50 cm²) are being used in order to achieve selective stimulation of paralyzed muscle tissue. Accomodation - loss in denervated fibres is utilized alongside with a low amplitude to evoke the desired selective contraction.

In some cases patients are able to increase their treatment frequency up to 15min/ day by using portable home therapy equipment. That is to say the common practice of electrical stimulation is characterized by electrodes which are too small, amplitudes too low and treatment times and frequency too short. These parameters may be effective in treating temporary lesions but are definitely unsuitable to prevent atrophy and degeneration in the denervated muscle.

At the end of the 70's Eichhorn and Schubert /32/ have developed an electrical stimulation unit using 5cm² carbon electrodes and low amplitudes. In consequence of this, Mokrusch and Kern began to employ this treatment approach in the area of human medicine and the Vienna group has been developing it further ever since. First results from muscle biopsy, chemical analysis of enzymes, as well as from circulation measurements using Xenon-clearance and Thallium-scintigraphy /21,27/, have hinted that denervated muscle fibres are indeed trainable.

MATERIALS AND METHODS

Since there are no appropriate stimulation units, which can be used for the training of denervated muscle are available, we were forced to design our own stimulators.

These units are controlled by microprocessors, allowing a maximum of flexibility regarding the generation of the required parameters, such as width, frequency, pulse duration and stimulation times etc.. In addition it supplies us with an exact documentation of date, time, duration and used parameters of stimulation.

We designed the stimulation device for pulse durations of 1 - 300 ms, stimulation voltages up to +/- 80 V and 200 mA maximum stimulation current.

The control unit is capable of generating 4 different charge balanced, biphasic rectangular or triangular pulse forms. To prevent the occurrence of direct current due to inexact charge compensation the stimulation pulses are capacitively coupled. This also prevents skin damage which occurs because of electrolyte disintegration.

Since there are no nerve endings for a conduction of current, the use of large electrode sizes is most essential /21/. For surface stimulation of denervated muscle we use anatomically shaped electrodes which are able to cover all of the muscle. This application ensures an even contraction of the whole muscle. Electrodes made of soft flexible rubber, which are applied with gel or on a wet sponge cloth directly to the skin.

The necessary re-evaluation in regular time intervals consists of stimulation of M. quadriceps with various parameters, determining the isometric knee extension-torque on the strength assessment chair at 90° knee flexion /5,21/.

CT cross-section determination

Since the physiological shape of our upper leg muscle is never cylindrical but more or less spindle-shaped, it is crucial for the CT - cut placement to be exact and well defined to reach relevant conclusions and so individual test results are comparable /3,21/. Therefore we chose the top of the trochanter to be our individual reference point, which is being determined by a CT scan. We did not allow a torsion of the body axis and our reference line is being established by linking the two trochanter tops. This method enables us to produce comparable results within a single upper thigh, as well as a right / left study per individual. We observed that the quadriceps surface varies highly in each individual, depending on the body type and individual constitution,

which led us to only evaluate the (individual) absolute increase respectively decrease of muscle cross-sectional area measured in cm^2 or percentage of base line value. All patients were positioned supine parallel to the table axis ("Feet-first position"). In the beginning a topogram of the to-be examined region was being made /21/. The first cut was positioned through the top of trochanter major. Three additional cuts were produced distally at equal distances of 100mm in the upper thigh. To differentiate exactly between fat and muscle tissue we used a soft window frame (window 350, center 50).

The complete cross section area of the upper thigh and the cross-sectional area of M. gluteus, M. quadriceps and hamstrings as well as their density were determined. Considering our raw data, we decided to do without an evaluation of single muscles, and concentrated our efforts on determining the total surface of flexors and adductors compared to the M. quadriceps surface.

Highly atrophic lower extremities with a high fat percentage within the muscle, being also influenced by the nutritional situation, could not provide us with relevant results to be used for statistical purposes. We examined this structural improvement, finding the method of muscle biopsy the most practicable solution in order to detect small structural changes /21/.

RESULTS

1. Exercise parameters

Pulse duration for denervated muscle has to be 100 - 1000x longer than in the case of spastic paralyzed or healthy muscle /6,17,21,23,26,32,34/.

Depending on the time elapsed since the accident, the extent of muscle tissue degeneration varies greatly, being influenced by secondary illness such as poly-trauma, metabolic crisis, long comatose states or local destruction of thigh muscle. Due to the fact that most of our clients reach us approximately 1 1/2 - 2 years after the accident, the degeneration of muscle tissue is already far advanced; only allowing us to start with single contractions using very long pulse durations and long off-times. These single contractions are applied using modulations such as 120 – 150 ms pulse duration, with 300 – 500 ms pulse break (=1 - 2 Hz), 2 - 4 sec. on/ 1 - 2 sec. off, starting with 2x 15 min/d to prevent overstrain of muscle. Later on, we are able to increase the frequency up to 2x 30 min/day, 4 s on, 1 s off.

As soon as the quality of the muscle tissue has been improved, having more stable cell-membranes and an increased metabolism, we use with 70 – 80 ms pulse duration and equal off-times, which represent a frequency of 5 - 8 Hz (5 - 10s on , 1s off) performed 15 min 2x/day. Once a significant structural and metabolic improvement of muscle tissue and quality of contraction have been achieved, and the required pulse duration of the muscle cell excitability has decreased, the stimulation pulse (35 – 50 ms), off-time 10 ms, can be shortened to achieve a higher frequency of 16 - 25 Hz. Under these circumstances a tetanic muscle contraction can be produced.

Contrary to the conventional use of electrical stimulation of denervated muscle which uses equally long off-times or on/off ratios up to 1:3, we reduced the off time to 10 ms without any difference in muscle fatigue.

Our amplitudes presently do not comply with the MED - GV regulations nor with the ÖNORM. We have already submitted a petition to change these regulations to better serve the needs of our clients, which should be our foremost concern.

We try to exercise the muscle with tetanic muscle contractions to facilitate functional movement against gravity at first, followed by functional movements such as knee extension with weight and against gravity until we obtain a torque which compares to approx. 1/4 of the body weight.

From this moment on it is possible to start the "standing up - exercise program".

2. Electrode size and material

Working with denervated conus-cauda patients, electrodes have to cover the whole muscle since there is no conduction of the stimuli within the muscle /21,25/. For this purpose, we used large anatomically - shaped electrodes (200 cm^2) made of a silicone-graphite material. It is most important to use flexible electrodes that accomodate to the uneven surface providing even surface-pressure. In order to create a homogenous electrical field underneath the electrodes silicone-graphite electrodes with their specific resistivity of $20 \text{ Ohm} / \text{cm}^2$ have been proven to be most effective. They can be applied with electrode gel or placed on a wet sponge directly onto the skin.

3. Amplitude gain - strength test

To evaluate the training status of the thigh muscle we assess the extension torque (Nm) /5,21,24/ using increasing stimulation amplitudes. We gradually increase the stimulation amplitude from 0 - 160 V_{PP} in 10 V steps (Fig.1).

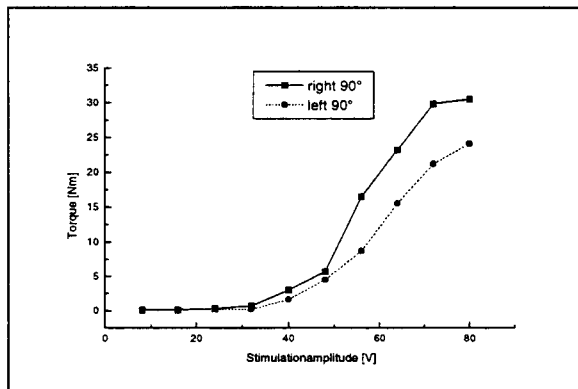


Fig.1: Amplitude gain measured at 90° knee flexion stimulation of M. quadriceps with 34 ms pulse width and 22 Hz stimulation frequency.

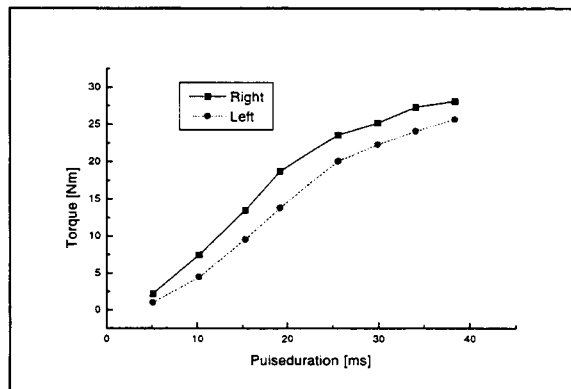


Fig.2: Torque measured at 90° knee flexion with varying pulse duration, constant amplitude and constant frequency.

The assessment of strength development using varying pulse widths at constant stimulation amplitude and constant frequency is being employed to determine the clients optimal stimulation parameters. Fig. 2 shows the extension torque evoked with varying pulse widths between 5 and 38 ms and a constant pulse frequency of 20 Hz. It is clearly shown that at this point in time a training using stimulations below 25 – 30 ms would not be effective since no sufficient contraction could be produced.

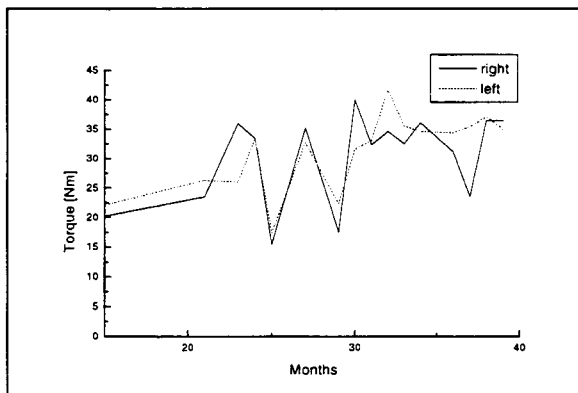


Fig. 3: Knee extension torque measured at max. stimulation amplitude over a period of 24 months.

The overview in fig. 3 shows a significant increase of strength during the observed time period of 24 months. A wide range of results among the control measurements have been observed. Nonetheless an average of 53 to 73% of strength gain constitutes a 4 - 6% increase in strength per month of training.

Strength testing in SCI patients using FES always poses the problem of an unwanted simultaneous stimulation of the antagonistic muscle groups (e.g. hamstrings - M. quad. fem.). Using higher voltages we are unable to assess the muscle performance of knee extension in correlation with the muscle tension [21]. Due to unwanted cocontraction of hamstrings at higher stimulation voltages the extension torque does not correlate exactly to the muscle tension.

4. Computertomography

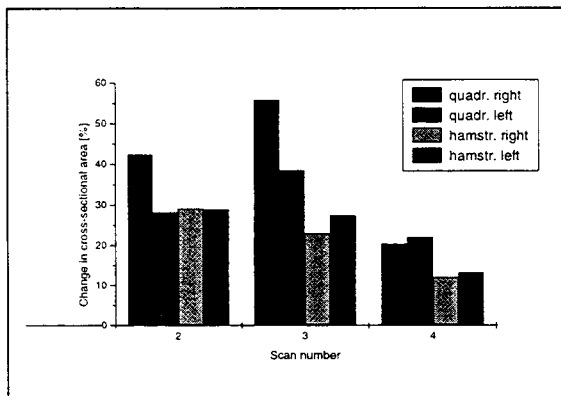


Fig. 4: Change in cross-sectional area M. quadriceps and hamstrings within 1 year of electrical stimulation.

The ongoing control-CT's clearly show an increase of muscle cross-sectional area of 48% as well as increasing density of muscle fibres, which proves a structural improvement of muscle tissue (decrease of fat and connective tissue).

The CT density factor shows an increase of 62%. What is particularly striking is, as preliminary tests have already shown, that not only the stimulated M. quad. fem. has grown, but also the thigh flexors have increased their area by 27%.

Owing to the fact that electrical stimulation concentrates on the thigh muscle and thus stimulating the lower leg and gluteal muscle much less, (1x / d 15 min) a slight decrease of muscle bulk during the observed time period can be

noted. If an increase of muscle bulk in this area were a desired goal, an intensive exercise program would have to be designed accordingly. 5 minutes of electrical stimulation once a day is too less.

5. Functions and functional training

The improvement of the muscle qualities through single contractions accompanied by long off-times to prevent muscle fatigue, is followed by an electrical stimulation program which generates tetanic contractions (according to the increasing of muscle tissue). It allows functional knee-extension in a sitting position starting within 10 - 20 degrees of ROM without resistance. The client exercises in the following manner: 6 sets of 8 repetitions, 2 seconds on, 2 seconds off-time performed once per day later on twice per day.

Corresponding with the increase of strength and according to the principles of training, ankle weights (0,5 - 4 kg) are added. A maximum strengthening program continues with 6 sets of 8 - 10 reps., 2 seconds on/off, 2 minutes break between sets, performed 1 - 2 times / day. Afterwards 6 sets of knee extensions with 15 repetitions and 2 min. break in between sets are performed. Primary focus is given to the actual daily muscle performance, which is often quite variable, and sometimes over-strain the muscle since pain or muscle tension cannot be perceived as a reliable stress parameter. Signs of an overstrained muscle are muscle tiring during exercise or not seldom with a one day delay, a dramatic decrease of its performance. In this case the exercise program needs to be interrupted to allow for a few days of regeneration.

6. Standing up with denervated muscles

The further functional training is aimed toward a verticalisation of the patient, not only to train the upper thigh muscle, but also to improve the cardio-vascular fitness as well as for balance reeducation purposes. This is achieved through standing-up and sitting-down exercises, with short standing intervals of 2 - 3 sec., also utilizing the patients varying upper extremity

capabilities. This particular training method is greatly appreciated by most patients since getting-up under their own power, plus the regained body height are highly motivational. Subsequently the standing phase is increased to a maximum of 10 seconds. Alternately stepping in place to relax the muscle and improve circulation also prevents an overstrain of the local metabolism. In practice the patient stands up, supporting himself on the parallel bars, alternately switching the right and left leg off, using his index finger, which simulates the swing leg phase. Balance is maintained through support of the upper extremity. Body weight is held mainly by the stimulated leg.

DISCUSSION

In our earlier work /21/ we were able to demonstrate the effects of training on denervated muscle, causing enormous structural and metabolic improvements. The goal of our latest research efforts was the transformation of these metabolic and structural changes into true functional gains. The first step consisted of the increase of muscle strength using sufficiently strong stimuli and choosing training parameters which were optimized in regular intervals. The stimulation of denervated muscle fibres requires amplitudes which do not comply with the currently valid MED - GV, EC - Norm and ÖNORM. It is our responsibility to modify these regulations accordingly, which are meant to ensure our patients safety, by supplementing these specific therapeutic applications to obtain an effective tool of therapy.

Gaining an average of 4 - 6% of muscle strength per month, starting mostly from very low performance levels, enables the client to get up and to stand within 1 – 2 years. Our therapeutic goal is not to achieve the longest possible standing time but to produce the change between stance and swing phase, an improved coordination of the upper body and an increase of upper extremity strength, leading to the ultimate goal of "ambulation with denervated muscles."

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PERMANENT CARDIAC ASSISTANCE FROM SKELETAL MUSCLE: A PROSPECT FOR THE NEW MILLENNIUM

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SUMMARY

In this paper I look at the prospects for new surgical solutions to the problem of end-stage heart failure based on cardiac assistance from skeletal muscle. The current status of the main biological approaches—cardiomyoplasty, aortomyoplasty, and the skeletal muscle ventricle—is given, followed by a consideration of some of the important basic issues that need to be addressed if these techniques are to achieve their full potential. Although there is a review element to the paper, the main emphasis is on the work of our own research group and collaborating workers.

STATE OF THE ART

At previous Vienna International Workshops, I have spoken of the clinical need for alternatives to current treatments for end-stage heart failure /1, 2/. In no way has that need become less pressing. All over the developed world, the number of heart transplants has reached a limit set by the availability of donor organs. Transplant lists continue to grow, and patients are excluded for no better reason than that they are over the age of 55 or 60. Of those admitted to a waiting list, between 20 and 30% still die while awaiting a transplant. The availability of xenografts from transgenic pigs or baboons could reduce the waiting list mortality, but would carry the additional risk of infection by latent animal viruses /3, 4/. Ventricular reduction has recently attracted interest, but an adequate assessment of its benefits awaits the outcome of properly conducted clinical trials /5/. It currently carries a high peri-operative mortality, and since it involves discarding up to 300 g of functional myocardium it is difficult to view it as other than a temporary expedient for extreme cases of dilated cardiomyopathy. Mechanical artificial hearts will continue to be used mainly as a bridge to transplant. Even if the problems of haemocompatibility and infection were solved, the continuous presence of an external power supply may pose an unacceptable psychological challenge to the patient in the longer term /6/.

Against this background, a surgical approach to cardiac assist based on a redeployment of the patient's own skeletal muscle remains an attractive prospect. It offers a biological solution that is free from the risks, debilitating side-effects, and costs associated with long-term immunosuppression; it is not limited by donor availability; and it does not require the patient's own heart to be discarded, but shares the work-load, offering some potential for myocardial recovery. The costs are mainly those associated with the surgical procedure itself, including the implantable stimulator used to activate the grafted muscle.

Principles of skeletal muscle assist

As a biological source of power, skeletal muscle has the great advantage that it allows a small expenditure of energy, needed to stimulate the motor nerve, to trigger the release of a potentially large amount of energy, derived ultimately from the normal intake of food and oxygen. Muscle converts that energy with great efficiency into mechanical work which can, in principle, be harnessed in various ways to assist a failing circulation /7/. The cardiomyostimulator, like a conventional pacemaker, would have to be renewed every 5 years or so, but no other energy source would be required.

Why, then, was this solution not adopted years ago? There is an early history, going back almost to the beginning of the century, of the use of skeletal muscle as a passive surgical biomaterial. However, the first

attempts to utilize the contractile properties of muscle in cardiac assistance date from about 40 years ago /8-10/. These and other pioneering attempts were defeated by the problem of muscle fatigue. The solution to this problem was contained in the discovery that, given time, skeletal muscles could adapt their physiological, biochemical and structural characteristics to a more demanding pattern of use /11, 12/. Although an attempt was made to point out the relevance of the discovery /13/ it was several years before it was picked up, by Dr J. Macoviak in Dr L.W. Stephenson's laboratory, which was then at Philadelphia. My research group and Stephenson's began a productive collaboration and soon confirmed that the use of chronic electrical stimulation to induce fatigue-resistant characteristics, a procedure now referred to as 'conditioning', would enable the muscle to work as a pump for prolonged periods. Using an implantable mock circulation, we established that even cardiac levels of work could be sustained /14/. With these developments the technique underwent a renaissance. In several laboratories, surgical techniques were developed for diverting a non-essential muscle from its normal role, transferring it into the chest, and configuring it appropriately to provide cardiac assistance. A number of muscles continue to be investigated for this purpose, and these have included diaphragm, rectus abdominis, pectoralis major, and serratus anterior, but the most frequent choice is latissimus dorsi (LD). The basic requirements were completed by the availability of an implantable electrical stimulator, triggered by the R-wave of the patient's ECG, and capable of delivering a train of impulses to the motor nerve to elicit a contraction from the muscle at the right moment of the cardiac cycle and for the appropriate duration. This last development was an essential step toward full clinical realization of the new technique.

Cardiomyoplasty

To date the clinical use of skeletal muscle assistance has been confined to cardiomyoplasty and aortomyoplasty. In these procedures the LD muscle is wrapped around existing structures, the ventricles of the heart in cardiomyoplasty, and the ascending or descending aorta in aortomyoplasty. Experience with aortomyoplasty is limited as yet, in terms of the number of patients (still less than 20 worldwide) and the duration of follow-up /15/. Cardiomyoplasty, on the other hand, has been carried out in over 700 patients worldwide since its introduction in 1985 /16/, and there is now a substantial body of follow-up data /17-22/. Although there is still some discussion about the way in which cardiomyoplasty works, a consensus is emerging that the main benefits derive from a girdling action of the muscle, which tends to prevent further enlargement of the ventricles and in some documented cases actually reduces their size /18, 20, 23-25/. Gealow, in a thoughtful and incisive commentary on the field /26/, has suggested that these changes in our understanding of the mechanism should prompt a reconsideration of the protocols for conditioning and activating the muscle wrap, and she discusses a series of key issues that need to be resolved. I will be looking at some of these issues later.

Procedures like cardiomyoplasty and aortomyoplasty have the considerable advantage that they do not place new, non-endothelial, surfaces in contact with the circulating blood. However, they suffer from one serious limitation: the geometry of the pump is dictated by the size and shape of the existing organs. In some respects the consequences of this limitation are obvious. A grossly hypertrophied heart may be too large to be wrapped effectively by the patient's LD muscle. Branching of major vessels makes it difficult to wrap an appreciable length of the ascending aorta. The small lumen of the descending aorta restricts the stroke volume that can be achieved by compressing it. But just as important as these anatomical considerations are the loading conditions imposed on the muscle wrap. In such a situation, the muscle is constrained to operate far from the peak of its power curve /27, 28/.

Skeletal muscle ventricles

The power available for assisting the heart can be harnessed much more effectively if the grafted muscle is formed into a separate auxiliary pump, or skeletal muscle ventricle (SMV). The SMV is not constrained by existing geometry but is limited only by the size, shape and fibre orientation of the muscle that is available. Subject only to these limitations, factors such as cavity volume, wall thickness and direction of wrap are all within the control of the surgeon and can, in principle, be optimized to provide the maximum pumping performance of which the muscle is capable. Set against this functional potential is the need to ensure that

the introduction of such a device into the patient's circulation does not cause thrombus formation, with the attendant risks of obstruction of flow through the device and embolism to vital organs. In this respect, the research to date gives grounds for optimism. In the Detroit laboratories of our collaborator, Dr L.W. Stephenson, SMVs have pumped as diastolic counterpulsators in dogs for over 2 years /29, 30/ and since those papers were published some have gone on to function in circulation for over 4 years (work in progress).

To develop a better understanding of the factors influencing the flow within an SMV we developed an apparatus that physically simulated flow behaviour in a transparent elastomeric SMV model /31/. With this apparatus, we showed that flow was dominated by the formation of coherent vortices. We explored the dependence of these structures on pulse shape, amplitude and frequency, and the influence of inlet configuration and flow in the pumped circuit /32/. We were able to show that extended quiescent periods at the end of the filling phase generated travelling vortices, which acted as mixing structures, reducing the residence time of fluid in the apex of the ventricle /33/. This work, complemented by parallel studies using the latest Computational Fluid Dynamics codes /34/, established basic design rules for SMV configurations that minimize the risk of thromboembolic complications.

We consider that flow conditions, rather than the nature of the lining, are the prime consideration in seeking to avoid the formation of thrombus within an SMV. Nevertheless, parallel work indicates that it would be technically feasible to endothelialize the SMV lining should this prove necessary /35/.

Much of the experience to date has been obtained with SMVs connected in an aorta-to-aorta configuration and operated in counterpulsation with the host heart. This configuration provides considerable potential for myocardial recovery, since the filling cycle of the SMV unloads the left ventricle, while the ejection cycle of the SMV boosts the coronary circulation and contributes to the pumping of blood through the systemic circulation. Recently, however, promising results have been obtained with a configuration in which the SMV pumps between the left ventricular apex and the aorta /36/.

Measuring hydraulic performance

The potential benefits of the SMV approach can best be realized if the configuration of the SMV and its interaction with the host heart can be explored experimentally. Dr J.C. Jarvis in this laboratory is currently conducting a series of experiments in which the pumping work performed by the left ventricle and the SMV can be determined when the latter is activated at different times and for different durations during the cardiac cycle /37/. These observations are being compared with predictions generated by an analog model of the SMV in circulation.

PROBLEMS AND FUTURE DEVELOPMENTS

Keeping the graft alive

Although the majority of patients who undergo cardiomyoplasty enjoy an improvement in their quality of life, between 15 and 20% derive no benefit from the procedure /18/. Furthermore, in a review of 127 patients who underwent cardiomyoplasty over a 10-year period it was reported that less than 60% of patients survived for more than 2 years after the operation /22/. This somewhat disappointing outcome has been attributed to functional deterioration of the muscle wrap, based on evidence from animals /38-42/ and man /43, 44/. Graft damage, involving replacement of muscle by fibrous tissue and fat, appears to be caused by a combination of factors, including changes in vascular conformation, loss of resting tension and chronic electrical stimulation /42, 45/, but ischaemia, particularly of the distal part of the muscle involved in the wrap, is increasingly regarded as the most important factor of all. The ischaemia arises when the flap is lifted, because of the need to divide perforating branches of the intercostal arteries that enter the distal part of the muscle; sacrifice of these so-called collateral vessels has been shown to cause damage in both sheep /42/ and goats /46/. This damage is exacerbated by the increased metabolic demand associated with the stimulation needed to condition and to activate the graft /45/.

Mannion and his colleagues /47, 48/ tried to overcome this problem by enforcing a 'vascular delay' of 3 weeks after reconfiguring the muscle and before initiating stimulation. (We agree with Gealow /26/ that such a period is not a vascular delay in the true sense, since the muscle is reconfigured in the same procedure.) The clinical cardiomyoplasty protocol that is most widely used also includes such a delay, in this case of 2 weeks /19/. The idea is that this would provide time for neovascularization, extending the area effectively perfused by the thoracodorsal artery. The problem is that it also delays the benefit that the patient might otherwise be deriving from the operation. Moreover it is by no means sure that the delay is effective: even with a delay it is still possible to demonstrate the additive damaging effects of stimulation and division of collateral vessels /42, 46/. Better results have been obtained by implementing a true vascular delay, in which the collateral vessels are divided but the LD muscle is left *in situ* for 10 d before elevating it as a graft /49, 50/.

Loss of the perforating arteries cannot be avoided, but the anatomy of the vascular supply to the LD muscle offers a potential solution to the problem. Several radiographic and resin injection studies have provided evidence of arterial anastomoses that connect the vascular trees of the thoracodorsal artery and perforating arteries in the LD muscle. Some recent experiments that we have conducted in sheep have confirmed that these anastomoses are functional under normal physiological conditions of pressure and flow /51/. In principle, such anastomotic channels should enable blood delivered by the thoracodorsal artery to perfuse the distal region of the mobilized muscle without the need to wait for neovascularization. Why, then, does the LD muscle become ischaemic at all? We formulated the hypothesis that disturbance of the muscle during surgical mobilization—including handling and cooling of the muscle, electrocautery, and reduced muscle tension—caused these arterial anastomoses partially to close down, producing ischaemia in the distal region of the muscle.

To test this idea we used a fluorescent dye-dilution microspheres technique to study, again in sheep, the regional blood flow contributed by the two main arterial supplies to the LD muscle. We confirmed that the territory supplied by the thoracodorsal artery extended over the whole LD muscle, diminishing in the proximodistal direction; the territory supplied by the perforating arteries also extended over the whole muscle, diminishing in the distoproximal direction. After 2 weeks of continuous electrical stimulation at 2 Hz, these characteristic gradients were abolished, almost certainly because flow through the anastomotic connections between the two vascular trees was enhanced /52/. In support of our hypothesis, prestimulation also rendered the muscle more resistant to surgical intervention. When untreated muscles were lifted, handled, and cooled and replaced at reduced tension, the usual signs of distal ischaemia were observed, and these had not recovered to a significant extent 5 days later. When prestimulated muscles were subjected to the same manipulations there was a smaller reduction in blood flow, the distal region was no longer selectively affected, and any initial ischaemia was completely reversed by 5 days /53/. These findings make a substantial case for stimulating the LD muscle before raising it as a graft, as this can both improve the viability of the muscle and enable cardiac assistance to be delivered to the patient at an earlier postoperative stage.

Are there alternatives to conditioning by electrical stimulation?

Skeletal muscle responds to electrical stimulation with a coordinated sequence of changes in its blood supply, enzymes of energy metabolism, kinetics of calcium transport and contractile proteins; it is these changes that enable it to sustain cardiac work. Thus, conditioning makes use of an inherent adaptive capacity of skeletal muscle, seen in less extreme form in the familiar response to endurance exercise. In recent years, cloning of the myogenic determination factors has shed light on the earliest stages of myogenesis, in which mesenchymal stem cells become committed to the muscle cell lineage. As yet no corresponding transcription factors have been identified for cardiac myogenesis or for the expression of skeletal muscle fibre types. In time such factors may be discovered, and could then conceivably be cloned and introduced by the techniques of molecular biology. Currently, however, stimulation provides the only realistic route to inducing the cellular infrastructure for fatigue resistance in a coordinated way and across the entire muscle.

Although there is scope for the use of pharmacological techniques as an adjunct to stimulation for improving graft function, the author would strongly encourage investigators to resist the temptation to seek a 'magic bullet'. In many cases an understanding of the scientific phenomena, resulting in appropriate modifications to the clinical protocol, will have the desired effect without the additional risks, side-effects and costs of long-term drug therapy.

Improved stimulation protocols for conditioning and activation

As indicated above, the crucial element in obtaining cardiac assistance from skeletal muscle is 'conditioning' by electrical stimulation over a period of weeks. This induces the adaptive changes that underpin the ability of the muscle to perform cardiac work. A variety of stimulation patterns has been used to produce these changes. In basic scientific studies it is common to use continuous stimulation at 10 Hz in rabbits or rats, and a lower frequency, such as 2 Hz, in larger species such as dogs and sheep. Short bursts of stimulation at a higher frequency, such as 30 Hz, are also used, often with some protocol for escalating the challenge to the muscle over a series of weeks. The clinical protocol that is in most widespread use is of this type. It is, however, important to note that this protocol is largely intuitive, rather than scientifically based. It is certainly far from optimal, for it takes too long and results in the development of slow contractile characteristics, which reduce the available power and pose problems of synchronization with the cardiac cycle /54/.

We have argued elsewhere /1, 55-57/ that a far better outcome of conditioning would be a muscle of the '2A' type, which would have a highly developed capacity for generating energy via oxidative pathways yet retain fast contractile characteristics. We have shown that it is feasible to establish such a state, and to maintain it stably, by conditioning the muscle with a pattern of stimulation that delivers a smaller aggregate amount of impulse activity /58-60/. How could a reduction in the amount of stimulation be achieved in practice?

One approach is to replace the conventional, but completely unphysiological, constant-frequency bursts of impulses with bursts in which the interpulse intervals are optimized to produce the greatest force per impulse /61/. Another approach is to deliver stimulation for only part of the day. Thus assist could be delivered at specified times during any 24-hour period, or could be restricted to times when a rise in the patient's heart rate indicates an increased demand. Recently the latter approach was applied clinically in a study that provided clear evidence of an increase in the contractile speed (and therefore power) of the grafted muscle when stimulation was switched from the conventional régime to the more intermittent 'demand régime' /62/.

Another measure that can be taken to reduce aggregate impulse activity is to provide assistance on a smaller proportion of cardiac cycles. Indeed there is an even more compelling reason for taking this measure, namely the growing evidence that more intensive regimes produce irreversible damage in the graft /43, 44/. This may be related to compromise of blood flow in the muscle flap. When a skeletal muscle contracts, its arterial blood flow may be arrested or even reversed by the rise in intramuscular pressure. When the muscle relaxes, a compensatory increase in forward flow takes place, and mean flow is not affected. If such a muscle is wrapped around the cardiac ventricles and contractions are repeated too frequently there may be insufficient time for reperfusion of the muscle during relaxation. The clinical experience of cardiomyoplasty in Russia is worth noting in this regard, for there it was quite usual to use synchronization ratios between 1:4 and 1:16, apparently with good results /63/. Van Doorn and her colleagues studied this situation in the sheep and found an increase in thoracodorsal venous lactate concentration and a high incidence of reactive hyperemia if the muscle was stimulated on every cardiac cycle; this is evidence that a 1:1 regime of stimulation produces partially anaerobic, and therefore unsustainable, working conditions in the muscle /64/. Whether the LD muscle is configured as a cardiomyoplasty wrap or as an SMV /65/, its long-term viability will be improved if it can be activated at a synchronization ratio of 1:4 or less. Again this is a variable that could be manipulated according to demand.

Monitoring for optimized timing

Despite the number of cardiomyoplasty operations that have been performed to date there appears to be no universal agreement about the point in the cardiac cycle when the muscle wrap should be stimulated to contract. It is usually recommended that contraction should start immediately after closure of the mitral valve, presumably on the basis that this is the moment of maximum ventricular wall stress. Another possible strategy is to time contraction so that it maximizes aortic flow velocity /66/. Then again, contraction towards the end of ejection might be more effective in reducing the end-systolic volume, with the prospect of producing a beneficial reduction in cardiac size in the long term. Until now there has been no systematic body of evidence on which to base such decisions. The need for such studies was underlined by the work of Schreuder and his colleagues /25/ who used advanced catheter techniques to record pressure-volume loops in a number of cardiomyoplasty patients. They found that the chronic settings of the cardiomyostimulators were often far from optimal. The importance of correct timing was borne out by a corresponding experimental study in goats /67/. Thus there is a need for simple, non-invasive techniques that would enable the timing to be optimized for each individual. Some suitable techniques are beginning to emerge /62, 68/.

Defibrillator/stimulator

Between 40 and 50% of heart failure patients, including those who have had cardiomyoplasty, will suffer a fatal arrhythmia rather than die through pump failure /69/. The survival of cardiomyoplasty patients could therefore be extended if the cardiomyostimulator were combined with an implantable cardiac defibrillator (ICD). Such a device is now made by Medtronic, Inc. and is undergoing clinical evaluation. The preliminary results are promising: 10 out of the 28 patients included in the study so far (mean follow-up time 11.4 months) have had a potentially fatal event, with normal rhythm restored successfully by the ICD /70/. Use of these devices, in addition to anti-arrhythmic medical therapy, will undoubtedly become more common.

CONCLUSION

Cardiomyoplasty and aortomyoplasty have the advantage of being fairly conservative procedures; the SMV has a greater potential for sharing the pumping work of the heart. In practice, therefore, all these approaches are likely to find a place in the surgical armamentarium. A thorough understanding of the way in which the different configurations interact with the heart in various pathological conditions, together with a more detailed knowledge of the scientific phenomena on which they are based, will be essential if cardiac assistance from skeletal muscle is to become a safe, reliable and effective surgical treatment for end-stage heart failure in the next century.

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EFFECT OF NERVE STIMULATION ON RAT SKELETAL MUSCLE. A STUDY OF PLASMA MEMBRANE

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SUMMARY

Acute effects of electrical stimulation of the sciatic nerve are mediated via a plasma membrane change, are dependent on the strength as well as the duration of the current, and are reversible. These changes may be of significance in explaining the observed beneficial effects of chronic electrical stimulation.

STATE OF THE ART

The chronic effects of direct electrical stimulation on denervated rat skeletal muscle have been studied extensively /1-2/. However, there are no systematic studies of the immediate effects of electrical stimulation of nerve on normal skeletal muscle, especially with reference to plasma membrane changes. This investigation reports on the acute effects of electrical stimulation of sciatic nerve on the morphology, histochemistry, histometry, and ultrastructure of rat gastrocnemius muscle. The state of the muscle plasma membrane was studied by lectin binding techniques.

MATERIALS AND METHODS

Sprague-Dawley rats weighing up to 250 grams were used in this study. In all the experiments, rats were anesthetized with Nembutal and the sciatic nerve of the right leg was exposed and stimulated by a monopolar microelectrode (150 μ s, 10 Hz). The indifferent electrode was placed on the dorsum of the right foot. Six groups of rats with five rats in each group were used for six different time-current studies /1/. Groups I and II received a 5-mA current for 30 and 60 minutes respectively while groups III and IV received a 10-mA current for a period of 30 and 60 minutes. In addition, dosages of 10 mA for 200 minutes (group V) and 15 mA for 5 minutes (group VI) were selected for the last two groups to determine the effects of longer time and higher current strength respectively. Gastrocnemius muscle was removed at the end of the stimulation period in all groups. Muscle biopsies from another similar set of six groups were taken following a 60 minute rest period at the end of stimulation to investigate the reversibility of changes. The sciatic nerve of the left leg in all the experiments was not stimulated and served as a control. The sciatic nerve from the stimulated as well as the nonstimulated leg was removed in all cases and observed for morphological changes at light and electron microscopic (EM) levels. The experimental and the control muscle was immediately frozen and processed for routine histology and histochemistry /3/. Histometric studies were carried out with respect to mean fiber diameter and percentage of two fiber types using an MOP-3 Image Analyzer System (Carl Zeiss, Inc.). A part of the fresh sample was fixed in glutaraldehyde and processed for routine EM studies /4/.

Sciatic nerve was processed for electron microscopy in a similar manner. Part of the muscle tissue was processed for ultrastructural study of plasma membrane state using peroxidase loading /5/, peroxidase labeled lectin (Concanavalin A) binding /6/, and the ferritin-conjugated Concanavalin A (Con A) technique /7/.

RESULTS

In all six groups, the muscle morphology was preserved. Since the normal rat skeletal muscle does show ragged red fibers, the percentage of these fibers was determined in the control as well as the experimental side of all the groups (Table 1). As seen in Table 1, this increase was 3.1 and 2.56 times of control in groups IV and V respectively while the remaining groups showed an increase of 1.06 to 1.55 times of control. This increase did not persist following the rest period.

Table 1. Effects of various dosages on number of ragged red fibers.

Muscle	Group I	Group II	Group III	Group IV	Group V	Group VI
Control	23.20%	23.30%	29.80%	15.40%	20.80%	20.30%
Experimental	32.60% ^x	36.20%	43.10%	47.80%	53.30%	21.60%
X increase - Experimental group	1.40 ^x	1.55 ^x	1.44 ^x	3.10 ^x	2.56	1.06

Histometry. Percentage of fibers. The high percentage of type II fibers in the gastrocnemius reflected its composition. The fiber type ratio (Type I/Type II) of the experimental side (range 0.09 to 0.44) was not significantly different from that of the control side (range 0.17 to 0.36) in all the groups. In all six groups the mean fiber diameter of type I and type II fibers in the stimulated muscle was not significantly different from the control (nonstimulated) muscle and ranged from 25 to 40 μm . In groups I, II, III, and VI, the muscle fibers showed no ultrastructural alterations. The group IV and V rats receiving the current of 10 mA for 60 and 200 minutes respectively showed mitochondrial and structural changes. The muscle of these groups showed large aggregates of mitochondria in the subsarcolemma. The mitochondria were swollen and occurred in a variety of shapes. Mitochondrial cristae were convoluted and partially destroyed. Focal disruption of myofibrillary architecture was seen in some fibers. In many areas, myofibrils were rarefied and sarcotubules dilated. The sciatic nerve of the stimulated side showed no morphological changes when compared to the control in all six groups. In order to guard against drawing incorrect conclusions, the state of the plasma membrane was carefully checked in the serial sections of all the blocks in six groups, and we made sure that all cytochemical methods /5-7/ gave consistent results in each group. In groups I, II, III and VI, the plasma membrane was intact and showed no abnormality. The membrane integrity was first checked using phase contrast microscopy with the peroxidase loading /5/ and Con A-peroxidase /6/ techniques. Epon sections, 1 μm thick, showed uniform density around muscle fibers and no penetration of peroxidase by the Con A-peroxidase method. At the ultrastructural level, the plasma membrane showed a dense reaction all along the cell surface with the peroxidase loading and Con A-peroxidase binding. Ferritin-Con A labeling was seen as Con A binding external to the plasma membrane and ferritin granules distributed along the basement membrane. However, groups IV and V showed plasma membrane abnormalities. With peroxidase loading and Con A-peroxidase techniques, the population of fibers showed focal alterations on the cell surface in phase contrast microscopy.

The focal lesions in these fibers appeared as wedge-shaped, and the sarcomeres were highly contracted. At the ultra-structural level, the breaks in the membrane were evident by the absence of the reaction product in focal areas along the membrane. Ferritin-Con A labeling also showed an absence of Con A binding and ferritin granules where the membrane was not intact.

The subcellular abnormalities were marked in the areas where the membrane was indistinct and showed focal breaks. Myofibrillary dissolution, aggregation of glycogen and abnormal mitochondria were evident in this region. Following the 60 minute rest period, muscle in all groups showed no pathological changes. Biopsies from groups IV and V were particularly investigated to detect mitochondrial and plasma membrane alterations showed no lesions.

DISCUSSION

The direct electrical stimulation of muscle has shown beneficial effects in retarding atrophy in the denervated rat muscle /1-2/. This technique has also been tried clinically as a therapeutic measure to reduce spasticity, develop muscle force in paraplegics /8/ and affect ambulation in spinal cord injury patients /3/. In the present study, we observed the acute effects of sciatic nerve stimulation using various current strengths and duration on the skeletal muscle. The results of histometric measurements on fiber size and ratio showed that the experimental and control values were not significantly different in all the groups. This indicated that unlike denervated rat muscle, the normal rat muscle was not effected in terms of the muscle fiber size and percentage distribution of fiber types by the strength and duration of the current applied to the sciatic nerve. The nerve stimulation with the current strengths of 5 mA for 30 and 60 minutes, 10 mA for 30 minutes, and 15 mA for 5 minutes (groups I, II, III and VI) did not exert any morphological changes or influence the state of plasma membrane. The failure of a 15 mA current employed for a short duration (5 minutes) to cause any morphologic change, showed that in addition to the current strength the duration of nerve stimulation was also an important factor in causing muscle abnormalities. The increase in the number of ragged red fibers and mitochondrial abnormalities with a 10 mA current applied for 60 and 200 minutes (groups IV and V) was noteworthy. Walter et al /9/ also showed similar mitochondrial changes after 60 minutes of stimulation with 5V and a frequency of 10 Hz. As in Walter's experiment /9/, the mitochondrial abnormalities in our study were not permanent and were absent after a 60 minute rest period. Green and Harris /10/ have attributed such mitochondrial changes to a variety of energized states. The muscle fibers in these groups did not show any inflammatory response or muscle necrosis. The mitochondrial changes, therefore, are more likely to represent an adaptation to an altered energy state. The muscle in groups IV and V also showed plasma membrane alterations following the nerve stimulation. They were characterized by the penetration of peroxidase into the affected fibers, observed under phase contrast microscopy, and focal breaks in the plasma membrane at the ultrastructural level. Similar plasma membrane defects have been shown in dystrophic muscle using these techniques. Based in our observations in groups IV and V, we suggest that the electrical stimulation of the nerve in these groups was of "supramaximal" strength and resulted in the muscle contraction and subsequent mitochondrial and plasma membrane changes. These changes were, however, reversible as seen by their absence following a 60 minute rest period. The reversible nature of the alterations suggests that this is a physiological rather than a pathological response.

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EFFECTS OF DIAPHRAGMATIC PACING ON IMMATURE CANINE DIAPHRAGM

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SUMMARY

After four weeks of continuous, low frequency stimulation of the immature canine diaphragm, diaphragmatic ultrastructure showed no evidence of cellular damage. Increases in capillary area and mitochondrial volume are consistent with our previous report of increased oxidative enzyme activity and isomyosin alteration to type 1 fiber isoforms.

STATE OF THE ART

Skeletal muscle demonstrates extraordinary plasticity and adapts to increase and decrease in metabolic demands with functional and structural changes /1/. Activity, induced by chronic electrical stimulation or exercise, has been shown to affect the calcium regulatory system, energy metabolism, and the contractile apparatus of the activated muscle fibers /2/. These adaptational changes are considered to be related to transcriptional and translational alterations of the genetic material of the muscle cell taking place in a time-ordered sequence. In an earlier study, we reported the histochemical and biochemical transformation of type 2 fibers to type 1 with stable paced tidal volumes and airway occlusion pressures following continuous (24h/day), chronic (24-28 days), low frequency diaphragm pacing of five immature ^65 days) dogs /3/. The present study, tested the hypotheses that continuous low-frequency electrical stimulation altered muscle morphology using measurements of Z band widths for fiber type determination, the individual mitochondrial size, area and shape and the total mitochondrial area as a percentage of the fiber (mitochondrial volume), and the capillary density in both paced and non-paced hemidiaphragms.

MATERIALS AND METHODS

The techniques for electrode placement, stimulation, and physiological parameters, and the collection of the hemidiaphragm samples have been detailed earlier /3/. Briefly, in each of five animals, a unipolar stimulating electrode was placed on the left phrenic nerve. The left hemidiaphragm was paced 24h/day using a stimulus frequency of 11.1Hz., an inspiratory time of 810ms, a respiratory rate of 20 breaths/min., and 10 stimulus pulses/breath. The physiologic parameters, including tidal volume and airway occlusion pressure, were measured over time at various stimulus frequencies before arriving at the above standard. Part of the paced and non-paced hemidiaphragm was processed for routine electron microscopy (EM). The specimens in longitudinal as well as transverse planes were viewed under a Philips EM 300 transmission electron microscope. For all measurements, the Bioquant System IV Image Analyzer (R.&M. Biometrics) was employed. The data were collected in a blind fashion.

The Z band width measurements were carried out on the longitudinally sectioned fibers at 30,000x magnification. A total of 25-30 fibers were randomly selected from each hemidiaphragm of five animals. For all mitochondrial measurements, random sampling was achieved by analyzing two blocks of tissues per hemidiaphragm, (two to four sections per block, and ten micrographs per section). Mitochondrial measurements consisted of size (longest diameter across the lesser aspect of the mitochondrion), area, and shape and magnification of 10,000-30,000x was employed. In our system, the shape factor value ranges from 0 to 1 where 0 represents a straight line and 1.0 denotes a circle. With this reference, values from 0.70 to 0.85 were considered to represent an oval shape. At least 300-350 mitochondria were measured in each region (subsarcolemmal and intermyofibrillary). The mitochondrial volume was determined by calculating the ratio of mitochondrial area to the total fiber area. Five fibers of each type (I&II) were included for each pair of diaphragms and the mean percentage volume was calculated for paced and non-paced diaphragms. This was counterchecked by the classical point counting method /4/, in which fiber type distinction was not made. For point counting a grid (1 cm. square) was utilized and approximately 42,000 points were counted. The ratio of points falling on mitochondria to points on other cellular components was related to the mitochondrial volume. For capillary measurements, one-micron thick plastic sections in the transverse plane were stained with methylene blue, then viewed and photographed under the light microscope. The number of capillaries in a defined area of the section was counted at 200-300x magnification. At least three areas for each side of the pair were included. The capillary area was measured in photomicrographs at a magnification of 400-800x and used to determine the total fiber and capillary area in each photograph. Five photomicrographs of matching magnification and covering different regions were selected from each hemidiaphragm of each animal. The mean percentage of capillary area for each pair based on five values was statistically tested to determine the significant difference between the paced and non-paced side. Paired t-tests or Wilcoxon matched-pairs signed ranks test (for non-parametric data) were performed for comparisons of Z band widths, mitochondrial structure (size, area, and shape), mitochondrial volume, and capillary density in the paced and non-paced hemidiaphragms.

RESULTS

In agreement with previous light microscopic and histochemical observations /3/, the muscle ultrastructure too was preserved in the paced hemidiaphragm. The distribution of Z band width showed a clear bimodal distribution. The Z band widths were not significantly different with means of $120.7\text{nm} \pm 6.3$ and $121\text{nm} \pm 8.1$ for type 1 fibers and $90.5\text{nm} \pm 5.9$ and $89.5\text{nm} \pm 8.7$ for type 2 fibers of the paced and non-paced sides, respectively. The percentage of type 1 and type 2 fibers in the paced samples was 66/34, and in the non-paced samples, 64/36, this distribution not significantly different between the two sides. Mitochondrial size: The mean mitochondrial size of paced and non-paced sides was 0.23 and $0.26\mu\text{m}$ in the subsarcolemmal and 0.23 and $0.22\mu\text{m}$ in the intermyofibrillary regions, as well as 0.27 and $0.25\mu\text{m}$ for type 1 fibers and 0.24 and $0.21\mu\text{m}$ for type 2 fibers, respectively. This difference was not significant in either regions or fiber types. Mitochondrial shape: The mean mitochondrial shape factor values of paced and non-paced sides were 0.80 and 0.77 for subsarcolemmal and 0.75 and 0.76 for intermyofibrillary regions, and 0.77 and 0.71 for type 1 fibers and 0.76 and 0.77 for type 2 fibers, respectively. The mitochondrial shape was thus oval and was not significantly different between the paced and non-paced samples. The mean mitochondrial volume ($10.4 - 16.7\%$, $7.3 - 10.4\%$) was significantly increased in the paced hemidiaphragms ($p=0.03$, one tailed t test). The mean percentage of mitochondrial area ($5.7 - 13.4\%$, $4.5 - 5.0\%$) however was found to be significantly higher ($p=0.001$) only in the type 2 fibers of the paced hemidiaphragms.

The pooled data from all five puppies showed significantly higher mitochondrial content in the type 2 fibers of paced hemidiaphragms ($p=0.05$, one tailed t-test). Capillary density: The capillary morphology appeared normal in video images of semi-thin sections as well as in the electronmicrographs of ultra-thin sections. The number of capillaries showed no significant difference between the paced and the non-paced side in all five animals, but the mean capillary area was significantly increased (0.24 - 6.4%, 0.08 - 1.44%)($p=0.001$) on the paced side. This suggests larger capillaries in paced tissues. Considering the data of all five puppies, the Wilcoxon matched-pairs signed ranks test showed a significant increase in the capillary area of the paced side of diaphragm ($p=0.04$).

DISCUSSION

The present study showed two distinct fiber types with a bimodal distribution of Z band widths in the paced and non-paced diaphragms of all five puppies. The differences between the Z band width in the paced and the non-paced samples were not significant. These observations contrast with the studies by Salmons and Eisenberg /5/ which showed Z band changes after two weeks of low frequency stimulation. However, our findings agree with the reports on chronic endurance training which failed to show Z band width changes six months following endurance exercise in humans and in the comparison of runners and controls /6/. Muscle fibers in different species and within themselves exhibit molecular diversity and structural complexity. The stimulated fast twitch rat muscle differs from the stimulated fast twitch rabbit muscle with regard to enzyme activity, myosin light chain, and mRNA calcium regulating protein levels, and twitch properties /7/. Thus, parallels within different species, muscles, and ages may be limited. We suggest that chronic stimulation induces a change in the regulatory proteins governing structural cellular components which vary in response based on species type of the muscle and the stimulation pattern. The mitochondrial content of the muscle is readily altered by the increased metabolic demands. Variation in the mitochondrial size, shape, area, and volume has also been reported in a variety of normal mammalian skeletal muscles. In our study, the individual mitochondrial size, shape, and area measurements showed no significant difference between the paced and the non-paced diaphragm. However, the mitochondrial volume based on the ratio of mitochondrial area to total fiber area was significantly higher ($p=0.05$) in the type 2 fibers of the paced diaphragms. This finding of increased mitochondrial volume of type 2 fibers concurs with the histochemical findings of increased oxidative enzymes in the type 2 fibers /3/ and is similar to the reports on fast to slow transformation following low frequency stimulation as well as chronic endurance training. The increase in mitochondrial volume but not in Z band thickness of type 2 fibers indicates that the mitochondrial increase precedes the Z band transformation, if indeed the Z band width would eventually change with even more prolonged stimulation. Increased capillary area in paced specimens from three puppies is consistent with the observation that the number of capillaries around muscle fibers is proportional to the oxidative metabolic activity /8/. Hoppeler et al /7/ however showed that higher mitochondrial volume was consistently seen with higher capillary counts in the case of diaphragm muscle. Higher mitochondrial volume and consequently increased oxidative activities would place increasing demands for substrates, and hence, the delivery of these substrates via an increase in capillary area. The regulatory influence of low frequency pacing thus first affected the capillary area and the mitochondrial volume of type 2 fibers but did not effect the type 1 fibers.

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THREE PARAMETERS OPTIMIZING CLOSED LOOP CONTROL IN SEQUENTIAL SEGMENTAL NEUROMUSCULAR STIMULATION

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SUMMARY

In conventional dynamic myoplasties the force generation is poorly controlled. This causes unnecessary fatiguing of the transposed/transplanted electrically stimulated muscles and causes damage to involved tissues. We introduced Sequential Segmental Neuromuscular Stimulation to reduce muscle fatigue by allowing part of the muscle to periodically rest, while other parts work. In spite of this improvement we hypothesize that fatigue could be further reduced in some applications of dynamic myoplasty, if the muscles were made to contract according to need. This would also protect against damage to involved tissues. The first necessary step is to gain appropriate control over the contractile activity of the dynamic myoplasty. Therefore, closed loop control was tested on a sequentially stimulated neo-sphincter in order to strive for the best possible control over the amount of generated pressure. A selection of parameters was validated on optimizing the control. A control algorithm was created with the following built in variables: the frequency of corrections; the threshold for corrections and the transition time, during which no corrections were allowed. In dogs, neo-sphincters were created and stimulated to generate a closed loop controlled pressure. The accuracy of the generated pressure was measured while the values of the parameters were changed according to a protocol. Statistically significant optimum values were found for the tested parameters. Therefore we concluded that the frequency of corrections, the threshold for corrections and the transition time, are meaningful parameters in the controlling algorithm of the closed loop control in a sequentially stimulated myoplasty.

STATE OF THE ART

In dynamic graciloplasty the gracilis muscle is used to replace sphincter function. Outcome of this procedure has been variable /1,2,3/. Problems with muscle fatigue, ischemia, necrosis and fibrosis have been reported /4,5/. Current methods remedy fatigue using lengthy training protocols that transform the muscle from fatigue prone to fatigue resistant /7,8,9,10/. During this training period the muscles loose power and responsiveness and the patient does not benefit from the procedure. /6,7,8/. During training the patient is not experiencing benefit from he procedure and the muscles loose power and responsiveness. Additionally, as the result of constant performance, blood perfusion decreases, producing adverse effects on stamina and promoting fibrosis and necrosis.

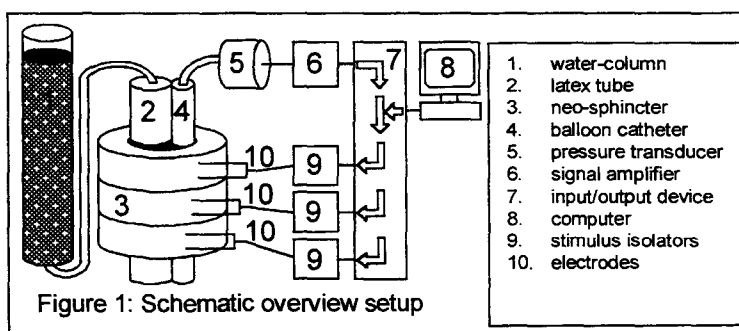
In previous work we described Sequential Segmental Neuromuscular Stimulation (SSNS/ alternating stimulation) that improves blood perfusion during stimulation by allowing parts of the muscle to rest while other parts contract /9/. This improves the fatigue resistance of the muscle at the cost of a lower maximum power output, because only part of the muscle is stimulated at a time. In a graciloplasty dog model we found that SSNS significantly improved neo-sphincter blood perfusion and fatigue resistance during stimulation /10/. However, In spite of these improvements the neo-sphincter could not maintain contraction indefinitely and did go on to fatigue.

Based on our previous findings we decided to approach the problem differently. Rather than trying to optimize methods to maintain constant pressure around the urethra we decided to apply a more physiological approach and apply pressure only when it is needed to maintain continence. In the case of a normally functioning true sphincter control mechanisms regulate when and to what degree contraction occurs. This results in maintenance of continence without prolonged periods of maximum sphincter contraction. If we could apply the same principal to a neo-sphincter i.e. stimulate it precisely when and to the degree necessary to maintain continence we could minimize or eliminate muscle fatigue and oppose the reported fibrosis and necrosis of involved tissues.

Successful regulation of output using electrical stimulation with closed loop control has been reported in research concerning paraplegia /11,12/. In this study we tested the feasibility of using closed loop control to regulate neo-sphincter pressure. Herein we investigated the effectiveness of three separate parameters in the algorithm.

MATERIAL AND METHODS

Sixteen neo-sphincters were created in eight dogs using both gracilis muscles. These muscles were wrapped around compressible latex tubes containing fluid at a hydrostatic pressure of 30 cm H₂O and balloon dilatation catheters (BMX/8-3/5.8/120, Boston Scientific Corporation, Quincy, MA). An input/output device (CED 1401^{plus}, Cambridge Electronic Design, Cambridge, England) was used to generate a three-channel SSNS signal (mono-phasic rectangular block-pulse; frequency 30 Hz; pulse-width 500 μ -seconds; transition to next segment after 1.0 second). The amplitude of the stimulation signal was controlled for all individual segments by customized sequencer files and script files in Spike2 data acquisition software (version 2, Cambridge Electronic Design, Cambridge, England). Stimulation signals were isolated using linear stimulus isolators (A395's, World Precision Instruments, Sarasota, FL, USA) and thereafter led to the neo-sphincters using three pairs of Teflon coated stainless steel wire electrodes ($\varnothing$ 0.007 inch; Medwire®, Mount Vernon, NY). Pressures generated by the neo-sphincters were picked up by balloon dilatation catheters and captured by pressure-transducers (P23 ID, Gould, Statham, USA). The generated pressure signals were amplified using CED1902's (Cambridge Electronic Design, Cambridge, England) and recorded with the CED 1401^{plus} (Fig. 1).



All neo-sphincters were stimulated to generate 30 cm H₂O. After reaching 30 cm H₂O pressure, this pressure was maintained for 15 seconds. During these 15 seconds, the actually generated pressure was measured and the average (from 150 samples) of the standard deviations was recorded to verify accuracy. This procedure was repeated 24 times with intervals of 6 minutes. Adjustments were made in the algorithm of the closed loop control with every repetition according to a protocol. In this protocol three parameters of the algorithm were evaluated for eight discrete values. Correction frequency: The number of corrections conducted by the closed loop control was varied from 1 per second up to 8 per second in steps of one (1-8 Hz). Allowable deviation: The threshold for the algorithm to conduct a correction by changing the amplitude of the signal was varied from 1% deviation of the goal pressure of 30 cm H₂O to 2%, 3%, 4%, 6%, 8%, 12% and 16%. In the SSNS every step to the next segment was started with a transition time. This transition time, in which no corrections were conducted, was varied from 0.0 up to 0.7 seconds, with steps of 0.1 seconds. This protocol of adjustments was constantly rotated to avoid bias in the measurements caused by fatigue of the neo-sphincters.

Statistical analysis of the data was performed using Friedman Repeated Measures Analysis of Variance on Ranks (RM ANOVA) and All Pairwise Multiple Comparison Procedures (Dunnett's Method).

RESULTS

The standard deviations generated with the 8 discrete values of the frequency of corrections showed a minimum at 4Hz (Fig 2). Differences with all other frequencies were statistically significant ($p < 0.05$). For the 8 values of the allowable deviation, a minimum standard deviation was found when the allowable deviation was 4% of the requested pressure of 30 cm H₂O (Fig. 3). Again, differences with all other values were statistically significant. A transition time of 0.3 seconds produced minimal standard deviations (Fig. 4). At this transition time the difference in standard deviation was not statistically significant when compared to 0.2 or 0.4 seconds, but all other values showed significantly higher standard deviations.

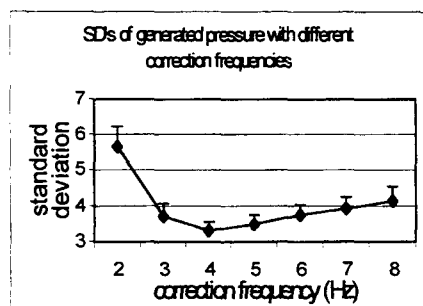


Figure 2

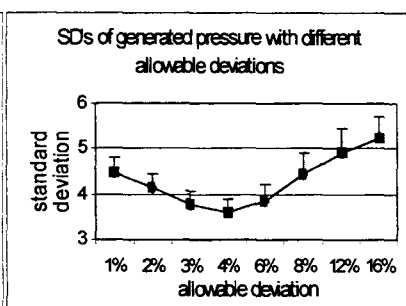


Figure 3

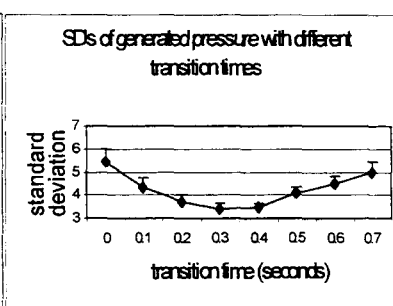


Figure 4

DISCUSSION

In dynamic myoplasties like dynamic graciloplasty major progress can be achieved if generation of output could be controlled and immediately adjusted according to necessity. Closed loop control using biofeedback is a useful means of acquiring this control. This approach was elaborated in the above described experiment: A neo-sphincter squeezing an artificial urethra containing a hydrostatic pressure of 30 cm H₂O and a balloon sensing the pressure generated by this neo-sphincter (biofeedback). With a specified frequency, this generated pressure was evaluated and when the specified threshold was exceeded the amplitude was proportionally corrected (closed loop control). Efficiency of the controlling algorithm was evaluated by calculating the average standard deviations during functioning. The frequency of corrections was evaluated on efficiency and showed an optimum value at 4Hz. At lower frequencies, corrections were relative late allowing greater deviations. At higher frequencies, adaptation of the muscle on changed stimulation amplitudes was too slow to react efficiently. This led to over-correction of the amplitudes and overshooting of the goal-pressure. The threshold for corrections showed an optimum in efficiency at a value of 4%. With lower thresholds the system over-reacted for the minimal corrections necessary, leading to over-correction. With higher thresholds the system was more indifferent to deviations allowing inefficiency. The neo-sphincter was divided into three segments and sequentially stimulated to improve perfusion during stimulation and thus endurance. The algorithm controlled these three segments as if three neo-sphincters were working in a sequential fashion, each having its own amplitude and individual correction of this amplitude. When switching from one segment to the next, the muscle and the biofeedback did procrastinate. Therefore, it was possible that a correction in amplitude was executed on a just starting segment, with biofeedback information referring to the previously stimulated segment. This faulty information led to poor corrections in amplitude of the stimulation signal. Therefore, a transition time in which no corrections were fulfilled was introduced. An optimum was found around 0.3 seconds. Lower transition times showed interference of segments and their biofeedback, resulting in higher standard deviations.

Higher transition times also resulted in less efficiency caused by the lack of corrections during stimulation.

It is concluded that closed loop control and sequential segmental neuromuscular stimulation can be combined in a system that control generated output. The frequency of corrections, the deviation allowed before corrections are effectuated and the transition time when switched to the next segment prove to be useful parameters in optimizing the efficiency of this closed loop control. The actual optimal values will probably differ between different muscles and different applications.

Efficient control of generated output of dynamic myoplasties will reduce fatigue and the necessity to train the muscle extensively. It will prevent ischemia and compromise of involved tissues and broaden the application area of dynamic myoplasty.

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NEW NON-INVASIVE MONITORING AND LIGHTER DEMAND STIMULATION OF LD WRAP IN DYNAMIC CARDIOMYOPLASTY: RATIONALE OF THE IMPROVED CLINICAL RESULTS

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SUMMARY

Clinically, it is fully accepted that LD benefits the patient's quality of life only if its activation is critically delayed after sensed QRS to avoid mitral regurgitation. Since maximum instant power of a fully conditioned LD is smaller than the peak power of the left ventricle, we share the opinion that the grafted muscle could assist the heart principally during mid and late systolic phases. Of course, such a short time window asks for a fast, powerful contraction which is not delivered by a fully transformed LD. Having a technique to non-invasively monitor the LD contraction and relaxation in dynamic cardiomyoplasty would facilitate the evaluation of new stimulation regimes or other techniques for improving LD function. We developed a new method for non-invasive, bedside monitoring of LD function using a standard polygraph, previously used for monitoring cardiac apical motion and heart sounds. ECG and heart tones are registered together with the pressure changes due to LD flap contraction and relaxation which are measured near the rib window with the probe normally used for recording an apicocardiogram. From LD "mechanogram," we can determine: 1) LD activation threshold, 2) optimal synchronization delay between cardiac events and the actual contraction of the LD flap, 3) the duration of the full LD contraction-relaxation cycle, and 4) the dynamic contractile characteristics of the LD flap based on the determination of the tetanic fusion frequency. The optimal setting induces LD contraction during the systolic ejection phase which can be assessed non-invasively in the same subjects using echo Doppler imaging of the aortic outflow tract. In a cohort of patients, we have shown that the LD flap becomes fatigue resistant by the end of the conditioning period, *e.i.*, within two months after the operation, and can remain viable at least up to fifty months. The extent of fast-to-slow transformation of contractile characteristics of the LD flap can be related to the stimulation protocols used, *i.e.* the amount of impulses delivered per day. Transformation is reversed by a "demand" stimulation, that is, with an activity-rest regime which give rests LD several hours per day. After months of continuous daily stimulation it is possible to reverse the fast-to-slow transformation by an activity-rest stimulation protocol based on a frequency cut-off at around 80 bpm, so that the LD flap is rested during low-activity periods during both day and night. It is important to stress that with this lighter stimulation regimes patients' quality of life is substantially improved with reduction of heart failure symptoms from N.Y.H.A. class 3 to 1. One-year after Demand Dynamic Cardiomyoplasty maximal oxygen consumption increases 30% over pre-op analysis. If these preliminary data will be substantiated by long-term results in these patients and in those planned to be treated during 1998, we are confident that DDC could offer long-standing benefits to manage pharmacologically-intractable heart failure.

STATE OF THE ART

Full transformation of latissimus dorsi muscle from a fast-fatigable to a slow fatigue-resistant muscle has been considered until recently as a key step in Dynamic Cardiomyoplasty /1, 2/. Unfortunately, muscle power has been shown to decrease with extent of fast to slow transformation /3/. Clinically, it is accepted that the LD benefits the patient's quality of life only if its activation is optimally delayed after the sensed QRS complex in order to avoid mitral regurgitation /4/. Since maximum instantaneous power of a fully conditioned LD is smaller than the peak power of the left ventricle /5,6/, the grafted muscle could assist the heart principally during mid and late systolic phases. Such a short time window requires a fast, powerful contraction which is not delivered by a fully transformed LD.

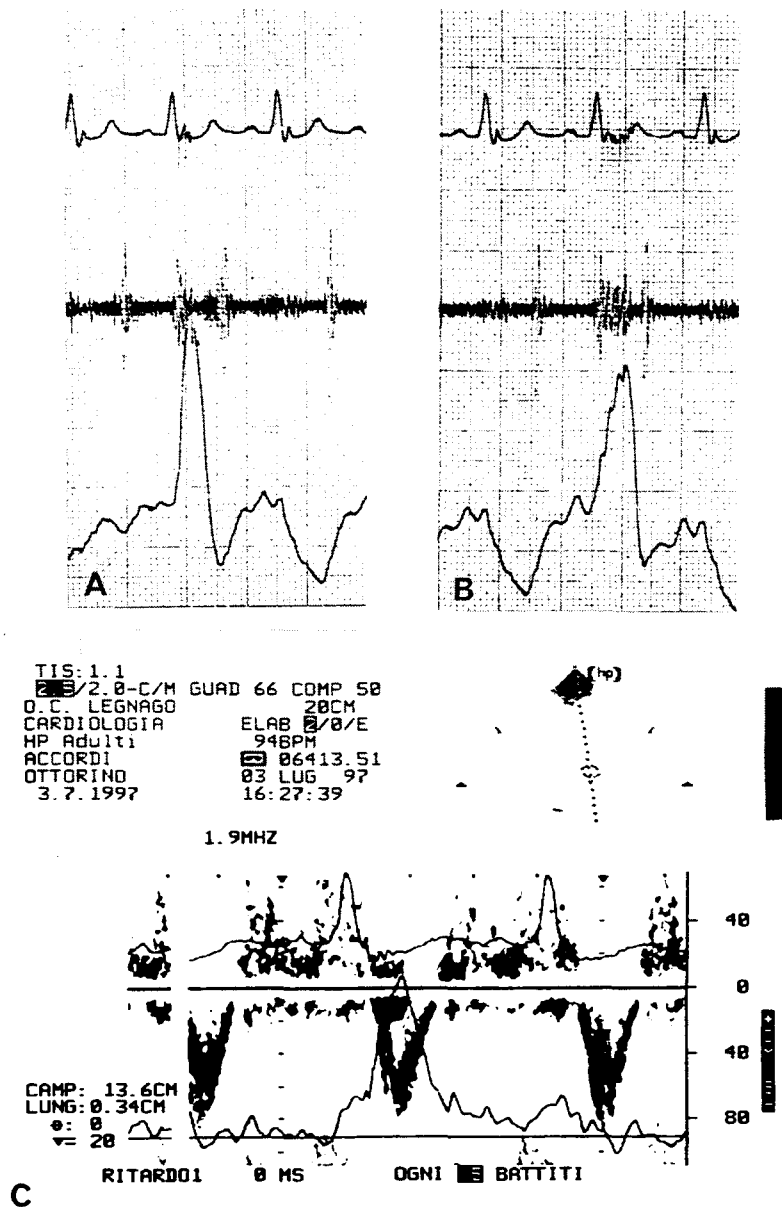
MATERIAL AND METHODS

Monitoring LD function is essential for evaluating and implementing new concepts aimed at improving LD function for greater systolic benefit /7/. To perform this monitoring we have implemented the basic concept of tetanic fusion frequency analysis. We developed the new method for non-invasive, bedside monitoring of LD function using a standard polygraph /8/. Originally developed for monitoring cardiac apical motion (apicocardiogram) and heart sounds, we have used this technology to provide a simple, non-invasive way

to monitor LD contraction. ECG and heart tones are registered together with the signals registering the contraction and relaxation of the LD, measured by placing the transducer normally used for recording the apicocardiogram over the rib window through which the LD enters the thoracic cavity.

In Figure 1,a the upper trace is the electrocardiogram which shows a burst of four impulses (23 msec interval) delivered every third cardiac cycle. The middle trace is the phonocardiogram, and the lower trace is the mechanogram of the short tetanic contraction of LD wrap. Figure 1,b shows that muscle contraction became a non-fused tetanus when the impulses were delivered at 55 msec intervals (18 Hz). Indeed, varying the interpulse interval makes it is easy to determine the frequency at which the tetanus is fused, *i.e.* tetanic fusion frequency (TFF). From LD "mechanogram" we can determine: 1) LD activation threshold, 2) the dynamic contractile characteristics of the LD flap based on the determination of the tetanic fusion frequency optimal, 3) the duration of the full LD contraction-relaxation cycle, and 4) the synchronization delay between cardiac events and the actual contraction-relaxation cycle of the LD flap (Figure 1,c). The activation threshold is easily determined by measuring the peak contraction at different amplitudes of stimulating voltage (from 1 to 8 Volts).

Figure 1. LD flap mechanogram. a, fused tetanus; b, non-fused tetanus; c, mechanogram trace obtained with the apicocardiogram probe superimposed to the four spikes of the ecg and to the area of the aortic outflow by echodoppler imaging.



The point at which the muscle is first activated is easily recognized, even in patients whose LD contraction is not readily identified through standard palpation of the axillary region. The duration of the complete mechanical event in response to delivered impulses is measured on the mechanogram.

The dynamic characteristics of the LD flap are determined from the LD response to stimuli delivered at increasing frequency rate. The LD tetanic fusion frequency (TFF) can be identified by delivering triplets of stimuli at intervals ranging from 8 to 75 msec (126 to 13 Hz, respectively) or doublets of stimuli at intervals ranging from 75 to 200 msec (13 to 5 Hz, respectively). The duration of the complete mechanical event in response to clinical stimulation protocol (number of impulses delivered at established msec intervals) is measured. Finally, the optimal synchronization between the cardiac cycle and contraction of the LD flap is determined, using the mitral and aortic valve tones as measured on the phonocardiogram or, preferably, by connecting the mechanogram signal directly to echocardiography equipment. In this way, the LD mechanogram can be directly and simultaneously compared to the high-resolution images of cardiac events, either M-mode imaging of valve motion or Doppler imaging of the left ventricle outflow. The onset of LD contraction can be programmed to occur at the start of the isovolumic contraction phase of cardiac systole or just at the start of ejection (Figure 1,c).

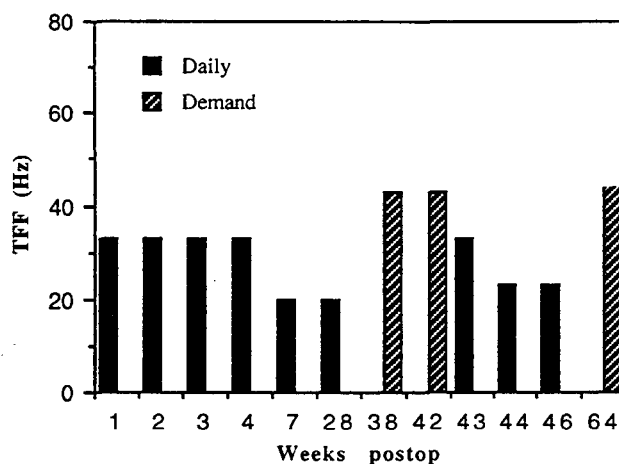
RESULTS AND DISCUSSION

In a cohort of patients, we have shown that the LD flap becomes fatigue resistant by the end of the conditioning period, *i.e.*, within two months after the operation, and can remain viable at least up to fifty months, the extent of transformation of contractile characteristics of the LD flap being related to the stimulation protocols used, *i.e.* the amount of impulses delivered per day /8/. Furthermore, we have developed a new clinical protocol based on activity-rest stimulation which provides resistance to fatigue at higher muscle power. Beside the sheep experiments of Arpesella team /5/, corroborating results have been recently presented in a rabbit model confirming that long-term daily stimulation increases blood flow but decreases muscle mass, while "interval stimulation", that is an activity-rest regime of stimulation, preserves muscle mass and force /9/.

Dynamic cardiomyoplasty was performed in selected subjects according the standard Carpentier and Chachques procedures /1,2/. Each subject's LD flap "mechanogram" was monitored bed-side using a standard polygraph (Siemens MegaCart or Mingophon). We chose a clinical stimulation amplitude at half the difference between the threshold and the maximal contraction accepted without discomfort for the patient. This is not the maximal activation of the LD, but in such a way the non-activated portion of the flap is "spare LD," available in case of long-term stimulation-induced muscle damage. The conditioning period was shortened to one month. Beginning with one impulse, one-two week after surgery, an impulse was added each week for a total of four impulses per burst. The pulse interval was 23 msec (43 Hz), and the LD was stimulated every third cardiac cycle.

This preliminary study included four patients with cardiac heart failure due to dilatative cardiomyopathy in NYHA class III with a mean preoperative peak VO₂ of 12 ml/kg/min.

Figure 2. Fast-to-slow-to-fast transformation of the LD flap by activity-rest stimulation (demand regime). TFF (Hz), Tetanic Fusion Frequency of LD flap.



After six to nine months of continuous "lighter" daily stimulation, two out of four patients were submitted to an activity-rest stimulation regime by special programming of the cardiomyostimulator (Transform®, Model 4710, Medtronic, Inc., Minneapolis, MN, USA). These patients were operated in June 1996 (a 48-year-old man and a 46-year-old woman). The patients' average heart rates during the day and night were first determined by 24-hour Holter analysis. For both patients, the average heart rate at night was less than 80 bpm and greater than 80 bpm during the day. The lower rate on the pacing channel of the cardiomyostimulator was then programmed to 80 but with minimum values for pacing amplitude and pulse width. In this way, the device will be pacing most of the time during night or resting hours but at a very low, sub-capture level. By programming the muscle channel output to "Sense," rather than "Sense + Pace," muscle stimulation will occur only when the heart rate goes above 80 bpm. When the heart rate decreases, indicating a period of low activity, the device begins to pace and muscle stimulation is inhibited most of the time, allowing the muscle to rest. This intermittent stimulation has been well tolerated by the patients with no sleeping disturbances. Furthermore, Figure 2 shows that after some degree of fast to slow transformation the LD wrap is retrodifferentiated by the "Demand Stimulation".

With this lighter stimulation regime, now used in patients at more than one-year of follow-up, substantial improvement in quality of life has occurred with a reduction in heart failure symptoms from NYHA Class III to I and improvements in peak VO₂ /10/. There are no deaths and all patients are in NYHA class I after a mean follow up of 11 months. One year after Demand Dynamic Cardiomyoplasty peak VO₂ increased up to 35% when compared with preoperative values.

If these preliminary data will be confirmed in a larger cohort, Dynamic Cardiomyoplasty by better monitoring of synchronization delay, and lighter and "Demand" LD stimulation could offer long-standing benefits to manage pharmacologically-intractable heart failure.

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FUNCTIONAL AND MORPHOLOGICAL TRANSFORMATION OF THE LATISSIMUS DORSI MUSCLE DURING MUSCLE CONDITIONING BY MULTICHANNEL STIMULATION

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SUMMARY

This study was undertaken to survey the changes in force and morphology of the Latissimus dorsi muscle (LDM) during the transformation into a fatigue-resistant muscle by multichannel stimulation via the thoracodorsal nerve. Therefore, in six sheep a silicon chamber connected to a pressure transducing system was implanted under the left LDM. Muscle biopsies from the left and right LDM were harvested at the beginning, at the end of Phase I and of Phase II of our conditioning protocol. At the end of Phase I the LDM contained 90% Type I muscle fibers with the highest level of mean maximum pressure (140,3mmHg). At the end of the conditioning protocol (Phase II) the LDM contained 100% Type I fibers and reached a mean maximum pressure of 92mmHg. The increase of the frequency of the muscle contractions during Phase II resulted only in the reduced power of an completely transformed fatigue-free skeletal muscle. Concerning muscle power a 90% transformation of the LDM seems to offer distinct advantages compared with a total transformation to Type I fibers.

STATE OF THE ART

Various approaches have been made to rule out the optimal stimulation protocol for the conditioning of the LDM to a fatigue-resistant muscle by means of FES in the past. The fatigue-resistant LDM wrapped around the ventricles of the heart or around an artificial or biological neoventricle should then serve as a cardiac assist device. Concerning the resulting hemodynamic data clinically and experimentally a distinct loss of contractility of the transformed LDM is evident. In order to evaluate a new developed conditioning protocol with multichannel stimulation a functional and histomorphological analysis of the LDM was carried out in the time-course of the experiment.

MATERIAL AND METHODS

6 female sheep were used for this experiment.

Surgical procedure:

During operation the sheep were placed in right side position to perform a lateral incision on the left side. The left thoracodorsal nerve was prepared carefully and four ring-shaped electrodes

were sutured to its epineurium in different position to perform carousal stimulation. The electrode leads were led out percutaneously. A silicon chamber connected to a pressure-transducing system was placed under the left LDM. This configuration was designed to measure the pressure produced by the muscle under varying the stimulation conditions.

Muscle Conditioning:

Two weeks after the implantation the stimulation protocol was started. Muscle conditioning was performed by multichannel (carousel) burst stimulation of the thoracodorsal nerve. Eight bipolar standardized combinations of electrodes were formed with the four stimulation electrodes (Table 1). Stimulation parameters were: burst stimulation, burst duration 660 ms, pulse frequency 28,8 Hz and pulse width 540 μ s. The demanded amperage to achieve maximum tetanic tension seperately evaluated for each electrode combination. At least six combinations of equal contraction strength were selected. Amperage was adjusted to slightly submaximal levels for performance of carousal stimulation. The stimulation threshold of each electrode combination was determined every week and the amperage was readjusted if necessary. The electrode combinations were changed also if necessary.

Our stimulation protocol contained of two Phases: In Phase I of the stimulation protocol we started with 10 min/h work and 50 min/h rest. The duty circles ("on " periods) were increased according to the fatigue resistance of the muscle until 10 contractions/min could be performed chronically around the clock. In Phase II of our stimulation protocol the frequency of the contractions was increased from 10 to 70/min. During the conditioning program the changes of muscle force (= mean maximum pressure= MMP) were monitored by the silicon balloon system.

Synopsis of the Eight Standartized Combinations of Electrodes Used for Multichannel Stimulation of the Latissimus Dorsi Muscle:

Electrode	1	2	3	4
Combination 0	0	0	-	+
Combination 1	0	0	+	-
Combination 2	0	-	0	+
Combination 3	0	+	0	-
Combination 4	-	0	0	+
Combination 5	+	0	0	-
Combination 6	-	0	0	+
Combination 7	+	0	0	-

+ = electrode used as a positive pole
 - = electrode used as a negative pole
 0 = electrode not used

Histomorphological analysis:

Muscle biopsies were harvested from the cranial, the caudal and scapular part of left LDM at the begin of the stimulation protocol, at the end of Phase I and at the end of the stimulation protocol (end of Phase II). The biopsies were immediately snap-frozen at -80°C in isopentane, cooled by dry ice and stored at -80°C until use. Serial transverse cryosections of $10\mu\text{m}$ thickness were stained with actomyosin ATPase after alkaline (ph 10,2) and acid (ph 4,3) preincubation according to Guth and Samaha. All stained sections were examined by light microscopy at a 100-fold magnification. The resulting fields were displayed on the monitor of a personal computer by means of a video camera mounted on the microscope. The analysis was performed with a pen linked to the personal computer by one experienced investigator. More than 300 muscle fibers were evaluated in each section. After comparison of the serial sections stained for actomyosin ATPase with alkaline (ph 10,2) and acid (ph 4,3) preincubation, the muscle fibers were divided into Type I, Type II and Type IIc.

The following histomorphometric parameters were determined for the left LDM:

- the percentage of Type I, Type II and IIc muscle fibers in relation to the number of muscle fibers counted
- the equivalent diameter of Type I, Type II and Type IIc muscle fibers in μm
- the percentage of perimysial and endomysial connective tissue in relation to the measured area of the section

RESULTS

At the beginning of the stimulation the LDM performed a MMP of 112,7 mmHg in the silicon balloon. The histomorphological analysis revealed $78,7 \pm 10,5\%$ Type I, $3,1 \pm 3,4\%$ Type II and $3,1 \pm 3,4\%$ Type IIc fibres at the beginning of the stimulation protocol. The equivalent diameter of the Type I fibers revealed $55,6\mu\text{m}$, of the Type II fibers $57,1\mu\text{m}$ and of the Type IIc fibers $57,1\mu\text{m}$. The percentage of the peri-and endomysial connective tissue was 12,5%.

At the end of Phase I the MMP was 140,3 mmHg. At this time the LDM contained $90,1 \pm 14,9\%$ Type I, $7,6 \pm 8,2\%$ Type II and $2,2 \pm 0\%$ Type IIc fibres. The equivalent diameter of the Type I fibers revealed $49,9\mu\text{m}$, of the Type II fibers $58,7\mu\text{m}$ and of the Type IIc fibers $56,8\mu\text{m}$. The percentage of the peri-and endomysial connective tissue was 14,6%.

At the end of Phase II, i. e. the end of the stimulation protocol, the MMP was 92 mmHg. Histomorphometrically we found a completely transformed LDM with 100% Type I fibres. The equivalent diameter of the Type I fibers was $46,7\mu\text{m}$. The percentage of the peri-and endomysial connective tissue was 16,1%.

DISCUSSION

The results clearly demonstrate that the LDM containing 90% of Type I fibres increased the MMP from 112,7 to 140,3 mmHg at the end of Phase I. At the end of Phase II the LDM revealed 100% of Type I fibres but decreased the MMP from 140,3 to 92 mmHg. In Phase I of our stimulation protocol the distribution of the duty circles to 60 sec offers an overall stimulation-

frequency of 1,2 Hz. This low frequency stimulation of a sheep LDM resulted in the transformation to a fatigue-free muscle at the highest achievable power-level. The increase of the frequency during Phase II resulted only in the reduced power of an completely transformed fatigue-free skeletal muscle. Concerning muscle power a 90% transformation of the LDM seems to offer distinct advantages compared with a total transformation to Typ I fibers.

Taking into consideration that the LDM used in cardiomyoplasty or aortomyoplasty has to perform up to 50 contractions per minute depending on the stimulation mode, the question arises whether a stimulation protocol should be finished at contraction rates of 10 or 70 contractions per minute around the clock to obtain optimal muscle performance in cardiac assist.

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DAMAGE OF THE LATISSIMUS DORSI MUSCLE DUE TO VASCULAR DELAY TECHNIQUE AND PRECONDITIONING FOR THE USE AS AN ASSISTING SKELETAL MUSCLE: FIRST RESULTS OF AN HISTOMORPHOLOGICAL ANALYSIS

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SUMMARY

In an experimental series in sheep we wanted to produce a Latissimus dorsi muscle (LDM) capable of performing chronic work immediately after the construction of a skeletal muscle ventricle (SMV). The longitudinal division of the LDM into two branches and mobilization of the entire muscle in order to achieve vascular delay, followed by muscle preconditioning, produced disastrous results.

STATE OF THE ART

According to literature and plastic surgical clinical practice "vascular delay" is a well known surgical technique to increase the vascularisation of randomized and mobilized tissues. Concerning the power of chronic stimulated skeletal muscles used in cardiomyoplasty or aortomyoplasty preconditioning of the LDM in situ seems to be beneficial. Both described techniques were used to improve the performance of a chronic stimulated left LDM before its transposition around a biological neo-ventricle anastomosed in parallel to the descending aorta.

MATERIAL AND METHODS

Two adult female sheep, weighing 48 and 51 kg, were used for the experiment.

Stimulation device:

All implanted components were designed and manufactured at the Department of Biomedical Engineering and Physics. The nerve pacing leads are made from stainless-steel stranded wire, coiled and embedded in silicon. The battery-powered pulse generator is hermetically sealed in a titanium case. This newly developed pulse generator can be used for activating two skeletal muscles via the motor nerves, using constant-current impulses with a maximum current of 4 mA at a pulse duration of 0,2 to 1 ms.

Surgical procedure:

The sheep were placed in right side position to performed a lateral flank incision on the left side. The left LDM was detached from the thoracic wall, with all perforating vessels from the intercostal vascular bundles being ligated, while the LDM insertion into the humeral bone was kept unaffected. The thoracodorsal nerve was prepared, with the vascular pedicle being carefully preserved. The pulse generator, already connected to the electrode leads, was placed in a subcutaneous pocket at the back of the contralateral side and the electrode leads to the left side were led under the scapula to the nerve. Four ring-shaped electrodes of an inner diameter of 1 mm were sutured to the epineurium of the nerve in helical manner. After the intramuscular vascular architecture of the left LDM had been identified by translumination, the muscle was divided longitudinally from its caudal end up to the entry of the neurovascular bundle in order to create two muscle branches of equal size. The LDM was reattached to the thoracic wall with absorbable sutures in original position. Muscle biopsies were harvested from the cranial, scapular and caudal parts of the LDM. After skin closure the animals were brought in left side

position and a lateral flank incision was performed on the right side. The right LDM, especially its origin at the thoracic wall, was left untouched. Electrode leads were tunneled from the back to the scapular region of the right side and the electrodes were applied to the thoracodorsal nerve as described above. Muscle biopsies were harvested from the cranial, scapular and caudal parts of the LDM and again, the skin closure was made.

Conditioning protocol:

After a delay of 14 days the conditioning program was started. Stimulation was performed via the implanted stimulation device, which was activated and programmed by the external programmer. Rectangular pulses with a pulse width of 600 μ s at a pulse frequency of 26 Hz were used for stimulation. The conditioning protocol was set according to the classic stimulation protocol for cardiomyoplasty by Chachques et al., starting with single pulse chronic stimulation and a biweekly increment in the number of pulses to achieve burst stimulation. The rate of muscle contractions was raised from 35 to 50 contractions per minute in the course of the program. "Carousel-stimulation", a special kind of multichannel stimulation using four stimulation electrodes on each nerve, was applied. In the first step of our experimental sequence we could show that this stimulation technique leads to a less pronounced loss of muscular force after the end of conditioning. Only two electrodes out of four were activated at a distinct point of time. Selection of activated electrodes was changed automatically from burst to burst and repeated cyclically. Four bipolar combinations of electrodes, producing muscle contractions of equal strength, were selected. During the conditioning, the contraction strength of each electrode combination was evaluated by varying the stimulation current between 0 and 4 mA so that maximum tetanic tension was achieved. Both LDM were conditioned simultaneously regardless of the native heart rate. At the end of the conditioning program the construction and implantation of the SMV was planned. According to an unexpected and significant loss of contraction strength the chronic experiment was stopped and therefore no SMV implantation was performed. The two sheep were sacrificed in order to examine the LDM of the left and right side. Both LDMs were completely detached from their origin and insertion. Three biopsies were harvested from the cranial, scapular and caudal part of each muscle.

Histomorphological analysis:

A histomorphological analysis of the right and left LDM was performed. The muscle biopsies were cut into transverse slices with a razor blade. The slices were put on cork discs and immediately snap-frozen at -80°C in isopentane cooled by dry ice and stored at -80°C until use. Serial transverse cryosections of 10 μ m thickness from each slice were stained for the following histochemical methods: actomyosin ATPase after alkaline (pH 10,2) and acid (pH 4,3) preincubation according to Guth and Samaha and NADH tetrazolium reductase according to Dubowitz and Pearce. All stained sections were examined by light microscopy at a 100 fold magnification and the resulting random fields were displayed on the monitor of a personal computer by means of a video camera adjusted to the microscope. The histomorphometric measurements and counts were performed with a pen linked to the personal computer using a semi-automatic image-analyzing system. More than 300 muscle fibers per three random fields were counted in each section. After comparison of the serial sections stained for actomyosin ATPase with alkaline (pH 10,2) and acid (pH 4,3) preincubation and for NADH tetrazolium reductase, the muscle fibers were divided into Type I and Type II. The classification into the subtypes of the Type II muscle fibers, i.e. Types IIa and IIb, was performed on sections stained for NADH tetrazolium reductase enzyme activity. The following morphometric parameters were determined for the LDM:

- the percentage of Type I, Type IIa and IIb muscle fibers in relation to the number of muscle fibers counted
- the equivalent diameter of Type I, Type IIa and IIb muscle fibers in μ m
- the percentage of perimysial and endomysial connective tissue in relation to the measured area of the section

RESULTS

The conditioning protocol could be performed without any problems for the first four weeks in sheep 1 and for six weeks in sheep 2. When the stimulation frequency was raised from 2 to 3 impulses in sheep 1 and 3 to 5 impulses in sheep 2, the left LDM, which was splited and detached, showed signs of fatigue: contrary to the sudden drop in contraction strength known to occur when unconditioned muscles are strained, a gradual decrease in contraction strength over serveral days took place. The stimulation threshold of the nerve did not change and a rise in the stimulation amplitude did not lead to an increase in muscle force. Considering overstimulation we stopped the conditioning of the left LDM. On the other hand the right muscle showed no signs of fatigue. Conditioning was continued following the original protocol without any delays. After a four week phase for regeneration, conditioning of the left LDM was resumed at lower increments. No more fatigue occurred, contraction strength was visibly reduced, though. According to the significant loss of contraction strength no SMV implantation was performed in both sheep. The examination of the left LDM revealed severe signs of degeneration: in comparison with the right side we found a distinct atrophy of contractile muscle tissue and an strong increase of the perimysial connective tissue. During electrical stimulation no contraction was detected in the caudal part of the left LDM, whereas in the most cranial part muscle-contraction could be observed. Macroscopically the right LDM revealed no signs of degeneration and contractions of all parts of the muscle were detected during electrical stimulation.

Histomorphological analysis:

Morphologically the right LDM showed signs of a completely transformed skeletal muscle. The percentage of the Type I fibers was 100% in the cranial and scapular part of the LDM. The caudal part revealed 96.04% Type I, 1.22% Type IIa and 2.74% Type IIb muscle fibers. The mean diameter of the Typ I fibers was 40.38µm in the cranial and 39.06µm in the scapular part of the LDM. In the caudal part the mean diameter of the Typ I fibers revealed 27.50µm, of the Typ IIa 39.45µm and of the Typ IIb 21.50µm. The percentage of the peri-and endomysial connective tissue was 18.28% in the cranial, 19.63% in the scapular part, and 26.71% in the caudal part of the muscle. We found also a distict fiber transformation in the cranial and scapular part of the left LDM, allthhough a high increase in the perimysial-and endomysial connective tissue together with a complete loss of muscle fiber architecture was evident. In the caudal part of the left LDM a histomorphological analysis according to the method decribed above was not possible. Beside the high increase of the connective and fatty tissue the muscle fibers showed typical signs of degeneration or necrosis. In the cranial part we found 93.65% Type I and 2.61% Type IIa muscle fibers. In the scapular part of the left LDM we measured 74.01% Type I and 25.99% Type IIa fibers. The mean diameter of the Typ I fibers revealed 14.52µm in the cranial and 46.47µm in the scapular part of the muscle. The mean diameter of the Typ IIa fibers revealed 23.97µm in the cranial and 33.99µm in the scapular part. The percentage of the peri-and endomysial connective and fatty tissue was 68.94% in the cranial and 47.51% in the scapular part of the left LDM.

DISCUSSION

Chronical FES changes muscle morphology but does not damage the muscle tissue, provided adequate stimulation parameters are applied. This fact has been reported in literature and is also shown in our results of conditioning of the right LDM. It was the increase from about 1 to 2 Hz of chronic stimulation that led to severe damage of the mobilized parts of the muscle. The increment triggered a homogenous degeneration of the muscle fibers. The results of this analysis clearly demonstrate that the combination of "vascular delay" and preconditioning of a

skeletal muscle at the same time before using in cardiomyoplasty or aortomyoplasty is contraproductive for its morphological outcome.

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ELECTRICALLY STIMULATED BIOLOGICAL NEO-VENTRICLE FOR AORTIC COUNTERPULSATION: AN ANIMAL EXPERIMENT IN SHEEP

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SUMMARY

14 adult sheep were used for acute experiments: an aorto-pericardial pouch of a donor sheep was created. This biological conduit was anastomized in parallel to the descending aorta of a recipient sheep, using the aortic root as an inflow valve to the conduit. ECG-triggered nervous FES was applied during cardiac diastole to simulate aortic counterpulsation. Stimulation was performed during various hemodynamic conditions.

During 6 experiments a standardized surgical procedure suitable for long term studies was established. A neoventricle with 70 to 80ml filling volume was found to be optimal in size. In another 8 experiments hemodynamic measurements were performed. Under stable hemodynamic conditions the stimulation of the biological skeletal muscle ventricle induced a significant increase in mean diastolic pressure of 58.8% ($p < 0.0004$). During pharmacologically induced periods of cardiac failure the stimulation of the APPC increased the mean diastolic pressure significantly by 60.5% ($p < 0.002$). Supra-systolic pressures were obtained during all 8 experiments.

STATE OF THE ART

The chronic shortage of donor organs for cardiac transplantation and the high costs for mechanical assist devices demand the development of alternative cardiac assist devices for the treatment of severe chronic heart failure. Therefore, cardiac assistance by stimulated skeletal muscles is currently investigated as a possible alternative. The goal of the presented study was to evaluate the hemodynamic efficacy of a newly designed biological skeletal muscle ventricle in an acute sheep model. The biological pump was used as an aortic counterpulsation device.

MATERIAL AND METHODS

14 sheep weighing 57.5 $\pm$ 6.2 kg were used. The animals were put under general anesthesia and intubated. Anesthesia was maintained with halothane and nitrous oxide. At the end of experiment the animals were sacrificed.

Surgical procedure:

The pericardium and the entire thoracic aorta including the aortic valve were excised from fresh sheep cadavers prior to the operation. These excised homografts were cryopreserved according to clinically approved techniques and defrosted at the time of the experiment. Surgery was started by two teams, one preparing the recipient animal and the other constructing the neo-ventricle from the aortic homograft.

Construction of the biological neo-ventricle:

The aortic homograft was incised longitudinally twice in its middle section and enlarged by two strips of pericardium to create an aorto-pericardial pouch conduit (APPC).

Preparation of the recipient sheep:

The left latissimus dorsi muscle (LDM) was detached from the thoracic wall under careful preservation of its insertion to the humeral bone and the supplying neurovascular pedicle. LDM was divided longitudinally into two branches with respect to the intramuscular neurovascular supply. A segment of the third rib was removed and LDM was placed in the left hemithorax. To continue the procedure the fifth and sixth rib were resected.

Connection of the APPC to the circulation and positioning of LDM:

The APPC was connected in parallel with the descending aorta of the recipient sheep. The proximal part was anastomosed with the recipient aorta distal to the common brachiocephalic trunk, using the aortic root as an inflow valve to the conduit. The distal end of the APPC was cut back to the appropriate length and connected with the descending aorta above the diaphragm. The two branches of LDM were wrapped around the APPC in counterrotating fashion and fixed to each other and to the remaining parts of the fifth and sixth rib.

Activation of the biological skeletal muscle ventricle (SMV) by FES:

Device:

Four stimulation electrodes were applied to the epineurium of the thoracodorsal nerve and the electrode leads were led out percutaneously. Three ECG-sensing electrodes were fixed to muscles of wall and both, pacing and sensing leads were connected with an external stimulation device.

Stimulation parameters:

Rectangular pulses with 0.6 msec duration at a frequency of 28 Hz were used for burst stimulation. Current was adjusted to achieve maximum tetanic contraction of LDM. R-wave triggered stimulation at a rate of 1:2 or 1:3 with the native heart rate was applied during diastole to simulate counterpulsation.

Hemodynamic Measurements:

A flow-directed pulmonary artery catheter was introduced from the left jugular vein. A aortic catheter was introduced into the left ventricle from the left carotid artery. Saline-filled plastic catheters were placed either directly into the left carotid artery close to the brachiocephalic trunk and introduced into the abdominal aorta from the left femoral artery. These hydraulic pressure catheters were connected to Van-den-Burg disposable pressure transducers. For flow measurements three Flow Probes were placed around the proximal and distal part of the homograft and around the descending aorta between the proximal and distal anastomosis. All hemodynamic variables were recorded simultaneously by a computerized registration unit. This unit includes an analog to digital converter and systems for data analysis

Experimental sequence (N=8):

Short periods of stimulation, consisting of 10 to 20 contractions were performed repetitively to avoid fatigue of the unconditioned, fast fatigable LDM. Heart failure was induced by rapid intravenous infusion of a betablocker (Breviblock[®]) and stimulation was repeated.

RESULTS

Surgical procedure:

During six experiments a standardized surgical procedure, suitable for long term studies was developed. Two pericardial patches, each sized 8 x 4 cm, created a neo-ventricle of 70 to 80ml filling volume, which turned out to be optimal in size and therefore was used in all further experiments. Macroscopically the division of the LDM did not cause marked cyanosis of parts of the muscle or denervation of parts of the LDM in any case (n = 14). At the end of each

experiment an investigation of the inner surface of the APPC was performed (n = 14). Visual inspection did not reveal any aggregates or thrombotic formations.

Hemodynamic measurements:

During eight experiments the hemodynamic efficiency of the neo-ventricle was evaluated. Stimulation was performed under stable conditions and did affect left ventricular peak pressure (*LVP-max*), mean arterial pressure (*p-mean*) and mean diastolic pressure (*p-dia*), which increased to supra-systolic values in all experiments. Right ventricular (*RVP*) and pulmonary artery (*PAP*) blood pressure did not reveal alterations due to stimulation.

Measurements during normal heart function:

Stimulation of the SMV caused a significant increase of *pT-max* by 19% ($p < 0,04$) and *pA-max* by 27% ($p < 0,02$), while *LVP-max* decreased not significantly by 5% ($p < 0,1$). *pT-min*, *pA-min* and *LVPmin* showed a tendency to decrease, but were not altered significantly by FES. *pT-mean* and *pA-mean* increased significantly by 14% ($p < 0,02$) and 17% ($p < 0,02$) and *pT-dia* showed a significant increment of 26% ($p < 0,01$). *pA-mean* was not applicable, because the pressure curve derived from the abdominal aorta did not allow differentiation between diastole and systole.

Measurements during induced heart failure:

Under this condition the stimulation of the SMV caused a significant increase of *pT-max* by 13% ($p < 0,04$) and *pA-max* by 28% ($p < 0,01$), while *LVP-max* decreased significantly by 8% ($p < 0,04$). *pT-min*, *pA-min* and *LVPmin* were not altered significantly by FES. *pT-mean* and *pA-mean* increased significantly by 13% ($p < 0,002$) and 11% ($p < 0,002$). *pT-dia* showed a significant increment of 19% ($p < 0,01$). Again *pA-mean* was not applicable, due to the reasons mentioned above.

Flow measurements during normal and induced heart failure:

Flow measurements under stable hemodynamic conditions and also under induced periods of cardiac failure revealed that the proximal as well as the distal part of SMV was filled from the aorta during the systole. During the stimulation of the SMV under both hemodynamic conditions blood was ejected from the proximal and distal part of the homograft and led to an inversed cranial flow in the aorta (Mean: Q-graft prox suff: -7,1l/min, Q-graft dist suff: 3,5l/min, Q-aort suff:

-0,5l/min; Q-graft prox insuff: -6,4l/min, Q-graft dist insuff: 3,2l/min, Q-aort insuff: -0,1l/min).

Despite the existence of the aortic valve this flow phenomenon was observed in each acute experiment .

DISCUSSION:

Various approaches have been investigated to achieve chronic cardiac assistance using skeletal muscles in the past, but only dynamic cardiomyolasty and recently dynamic aortomyoplasty have found their way into clinical practice. Both configurations are characterized by the presence of an uninterrupted endothelium and a direct coupling of the skeletal muscle contraction to the circulation. In our experimental setup we wanted to combine some basic aspects of cardio- and aortomyoplasty, with new ideas concerning the positioning of the LDM.

The presented APPC is made of hemocompatible biological materials only. Although an endothelium is not present at the time of operation, the preserved basal lamina will provide reendothelialisation of the aortic homograft and the pericardial patches according to the used preservation technique. The activation of the SMV by its muscular envelopment means direct coupling of the skeletal muscle contraction to the circulation, thus fulfilling another basic requirement for efficient cardiac assist with skeletal muscles.

As a result a new type of skeletal muscle ventricle, different from already presented configurations was realized in sheep and a standardised surgical procedure, suitable for long term experiments was established. Activation of the APPC led to reduction of left ventricular

peak pressure and induced marked increases of mean arterial and mean diastolic blood pressure. Referring to criterias for aortic counterpulsation the configuration did produce some of the required hemodynamic changes. In fact counterpulsation-efficacy was not to be expected in this series of acute experiments, in which an unconditioned LDM was used.

According to our flow data we found aortic valves with different states of insufficiency in the proximal part of the homograft in all animals. Taking into account that the highest increase of mean diastolic pressure was produced in case of a completely insufficient aortic valve of the SMV, no further use of this valve should be considered for the next experiments

Summarizing our experimental studies, it is too early for direct comparison with Stephenson's pericardium lined SMV, which worked in circulation up to 589 days or aortomyoplasty, which already has been performed clinically. However, the achieved results encourage us to continue the investigation of our newly designed fully biological SMV. The presented data clearly demonstrate the hemodynamic efficacy of this configuration as an aortic counterpulsation device. Chronic animal experiments using a conditioned LDM will be performed in order to investigate the long-term behaviour and reliability of the configuration and its overall influence to the circulation.

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A COMPUTER-MODEL FOR THE EVALUATION OF THE HEMODYNAMIC EFFICACY OF A SKELETAL MUSCLE VENTRICLE IN COUNTERPULSATION MODE

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SUMMARY

Bio-artificial ventricles wrapped with skeletal muscles are studied by several groups as a support for the failing heart. The goal of this study was to design a computer model for the evaluation of the hemodynamic efficacy of a skeletal muscle ventricle (SMV). In acute experiments in eight sheep a homologous aortic graft with wrapped latissimus dorsi muscle (LDM) was anastomosed in parallel to the aorta. ECG-triggered counter-pulsation was performed during normal heart function and pharmacologically induced heart failure.

The measured data of these experiments were used to design a computerised lumped parameter model in order to perform parameter variation studies of the left ventricle, the SMV and the counterpulsation mode.

The results of this computer model demonstrate that even significant changes of the arterial pressure waveform do not necessarily correspond to a reduction of the stroke work of the left ventricle during counterpulsation. Only after careful timing of the stimulation delay and burst duration a reduction of 16% of the stroke work during normal heart function was observed. Furthermore, the endocardial viability ratio was raised to 130% in case of induced severe heart failure.

In conclusion, the application of counter-pulsating bio-ventricles requires careful analysis of hemodynamics to discriminate between transient effects on pulse waveforms and effective heart unloading.

STATE OF THE ART

The chronic shortage of donor organs for cardiac transplantation and the high costs for mechanical assist devices demand the development of alternatives for the treatment of severe chronic heart failure. Therefore, cardiac assistance by stimulated skeletal muscles is currently investigated as a possible alternative /1/.

An interdisciplinary research group consisting of cardiac and plastic surgeons, physicans, biotechnicians and anatomists, was established to investigate the use of stimulated skeletal muscles for chronic circulatory assistance. In a first step the LDM was conditioned for chronical use at high contraction rates /2,3/, in a second step a SMV, consisting of biomaterials only, was designed to perform counterpulsation in parallel to the descending aorta /4/. Now, in a third step a computer model imitating the previous described SMV configuration was developed to improve and optimize the evaluated hemodynamic data. It is the first attempt to analyse the influence of a SMV anastomosed in parallel to the descending aorta on the entire circulation.

The results generated by this computerised lumped-parameter model were compared to the hemodynamic data obtained in the clinical experiments to assess the significance of the predicted findings.

MATERIAL AND METHODS

Clinical Experiment

Eight female sheep were used for acute experiments following the Austrian laws of animal research. The cryopreserved aortic homograft including the aortic valve was longitudinally arteriotomized and enlarged by two patches of pericardium. The left LDM was detached from the thoracic wall and divided longitudinally to create two branches. After resecting a segment of the third rib the LDM was placed into the left hemithorax. The fifth and sixth rib were resected for the implantation of the neoventricle. The proximal part of the neoventricle was anastomosed distal to the brachiocephalic trunc and the distal end was connected with the descending aorta above the diaphragm. The two branches of LDM were wrapped around the neoventricle in counterrotating fashion (see Figure 1) and fixed to each other and to the remaining parts of the fifth and sixth rib. Stimulation of the LDM was performed using carroussel stimulation (Burst 28Hz, current 0-4mA, ECG synchronised to 1:2 or 1:3).

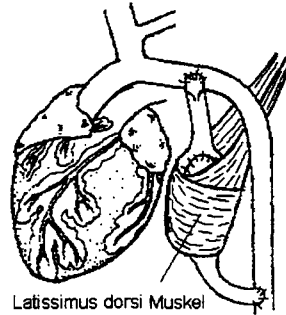


Fig. 1. SMV configuration after LDM wrapping

Numerical Model

In Figure 2 the circuit diagram of the computer model is shown. Major features of the model used in this investigation are its closed-loop nature, a detailed description of the aorta and the left ventricle, branches to head, arm and leg arteries and a SMV with nonlinear active and passive pressure-volume curve.

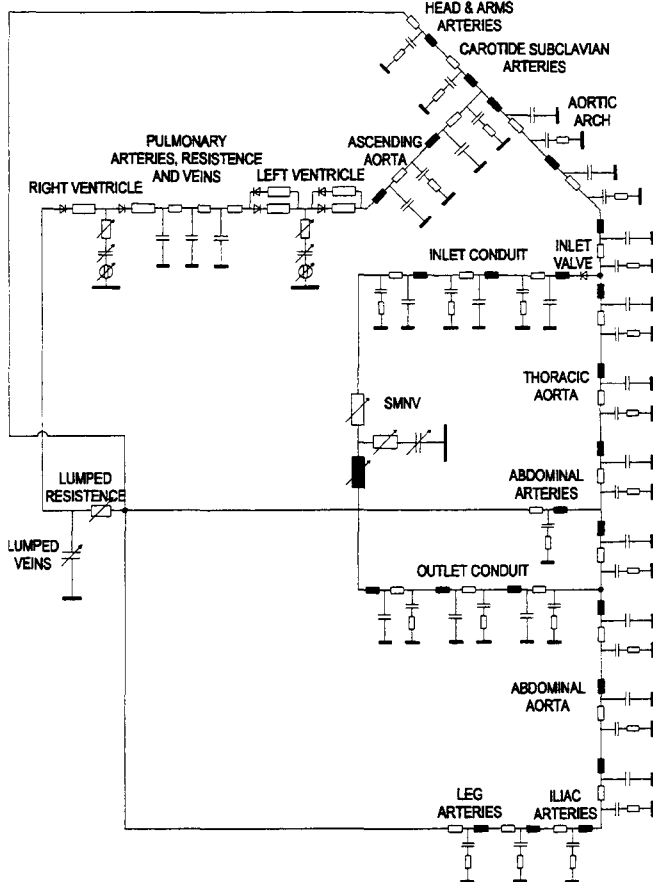


Fig. 2. Electric circuit diagram

The system of ordinary differential equations resulting from this circuit diagram was solved numerically on a PC-586 using the software package AGO-1000.

The aorta is divided into the equal segments. For each segment a combination of two capacities was used to represent the static and dynamic elasticity. The large branches are located in three main regions, corresponding to the aortic arch, the abdominal aorta and its bifurcation. These main regions represent distinct places where wave reflection essentially occurs. The parameters of the capacities, inductance and the resistance for the segments of the aorta and the main branches were derived from other animal models and from the literature /5,6/.

With the simplification of the SMV shape like a tube with a fixed length of 10cm and a variable diameter the circuit diagram is similar to an aortic segment, with respect that all parameters for the capacitance, inductance and resistance depend on the actual state of the SMV.

The pressure-volume curves of the SMV were implemented by a polygon for the active curve and by an exponential function for the passive one /7,8/. For a detailed description of the left and right ventricle, the systemic resistance and veins and the pulmonary circulation the reader is referred to the work of Schima and Honigschnabl /9/.

COMPUTER-SIMULATION RESULTS

Evaluation of the timing parameters

Concerning the aortic counterpulsation at a 1:2 (SMV:heart) ratio all performance indexes were calculated with the mean value of two heartbeats. A widespread indicator of the SMV effectiveness is the endocardial viability ratio (EVR), which is a measure of the coronary blood flow. In Figure 3 the dependence of the EVR on the SMV phasing is shown. There is a distinct optimum in timing with the optimal values of the burst-delay at 200 ms and burst-duration at 400 ms.

Hemodynamic measurements

In the case of normal heart function the stimulation of the SMV caused a significant increase of the mean diastolic pressure (MDP) by 35%, while the EVR increased by 93,4% compared with the normal circulation. The mean aortic pressure (AoP) and the mean aortic flow (AoF) increased by 4,7% and the stroke work (SW) of the left ventricle was reduced by 13%. In the case of induced severe heart failure (elasticity of the left ventricle reduced to 30%) the MDP increased by 53% and the EVR increased significantly by 134%. The mean AoP increased by 20,7%. Remarkably, in the case of severe heart failure the SW of the left Ventricle was increased by 4%.

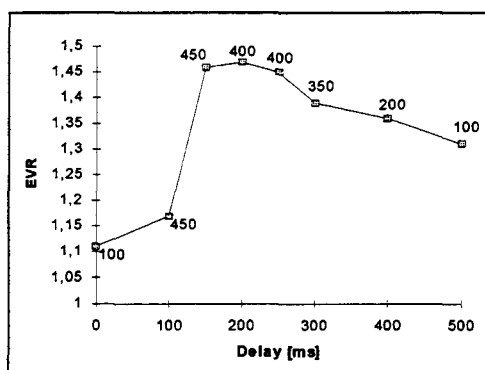


Fig. 3. Dependence of the EVR on the burst-delay. Every point is marked with the corresponding burst-duration.

Dependence on the degree of cardiac failure

Except SW, all indices of the SMV-assisted circulation increased with the higher grade of cardiac failure. Remarkably the EVR is in the 30%-cardiac failure even higher as in the circulation without assistance and normal elasticity of the left ventricle.

DISCUSSION

Computer models have not been used for the evaluation of the hemodynamic efficacy of artificial ventricles previously. However, the flexibility in varying the parameters of the computer simulation during the simulation run makes it possible to analyse the interaction of the SMV with the entire circulation.

As the results of the acute experiments /4/ and the computer simulation clearly demonstrate the bioventricle can highly influence the aortic hemodynamic and is filled properly even at low aortic pressures in the case of severe heart failure. The stimulation of the SMV in the 1:2 counterpulsation mode increases highly the EVR, which corresponds to an increase in the coronary blood flow. Although the left ventricle SW in stimulated vs nonstimulated beats could be reduced to 75%, the mean cardiac SW of the left ventricle was only slightly affected by the SMV. Only after careful timing of the stimulation delay and burst duration a reduction of the SW during normal heart function was observed. Consequently, the unloading effect of the heart is hardly limited in the current configuration. The timing of the stimulation was rather influenced by the specific configuration of the SMV than by the condition of the left ventricle or the bioventricle.

Major features of the model used in this investigation are its closed-loop nature, a detailed description of the aorta and the left ventricle. These features are essential for the determination of the significant effects of an assist device. The closed-loop nature allows the model to predict changes in venous return and the resulting effects on ventricular preload.

The developed computer model of the circulation including a SMV parallel to the descending aorta, different from already presented configurations, is able to reproduce the essential effects of the natural circulation. Consequently, it can be used for the further investigation of the interaction of a SMV and the circulation.

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Numerical prediction and experimental measurement of cardiac assistance from skeletal muscle ventricles

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Skeletal muscle ventricles (SMVs) are hydraulic pumps formed from autografts of skeletal muscle arranged to provide extra hydraulic work to the cardiovascular system in heart failure. We have investigated one configuration of such a system in which the SMV acts as an aortic counterpulsator. The SMV is connected by a single conduit to the descending aorta and, by analogy with an intra-aortic balloon pump for example, contracts during diastole to enhance coronary perfusion and relaxes during systole to reduce the work of the left ventricle. We have investigated both by numerical modelling and now by experimental measurement how the degree of SMV assistance depends on the placement of the assist phase within the cardiac cycle. Cylindrical SMVs were made in pigs by wrapping the latissimus dorsi muscle around a PTFE former. The SMVs were electrically stimulated at 1 Hz for 4 weeks to render them resistant to fatigue. In a terminal procedure the SMVs were connected to the descending aorta via a GoreTex conduit. We recorded left ventricular volume via a conductance catheter and SMV volume via a sonomicrometer system. Pressures were measured within the left ventricle, aortic root and SMV. Flow was recorded from the aortic root, and proximal and distal to the site of anastomosis of the SMV conduit with the aorta.

The timing of SMV activation was controlled relative to the prevailing systolic and diastolic durations of the left ventricle. The delay between the QRS complex and the start of SMV activation was varied between 20% and 140% of the systolic duration and the duration of SMV activation was varied between 60% and 140% of the diastolic duration. Various timing combinations were delivered in a pseudo-random order, after a short period with the SMV OFF. The complete matrix was achieved in 6 experiments. In two of the experiments it was also possible to evaluate the isolated pressure-volume characteristic of the SMV.

Results and conclusions:

The pressure-volume loops for the LV and SMV show that the timing of SMV action has a profound effect on its influence on the LV. SMV action can reduce the work done by the heart, but can also increase it if the timing is inappropriate. The experimental results contain trends similar to those predicted by our numerical model of the assisted circulation.

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1978-1998 TWENTY YEARS COCHLEAR IMPLANTS IN VIENNA

FROM EPOXY SINGLE TO CIS FAST STIMULATORS

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Vienna ENT department was one of the very first medical schools performing cochlear implant surgery. First implantation was in 1978. A postlingual deafend adult received an eight channel hybrid prototype, manufactured at the Vienna technical university. The first implantation in a child was in 1984. Since this early stages we performed more than 200 cochlear implantations, out of them 30 children between 16 and 48 months old and 30 children between 5 and 14 years old.

After different epoxy devices, 3M-Vienna, single and various multichannel cochlear implants we use at the moment, small laser sealed multi channel very fast stimulators. The most advanced technology is now realised in the MED EL Combi 40 plus cochlear implant. There are 12 pairs of electrodes on an electrode array, which can be inserted up to 30 mm into the cochlea. The electrodes are spread over 27 mm. The consistence of the siliconised platinum-iridium electrode array is very soft. In nearly all cases a complete insertion of 30 mm can be achieved. The tip diameter of the electrode is 0.4 mm at the base it is 0.65 mm. The implant body covers 33.5 x 23.4 x 3.95 mm. The coding strategy is continuous interleaved sampling in monopolar stimulation at 18.180 pulses per second. It is possible to choose the pair of electrodes for stimulation. Theoretically pair one at all 18.180 per second (which does not make sense) up to all the 12 pairs at 1.515 pulses ($12 \times 1.515 = 18.180$). As we see, for some patients, there is more benefit to use 8 pairs of activated electrodes at a pulsrates of about 2.270 per second per channel. As a result of the last two decades the monopolar very fast stimulation (at least 1.500 pulses per second per channel) over at least 6 up to 12 channels is superior to all other coding strategies.

According to enormous technical advances, improved surgical technique brought optimal benefit for implanted patients. Facial nerve monitoring, cochleostomy, soft surgery, in vivo endoscopy and individual electrode arrays lead to maximised surgical safety. Additionally we established special surgical procedures and split electrode arrays in case of total ossification or malformation. Intraoperative telemetry, stapedius tendon reflex measurements and intraoperative electric brainstem evoked response audiometry, represents direct interaction and control to the surgical procedure.

Prae and postoperative radiologic evaluation brought steps forward predicting and understanding surgical considerations. We perform high resolution CT scans, MR imaging, 3D reconstruction of the cochlea, brainstem and cochlear nerve and a

imaging of the cochlear implanted patient is nowadays possible.

For a postlingual deafened adult the mobil phone became the new statussymbol. Over the years the results came up from environment sound perception to the use of the telephone. All postlingual deafened adults (deaf up to ten years) reach open set speech understanding within two years. 70 % use the telephone. In small children (up to 4 years old) without additional handicap regular school and education will be possible.

Cochlear implantation has become a safe, efficient and costeffective high technology routine treatment which is absolutely indicated in all postlingual deafened adults and in small children.

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MAN VERSUS CAT: THE MORPHOLOGICAL DIFFERENCES IN THEIR COCHLEAR NEURONS LEAD TO ESSENTIAL DIFFERENCES IN FIRING PATTERN

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SUMMARY

The soma of the cochlear neuron of almost every species known is covered by myelin. This does not apply to the human soma. Among other differences between the human and the animal cochlear neuron, this is one reason why modelers have refrained from incorporating human data into their models. Our model of the cochlear neuron is capable of both human and animal data. Computer simulations that compare the course of action potentials in man and cat show that there is an essential difference: passing a human soma is much more difficult to achieve than overcoming a cat soma!

STATE OF THE ART

More than 16,000 hearing impaired people have already been supplied with cochlear implants. These are auditory prostheses that mainly consist of an external speech processor and a set of electrodes that are inserted into the inner ear to electrically stimulate the 30,000 fibers of the primary auditory nerve. A model of the electrically excited cochlear neuron would be a valuable tool to understand the phenomena encountered during electrical stimulation. Although the human and animal cochlear neuron essentially differ, modelers have concentrated on animal models so far (see e.g. /1/ and /2/). As a consequence, wrong assumptions of the nerve fiber's morphometric and electric properties were made.

We will present a model of the human cochlear neuron that for the first time closely sticks to human morphometric data as known so far. When comparing simulations with human and cat data essential differences in firing pattern will become obvious.

MATERIAL AND METHODS

Fig. 1 illustrates the morphological differences between a human cochlear neuron and that of a cat. Both fibers have a bipolar shape starting with an unmyelinated initial segment (10 μm) in the periphery (left) and terminating in the central region (right). While the soma of the human auditory neuron is covered by two satellite cells only, the soma of the auditory neuron of the cat (and of all other species used in electrical stimulation experiments) is isolated by several layers of satellite cell membranes. Therefore human somatic capacitance is at least one order of magnitude higher. Additionally, the somatic positions differ: 6 peripheral internodes precede the human soma, whereas just 3 peripheral internodes are found in the cat.

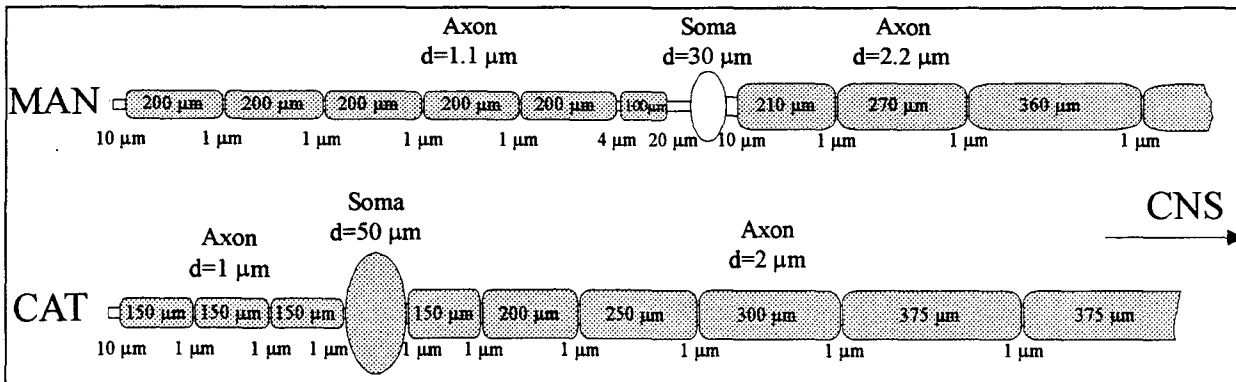
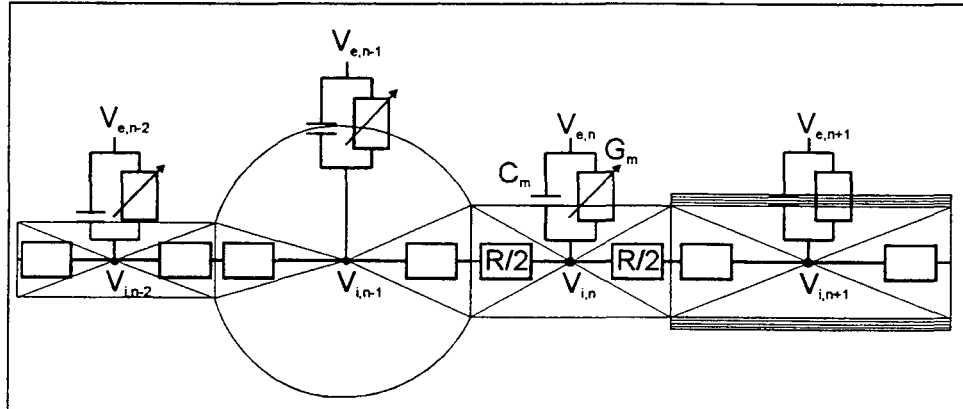


Fig. 1. Scheme of a human (data taken from Felix et al. /3/) and cat (data taken from Liberman and Oliver /4/) cochlear neuron as used for simulation. Parts covered by myelin are marked in gray.

Following the natural course of an action potential, the initial unmyelinated segment of the neuron is stimulated due to its synaptic connection with an inner hair cell. Passing the soma, much of the spike's energy is needed to load the somatic capacitance, which is much more difficult to achieve in human cochlear neurons due to their high somatic capacitance. As for the electric stimulation, the situation changes: different places of stimulation are possible, determined by electrode position and electrode current.

A model of a neuron should consist of different compartments according to their physiological task and to different geometric and electrical parameters. The diagram in Fig. 2 is reduced to the pre- and postsomatic compartments, the soma, and the first central internode (comp. Fig. 1).

Fig. 2. Electric network to simulate an auditory neuron. The electric parameters are shown for compartment n : axoplasmic resistance to the neighbors ($R/2$ for cylinders), membrane capacitance C_m and the membrane conductance G_m which is only constant in



In general, the ohmic membrane current consists of different types of ion currents that are governed by rather complicated gating mechanisms of specific voltage sensitive ion channels. We have decided on the Hodgkin and Huxley equations /5/ adjusted for mammalian node characteristics, for this set of equations reflects important experimental phenomena such as multiple spiking and chronaxy. For a detailed description of the spatial model we refer to Rattay /6,7/.

RESULTS

Assuming a homogeneous extracellular medium surrounding the schematic neuron as seen in Fig. 1, we applied cathodic $50\mu\text{A}/100\mu\text{s}$ pulses with the electrode situated 0.1mm above the first compartment. The course of these simulated nerve reactions can be followed in Fig. 3. In this simplified approach the spikes are generated at the beginning of the neuron, and the situation is rather close to the natural one. Taking the fact into account that the real neuron follows a curved pathway it turns out that the point of spike origin is either within the peripheral or within the central axon. Simulations show that small variations in electrode current or in electrode position can result in essential changes in the temporal pattern. Based on human auditory nerve data, a case study of this effect is presented in Ref. 7.

Among new human screening techniques, neural response telemetry (NRT) is most promising. Hereby, the electrically evoked activities in the human auditory neuron can be measured with specific electrodes of modern cochlear implants, an exciting experimental counterpart for our model. Fig. 4A illustrates such an NRT measurement from a human cochlear nerve that is electrically stimulated. With increasing intensities responses get more prominent, and a double peak evolves.

To compute the results shown in Fig. 4B a two-step procedure was necessary. Firstly, the membrane currents along a neuron in reaction to a -0.6mA electrode stimulus were calculated. Secondly, every center point of the compartments of this specific neuron was considered to be a current source. The sum of these contributions led to the extracellular voltage resulting from the activity of one single neuron (see upper trace). Again a double peak is visible due to the time delay caused by the soma.

This might be an explanation for the double-peaked NRT measurement, as seen in some cases. If there is only one peak in a cochlear implant patient's NRT measurement there exist two explanations: this is either an indicator for a high degree of peripheral degeneration or the position of the electrode causes poor generation in the existing peripheral axons.

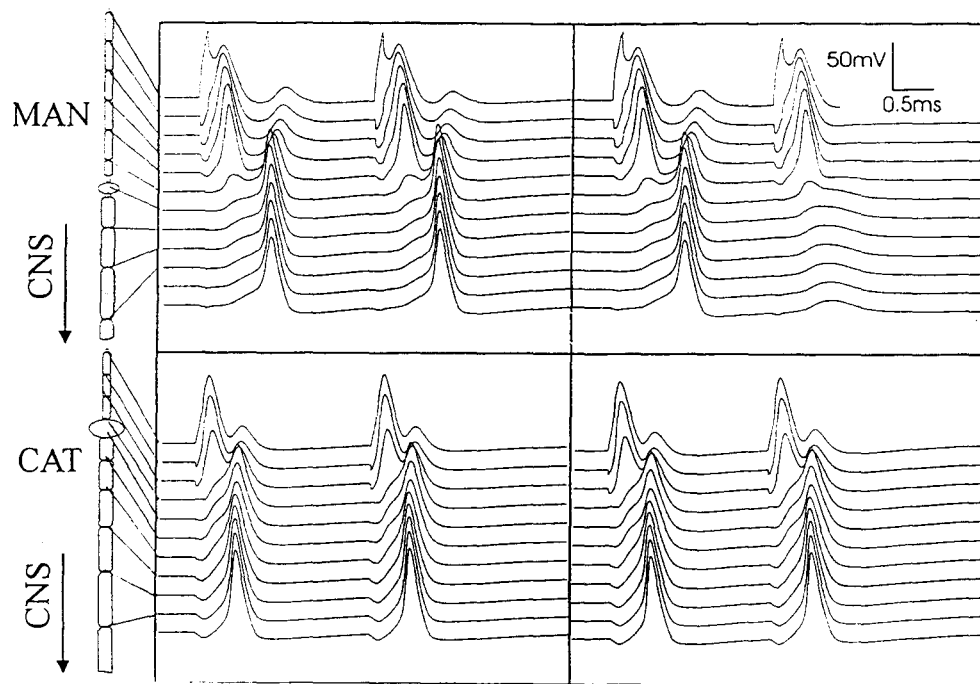


Fig. 3: Behavior of man (top) and cat (bottom) auditory neuron in reaction to stimulation by a small electrode close to the first element, where spikes are generated. Every line shows either reactions of a node of Ranvier or of the soma. The delay at the soma is longer and excitation of the central axon is more difficult for man. The pictures on the right reflect the same situation but the interpulse interval is reduced to 1.8ms. Obviously, refractory behavior hinders the second spike to overcome the barrier of the soma in man.

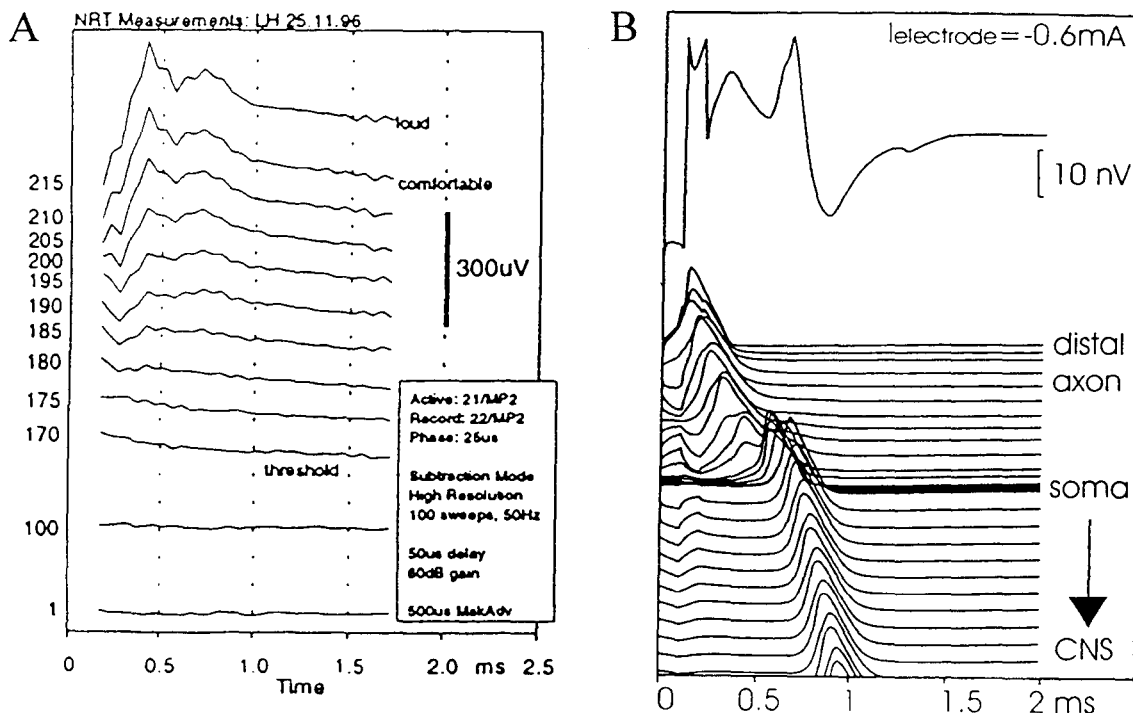


Fig. 4: Extracellular voltage as a function of neural activity evoked by biphasic stimuli from a human cochlear implant. A) NRT measurement reproduced from Dillier et al. /8/ B) Simulated nerve reactions; upper trace: extracellular voltages at the electrode generated by a single activated neuron, lower traces: membrane voltages along the neuron as functions of time. Simulation with modified Hodgkin-Huxley dynamics for the nodes. Every line belongs to a node, an internode or to the soma.

DISCUSSION

We have shown that it is important to incorporate human data into a model of the cochlear neuron in order to understand temporal effects in the firing pattern of cochlear implant users. The position of the electrode in relation to the neuron, the geometry of the neuron and the geometric and electric parameters of the surrounding tissue essentially influence the point of spike generation. Even with constant electrode position the point of spike generation can alternate between pre- and postsomatic areas as a consequence of stimulus level. This means that stimulus amplitudes that follow the shape of the speech signal will cause artificial irregularities in the spiking times with time shifts that are related to the propagation delay at the soma.

Furthermore, simulations show that there are essential differences in the temporal behavior between cat and man, especially because of the large capacitance of the human soma. Short absolute refractory times (0.7-0.8ms) as observed in experiments and in computer simulations of the electrically stimulated cochlear neuron in cat are not expected in humans if the stimulation is restricted to the peripheral axon.

With promising new human screening techniques evolving, a model that includes the geometry of the human cochlea could help to investigate and predict auditory nerve function. First results are in good agreement with NRT data. This opens up a wide field of applications for cochlear implant patients. Simulations of the human cochleogram are near at hand!

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NEW EASY TO INSTALL NERVE CUFF ELECTRODE USING SMA ARMATURE

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SUMMARY

This paper presents an easy to install nerve cuff electrode dedicated to functional electrical stimulation. In this new device, a shape memory alloy (SMA) armature is used to perform the closing of the electrode. This technique makes the electrode installation around the nerve much easier, quicker and safer. Both remarkable mechanical properties of SMA materials namely shape memory effect and superelasticity, can be used to obtain the desired mode of electrode closing. The fabrication procedure of the new electrode is described. It does not require any expensive or complex techniques. Bipolar and tripolar electrodes have been manufactured with an inner diameter of 1.6 mm and a cuff wall thickness of 0.8 mm. These electrodes are to be used for functional electrical stimulation of the bladder in spinal cord injured patients. Acute studies in dogs are being carried out to validate the device and the implantation procedure.

STATE OF ART

Nerve cuff electrodes are widely used for functional electrical stimulation (FES) of lower extremities, bladder /1/, etc. They offer accurately reliable and flexible interface between the stimulator and the biological tissue. Nevertheless, presently used split-cylinder cuff electrodes /2/ as well as spiral cuff electrodes /3/ are difficult to manipulate and install around the nerve due to their small dimensions and the restrained area available for implantation. The use of a Shape Memory Alloy (SMA) structure for closing the electrode enables to overcome these difficulties. These materials are used in a large spectrum of applications, from electrical engineering and aeronautics to biomedicine. The biomedical devices using SMA, such as cardiovascular stents, are quite an ongoing research field /4/. The SMA armature technique has already been experimented by Niemi and Harry /5/ for another type of nerve electrode but the device realization requires complex and expensive laser technologies. In the present paper, we report the design and manufacturing of a new split-cylinder nerve cuff electrode that can be easily and quickly installed around the nerve. Its closing is performed by a SMA structure embedded in the silicone rubber cylinder cuff.

MATERIALS AND METHODS

General description and materials.

The new nerve cuff electrode with SMA armature is presented on figure 1. Its design is based on classic split-cylinder cuff electrodes but a SMA armature has been added inside the cuff wall. This SMA structure enables the electrode to close by itself around the nerve and to be maintained in place without requiring any external fixation means such as sutures.

The electrode is exclusively made of biocompatible materials. The electrode cuff is molded in Silastic® and electrode contacts are made of a 0.025 mm thick platinum foil. The leads are multi-strands stainless steel wires coated with Teflon® (e.g. Cooner Wire, AS634). For the SMA armature, medical grade NiTi wires of 0.1 mm of diameter are used (Shape Memory Applications, inc.). This shape memory alloy (50.7% Nickel, 49.3% Titanium) is considered as biocompatible and has already been used in different biomedical applications such as cardiovascular stents. Nevertheless, it is still undergoing acute long term

biocompatibility testing. For this reason and also because the armature needs to be electrically isolated, the electrode SMA structure is completely embedded in Silastic®.

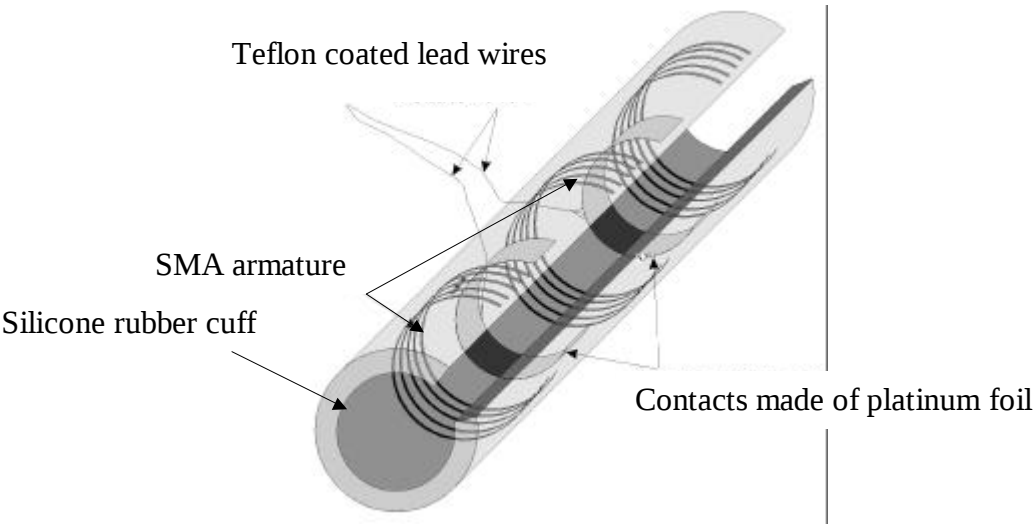


Fig.1: The nerve cuff electrode with SMA armature.

Mechanical properties of shape memory alloys and electrode closing mode.

SMA materials are well known and widely described in literature /6/. In order to understand the closing mode of the electrode, the two remarkable properties of SMA materials – the shape memory effect and the superelasticity – are shortly described here. The shape memory effect is the capacity of a SMA to recover a memorized shape when deformed at a certain temperature and then heated to a higher temperature. The material can memorize any desired shape by undergoing a specific thermal treatment. Its recovery shape temperature can be fixed at a desired value. Above this recovery shape temperature, the alloy becomes superelastic. This means that, over a certain amount of mechanical stress, the material can be easily and reversibly strained up to 8% or more, rather like a rubber band than like classic metallic materials.

As describes on Figures 2 and 3, the way of installing the electrode around the nerve depends on the chosen method (shape memory effect armature or superelastic armature). If a shape memory effect armature is to be used, then the alloy recovery shape temperature will be fixed slightly under 37°C. At room temperature, the electrode is initially closed (fig.2a). By cooling the electrode around 10°C, the surgeon can easily open the cuff and the electrode will remain in open position even if it is taken back to room temperature (fig.2b). In this open configuration, the electrode can be easily placed under the nerve (fig.2c). In the biological environment, the SMA armature warms up to its recovery shape temperature and then recovers its initial shape, activating the electrode closing (fig.2d). When closed onto the nerve, the SMA armature makes the cuff rigid enough to insure the cuff mechanical stability . If a superelastic

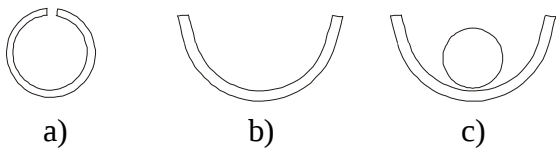


Fig.2: Installation procedure of a cuff electrode with a shape memory effect armature. a) Electrode at room temperature, b) Electrode opened by the surgeon at 10°C, c) Placing of the electrode around the nerve, d) Self-closing of the cuff at 37°C.

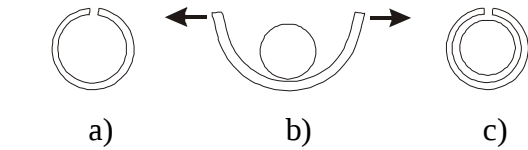


Fig.3: Installation procedure of a cuff electrode with a superelastic armature. a) Closed electrode at room temperature, b) Electrode opened by the surgeon at room temperature, c) Elastic closing of the electrode around the nerve.

armature is to be used, the recovery shape temperature is fixed below room temperature. At room temperature, the electrode is initially closed (fig.3a). The physician pulls apart the two edges of the electrode cuff, strongly enough to reach the SMA material superelastic state. Then, the electrode cuff opens easily (fig.3b). Keeping the cuff opened, the surgeon can place the electrode near the nerve. When he slackens the cuff, the electrode comes to close elastically around the nerve (fig.3c). The installed electrode is once again rigid enough to keep stable on the nerve.

Fabrication procedure.

As shown on figure 1, the armature is composed of several sets of split rings of NiTi wire. In order to give the NiTi wire its final shape, it is wound into a spring on a metallic rod of 1.9mm of diameter. It is then thermally treated at 470°C during one to three hours depending on the type of mechanical behavior – shape memory effect or superelasticity– we want to obtain. The treated SMA spring is covered by a first thin layer of Silastic® in order to create an additional cohesion between the different spring curls. Then, we longitudinally cut the spring to obtain the armature elements presented on Figure 4.

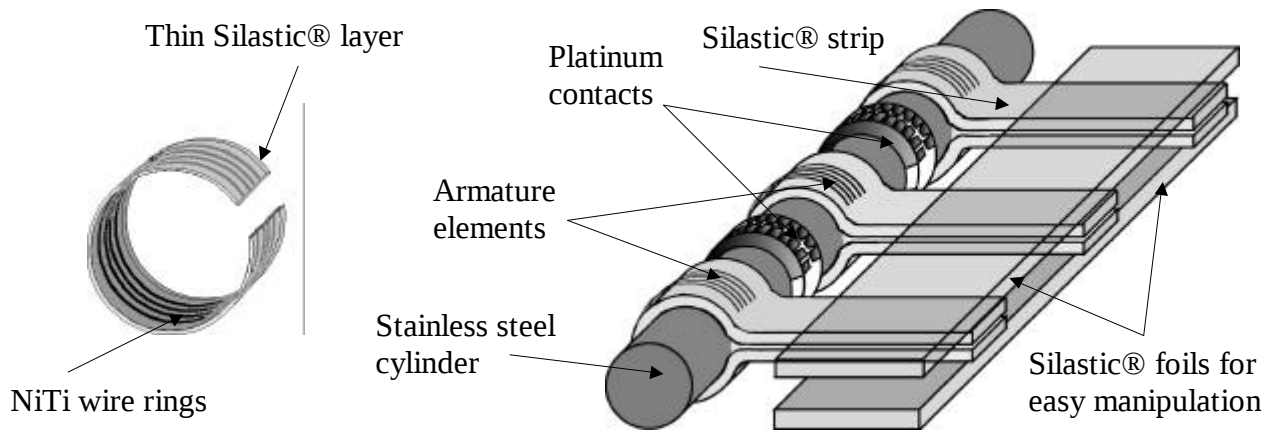


Fig.4: SMA armature element composed by several split rings of NiTi wire maintained by a thin layer of Silastic®.

Fig.5: Bipolar electrode under fabrication, before deep coating in Silastic®. The platinum contacts are maintained onto the steel cylinder by silicone rubber elastic bands. The armature elements are fixed onto Silastic® strips.

The electrode is assembled on a stainless steel cylinder according to the Haugland's method /2/. The armature elements are placed in between the electrode platinum contacts. They are isolated from the internal side of the cuff by a Silastic® strip. The exceeding Silastic® strip lengths of the different armature elements are linked together by an extra Silastic® sheet (Figure 5) in order to facilitate the electrode manipulation. When all the armature elements and contacts are mounted on the mandrel, they are deep coated in a fluid Silastic® and heptane solution in order to obtain a cuff of minimal thickness. The overlapping Silastic® parts are cut by the physician after installation of the electrode. In acute experiments, they can be left on the cuff so that the electrode can be easily removed and left intact.

RESULTS

Different types of electrodes have been fabricated: bipolar electrodes for FES of the bladder and tripolar electrodes for electroneurograms (ENG) recording. For both types, electrodes with memory effect armature and others with superelastic armature have been completed. The shape recovery temperature of the SMA material is fixed at 35°C in the first case and at 10°C in the second case. The electrode cuffs are 1.6 mm of diameter and about 0.8 mm of thickness. Their lengths are 12 mm for bipolar electrodes and 15 mm for tripolar ones. These dimensions are adequate for implantation on S2 sacral root of dogs and respect the AAMI recommendation for safe cuff electrode use /7/.

As expected, the electrodes with superelastic armature are closed at ambient temperature and can be easily manipulated and opened by pulling the Silastic® edges of the cuff apart. And as soon as the stress

is released, the cuff returns to close again. The behavior of the electrodes with SMA is slightly different of the one predicted (Figure 2). They almost behave as the electrodes with superelastic armature because of the high elasticity of the silicone cuff. It is difficult to keep the electrode opened even at low temperature because the silicone cuff spring back force is high compared to the armature rigidity. The rigidity can be improved by increasing the number of SMA rings in the different sets of the armature. Acute experimentation on dogs has started recently and our results will be reported soon.

DISCUSSION

The armature rigidity has to be carefully chosen. Undertaken experiments show that a low rigidity shape memory armature does not lead to a correct behavior of the whole electrode. Inversely, a too rigid armature could tear the silicone cuff during closing. The armature rigidity is evaluated by mechanical testing and by simulating the SMA material mechanical behavior.

CONCLUSION

We have described a new type of nerve cuff electrode activated by a SMA armature. It is easier to install on the nerve than other available electrodes. It is also fabricated at low cost without requiring any complex technique. The superelastic armature design seems to be more promising than the one with a shape memory armature. Acute and chronic studies are undertaken in animals (dogs) to evaluate the electrode mechanical behavior and biocompatibility. In the future, we will consider the feasibility of electrode cuffs of smaller diameter that could extend in case of nerve diameter increase.

ACKNOWLEDGMENTS

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EVALUATION AND EXAMINATION OF WIRELESS COMMUNICATIONS FOR NEURAL PROSTHESES

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SUMMARY

At present, many studies are dealing with the design and development of neural prostheses that might one day help handicapped people to restore part of their physical capabilities. Especially in Functional Electrical Neural Stimulation, the amount of data which has to be acquired and computed for closed loop designs is very large. In order to cope with the needed data exchange between implants and remote system components without using cables, a wireless solution is presented and discussed here.

STATE OF THE ART

Wireless communication has become a fast growing market which has produced numerous highly sophisticated integrated circuits at low cost. There are many applications which take profit from this trend providing both, professionals and consumers, services like mobile and cordless telephones etc.. In the health sector, wireless data acquisition may be considered for functional neural prostheses:

Here, one or more implanted stimulators and electrode arrays need to be controlled by an external device which is responsible for data processing. It is expected that this device will be too bulky and energy consuming to be implanted. Depending on the specific prosthesis design, one or more transcutaneous power and data links will have to operate in order to accomplish a connectivity to the implants which preferably will be powered inductively. A sensor will pick up information from deliberate muscle movements by the patient for general prosthesis control. This sensor might be implanted in the thorax or worn externally, for instance at the patient's head.

Thus the overall system consists of distributed implanted and external components which have to be linked somehow. One approach is to interconnect the implants with implanted cables and using one common inductive link to provide the transcutaneous connectivity. The external devices like control sensor, external inductive unit and processing unit might be interconnected via external cables which restrict the freedom of movement. One interesting alternative to this approach is the use of wireless communication for intra-system information exchange.

MATERIALS AND METHODS

Fig. 1 depicts a sample prosthesis consisting of one external sensor unit for the patient's control, one external processing system and one implanted stimulator and recording unit in the forearm of the patient. The implant is inductively linked to an external inductive transceiver.

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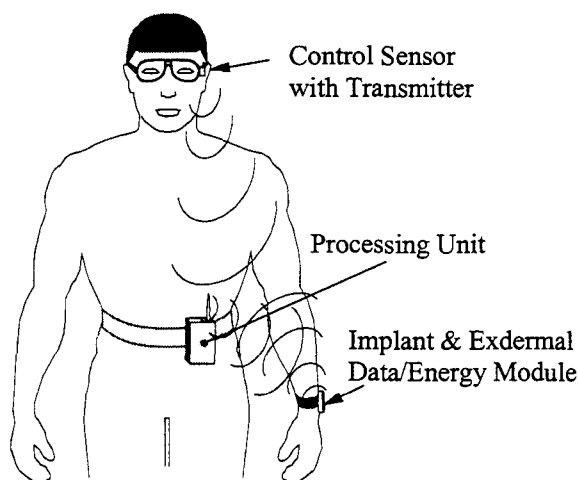


Fig. 1 Communication system for a neural prosthesis

In order to design a wireless communication system for a neural prosthesis, it is essential to know at least the approximate amount of data which will have to be exchanged. As closed-loop controlled prostheses are desired, not only nerve stimulation but also the recording of nerve signals have to be carried out. In a commercial system it is probable that some kind of data compression will be used to save transmission bandwidth. In the prototype stage no compression scheme is tolerated for the sake of undistorted signal data. There are a considerable amount of publications in which different sampling rates and quantizing resolutions are suggested for the extracellular recording of peripheral nerve signals.³ Values between 6 and 12 ksamples/s at 8-12 bit resolution and even higher are reported /1/. If using a conventional PCM system, the amount of data during recording would lie

between 48 kbps and 144 kbps per recording site.

By using arrays of recording electrodes it is desired to gain information about the location of the active nerve fibre within the nerve and to be able to stimulate more specifically. Thus the amount of data would be multiplied by the number of electrodes on an array per site. For a Grasp prosthesis, a number of around 4 stimulation and recording sites will be needed. As a consequence, the overall data originating from the implants to be transmitted to the external processing unit and vice versa may easily reach 2 Mbps. In contrast, the sensor which picks up the patient's control movements will generate much less data. This will be in the order of 80 to 1000 bps.

Considering a wireless communications scheme, there are important conditions which have to be met:

- The system needs to be robust against any kind of interference.
- Operation of the same system in parallel has to be possible without performance loss.
- The wireless components need to be small and light in weight.
- Energy consumption has to be reduced to a minimum as every isolated component has to operate from its own battery with the implants being provided with energy by their exdermal counterparts.

Various technologies may be considered to implement wireless data links like radio frequency, inductive and capacitive coupling, ultrasound and infrared light. Inductive links are reasonable for transcutaneous energy and data links covering very short distances. These are predestined for connecting one or more implants to an external aligned counterpart. For the free space connection between external components such as a control sensor, an external inductive device and a central processing unit, inductive links are too restricted in transmission range. Ultrasound links are inefficient from the point of power consumption. Capacitive coupling may be practical for slow data transmission e.g. the connection between the processing unit and the control sensor, but there is not much expertise in this field and there still seem to be problems in maintaining a stable link /2/. Infrared links are easy to implement, low in cost and can be implemented at very small size. Practically, the speed of data transfer is merely limited by the speed of the switching circuits. The drawback of infrared communications is that any obstacle between sender and receiver interrupts the transfer unless indirect reception is enabled by reflections. On the other hand, the infrared channel is more robust against man made interference than the radio transmission channel. Choosing an appropriate frequency band, RF transmission can be made very fast and effective. But safe transmission can only be realised with sophisticated designs which has negative effects on the size of the transceiver, unless highly integrated chips are used.

³ For the communication concept in this particular case only peripheral nerve interconnections are planned

In order to evaluate a wireless communication scheme for neural prostheses, sample designs of transceivers for each specific link mentioned above have been carried out, including an inductive transcutaneous telemetric link for high bit rate communication [3], an infrared data link, 433 MHz UHF modules and a 2.4 GHz spread spectrum radio based on the novel wireless ethernet standard IEEE 802.11.

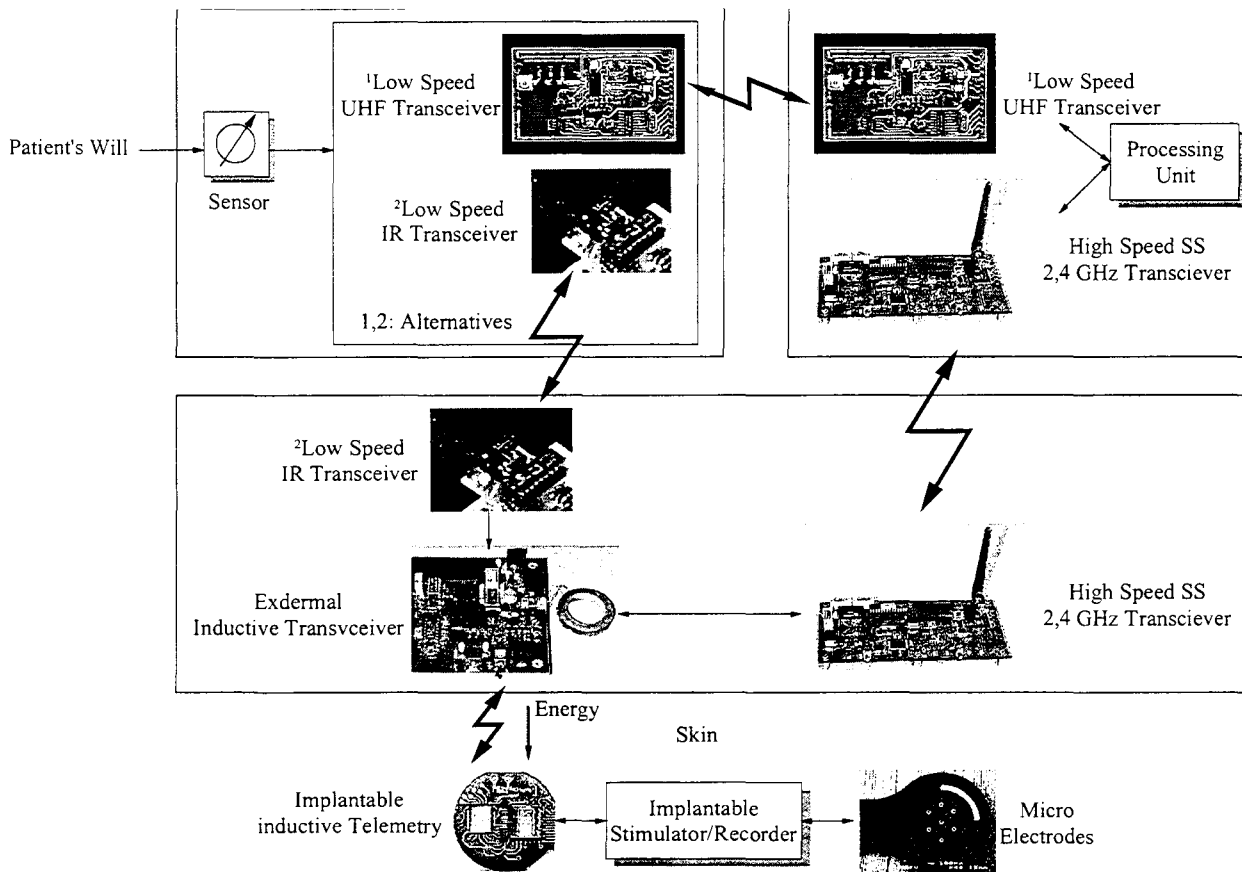


Fig. 2 Communication's Concept

The transmission channels can be classified in fast channels (carrying sensitive stimulation and recording data) and slow channels (carrying the patient's control information). In the first case, the data has to be transported from and to the implant, traversing the skin and tissue barrier. As energy has to be transported to the implant as well, an inductive link is used here. The connection between the external inductive module and the processing unit carries the same data. Infrared is not practical in this case, as a line of sight cannot be guaranteed, so this link is implemented as a high speed RF link.

RF modules in the UHF frequency band are intended for the slow channel between processing unit and sensor interface. Alternatively, an IR link is set up for this channel to benefit from the very small size of this solution. If the sensor is worn at the head of the patient, a line of sight cannot be maintained to the processing unit either if the latter is worn on a belt or mounted to a wheel chair. Thus, the concept incorporating an IR link physically provides an optical link between the sensor and the external inductive unit worn on the wrist. Thus it takes over functions as a relay, diverting the IR data stream by backpacking the data onto the existing high speed RF data stream to the processing unit. In this manner, the link will be less obstructed, as in most cases the patients will watch there hand/prosthesis while operating them.

The more challenging data link is the one which connects the external inductive devices with the processing unit. Integrated Chip manufacturers offer various solutions for high speed data links, especially since the IEEE 802.11 standard for Wireless LAN has been announced. Harris Semiconductor for instance with its PRISM series markets a chipset which they claim to be able to transmit at 11Mbit/s

half duplex. For better interference immunity, Direct Sequence Spread Spectrum technology is used in the base band.

RESULTS

A sample wireless communication system for the use in functional neural prostheses has been developed and various types of transceivers have been constructed for this application (see also Fig. 2):

1. One low speed (9,4 kbit/s) IR link using an IrDA compliant infrared frontend for the connection to a sensor module. The size at present is 25 x 25 mm² which can be further reduced by using stripped dice. At a transmission range of 2m the interface consumes 17 mA at 5V.
2. For the same purpose, a slow (9,4 kbit/s) UHF transceiver has been set up. To ensure simultaneous operability with other systems, a more complex synthesizer design has been chosen, thus providing the ability to change the channel within the designated frequency band. The transceiver measures 70 x 60 mm and consumes 24 mA transmitting with an output power of 0dBm.
3. A 2,4 GHz spread spectrum transceiver has been constructed for the high speed link between the processing unit and external inductive units. The present design can transmit up to 2 Mbit/s but uses a considerable amount of pcb real estate (170 x 95 mm²) and energy (approx. 450 mA during transmission). As this is just a sample transceiver, both energy consumption and size can be reduced drastically by using multilayer technology and low power digital interface circuits.
4. For the transcutaneous link, an inductively coupled interface has been set up which will be discussed in more detail in /3/.

DISCUSSION

With today's chip technology, a wireless communication system for functional neural prostheses as discussed above is feasible. The objective is to give the patient as much freedom in his movements as possible. Despite the advantages, there may be objections against using wireless links for neural prostheses which in first line concern safety and reliability. Especially the high data rate exchange carrying the stimulation and recording data is sensitive to interference. For this reason it is essential that the frequency bands in use have to be reserved for these applications by regulations. Furthermore, as the system does not carry only one single battery, the changing and recharging of the batteries become more difficult, in particular for handicapped persons. Therefore it is important to reduce the power consumption to a tolerable limit. Future work will not only be concerned with enhancing the individual links concerning size and power efficiency but also with incorporating an adequate transmission protocol which allows multiple systems to operate simultaneously.

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FAST PROTOTYPING OF IMPLANTABLE SYSTEMS FOR STIMULATION AND RECORDING BASED ON A BI-DIRECTIONAL AND RF POWERED TELEMETRY INTEGRATED CIRCUIT

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SUMMARY

The use of implantable systems is required for biomedical studies about neuromuscular and functional electrical stimulation and biosignal recording. Such systems have to send and receive information from external units that manage and store the data controlling the stimulation, the recorded data and the status of the implanted device. A new RF powered telemetric system, incorporating a Telemetric IC (TIC) and one or more application specific chips, is presented and described in this paper. The main objective of the former is to provide multiple methods of communication between the specific application circuitry of the implant and the external unit. It also generates the regulated supply voltage for the rest of the implanted unit and provides a controlled global reset of the system.

The TIC system offers a wide range of possibilities to be connected to common microcontrollers (e.g. Microchip's PIC controllers) using different bus architectures such as serial or parallel. Also, the TIC provides a number of different transmitters to choose from in order to transmit the data from the implant using different carrier frequency and modulation schemes. In-link and Out-link data transmission channels allow a bi-directional transmission with bit rates higher than 100Kbps. The TIC practically does not depend on the microcontroller or ASIC used which can focus on the stimulation/recording process. Two initial applications of the TIC system are presented: a stimulation system for the use in neural prostheses and a 5 channel micro-stimulator.

STATE OF THE ART

The initial stages of biomedical studies requiring implantable systems for neuromuscular electrical stimulation and biosignal recording often have a certain number of non well-known characteristics: the definition of stimulation waveforms, the control of the stimulation/recording process and the number of channels required. In these cases, the use of microcontrollers within the implanted stimulation unit is a good solution in the early stages for the digital control because of their flexibility and low cost. The main effort can thus be centred on the development of the customised application circuitry. A full duplex telemetry system with an adequate bi-directional bit rate and an interface for various microcontrollers or ASICs could be used during both initial and final stages of prototyping. This way, the effort to control the telemetry can be reduced: demodulation and decoding to receive data and coding and modulation to send the data.

MATERIAL AND METHODS

The designed telemetry unit (TIC system) becomes a complete interface between the external unit and the implantable application unit. The TIC was designed to be well adapted to PIC microcontrollers. As a consequence, the final result is a common architecture which allows easy connection to other devices using multiple methods. In any case, this paper refers to PIC as a generic name for the customised part of the application, which provides or uses information to be transmitted or received from the ETU. This section describes the main blocks and modules of the TIC, giving detailed information on its configuration.

An overview about the complete TIC system is shown in figure 1. The external transceiver unit (ETU) is based on a high efficient class-E driver generating a carrier frequency between 6 MHz to 12 MHz, depending on the application, providing enough energy to power the implanted system [1-2]. An accurate

coil design maximises the coupling coefficient for the range of distance between the coils. The antenna system has to be tolerant to lateral and angular misalignment, keeping the Bit Error Rate (BER) as low as possible but taking into account the restrictions imposed by the maximum dimensions of the coils and data bandwidth /3-4/. Data from the ETU to the implant is provided by means of amplitude shift keying the class-E driver supply voltage. Information is restored by passing on the received signal to the TIC's onchip envelope detector, filtering stage and decoder. On the other side, the TIC transmits data to the external receiver by using BPSK or OOK. Special effort was done to minimise the crosstalk between the In-link (ETU to TIC) and the Out-link (TIC to ETU).

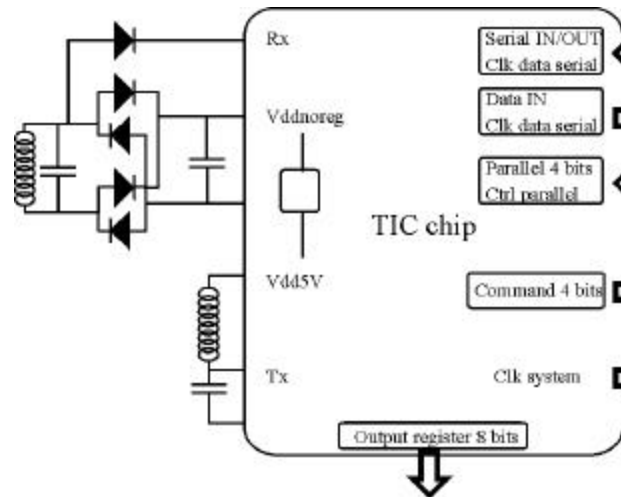


Figure1: TIC scheme

TIC configuration and global reset definition

Data from the ETU is coded using a variable duty cycle to determine the changes of the ASK signal. A duration about 14.8 μ s and duty cycle of 3.2 μ s defines the global reset of the TIC, which can be used to reset the rest of the implanted system. The start up sequence of the TIC is defined by the initial reset (external reset) and 5 bits (Prog1 to Prog5) which program the TIC's configuration register. Figure 2. shows an example of start up sequence and table I. shows the data flow for the different possible transfers from the ETU to the PIC. The data bit rate for the Out-link channel is configurable using Prog2 bit selecting 234 Kbps or 460 Kbps. The TIC generates a system clock with frequencies of 234KHz, 468KHz, 3.75MHz or 7.5MHz (using Prog4 and Prog4 bits).

Two additional lines (CS1 and CS2) manage the information through the different busses of the TIC system. These lines can be set statically if only one communication channel is used.

Table I: Main data flow programming

CS1	CS2	Prog1	Data flow	Comment
0	0	X	ETU $\Rightarrow$ TIC $\Rightarrow$ PIC	Data reception by the 4 bits parallel bus
0	1	X	PIC $\Rightarrow$ TIC $\Rightarrow$ 4bits Command	Control another device using 4 lines
1	0	X	PIC $\Rightarrow$ TIC $\Rightarrow$ ETU	Data transmission using the 4 bits parallel bus
1	1	X	PIC $\Rightarrow$ TIC $\Rightarrow$ 8bits parallel Output	Parallel data transfer from PIC
X	X	0	Serial $\Rightarrow$ TIC $\Rightarrow$ ETU	Data transmission serial
X	X	1	ETU $\Rightarrow$ TIC $\Rightarrow$ Serial	Data reception serial

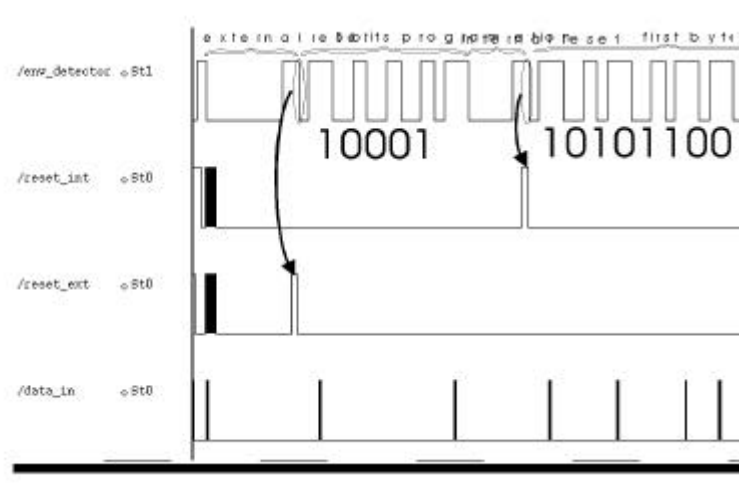


Figure1: Start up sequence and first data frame.

- Data frame definition: Each data frame is defined by an initial symbol called internal reset which is succeeded by eight data bits. The internal reset is defined with a duration of about $12\mu s$ and a duty cycle of $3.2\mu s$. The data is sent to the controller by using either the serial or parallel bus, depending on the programming and the state of the CS lines.
- Power supply regulation system: The TIC provides a stable 5V based on an internal bandgap voltage reference.
- Transmitters: Seven different transmitters are included into the TIC in order to use the most adequate in each application. Only one of them can be used at a time by hardwiring. Table II summarises the characteristics of each transmitter.

Table II: Transmitter description.

Power supply pad	Modulation scheme	Carrier freq.	Notes
Vdd1	BPSK	20 MHz	
Vdd2	BPSK	25 MHz	
Vdd3	BPSK	30 MHz	
Vdd4	BPSK	30 MHz	*manages two times more current than BPSK(Vdd3).
Vdd5	BPSK	40 MHz	
Vdd6	OOK	25 MHz	
Vdd7	LC **	-	**Peak generation at the free frequency fixed by the LC tuned circuit.

Receiver: A single ASK demodulation scheme based on filtering and triggering of the RF incoming signal is used to provide a digital signal to the decode circuitry.

RESULTS

Current applications

At present, the TIC system is working in some applications where a generic telemetric system is required. The TIC provides the interface between an external neural prosthesis control unit and the implantable stimulator/recorder system [5]. In this application, the internal control unit is a PIC16C71, which manages the TIC. Photos 1 and 2 show the top and bottom of a PCB carrying the TIC and PIC, both as die, and the transmitter coil using the BPSK-30MHz. The communication between the TIC and the controller is provided by the 4 bit parallel bus. The system clock, too, is generated by TIC. The external reset line is used to initialise the microcontroller. Another application for the TIC system is the control of a five-channel micro-stimulator. In this case, only serial communication between the TIC and PIC is possible because of the number of signals that have to be controlled by the microcontroller: amplitude and duration of pulse, charge recovery and channel selection.

Photo 1-2: Top and bottom of the TIC application. Diameter 1.6 cm.

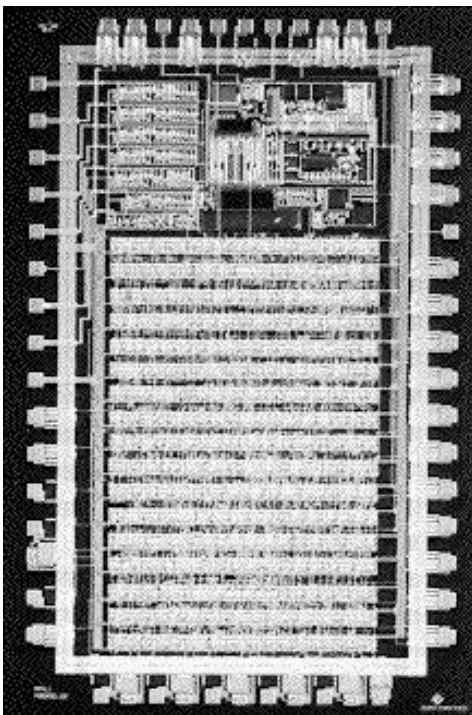
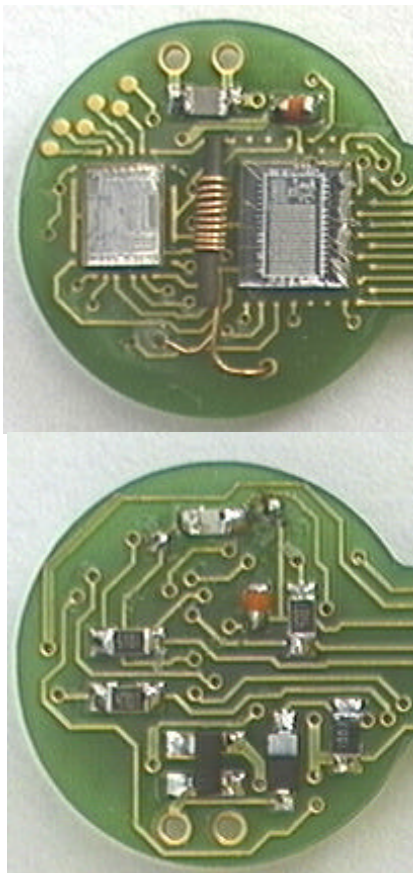


Photo 3: Microphotograph TIC chip

Improvements

A new scheme of modulation and decoding of the data received from the external unit was defined in order to use the TIC system in worst conditions. An additional single ramp integrator was added defining the coding based only on the external reset and internal reset symbols and OOK of the RF signal. In this case, the bit rate is reduced but the system works with lower BER and higher tolerance.

DISCUSSION

A new telemetry system for interface purposes is described. The telemetry chip guarantees the connection to several devices to complete the implantable unit during the initial phase of biomedical studies. Some examples of possible configurations are demonstrated and real examples with a description of the overall microsystem using unpackaged versions of the TIC and PIC16C71 chips.

The full telemetry system has been designed, tested and used in some applications. The telemetry system is ready to form part of new implantable units. The system can be used for fast prototyping of new implantable units using several methods to exchange information between the specific application and the telemetry unit. Further efforts will try to enhance the performance of the telemetry system increasing the bit rate and the power transfer, which are probably the hardest limitations of battery-less implantable devices.

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AN EFFICIENT, MISALIGNMENT-TOLERANT 0.6 W INDUCTIVE POWER TRANSMISSION LINK FOR IMPLANTABLE FES DEVICES

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SUMMARY

Inductive links are frequently used for powering of implanted devices for functional electrical stimulation (FES). They are used in applications where implanted batteries are not capable of supplying a sufficient amount of power over the time of implantation or where continuous data exchange with external components is necessary like in a leg pacemaker.

This paper describes an inductive power transmission link, which was developed for an implantable stimulator for direct stimulation of denervated muscles. The link transmits a power of 0.6 W over a distance range of 0 to 70 mm with an efficiency of more than 40%. The carrier frequency is around 2 MHz, the transmitter coil has a diameter of 80 mm, and the implant coil is 45 mm × 30 mm. Data transmission to the implant with amplitude shift keying (ASK) and back to the transmitter with passive telemetry can be added without major design changes.

The efficiency of the link was optimised with different approaches. A class E transmitter was used to minimise losses of the power stage. The geometry and material of the transmitter coil was optimised for maximum coupling. Phase lock techniques were used to achieve frequency tracking, keeping the transmitter optimally tuned at different coupling conditions caused by coil distance variations.

We chose the high range of coil spacing (0 to 70 mm) to care for lateral and angular misalignment, as it occurs in practical use. If the transmitter coil has a well defined and reliable position in respect to the implant, a smaller working range might be sufficient. Under these conditions the link can be operated in fixed frequency mode, and reaches even higher efficiencies of up to 68%.

STATE OF THE ART

The literature about inductive links offers many examples of inductive power links for implanted devices. There are links with high transferred power for short distances for implantable cardiac assist devices, like the total artificial heart. Miller /1/ described a 60 W link with an efficiency of 80% at a coil spacing of 5 mm. Links used to power implants for FES usually have lower transmitted power (<100 mW) and higher working range up to some centimeters. Clinical applications are, for example, cochlear prostheses and phrenic pacemakers /2/.

As we could see, there are many examples of inductive links both in research and in clinical practice. Nevertheless it was necessary for us to develop a new link for an implantable device for direct stimulation of the denervated posticus muscle /3/. In contrast to nerve stimulation

this task is much more power consuming, it takes up to 30 mA of stimulation amplitude at 20 V. So the aim of this development was a maximum efficiency at a high working range to keep the transmitter battery small and to achieve a safe operation of the system in everyday use.

MATERIAL AND METHODS

Coil design

The design of the transmitter coil affects the efficiency of the link in different ways: 1. Donaldson /4/ found that there exists an optimum transmitter coil diameter to obtain a maximum coupling coefficient for given coil spacing and geometry of the implanted coil. 2. The material of the coil can help to minimise resistive losses caused by the skin effect. 3. The coil forms an integrated part of the transmitter stage and has to meet design criteria from that side. Following the methods of Donaldson we found a coil diameter of 80 mm to be the optimum for a coil to coil distance of 35 mm. To make coupling insensitive to axial rotation we chose a circular coil. As a material we used Litz wire with 420 individually isolated strands of 50 μm diameter copper wire. We limited the number of turns to 10 to keep the transmitter smaller and more lightweight, for better convenience for the users.

Transmitter design

Use of class E transmitters has become common in the design of inductive links. The DC to AC efficiency of these amplifiers theoretically reaches 100% (/5/, /6/). A principle circuit is included in Fig.1.

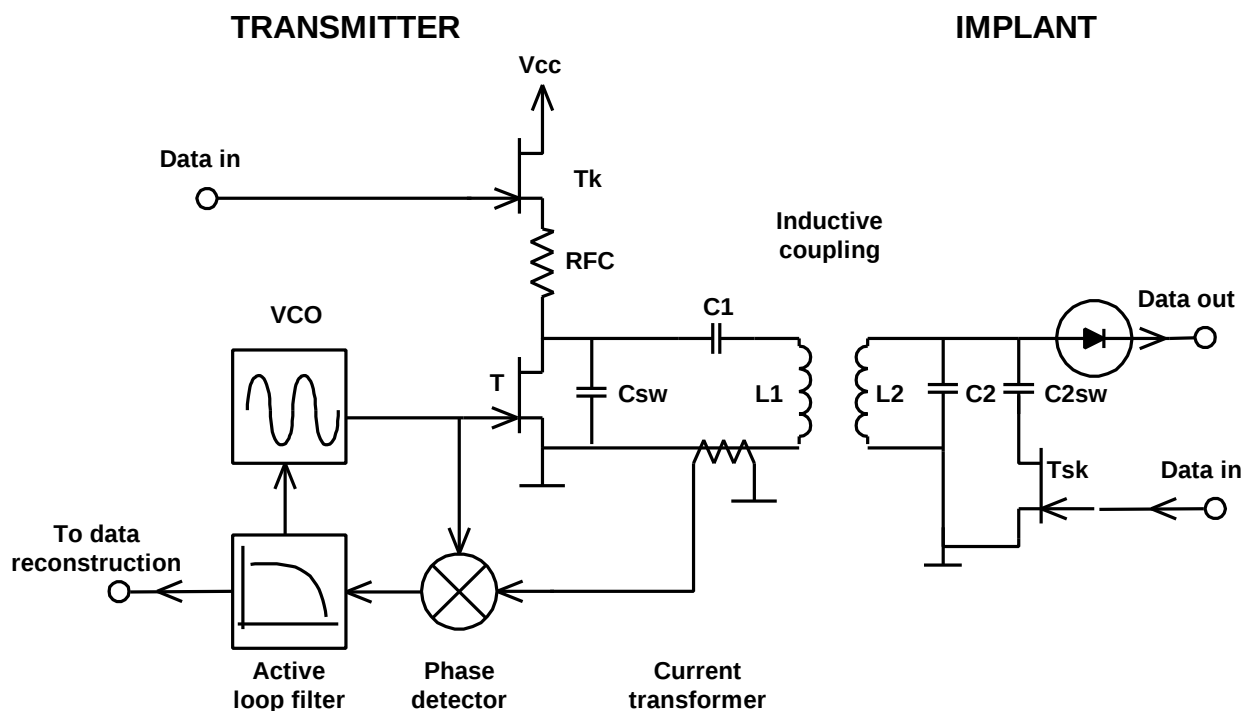


Fig.1: Principle circuit of the transmitter and the implant

Thorough analysis of the complete transmitter in MathCad® and Pspice® with the given transmitter and implant coils led to the calculated component values for C1 and Csw. A phase locked loop (PLL) circuit adjusts the transmitter frequency to different coupling conditions automatically. The transmitter current phase is sensed over a transformer, and compared to the output of the VCO. The resulting phase signal, adequately low-pass filtered, then controls the frequency of the VCO to form a self-adjusting transmitter.

To transmit data to the implant we used an MOS transistor (Tk) to key the transmitter supply on and off. The radio frequency choke (RFC) together with the capacitor Csw and the input capacity of the switching transistor T forms a low pass filter. This effect limits the maximum data rate. The link was designed for bidirectional transmission with 9600 bits/s.

Load shift keying (LSK) by switching a capacitor (C2sw) in parallel to the secondary resonant circuit (L2, C2) over a MOS transistor (Tsk) was used for passive back-telemetry from the implant. Switching Tsk causes a phase shift in the transmitter. The phase detector output can then also be used to recover the data signal.

RESULTS

The transmitter we built as described above transmits a power of 0.6 W over a distance range from 0 to 70 mm with an efficiency of more than 40%. If the transmitter coil has a well defined and reliable position in respect to the implant, a smaller working range might be sufficient. Under these conditions the link can be operated in fixed frequency mode, and reaches even higher efficiencies of up to 68%. Figure 2 gives an impression of the overall DC-to-DC performance.

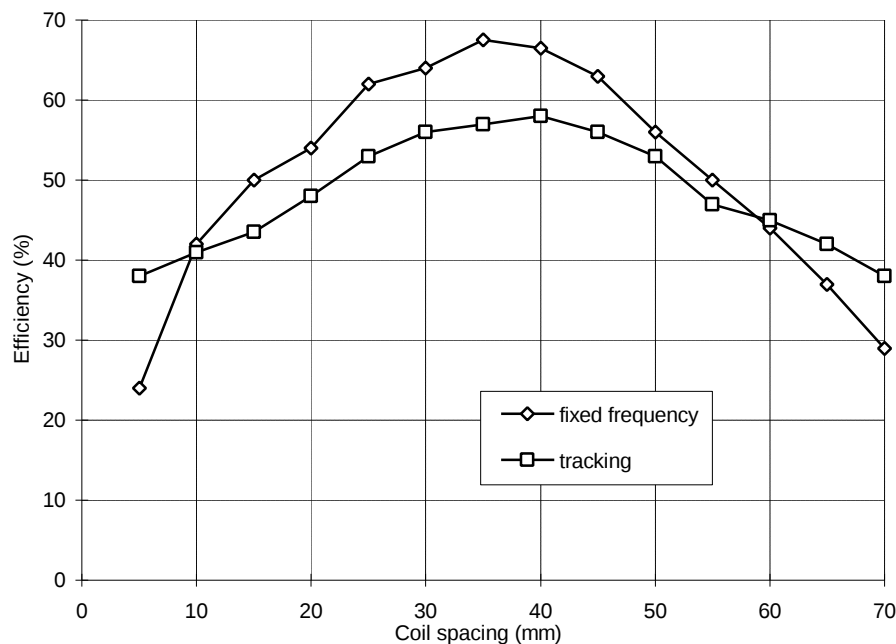


Fig.2: Efficiency of the link over coil-to-coil distance for the frequency-tracking and the fixed-frequency transmitter

DISCUSSION

With the design principles described above we achieved satisfactory energy transmission with a high amount of transmitted energy and a wide area of coil spacings compared to other links for FES devices. However our implant still contains a linear power regulator. This causes significant losses if the transmitter power is not lowered at smaller coil spacings. We overcame this by using a fixed-current power supply for the transmitter stage. Further improvement can be added by use of the telemetered implant supply voltage for online control of the transmitter power.

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A CUSTOM-DESIGNED CHIP TO CONTROL AN IMPLANTABLE STIMULATOR AND TELEMETRY SYSTEM FOR CONTROL OF PARALYZED MUSCLES

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SUMMARY

A custom-designed chip has been developed for the control of paralyzed muscles. The system is capable of fulfilling the stimulus and telemetry needs of advanced FNS applications requiring multiple channels of stimulation and multiple channels for sensor or biopotential sensing. An inductive RF link provides power to the implant device as well as a two-way transcutaneous communication. An application specific integrated circuit (ASIC) decodes the commands and provides functional control within the implant, and modular circuitry provides specific implant functions. The ASIC chip provides up to 32 independent channels of stimulation, with independent control of stimulus pulse duration, pulse amplitude, inter-phase delay, recharge phase duration, and pulse interval. It can also control up to 8 independent back-telemetry analog channels, with independent control of sampling rate and pulse powering parameters (amplitude and duration). The mixed analog digital chip has been fabricated in a 1.2 μm N-well CMOS technology.

STATE OF THE ART

Over the past twenty years, clinical researchers have been intensively using functional neuromuscular stimulation (FNS) for control of paralyzed muscles. The experience demonstrate the feasibility and the success of the intervention in individuals with spinal cord injury, and other central nervous system injuries. FNS systems can be accepted by the user when the basic motor function can be restored, and the maintenance is minimized. Such requirements necessitate an implantable system. The first generation of the implant at Case Western Reserve University used eight channels of stimulation /1/. The implant was under supervision of an external control unit and was operated by an external joint angle position /2/. This system provides hand grasp for individuals with C5 and C6 level spinal cord injury.

MATERIAL AND METHODS

Advanced FNS application requires an increased number of stimulation channels, and multiple sensory and bio-potentials channels. The implant should provide back telemetry capabilities to control the device or to diagnose the system status.

Extend capabilities of the system require a complex digital/analog circuitry. An application specific integrated circuit (ASIC) can provide minimal size and reasonable power consumption needed for an implantable stimulator-telemeter.

RESULTS

An application specific integrated circuit (ASIC) has been developed to control implantable stimulator-telemeters. This mixed analog-digital ASIC combines all command decoding, control and current regulators that are used by the stimulus output stages and the transducer powering circuitry.

The design constraints of the ASIC include physical size, circuitry complexity, number of I/O pads, and cost. These factors have led to implementing the command-control system in direct and expanded mode. Direct mode requires no additional circuitry. Expand mode need an external address decoding. **Figure 1** shows a simplified block diagram of the chip.

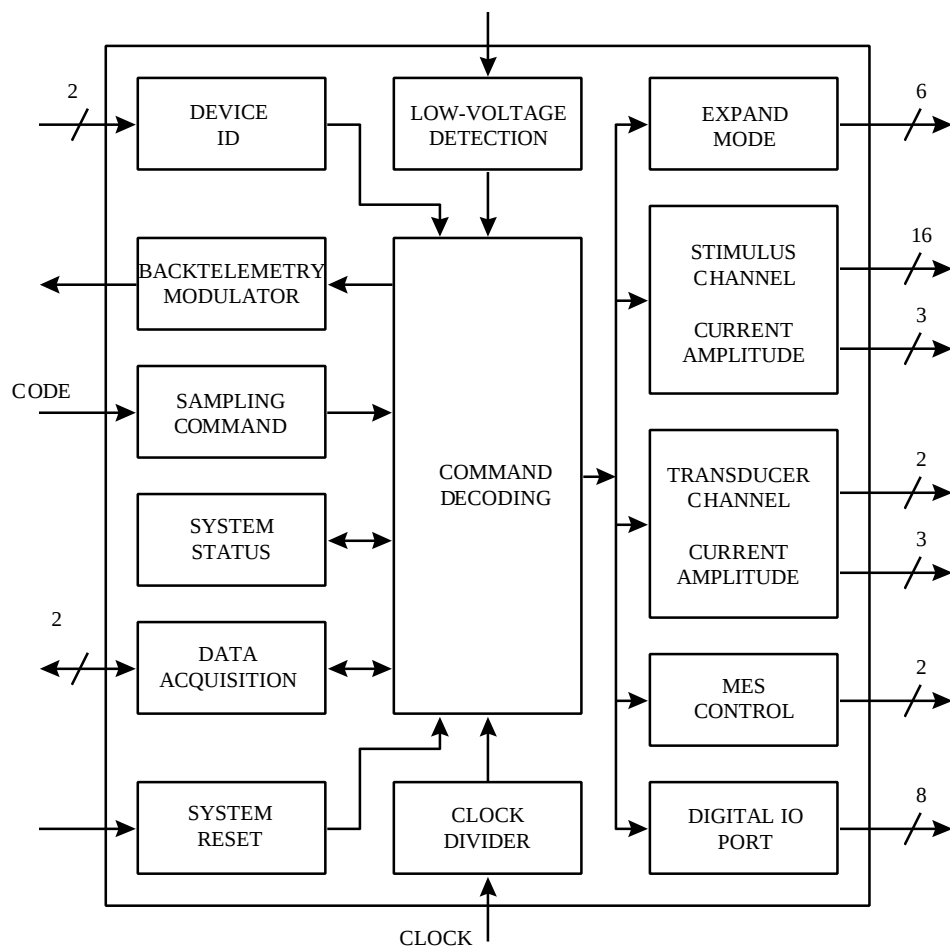


Figure 1. Simplified block diagram of the chip

In the direct mode, the ASIC can control sixteen channels of stimulation with independent control of stimulus pulse interval, pulse duration, pulse amplitude, inter-phase delay, and recharge phase duration, two myoelectric signal (MES) processing channels and two transducers.

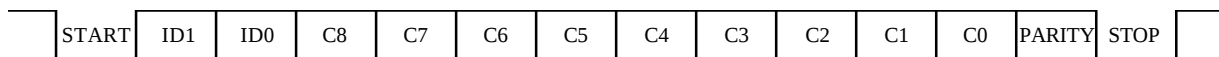
In the expanded mode, the chip provides up to 32 independent channels of stimulation. Up to eight independent telemetry channels for acquiring data from the implant device itself, such as error conditions and power supply status are provided.

Up to four uniquely addressable devices can be used under coordinated control of a single external controller (Device ID).

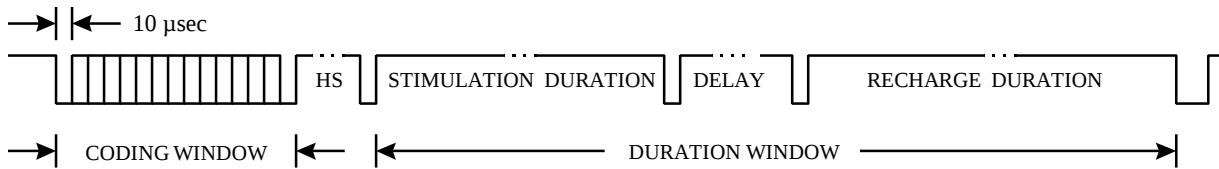
The ASIC control two forms of MES signal: processed MES and unprocessed MES. There are up to eight independent telemetry channels for processed MES. Each channel has control of sampling rate, processing control such as gain, filtering, integration duration, and stimulus artifact blanking. Stimulus artifact blanking is active across all implant devices being controlled. In this way, acquisition of MES data can be coordinated with stimulus output from other device present.

The ASIC has a 14-bit command structure (**Figure 2a**). The command includes one start bit, device identification field ID1-0, interface parameters field C7-0, parity bit, and stop bit. Received asynchronous commands are decoded and functions are executed using a 1 MHz master system clock. The control command is decoded by using two time windows generated by the ASIC logic(**Figure 2b**). The binary pulse burst is decoded within the coding window and enables the appropriate system functions and addressing. The duration window decodes the duration pulses and outputs these pulse duration and timing signals to the enabled channels and control logic in proper sequence. **Figure 2** shows a command structure of the chip.

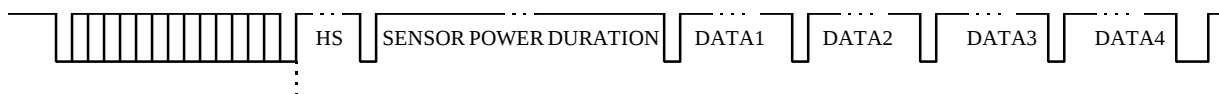
During the command decoding, any errors encountered are latched into the system status register, and can be read (telemetry) by the external control system with a subsequent system command. A supply voltage is monitored by the ASIC through external voltage limiting circuitry.



(a) coding window



(b) stimulation timing diagram



(c) Internal register control and data acquisition timing diagram

Figure 2. command structure

The choice of ASIC technology was based on the trade-off among electrical characteristics, power consumption, standard circuit element availability, development time, and production cost. The standard-cell technology CMOS 1.2 µm n-well was chosen. Integrated circuit layout software was used to design, simulate, and layout the ASIC.

Additional specialized gates, cells, input protection were custom designed and added to the library. The analog part of the circuit is full custom. This part contains the current regulators used to regulate the stimulus pulse current and the remote transducer current pulse. The current regulation is accomplished by using cascade type current mirrors. A low level reference current is set up on first side and this is mirrored into multiple devices wired in parallel. A total of eight mirrors are implemented for stimulus pulse and

transducer power pulse. The level of each current regulator is fixed by a single external resistor. The analog and digital part of the circuit were simulated based on the semiconductor foundry electrical specifications. **Figure 3** shows a photograph of the chip.

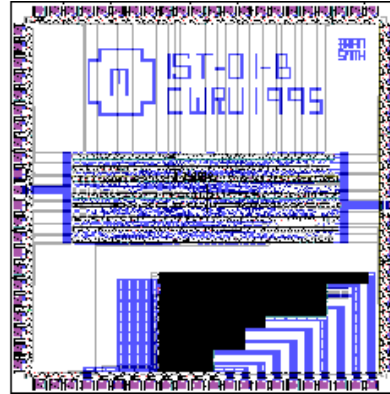


Figure 3. photograph of the chip, CMOS 1.2 μm , 4.5 mm x 4.5 mm

DISCUSSION

The ASIC is a modular system which can generate a wide range of functions. By selecting those functional blocks specified by a clinical application, an implantable device can be design having only the capabilities needed for a particular group of patient. This minimizes physical size, power consumption, fabrication effort, and cost for the development of the implant. The ASIC has been successfully developed, fabricated, and tested for an implantable stimulator and telemetry system.

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INCORPORATING FES CONTROL SOURCES INTO IMPLANTABLE STIMULATORS

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SUMMARY

With growing demands for more sophisticated neural prostheses, control sources are becoming increasingly important. As the cosmetic appearance plays an important role in the acceptance of neural prosthesis, a need is emerging to move the control sources out of sight and implant them under the skin. Implantable electronic transducers and natural bio-electric signals are considered to be most suitable for the purpose. Recently, an implantable joint angle transducer has been implanted in a C6/C5 tetraplegic volunteer to control hand movement. In a parallel effort, an EMG-processing stimulator-telemeter is being developed to include residual electromyographic activity as a control source for patients with C5 level lesions.

STATE OF THE ART

In the development of multichannel implantable stimulators, backtelemetry has been known for at least a decade /1/. Initially, it was intended for monitoring stimulation electrodes and for general implant housekeeping /2/. With the emerging need for implantable control signals and sources, implanted telemetry became a necessity.

For practical reasons, a single external antenna and a single implantable package became the preferred configuration for forward and back telemetry. In this configuration, implanted sensors are connected to the implanted stimulator package, which contains sensor powering and signal processing circuits as well as back-telemetry electronics. Several modulation schemes have been used for backtelemetry, including reflected load modulation and separate transmitter circuits /3,4/.

MATERIALS AND METHODS

There are a number of commercial sensors available that can help control an implantable prosthesis. Among them are angle transducers, accelerometers, linear displacement transducers, force transducers, and, to name just a few. Virtually none of them exists in an implantable form and few can be used in an implant because of their size, power consumption or supply voltage. Depending on their purpose they have to be modified to reside in the implant package or at a remote location, connected to the main package by power supply and signal lead wires.

EMG signals have been used as a control source in many prosthetic applications. Recently, myoelectric signals recorded from sternocleidomastoid muscles have been proposed for ipsilateral hand control /5/. Following this lead in the implantable environment, a stimulator-telemeter design was proposed with two EMG channels and 12 stimulation channels to facilitate hand control for patients that have no voluntary control over wrist motion. It was suggested that EMG activity of one or two target muscles, monitored by implanted electrodes, be amplified, rectified and bin integrated. The end values of the integrated EMG signals would then be digitized and sent to the external controller.

RESULTS

Two versions of implantable stimulators-telemeters have been designed to work with implantable control sources. Each one consists of a conventional multichannel stimulator circuit and a specialized control signal processing circuit. Backtelemetry is provided by a reflected impedance modulation.

Implantable Joint Angle Transducer (IJAT).

IJAT is a magnetic transducer connected to the stimulator package by a set of lead-wires. It consists of a miniature magnet and a magnetic sensor. The magnet is implanted in the lunate carpal bone in the wrist and an array of magnetic sensors is implanted in the head of the radius /6/. The change of the wrist position changes the magnetic field, which is recorded by the sensor. This information is telemetered to the external controller and processed for hand grasp and release. To conserve energy, the sensor is pulse-powered, as needed, on the request from the external controller. Two tetraplegic patients have been equipped with the IJAT, thus replacing the external wrist position transducer.

Myoelectric Signal Processor (MES)

MES electronic circuit or the MES Processor is the main characteristic of the second version of stimulators-telemeters. Connected to implanted EMG electrodes, it measures EMG signal within a defined time window and sends the final value of a bin-integrated EMG to the external controller.

Fig 1. shows the MES version of the implantable stimulator telemeter. It consists of the stimulator-telemeter in the upper section of the drawing and the MES processor in the dashed block below.

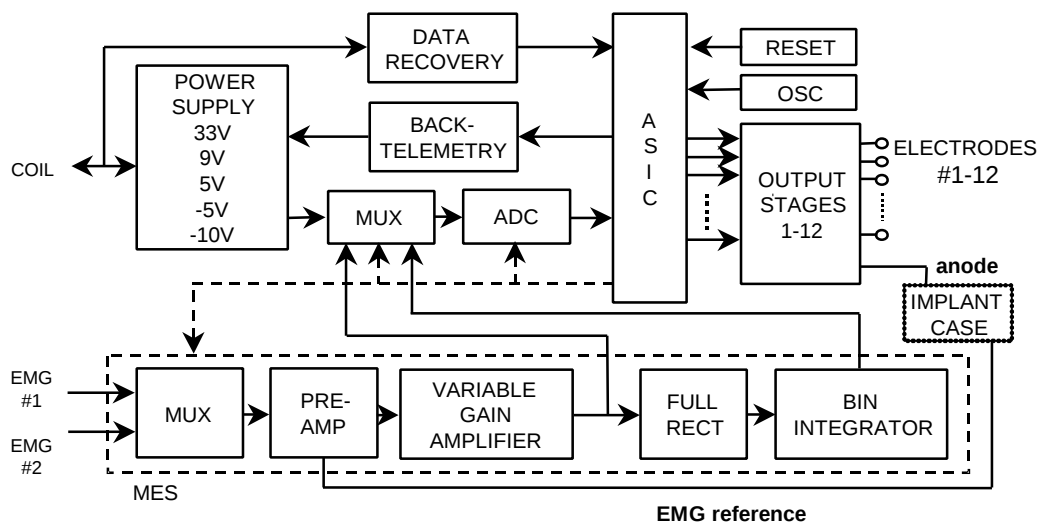


Fig.1. Stimulator-Telemeter with Myoelectric Signal Processor

The MES multiplexer enables the use of a single amplifier chain for two EMG sensing channels and can also disconnect both electrodes from the MES processor. It saves valuable space in the implant case and reduces power consumption.

The preamplifier is a differential, DC coupled two-stage amplifier with a fixed gain of 50. It is AC coupled to a programmable gain amplifier with gains of 2, 5, 10 and 20. The amplified EMG is fed into a simplified full wave rectifier followed by a 3.3 ms integrator. The value of the integrated signal is grabbed at the end of the integrating window and can be transmitted to the external controller.

The MES processor is controlled by the external controller via a custom designed Application Specific Integrated Circuit (ASIC), which is part of the implant's electronic circuit. The ASIC continuously maintains communication with the external control unit and carries out its commands.

The MES circuit can be instructed to select between two signals for back-telemetry: the bin-integrated EMG signal or the “raw” EMG signal, sampled at 1kHz. The latter option is designed for muscle EMG characterization, external EMG processing and system diagnostics. Because of the limited space in the implant package, there are no separate filters

When using conventional surface technology, simultaneous EMG recording and electrical stimulation is possible only by totally separating EMG and stimulation circuits and by blanking the stimulation pulse from the EMG signal. In the implant package, the stimulation and the EMG circuits share the same electrical ground, which is connected to the metal titanium case. This way, the titanium case is the return electrode for the stimulation current and also the reference electrode for the EMG amplifier. Both during stimulation pulse and also during the recharge phase of stimulation, current flows through the titanium case, thus compromising the reference of the EMG amplifier.

Several measures were taken to minimize the influence of the stimulation artifact on the EMG reading and to guarantee a clean EMG observation time window. First, the pulses of all stimulation channels, normally equidistantly spaced in time, are grouped together so that their artifact is not spread throughout the stimulation sequence. Second, during the EMG measuring window, the electrode recharge currents are disconnected. Third, the EMG integrator is opened only during the EMG window. Fourth, outside the EMG window, the variable gain is set to minimum. Fifth, during stimulation, the front-end multiplexer can entirely disconnect the EMG processor from the EMG electrodes.

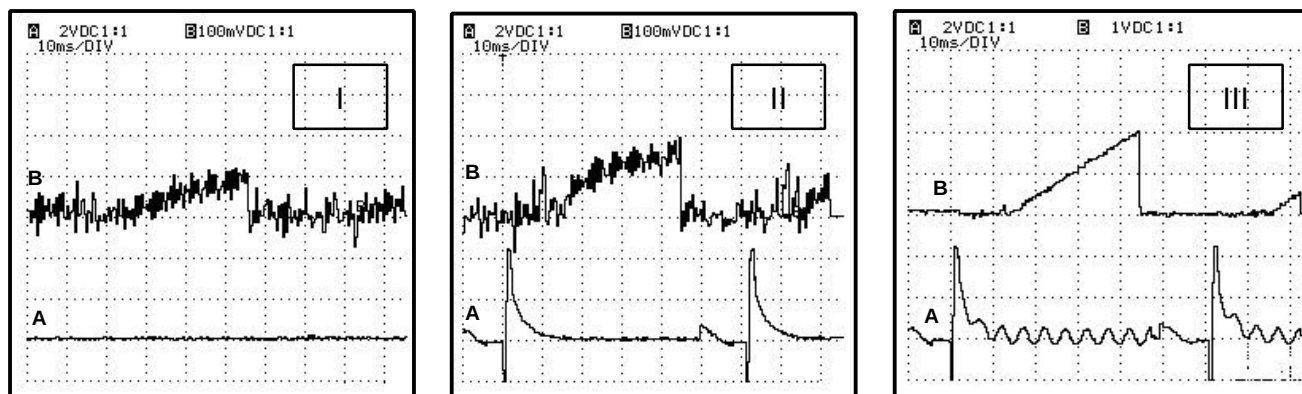


Fig.2. Amplifier (A) and Integrator (B) output for (I) ambient noise, (II) stimulation noise and (III) simulated EMG. Amplifier gain is 60 dB. (In saline solution)

Two sets of MES circuit tests have been performed. The first test was designed to demonstrate the MES circuit ability to reject stimulation artifacts. A small Plexiglas basin was filled with saline solution to mimic tissue environment. Epimysial stimulating electrodes, epimysial EMG electrodes and a titanium indifferent-reference electrode were positioned in the solution in various geometric configurations to imitate possible real life situations. In addition, a 1mV PP, 200 Hz sinusoidal signal, simulating EMG activity was injected into the saline solution via two stainless steel needles. The integrator output was monitored at different amplifier gains and with and without the simulated EMG activity. Fig.2. shows the results for a configuration with the sensing electrodes positioned between the stimulating electrode and the return electrode, 2cm away from the stimulating electrode.

The second set of tests was performed using surface EMG and stimulating electrodes on the forearm of a healthy subject. Again, usable EMG recording was obtained for different electrode configurations.

Technology

Hybrid thick film technology on a ceramic substrate is used for production of electronic circuits, with three (IJAT version) and four conductive layers (MES version) respectively. The hybrid circuit is mounted into a titanium case with eight bipolar feedthroughs for lead attachment and two monopolar feedthroughs for the antenna coil. A laser-welded titanium lid hermetically closes the enclosure. The case and the antenna are encapsulated in epoxy resin and conformally coated with silicone.

DISCUSSION

Implantable control sources, in connection with backtelemetry and digital signal processing, represent the next step in integration of implantable neural prosthesis. A former tetraplegic user of an external wrist transducer was able to switch to an implantable Joint Angle transducer and use it in a matter of hours. EMG has been shown to contain enough information to control simple functional tasks in hand grasp and release. Availability of implantable EMG processor in a stimulator case will allow subjects with high cervical lesions to control hand movements based on minimal muscle control. Much work has to be done to implant other transducers, presently used externally on the patient, and integrate them into the implantable systems

ACKNOWLEDGEMENT

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DEVELOPMENT OF A RETINA IMPLANT FOR EPIRETINAL GANGLION CELL STIMULATION FOR PATIENTS SUFFERING FROM RETINITIS PIGMENTOSA

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SUMMARY

This contribution describes the realization of microelectronic components for a retina implant system [1] that will provide visual sensations to patients with photoreceptor degeneration by applying electro-stimulation to the intact retinal ganglion cell layer [2].

Our system consists of five major microelectronic components: three for the external retina encoder and two for the implanted retina stimulator, all shown in Figure 1.1. The implantable active retina stimulator is built in CMOS technology and includes a highly flexible silicon structure carrying multi-electrode arrays, a programmable stimulation pulse generator, and the telemetry receiver for signal and power reception. The external retina-encoder consists of the corresponding power and data transmission unit, a signal processor for computing the so called *receptive field function* (RF-function, which emulates the basic functionality of the retinal layers), and the image sensor system which provides high dynamic range of more than seven decades corresponding to the performance of the human eye.

The hardware and software development for the system has been accompanied by a parallel effort which includes extensive research on implantation, morphological, and electrophysiological behavior [6].

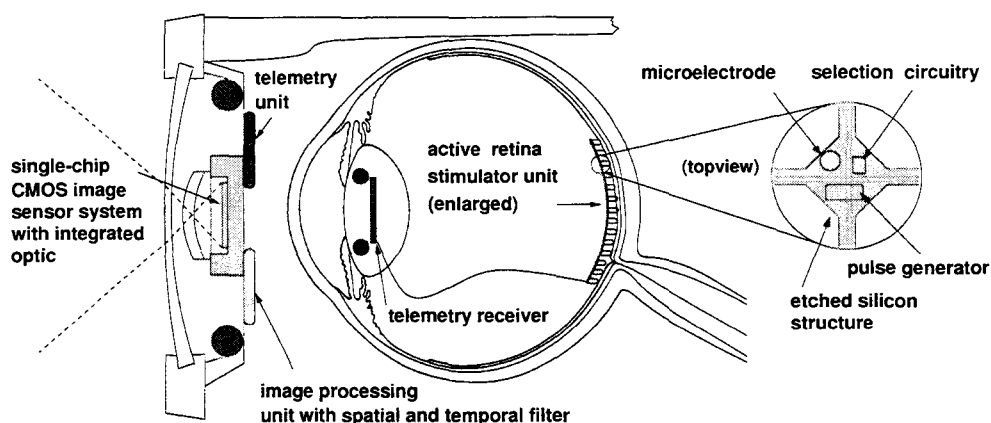


Figure 1.1: Architecture of the retina implant system for epiretinal ganglion cell electrostimulation

RETINA-ENCODER

The image sensor developed for the retina-encoder includes a photodetector matrix and all components necessary for readout of an full image frame, readout of regions of interest, and random memory-mapped single pixel access. It has been fabricated using in-house standard CMOS technology. The CMOS-compatible photodiodes with associated readout and sensor selection circuits used as picture elements yield a photosensitivity range covering more than seven decades (≥ 140 dB) of illumination range with a signal-to-noise ratio of 56 dB without any global electronic or mechanical shutter [3, 4] (see test image in Fig. 2.1). The on-chip standard signal processor interface eliminates the need for an additional frame buffer as required for conventional CCD image sensor. This increases the total readout rate by a factor of 10 when compared to full frame readout. This rate is necessary since not only spatial, but also local temporal filtering operations (within milliseconds) have to be implemented for realization of RF-functions.

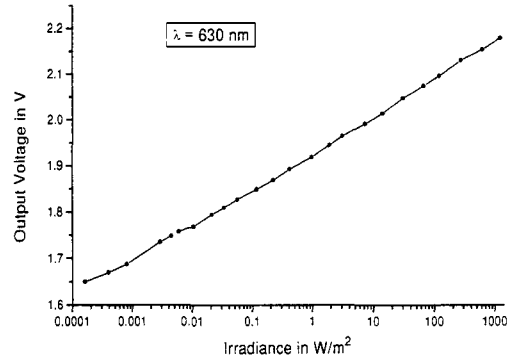


Figure 2.1: Test images captured with the high dynamic CMOS integrated single chip sensor (left). Measurement of the light sensitivity of the active pixel element (right).

A further device developed for the retina-encoder is the spatial and temporal filter required for implementation of the RF-functions. Figure 2.2 shows the block diagram of the spatial filter which has been realized in hardware using a field programmable gate array (FPGA) featuring as configurable filter for both on- and off-center RF-functions. Besides the spatial filtering, a biological RF-function also performs temporal filtering and spike train generation in retinal ganglion cells. This has been implemented using a digital signal processor (DSP). The DSP also controls the telemetry unit required for wireless transmission of stimulus data (i.e. encoded spike duration, polarity, and electrode address information). Figure 2.2 shows a spike train generated by the retina-encoder prototype.

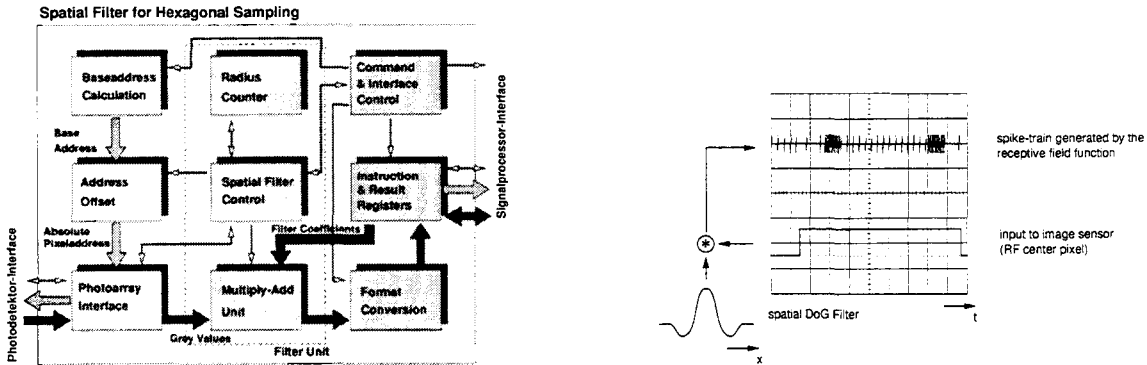


Figure 2.2: Block diagram of the spatial filter used for implementation of the on- off-center RF-spatial filter function (left). Spike-train generated by a retina-encoder prototype according to a Difference of Gaussians (DoG) RF-function (right).

RETINA-STIMULATOR

The second major subsystem of the retina implant system is the implantable flexible silicon multielectrode electrostimulator [5] (see Figs. 1.1, 3.1, and 3.2). The fabrication of this stimulator is based on modified in-house SOI/CMOS technology. The flexible stimulator carries circuitry for separation of power and stimulation data, error correction as well as programmable current sources and electrode selectors including electrodes. The mechanical flexibility of the stimulator silicon grid structure shown in Figure 3.2 has been achieved by applying backside etching of the silicon wafer to thin the silicon substrate at selected sites. The electrodes and electronics are located at thick "islands" connected by thin crosspieces that ensure the flexural response of the stimulator (see physical arrangement in Fig. 3.1 (right) and 3.2). The circuitry required for electrostimulation as shown in Figure 3.1 (left) has been designed to generate pulses with a programmable pulse width ($10 - 500\mu s$), controlled pulse polarity (including bipolar pulses), adjustable pulse current ($10 - 100\mu A$), and variable pulse rate ($0 - 500Hz$) (see Fig. measurement in 3.3 (right)). Figure 3.3 also shows the test suite used for measurement and system test which includes the CMOS image sensor, signal processing and telemetry unit as well as prototype of the flexible silicon stimulator.

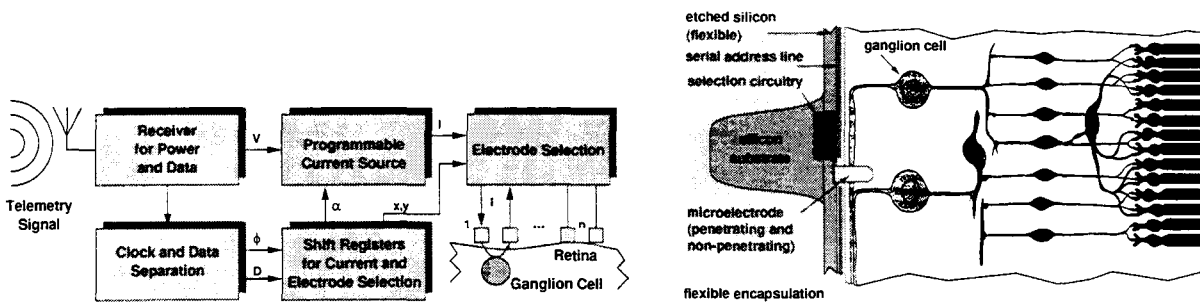


Figure 3.1: Block diagram (left) and physical arrangement (sectional view, right) of the flexible silicon multielectrode electrostimulator with circuitry for separation of power and stimulation data, error correction as well as for generation of programmable current pulses and electrode selection

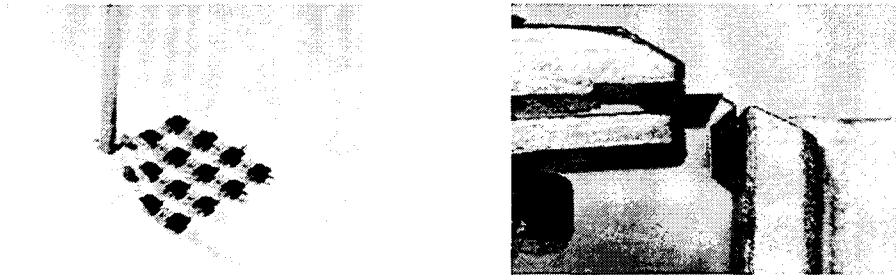


Figure 3.2: Highly flexible silicon test structures with small regions of thick silicon for circuitry and electrodes fabricated using a modified backside etching process compatible with standard SOI/CMOS technology (left: flexible silicon grid structure lifted with vacuum handler, right: etched silicon chip bended at 90°)

We feel that the hardware of the retina implant system as described in this contribution greatly exceeds the complexity of current bio-electronic systems, e.g. of cochlea implants [7]. This is due to the high number of photoreceptor cells that are required for vision and that must be "replaced" by our system. Also, the amount of signal preprocessing that is required is quite high. The project represents a major interdisciplinary effort and well coordinated team work.

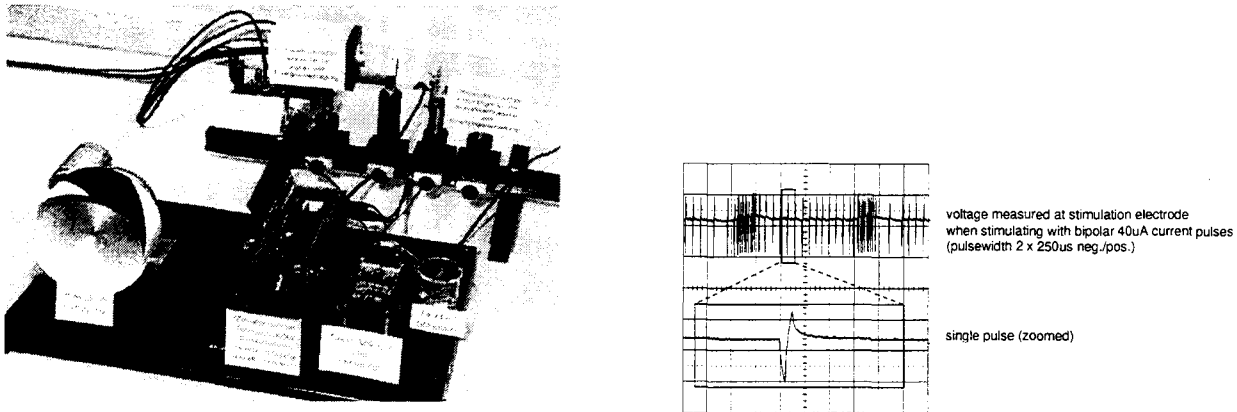


Figure 3.3: System test suite including the CMOS image sensor, signal processing and telemetry unit as well as a prototype of the flexible silicon stimulator (left). Measurement of electrode voltage for stimulation using 40 μ A bipolar impulses (right).

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IMPLANTABLE ELECTRICAL STIMULATOR FOR BLADDER CONTROL

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SUMMARY

In the present paper we describe a circuit intended for electrical stimulation of the bladder in spinal cord injured patients. The system has been fully integrated with a commercial available CMOS technology. The stimulator is based on a eight bit digital to analogue converter and three independent current amplifiers along with the correspondent discharge stage. A high performance inductive coupling is used to communicate data and energy to the implant.

INTRODUCTION

Continence and micturition depend on a set of peripheral nerves that are located in the spinal cord and regulate the activity of the detrusor muscle, which innervates the bladder. By means of electrical stimulation of the sacral nerve roots is possible to control the voiding of the bladder in medullar injured patients as has been widely reported [1-5].

The objective of our work is to develop a fully integrated passive sacral roots stimulator that allows to program and control all the parameters which define the stimuli waveforms (i.e. current amplitude, pulse width, frequency...). The telemetry used through a high performance inductive coupling provides a medium of wireless, independent distance transmission of information, and allows an implanted stimulator which contains no power supply inside. In this paper only the stimulation block of the whole circuit is presented.

The stimuli produced by the system consist on charge balanced bipolar current pulses with an exponential negative discharge that allows easily to totally eliminate the charge injected during the positive pulse. The amplitudes of the pulses range between 300 μ A and 40mA with pulse widths between 30 μ s and 1ms. Tripolar symmetrical electrodes with two short circuit anodes and a cathode are used. To perform the stimulation the electrodes have been electrochemically characterised given a parallel RC structure with values above 800k Ω for the resistance and above 3 μ F for the capacitor. Compliance voltage of 16 V has been used to provide 40mA current stimulation for a 400 Ω resistance load (expected tissue resistance surrounding the electrodes). This fact forces us to use technologies which makes feasible the use of voltages higher than 5V.

The stimulator is able to generate three independent, consecutive signals that are usually applied over S2, S3 and S4 sacral roots by means of three tripolar electrodes. Its primary purpose is to improve bladder emptying along with to assist defecation and enable male patients to have erection when they want. The system is also able to measure the impedance of the stimulated nerve and as a consequence, test the performance of the implanted system.

CIRCUIT DESCRIPTION AND RESULTS

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The stimulator circuit is composed by a digital to analogue converter, a current amplifier along a recovery charge block and a channel selector as an analogue multiplexer. A block diagram of the circuit is shown on **Figure 1**.

Since our aim is to generate three independent and non consecutive stimulating current pulses, we have used an unique DAC and three current amplifiers with their recovery charge block. The DAC current is delivered to one or other channel by means of three channel selection switches that select the appropriate current amplifier. The I2T 0.7 CMOS Mietec technology has been used to design the integrated stimulator. The advantage to use this technology is that provides us with power transistors both MOS and bipolar transistors which are able to deal with voltages bigger than 5V. As we have explained above we need to work at least with 16V.

Digital to analogue converter: The DAC is composed of seven binary weighted current sources made with MOS transistors. This configuration allows that the current levels double at each successive stage, obtaining an intrinsic monotonic DAC /6/. Bit 8 controls the DAC activation, enabling the DAC only when stimulation is being done so, a low power consumption circuit is achieved. The DAC is able to deliver a maximum of 2.17 mA to a current amplifier formed by bipolar transistors. The transfer characteristic of the 7-bits DAC is shown in **figure 2**. The Differential and Integral Linearity evaluated from the simulation results are 0.8 LSB and 1.6 LSB respectively. Nevertheless the DAC presents a monotonic behaviour.

Current amplifier and recovery charge block:

High voltage MOS transistors have very high channel resistance. Since currents of 40mA are

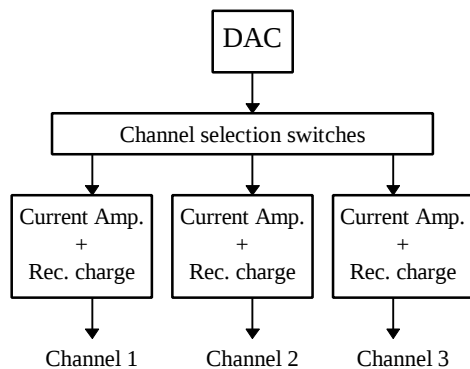


Figure 1: Block diagram of the stimulator circuit

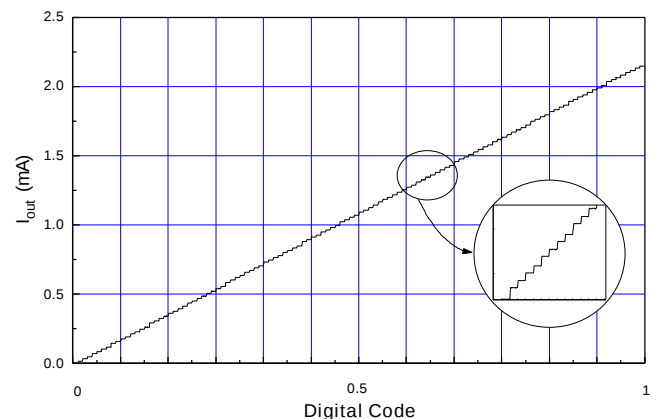


Figure 2: Transfer characteristic of the 7-bits DAC (Hspice simulated results). In the inset is shown a “zoom” of the characteristic.

required, high voltage drop takes place on these MOS transistors. On the other hand the voltage drop on bipolar transistors for the same level of current is lower, so we have decided to use bipolar transistors instead of MOS to design the amplifier even though the power consumption for these devices (due to the base current) is higher than for MOS transistors.

Bipolar transistors available on I2T have a very poor current gain (close to 25). In order to improve it, we have used a Darlington current mirror structure. On the other hand, we have added a transistor to provide the necessary current to the Darlington structure /7/. The schematic is shown on **figure 3** and the simulation results are shown on **figure 4**.

In order to get a safe stimulation the recovery of all the charge injected into the tissue is needed. The architecture we propose consists of a power MOS transistor that acts as a simple switch and connects the current amplifier output and both anodes of each electrode as has been widely used /8/. Once stimulation pulse has been generated, the charge injected during the primary pulse is recovered by the activation of this

transistor switch, obtaining a balanced bipolar stimulating current pulse. An specific circuit to provide the right voltages values to control this switch (V_{control} on **Figure 3**) has been implemented.

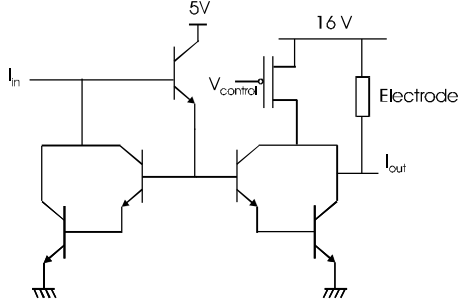


Figure 3: Current amplifier and recovery block. The MOS transistor acts as the recovery charge block, enabled when the DAC is off by V_{control} .

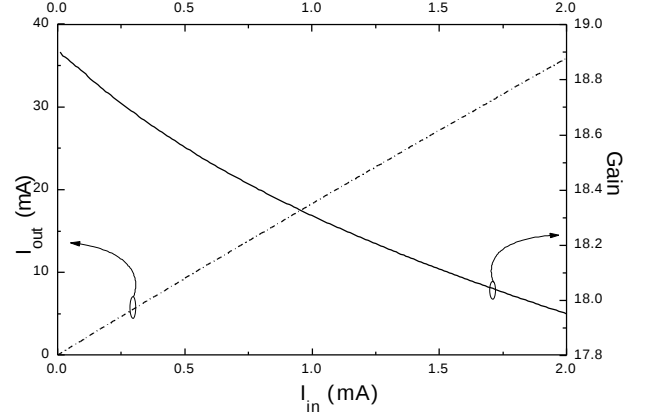


Figure 4: Current amplifier simulation. I_{out} and the amplifier gain versus I_{in} are shown. Note that the linearity error is less than 6%.

On **Figures 5** and **6** it is shown the simulated results for all the system using the measured model for the electrode. **Figure 5** shows the obtained signal for one channel. Note that the recovery of the charge is exponential with a very low time constant. In fact as the stimulating signals are at low frequency (the highest is around 50 Hz) we design the circuit to have a low time constant and thus to provide a very small negative peak. To obtain the results a 370Ω resistance has been used as the tissue impedance and the equivalent model of the real tripolar electrodes. **Figure 6** shows the three stimulating channels with different amplitudes. With our stimulator the three channels can not be simultaneous but the delay between them is negligible.

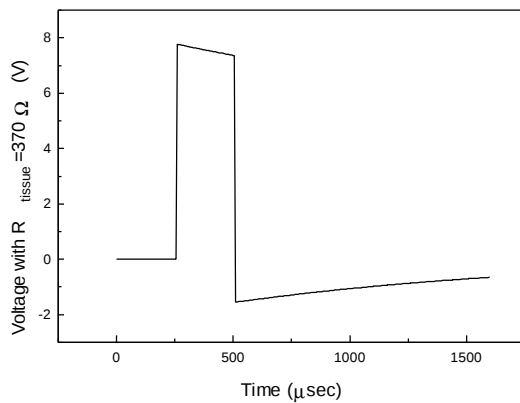


Figure 5: One channel stimulation waveform. The exponential recovery of the charge is shown.

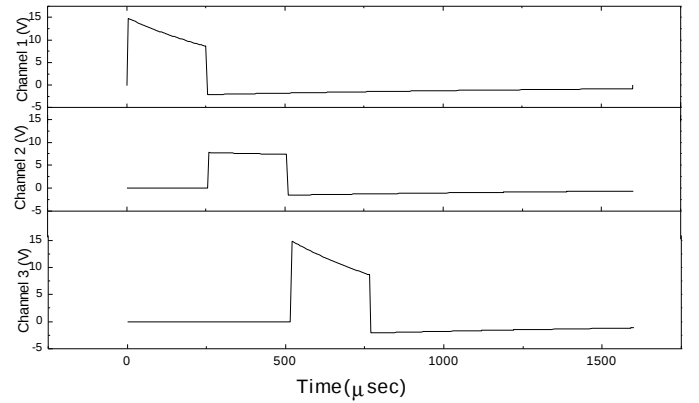


Figure 6: The three channels were programmed to stimulate with the same pulse width (250μs) an amplitudes of 40, 20 and 40 mV respectively.

CONCLUSIONS

A three channel bladder implantable electrical stimulation telemetric controlled circuit has been designed.

The full system allows the user to generate the necessary information to the implant (current amplitude, pulse width...) in order to get an independent distance stimulation. The versatility of the system allows the generation of different waveform shapes that can be very useful in the study of selective stimulation to control the bladder emptying avoiding the dissynergia between the sphincter and the detrusor.

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Battery-powered implantable nerve stimulator for chronic activation of two skeletal muscles using multichannel techniques

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SUMMARY

Chronic activation of skeletal muscle is used clinically in representative numbers for diaphragm pacing to restore breathing and for graciloplasty to achieve fecal continence. In both applications the skeletal muscle is extremely strained; muscle fatigue is consequently one of the exciting problems associated with these techniques. Various stimulation methods have been developed to improve on this. It was our aim to make some of these stimulation methods applicable for the above FES applications by a battery-powered nerve stimulator.

The implantable nerve stimulator can be used for activating two skeletal muscles. Stimulation of the motor nerve is achieved by either single channel or multichannel methods with up to 4 electrodes for each nerve. Carousel stimulation, sequential stimulation as well as optimized pulse trains can be implemented. All stimulation parameters can be adjusted with a high resolution using an external programmer. The system can be used for graciloplasty as well as for diaphragm pacing.

Nerve pacing is effected by ring-shaped stainless-steel electrodes. These epineurial electrodes are used clinically in the "Vienna Phrenic Pacemaker". The multichannel pulse generator is hermetically sealed in a titanium case and powered by a Lithium Thionyl Chloride battery. For diaphragm pacing we calculated a life span of 4.1 years, based on the stimulation parameters used by us clinically. The size of the pulse generator is 65 x 17 mm (diameter x height); it weighs 88 g.

STATE OF THE ART

Chronic activation of skeletal muscle is used clinically in representative numbers for diaphragm pacing to restore breathing and for graciloplasty to achieve fecal continence. In both applications the skeletal muscle is extremely strained; muscle fatigue is consequently one of the exciting problems associated with these techniques. In clinical use the phrenic pacemaker is set to an inspiration rate of 10/min at a stimulation duration of 1 s over 24 hours per day. The gracilis muscle for treatment of fecal incontinence is stimulated continuously over several hours each day.

For respiration in humans electrical pacing systems have been developed by three different groups /1/. These systems consist of electrodes placed on the phrenic nerves which are connected by leads to an implanted stimulator. The single or multichannel stimulators are powered and controlled via an external high frequency transmitter from a portable programmer. The programmer coordinates the overall timing, and stores the received stimulation parameters. For graciloplasty, battery-powered single channel implants, with the electrodes

usually positioned near the motor point of the skeletal muscle, are currently in use /2/. Activation of two muscles is not yet applied clinically.

Over the last few years our group has worked on developing a modular stimulation system usable for a variety of applications. Important components of the stimulation system, such as the implant case, the main module of the implant electronics, the stimulation electrodes, and the hardware of the programmer unit, remain the same in all applications. Useful applications and the limitations of such a battery-powered implant have been described in /3/ on the basis of first calculations and prototyping. Additionally, the first specific application of this modular concept, i.e. an ECG-triggered stimulator for cardiac assistance by skeletal muscle, has already been tested in an animal study and produced extremely satisfactory results.

The implantable device presented here was developed for use in electrophrenic respiration (EPR) and in graciloplasty. In developing the stimulator we had set ourselves the following goals: The system should allow the implementation of all stimulation techniques used so far in diaphragm pacing in humans (single channel or multichannel methods such as carousel stimulation /4/ and sequential stimulation /5/). The use of external devices should be limited to the time necessary for programming in order to maximize the patient's freedom of movement. Additionally, the system should allow alternating stimulation of two skeletal muscles as a further improvement in graciloplasty.

MATERIAL AND METHODS

The stimulation device is composed of a programmer with a transmitter unit, an implantable multichannel stimulator, and nerve pacing leads (Fig. 1).

The multichannel stimulator is powered by a Lithium Thionyl Chloride battery (WG8602, Wilson Greatbatch Ltd. NY, USA) and works as an independent system in the body. It includes an eight-channel output stage, a transmitter unit, and a controller unit. A microcontroller serves as the central unit of the controller. The number of pulses in one burst, burst frequency ($1\div 50$ Hz), pulse width ($0.2\div 1$ ms), pulse amplitude ($0\div 4$ mA), and current active output are set by the controller unit. All parameters and functions are programmable via the bidirectional telemetry circuit. The eight output stages provide a constant current pulse, each output channel can be switched as anode or cathode or can be deactivated.

The multichannel pulse generator is hermetically sealed in a titanium case and powered by a Lithium Thionyl Chloride battery. Its size is 65 x 17 mm (diameter x height) and it weighs 88 g. Nerve pacing is effected by ring-shaped stainless-steel electrodes. These epineurial electrodes are used clinically in the "Vienna Phrenic Pacemaker" /4/.

The stimulation data are input using a laptop computer (IBM-PC or compatible) instead of a specially designed programmer. A graphical user interface facilitates the setting and modification of parameters and reduces training time. Each modification of the parameters is stored automatically and can be processed in conjunction with additional data such as respiration flow, or the patient's medical history. Data are transferred between the PC and the implanted pulse generator in both directions by a radio-frequency transmitter unit linked to the serial port (RS-232) on the PC. The transmission link operates over a vertical displacement of up to 50 mm at a data rate of 1200 bit/s and a carrier frequency of 100 kHz.

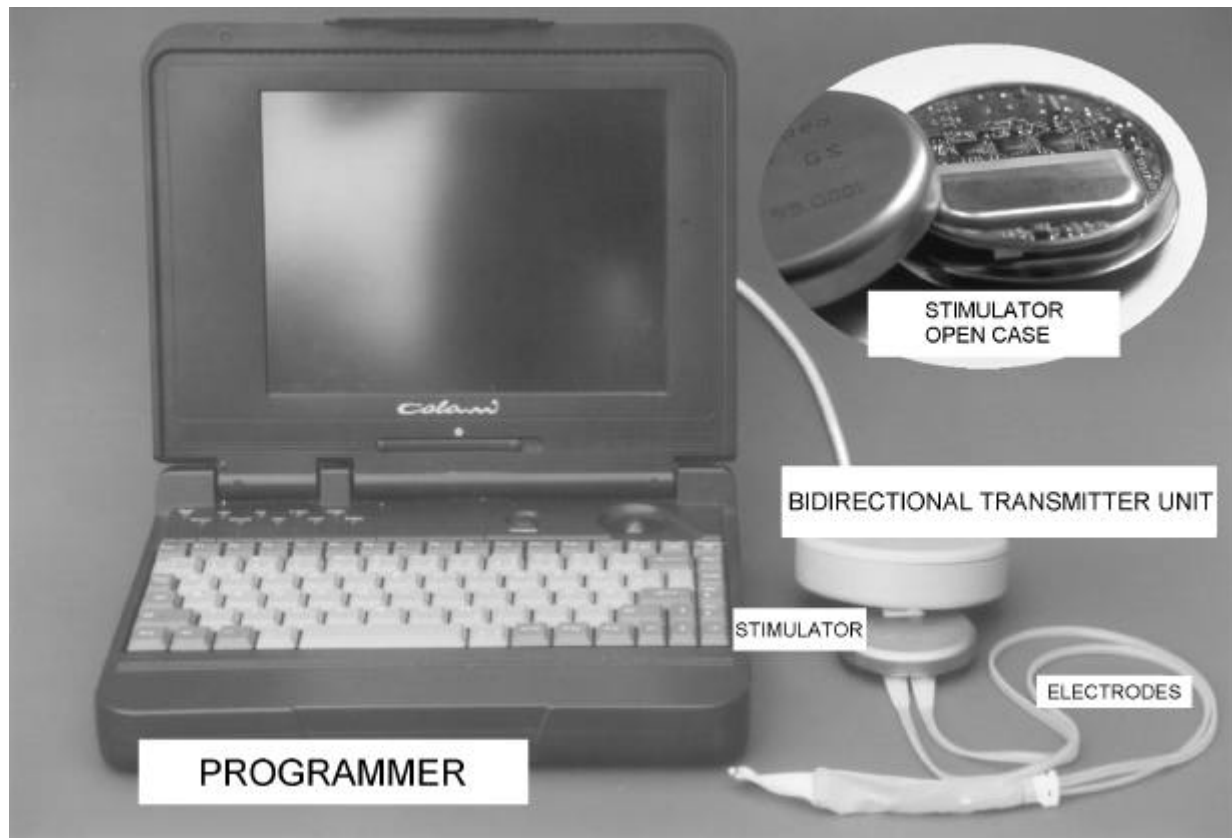


Fig.1 stimulation device, programmer (laptop computer), transmitter unit, implantable multichannel stimulator, and nerve pacing leads

RESULTS

This implantable neurostimulator can be used for activating two skeletal muscles. Stimulation of the motor nerve can be achieved by either single channel or multichannel methods with up to 4 electrodes for each nerve. The stimulation wave-form can be adapted to the requirements of EPR and of graciloplasty. Two skeletal muscles can be activated simultaneously, alternately or in un-interrupt mode.

Diaphragm pacing to restore breathing

The stimulation system allows implementation of all stimulation techniques currently in use in EPR, which differ greatly from each other in their use of either single channel or multichannel electrodes and in their selection of impulse parameters. Among the three groups that have developed phrenic pacing systems the group from Yale (USA) uses unipolar stimulation for each nerve with a remote indifferent electrode at low stimulation frequencies of 7-10 Hz and inspiration rates between 7-10/min. The other two groups use multichannel techniques with 4 bipolar electrodes applied to the phrenic nerves. The group from Tampere (Finland) implements sequential stimulation /5/, the active electrodes are changed for each impulse and the stimulation frequency decreases from 25 to 16 Hz during the inspiration burst. The Vienna (Austria) group implements carousel stimulation /4/, the active electrodes are changed after each inspiration burst, a constant stimulation frequency of 26 Hz is used. Furthermore, the stimulation current increases during an inspiration burst from the threshold current to adequate maximum current to achieve a smooth contraction.

All these functions are mastered by the developed device, which also allows all parameters to be adjusted within a large range with a high resolution. As an additional feature optimized pulse trains, a stimulation technique published in 1980 by Zajac FE and aimed at increasing fatigue resistance, can be implemented.

Graciloplasty for fecal continence

The developed device allows the application of all advanced stimulation techniques described above for graciloplasty, too. As a further improvement of this particular FES application the system makes it possible to alternately stimulate two skeletal muscles.

DISCUSSION

This stimulation system can be used for graciloplasty and for diaphragm pacing. The developed device is based on a modular system architecture, which is advantageous for several reasons. Time and effort necessary for developing a specific application are reduced, by integrating components already tested, such as the implant case, the risk of design errors is reduced.

The integration of different stimulation techniques in one stimulation system has to be considered the main achievement in the development of this device. Due to its versatility the stimulator is especially suitable for in vivo studies, in particular for the investigation of new methods for optimizing muscle output by electrical stimulation. Furthermore, all parts of the implant that have direct contact with body tissue use the latest pacemaker technology (titanium, silicone-rubber, epoxy resin) and have been tested in animal studies.

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DEMAND FOR AND USE OF FES SYSTEMS AND CONVENTIONAL ORTHOSES IN THE SPINAL LESIONED COMMUNITY OF THE UK

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SUMMARY

The use of and demand for FES systems and conventional orthoses in the spinal cord lesioned population was assessed. The assessment was conducted by a postal survey of the members of the spinal injury associations in the UK. Out of all the respondents only 2% had used an FES system for walking. In comparison 13% had used some kind of orthosis. Of the small numbers who had used an FES system for walking more than half had no functional walking abilities. The majority of orthosis users had some independent walking ability. Demand for walking improvements was high amongst the respondents although this was not matched by the demand for improved orthotic solutions. In conclusion, it would appear that there is a need for simple FES systems offering walking improvement to the incomplete SCL subject.

STATE OF THE ART

For many years orthotic solutions have been available for the restoration of walking in spinal cord lesioned (SCL) subjects. These solutions have been used in varying degrees of complexity to provide or improve walking ability. However the routine provisions of orthotics for the complete spinal cord injured subject has declined in recent years. This decline maybe due to the high dropout rate in the use of these devices/1,2/. More recently neuroprosthetic devices have become available but these devices have not yet achieved widespread use. The application of neuroprosthetic (functional electrical stimulation (FES)) devices for the SCL subject has focussed predominantly on subjects with no preserved lower limb motor function/3/. It appears that an increasing proportion of SCL subjects have an incomplete lesion of the cord leaving some preserved lower limb function /4,5/. Those subjects with some preserved lower limb function are often prescribed orthotic devices.

MATERIALS AND METHODS

The use of and demand for FES systems and conventional orthoses in the SCL population was assessed as a component of a European Union funded telemedicine project (Clinical rehabilitation using electrical stimulation via telematics (CREST)). This demand was assessed by a postal survey of SCL subjects in the UK. The survey was constructed in consultation with clinicians, spinal cord injury associations and the patients themselves. The memberships of the spinal injury associations were chosen as the target population as they offered access to a large proportion of the spinal lesioned population over an extensive geographical area. In total 4840 questionnaires were mailed and 1122 completed replies were received (23% response). The responses were coded and entered into a database for analysis.

RESULTS

The average age of the respondents was 47 years (Average age at time of injury was 31 years). They had a median time post injury of 14 years. Eighty percent had received a traumatic spinal cord injury with the largest proportion (46%) a result of road traffic accidents. Sixty-two percent had no upper limb involvement and 32% were motor incomplete (complete paraplegic 43%, incomplete paraplegic 19%, complete tetraplegic 25%, incomplete tetraplegic 13%).

Subjects were asked if they had ever used a stimulator and what they had used it for. Nineteen percent of the respondents (208 users) had used some kind of electrical stimulator. Table 1 summarises stimulator use with injury type. In the majority of cases (59%), a stimulator was used for muscle re-strengthening. Of all the respondents, only 2% had used a FES system for walking.

Table 1 Summary of stimulator users by injury type

Stimulator used for:					
<i>Injury type:</i>	muscle strengthening	walking	bladder management	pain control	other
Complete paraplegic	19%	5%	7%	14%	2%
Complete tetraplegic	17%	1%	1%	4%	2%
Incomplete paraplegic	12%	2%	1%	9%	0%
Incomplete tetraplegic	11%	2%	0%	6%	1%
total users = 208					

In comparison 13% of respondents had used a lower limb orthosis. Subjects were asked if they had ever used a lower limb orthosis and, if so, what type. Table 2 summarises the type of orthosis used. The ankle foot orthosis (AFO) is most commonly used by the incomplete subject with the knee ankle foot orthosis (KAFO) being predominantly used by paraplegics. The "hip guidance" and "reciprocating gait" type of orthoses (i.e. with a trunk component) are classified here as hip knee ankle foot orthoses (HKAFO).

Table 2 Summary of orthosis users by type of orthosis and injury

Type of orthosis:			
<i>Injury type</i>	AFO	KAFO	HKAFO
complete paraplegic	3%	25%	7%
complete tetraplegic	0%	1%	0%
incomplete paraplegic	27%	22%	1%
incomplete tetraplegic	5%	3%	1%
total users = 143			

Walking ability was assessed by asking subjects how far they could walk independently. Table 3 summarises the declared walking abilities of the respondents. Only 16% were able to walk independently and less than half of these could walk distances in excess of 50m.

Table 3 Summary of walking ability by injury type

Distance able to walk independently:					
<i>Injury type</i>	<5m	<10m	<50m	>50m	Total
Complete paraplegic	0%	0%	0%	1%	1%
Complete tetraplegic	0%	0%	0%	0%	0%
Incomplete paraplegic	1%	2%	2%	4%	10%
Incomplete tetraplegic	0%	1%	1%	2%	4%
Total	2%	4%	3%	7%	16%
Number in sample: 1122					

Table 4 summarises the independent walking abilities of orthosis users and FES walkers. More than half of the respondents who had used an FES walking system had no independent walking ability whereas the majority of AFO users could walk independently.

Table 4 Summary of orthosis users and FES walkers by walking ability

<i>Orthosis type:</i>	Distance able to walk independently :					Number of users
	can't walk	<5m	<10m	<50m	>50m	
AFO	24%	6%	12%	18%	40%	50
KAFO	66%	1%	11%	8%	14%	74
HKAFO	85%	0%	0%	0%	15%	13
FES walking	59%	0%	18%	9%	14%	22

Table 5 summarises the demand for improvements in different aspects of the respondents disability. Demand for improvements in walking can be judged in relation to the demand for improvements in bowel, bladder and sexual function. While a vast majority of respondents wanted improvements in bowel, bladder and sexual function, there was a demonstrable demand from a large number of respondents for walking improvements.

Table 5 Summary of demand for improvements in different aspects of disability

<i>In terms of quality of life, how important would improvements in the following areas be to you?</i>	Percentage response of: "more than or equal to important" (from very important, important, moderately important, not very important, unnecessary)
Bowel management	75%
Bladder management	77%
Sexual function	60%
Walking quality	33%
Walking speed	25%
Design of orthotics	18%
Increased muscle size on legs	36%
Number in sample: 1122	

DISCUSSION

Exposure of the survey group to electrical stimulation was low and although the majority of users had used a stimulator for muscle re-strengthening (Table 1). The proportion of users progressing from muscle strengthening to functional walking was very small. A much greater percentage of respondents had used an orthotic solution for walking improvement and this group demonstrated greater walking abilities (Table 4). However those subjects who could walk and used an orthosis tended to be motor incomplete whereas the subjects who had used FES systems for walking were, in the majority, complete paraplegics.

It would appear that we can usefully divide orthotic and FES system users into motor incomplete and motor complete categories. It would appear that those orthosis users with the greatest functional walking ability have predominantly incomplete lesions while those using more complex orthotic systems are motor complete and of limited walking ability. It appears that most of the FES walking system users are motor complete with limited walking ability.

It can be concluded that a need exists for simple yet flexible FES systems to be used by incomplete subjects with some walking ability. These systems have been shown to be effective in improving the gait of incomplete SCL subjects/6/.

When the respondents priorities for improvements in different aspects of their disability were assessed demand was greatest for improvements in bowel, bladder and sexual function. Walking improvements were also judged of great importance by a large number of respondents although orthotic improvements were not as popular. Given the popularity of increased (cosmetic) muscle size it would appear that there is a market for simple FES systems offering walking improvement to the incomplete SCL subject.

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FES CONTROL STRATEGIES FOR SINGLE JOINT MOVEMENT: SIMULATION AND EXPERIMENTS IN PARAPLEGICS

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SUMMARY

Different strategies for control of freely swinging shank in paraplegics have been studied. In order to fulfil the simulation phase, a generic musculo-skeletal model has been developed and then identified on the patient-specific parameters. It could be shown that both in simulations and in experiments, feedforward, feedback and a combination of both gave satisfactory results. Further improvement could be achieved by introducing an adaptive mechanism capable of compensating for time-variant parameters related to muscle fatigue. First experiments on paraplegics gave encouraging results.

STATE OF THE ART

Many control strategies have been studied and reported in literature. Both open-loop and closed-loop controllers have provided good performance depending on the model accuracy for the first and on the tuning of the parameters of the feedback controller for the second approach. In designing and testing the strategies, some authors used linearized models of the muscles – typically a nonlinear static function (recruitment characteristic) followed by linear dynamics (Hammerstein model) /1/, some of them opted for an extensive nonlinear muscle modelling /2/. The aim of this work is to compare different control strategies using – in the simulation stage – a model closely based on the physiological processes underlying excitation and activation of human muscle. An adaptive control is also proposed, showing that adaptive strategies can be practical and robust.

MATERIALS AND METHODS

Direct and Inverse modelling of the muscle.

The model we used considers the human knee joint with the thigh supported and the shank freely swinging; thus resulting in a one-degree of freedom mechanical system /3/. This direct complex model was identified with passive pendulum tests and isometric contractions so that it could be used in simulations as the plant for the design of control strategies.

A simplified model - still non linear and physiologically-based - was also developed to be implemented later in the controller. Input to both models are the pulse-width and frequency modulated signals as obtained from the stimulator, while output values are the knee joint angles and velocities.

The simplified model, after identification of the patient-specific parameters, was inverted; the input to this inverse model became then the desired trajectory of the knee angle while output was - as a consequence - the stimulation pulse-width for stimulating the quadriceps muscle.

Basically the inverse model is divided into a dynamic and a static part /4/.

In a first step, after double differentiation of the desired trajectory, the total moment M_{tot} is computed by applying the equation of motion. The required active moment M_{act} is then obtained by subtracting from the M_{tot} the passive moments caused by the elastic (M_e) /5/ and the viscous (M_v) properties of the muscle, respectively described by the following relations:

$$M_{elastic} = \exp(K_1 + K_2 \cdot \vartheta) - \exp(K_3 + K_4 \cdot \vartheta) + K_5 ; \quad M_{viscous} = -K_{damp} \cdot \dot{\vartheta}$$

In a second step the inverse static is modelled. The required active moment previously computed is multiplied by the inverse Moment-Angle and Moment-Velocity relations and by a Scaling Factor (Sf); the result is the Activation (Act) given by the following relation:

$$Act = M_{act} \cdot \exp\left(\frac{\theta - K_6}{K_7}\right) \cdot \left(1 + K_8 \cdot \dot{\theta}\right)^{-1} \cdot Sf^{-1} \quad \text{with } K_i (i=1..8) \text{ and } K_{damp} \text{ to be identified.}$$

In the last step, after having lineary approximated the inverse recruitment curve between a threshold and a saturation value, the predicted pulse width is calculated.

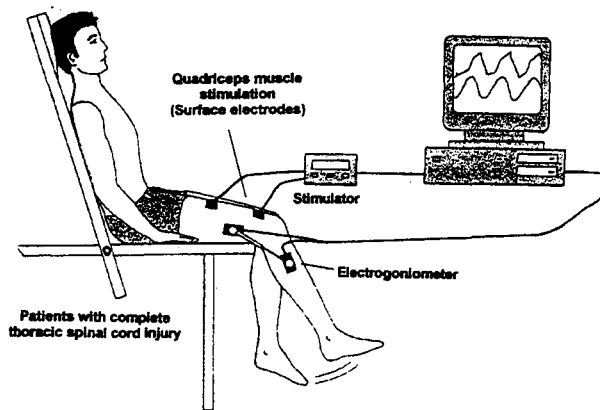


Fig. 1

Experimental setup. The shank is free to swing, the knee angle is measured by an electrogoniometer (see also /5/) and the stimulation is delivered to the extensor muscles of the knee joint via surface electrodes. The stimulator delivers biphasic current rectangular pulses up to 500 μ s wide.

Control Strategies

We started simulating and experimentally testing the control of the knee joint angle by using an *open-loop* configuration (A) where the inverse model was put in series to the model of the plant; we then considered a *closed-loop* (B) strategy using a simple PID controller /6/. A *hybrid approach* was also evaluated (C), resulting in a combination of the previous two: the total pulse width delivered to the plant was the sum of the pulse width predicted by the inverse model in the feedforward loop and the pulse width resulting from the PID, as already presented in /7/.

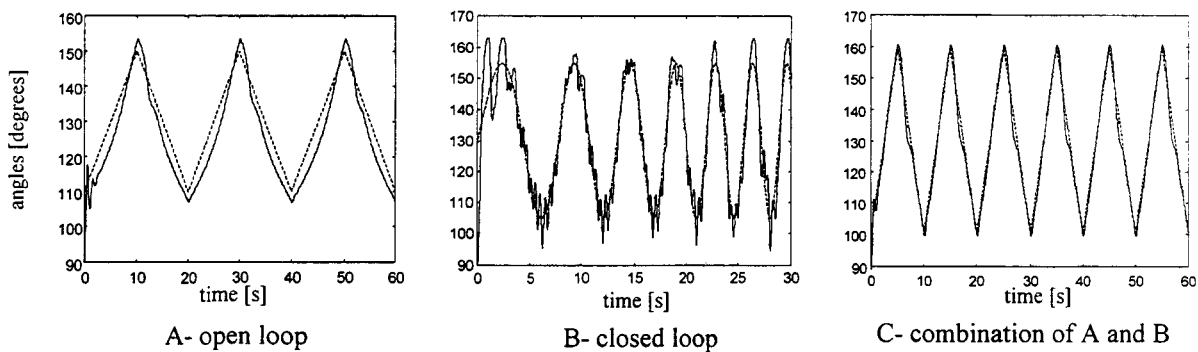


Fig. 2 Simulation results. The dashed line is the desired knee joint angle while the solid line is the obtained angle. 180° is full knee extension.

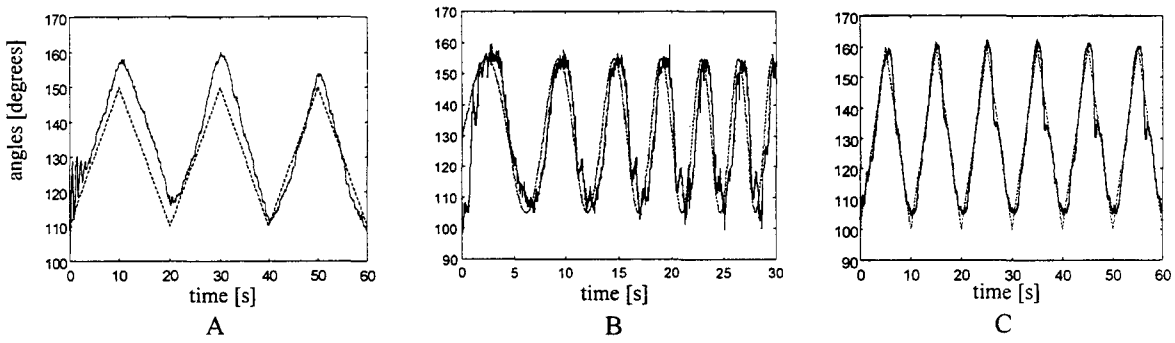


Fig. 3 Experimental results. Dashed line is the desired knee angle, solid is the measured angle.

The adaptive approach

The control strategies we just discussed are likely to fail if large disturbances due to muscle fatigue (such as changes in recruitment gain or in recruitment threshold) or external disturbance (changing load i.e.) occur. The adaptive strategy schematized in fig 4 was adopted. The two parameters adapted were the scaling factor (Sf) – the gain of the recruitment curve – and the threshold ($Thres$), the minimum pulse width value at which the muscle responds to stimulation. The iterative adaptation laws for these parameters follow:

$$Thres_i = Thres_{i-1} + G \cdot M \quad \text{and} \quad Sf_i = Sf_{i-1} + Sf_{i-1} \cdot G_1 \cdot (1 - Gain_Ratio) + G_2 \cdot M$$

where M = mean error, $Gain_Ratio = \frac{STD(DesiredTraject)}{STD(MeasuredTraject)}$ and G, G_1 and G_2 fixed gains.

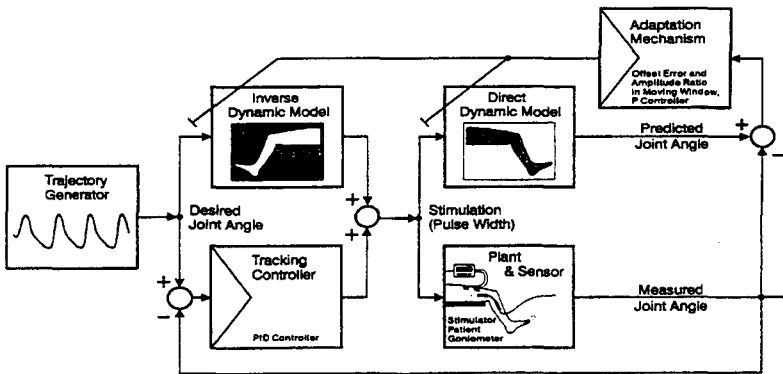


Fig. 4

The adaptive scheme. The adaptation mechanism minimizes the error, averaged over a moving window, between the measured angle and the predicted angle, modifying both the observer (direct model) and the inverse model.

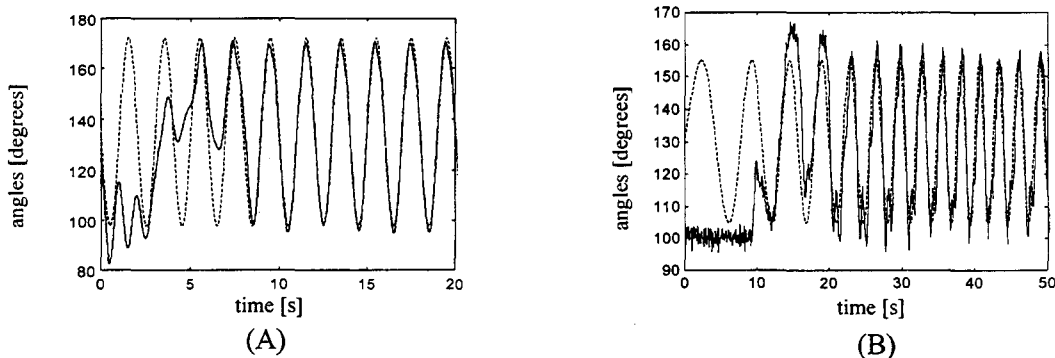


Fig. 5 Adaptation results. (A) in simulation, (B) in experiments.

RESULTS

In the open-loop control the tracking error derived from a non sufficiently-high accuracy on the inverse model parameters estimation. In the closed loop configuration, although the linear PID permitted a fairly good control, intrinsically it could not take into account all the high non-linearities of the plant itself. In combining the two strategies the quality of control improved both in terms of time-lag (fig 3C vs 3B) and in tracking accuracy (fig 3C vs 3A). However a controller with fixed parameters is clearly a strong limitation, thus the adaptive approach was considered. Testing a very bad case with an unlikely initial guess of the two parameters ($Thres_0 = 0\mu s$ and $Sf_0 = 90$) the adaptation algorithm adapted reasonably fast. A good range of motion (from 100° to 160° knee extension) and a sine of increasing frequency as a desired trajectory were successfully tested (fig.5).

DISCUSSION

In this study, computer simulations helped evaluation of different strategies for control of freely swinging shank in paraplegics. Experiments always confirmed the simulated results.

Among the classical control strategies the best performance was achieved using the hybrid approach. Nevertheless practical implementation of control systems must take into account the uncertainty of real-world plants. Even if some classical problems were encountered (mostly unpredictable muscle spasticity), the adaptation strategy proved to be a good mean for coping with critical points typical of parameters identification. The adaptive control methodology we implemented is based on the observation that human muscle – like most real world systems, even non stationary and/or non-linear – can be stabilized by simple controller configuration. More complex algorithm may be needed in order to improve the performance of the control system (adaptation rapidity i.e.).

The encouraging results seem to be a step towards more functional stimulation of paraplegic muscles especially for periodic movements like walking.

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PATIENT-DRIVEN CONTROL OF FES-INDUCED STANDING-UP AND SITTING-DOWN SUPPORTED BY A MECHANICAL SYSTEM: A SIMULATION STUDY

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SUMMARY

Different control strategies for standing-up (SU) and sitting-down (SD) have been studied by applying them to a generic musculo-skeletal model. According to an already existing experimental set-up, the simulated movement is supported by a seesaw construction that constrains the pelvis on a defined path. The patient's weight can be relieved by a counterweight placed on the seesaw. It could be shown that so-called patient-driven control strategies are able to reduce the amount of arm forces required during the movement. The advantage of these strategies is undisputed: stimulation and voluntary upper body efforts are synchronized and no predefined trajectory is required. Experimental validation, first with the support of the seesaw and later without, will follow in future studies.

STATE OF THE ART

In a *"controller-centered"* approach, where the patient has to submit to the controller (e.g., trajectory-tracking), artificial lower body and natural upper body control could adversely interfere, resulting in undesired or even dangerous motion and increased upper body effort. Artificial and voluntary control can be coordinated by adjusting the stimulation to the estimated voluntary contribution of the patient. In such a *"patient-driven"* approach the patient is able to influence the stimulation of the paralyzed limbs of his body, thus, the patient's CNS is an important part of the controller.

Recently, Donaldson and Yu /1/ proposed a theoretical approach, called CHRELMS, in which stimulation of the lower limbs depends on upper body effort, i.e. body posture and recorded hand reactions, and is aimed to minimize arm forces during standing-up and standing. An alternative strategy, called PDMR, was presented by Riener and Fuhr /2/, which accounts for voluntary upper body effort as well, but does not require estimation of hand reactions.

The objective of the overall project is to theoretically and experimentally validate several closed-loop control strategies for FES supported standing-up (SU) and sitting-down (SD) in a simplified situation. The patient is sitting on a seesaw construction (see accompanying paper of Ferrarin et al.), a mechanical frame that constrains the position of the pelvis in such way that it moves in the sagittal plane on a circular path about the seesaw axis (Fig. 1). Furthermore, the patient's weight can be relieved by a counterweight placed on the seesaw. The patient can support the movement by using crutches. In this paper different patient-driven control strategies are being assessed and compared to each other by applying them to a generic two-dimensional model of the patient and the seesaw system.

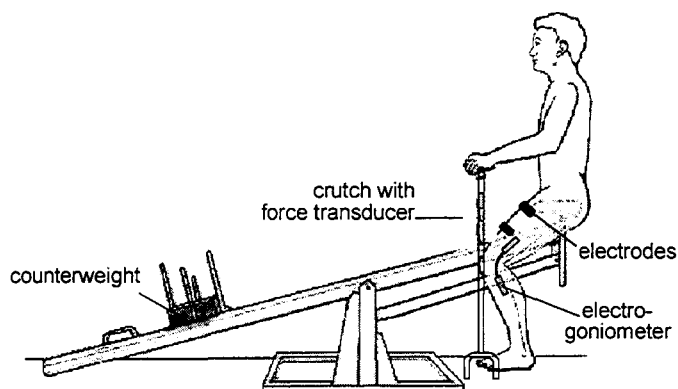


Fig. 1. Patient sitting on the seesaw-construction. The movement is driven by applying forces to the crutches.

MATERIAL AND METHODS

Model of the patient and the seesaw system

The model describes major properties of muscle and segmental dynamics during stimulation. Nine mono and bi-articular muscle groups are modeled in the sagittal plane inducing moments about the ankle, knee, and hip joints (Fig. 2). The set of muscle groups that produce active muscle force depend on the user-defined positions of surface electrodes. Input to each muscle group is the continuous time signal of the modulated pulse width and pulse frequency as provided by an electrical stimulator. Each group has its own activation and contraction dynamics taking into consideration temporal and spatial summation of muscle force, dead time due to finite conduction velocities, muscle fatigue and recovery, as well as passive viscoelastic joint coupling [3]. Complete details about the patient model can be found in [2]. In this study we assume that the maximum paraplegic muscle forces available are reduced to 50% of the maximum isometric muscle force produced by healthy subjects.

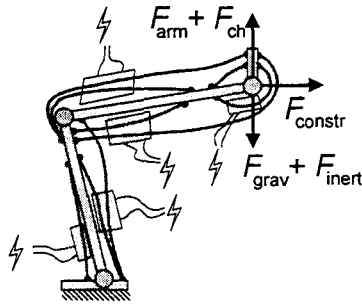


Fig. 2. Two segmental model with nine mono- and bi-articular muscle groups which can be activated by a certain electrode arrangements. In this simulation study only quadriceps muscle was stimulated.

F_{constr} : constraining force to fulfill closed-chain kinematics;

F_{arm} : vertical shoulder force;

F_{ch} : vertical chair force, active only during seat contact;

F_{grav} : effective force contribution due to gravitational influence of trunk, seesaw and counterweight;

F_{inert} : effective force contribution due to inertial influence of trunk, seesaw and counterweight.

In the model it is assumed that the patient's hip is rigidly connected to the seesaw construction, thus, yielding a three-segmental closed-chain consisting of shanks, thighs, and the seesaw boom (Fig. 1). The trunk was assumed to remain in the vertical during movement so that hip angle depends only on thigh orientation. This results in a system with only one degree of freedom (1 DOF), i.e. all angles can be expressed as a function of one generalized coordinate, e.g. the knee joint angle. A convenient way of describing the dynamics of the system was to model shank and thigh of the patient by 2 DOF equations of motion. At the hip a one-dimensional force was applied that constrained the position of the hip in such way that it could move only on a circular path about the seesaw axis. Also the gravitational and inertial influence of trunk, seesaw, and counterweight, were applied to the hip (Fig. 2). Interaction with the seat was modelled by a vertical nonlinear spring-damper [2].

Modeling Voluntary Arm Support

Paraplegic patients need their arms during FES-supported movements not only to maintain balance but also to sustain the desired movement due the available leg joint moments being limited. Therefore the upper body effort should be an integral part of any FES controller developed. In the presented model a one-dimensional vertical arm force applied to the hip joint was sufficient to represent upper body interaction. The voluntarily generated arm force F_{arm} was computed by the following equation:

$$F_{arm} = F_{max} \frac{2}{\pi} \arctan(a D_y D_v); \quad D_y = \frac{y_{des} - y}{y_{des} - y_{start}}; \quad D_v = \frac{\dot{y}_{des} - \dot{y}}{\dot{y}_{des}}; \quad (1)$$

where $F_{max} = 250$ N is the maximum shoulder force. Factor a is equal to 15 for SU and -15 for SD. D_y and D_v are factors that consider the actual vertical hip joint position y and vertical velocity $\dot{y}$ with respect to the desired position y_{des} and velocity $\dot{y}_{des}$ (SU: 0.3 m/s; SD: -0.3 m/s). At the beginning of the movement both D_y and D_v are equal to one yielding a high amount of arm force $F_{arm} \approx F_{max}$. During movement D_y and D_v lead to a reduction of the arm force; F_{arm} becomes zero either if the desired hip velocity or the desired hip position are achieved. The advantage of the arm model presented here is its independence from any given trajectory and thus from time (compare [2]).

Control Strategies

Several control strategies were tested in the model. In this study only the quadriceps muscle (i.e., rectus femoris and vasti muscles) is stimulated which yields to the generation of a extension moment in the knee and a flexion moment in the hip joint due to (unwanted) recruitment of the bi-articular rectus femoris muscle. The movement was supported by the patient's arms and a counterweight of 42 kg. In the model noisy knee angle recording was assumed.

- *Arm support only*: We applied equation (1) to model a movement that was generated by arm effort only. In reality most patients are able to stand up in this way even without any counterweight.
- *Arm support and open-loop FES*: Arms were relieved by linearly increasing pulse width from zero to maximum stimulation (500 μ s) within 3 s. In the model arm force production started simultaneously with the stimulation. In experiments such an optimal synchronization is difficult to achieve.
- *CHRELMS /1/*: In CHRELMS ("Control by Handle Reactions of Leg Muscle Stimulation") hand reaction force applied to the crutch is minimized by mapping this force to the equivalent leg joint moments and, as far as possible, adapt stimulation of the leg muscles to generate these moments (so-called moment deficits). An inverse recruitment characteristic was used to estimate the necessary stimulation pulse width from the moment deficits.
- *Patient driven motion reinforcement (PDMR) /2/*: This strategy accounts for voluntary upper body effort as well, but does not require the recording of hand reactions. The goal of reducing upper body effort is approached by presenting the controller with the movement initiated by the patient's voluntary effort. Actual joint positions and velocities are fed back into an inverse dynamic model, which predicts the stimulation pulse widths required to maintain the movement. The desired angular joint acceleration input to the inverse model is set to zero, and so changes in motion are left to the patient. The FES pattern adapts to the voluntary movement the patient initiates and - as with CHRELMS - no reference trajectory or path is required.
- *PDMR with model errors*: Since in experiments computational efforts should be limited the inverse dynamic model has been simplified by neglecting viscous, coriolis, and inertial effects as well as the influence of the rectus femoris muscle. Furthermore, we assumed an error in the mass distribution of the inverse dynamic model (trunk mass 11% lower than in direct dynamic model).

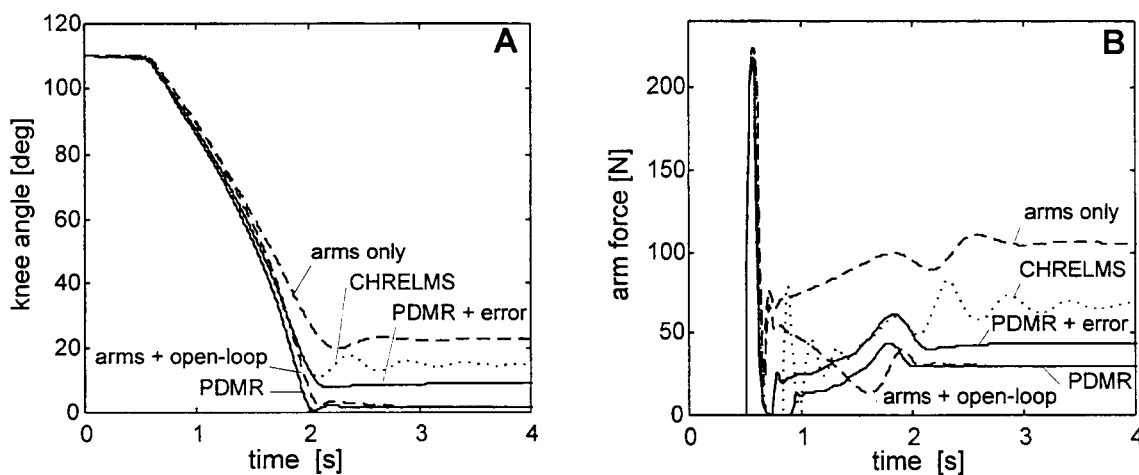


Fig. 3. Knee angle (A) and arm force (B) resulting for the different control strategies during standing-up (SU).

RESULTS

Movements were simulated by applying the presented control strategies to the patient model (Fig. 3). Highest reduction of arm force (mean reductions within first 3 s SU: 68%; SD: 80%) was obtained by the PDMR controller. Even with errors in the inverse dynamic model the arm force reduction was still high (SU: 54%; SD: 74%). Open-loop control reduced arm force only during SU (SU: 58%; SD: 7%) and was dependent on synchronization of arm force production and FES. In CHRELMS force reduction

was 42% during SU and 56 % during SD and arm force and knee angle have shown an oscillating behavior (Fig. 3). Best knee extension during standing could be obtained by the PDMR controller ($\varphi_k = 1.7^\circ$). Without stimulation, knee extension could not be obtained ($\varphi_k = 22.7^\circ$), see also /1/, /2/. It was observed that sensor noise had only a minor influence to the PDMR and almost no influence to CHRELMS.

An internal disturbance was applied during the rising phase. At different knee positions a short and high knee flexion moment, that simulates a spastic activation of hamstring muscles (also called spasticity torque /4/) was induced, thus, slowing down the rising movement. Clearly best compensation was observed with the CHRELMS algorithm. However, in all other simulation runs the disturbance test yielded acceptable movement delays and deviations compared to the undisturbed trajectory.

DISCUSSION

On the basis of a model several strategies were tested for the control of FES-supported SU and SD movements. Compared to classical FES closed-loop controllers, patient-driven approaches (CHRELMS, PDMR) require no predetermined reference input for the leg joints (e.g., desired trajectories). The generation of moments in the paralyzed limbs and, thus, the movements are driven by the patient's voluntary upper body effort, rather than imposing a pre-programmed reference trajectory on the patient. Furthermore, the arm forces are significantly lower than in movements without stimulation.

In the CHRELMS strategy as presented in /1/ arm reduction was low compared to PDMR. However, it could be increased by applying a more comprehensive inverse activation and contraction dynamics instead of the inverse recruitment characteristic. The oscillations observed in Fig. 3 can be explained by the fact that – compared to PDMR – sudden changes of arm forces promptly appear in the required stimulator output due to the structure of the system /1/. On the other hand this property results in the considerably good disturbance compensation capability.

In this study, the stability and robustness of the control strategies are difficult to prove using classical control theory. However, in simulations no unstable situation occurred, because the influence of the arms is quite strong and fast compared to the force produced by stimulation.

Experimental studies have to be performed to eventually validate the developed strategies on several patients with different muscle properties and anthropometry.

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PILOT APPLICATION OF A CLOSED-LOOP FES SYSTEM FOR THE STANDING UP TRAINING OF PARAPLEGIC PATIENTS

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SUMMARY

In this paper the development and the application of an innovative training procedure for paraplegic patients based on the recovery of sit to stand to sit movements induced by FES and with the assistance of a mechanical device for partial weight relief is presented. A closed loop system based on knee goniometers and a PID regulator is used to control quadriceps muscle stimulation. First application on a paraplegic patient showed a relevant increase in muscle strength and endurance. It is argued that the recovery of standing posture at early stage of rehabilitation program can provide positive effects on musculo-skeletal, cardiovascular, respiratory and vestibular systems.

STATE OF THE ART

One of the most important phases before the application of FES to restore walking function in paraplegic patients is the increasing of muscle strength and fatigue resistance by means of specific training /1/. The standard training technique consists in the application of electrical stimulation on both quadriceps with the sitting patient that causes alternate oscillations of lower legs /1/. In general the stimulation is delivered with a pre-defined fixed pattern. Only in few studies closed loop controlled system has been used both for knee extension weight exercise /2/ and for leg cycling exercise /3/ with the advantage to adjust continually the stimulation current on the basis of muscle's response and fatigue onset.

In our approach a closed loop controlled FES of quadriceps muscles combined with a mechanical device (Weight Relief System - WRS) is used to induce standing up-standing-sitting down movements /4/. A future step will be to consider the stimulation of gluteus muscles too.

MATERIAL AND METHODS

In fig.1 a scheme of the whole system is represented, both the mechanical device (WRS) and the stimulator controlling system. The WRS is composed by a see-saw construction : the patient is sitting on one side while on the other there are counterweights that relieve patient weight and facilitate the sit to stand

movement. The amount of counterweight is decreased during training progression depending on the increase of muscle force, in order to reach the maximal load on lower limbs at the end of training.

The control system uses flexible electrogoniometers applied on the knee joint of each leg and surface electrodes for quadriceps stimulation. The measured knee angles are sent to a PC that adjusts in real time stimulation pulse width (PW) by means of a digital controller.

A multichannels PC-driven stimulator delivers rectangular monophasic current pulses with the following parameters :

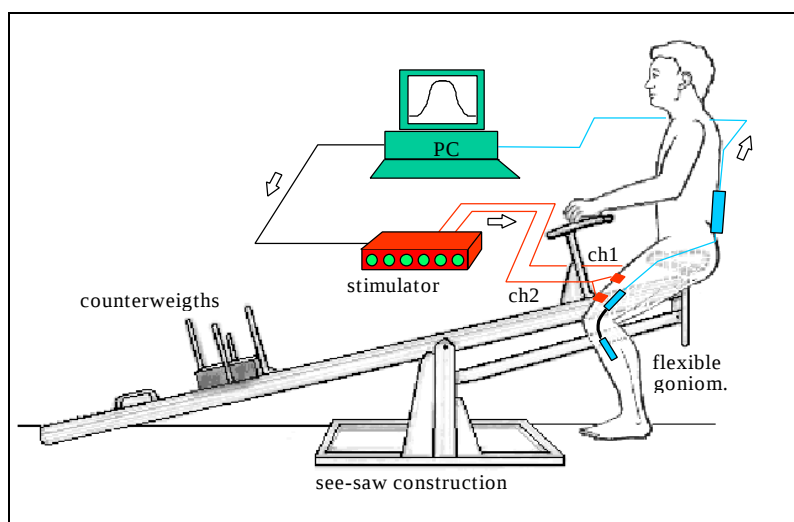


Fig.1 - Schematic drawing of Weight Relief System and closed loop controlled stimulator.

- pulse frequency: 1 - 100 Hz, 25 Hz in our application;
- pulse amplitude: 0 - 150 mA, 110 mA in our application;
- pulse width: 0 - 500 μ s, software controlled.

The control system is showed in fig. 2:

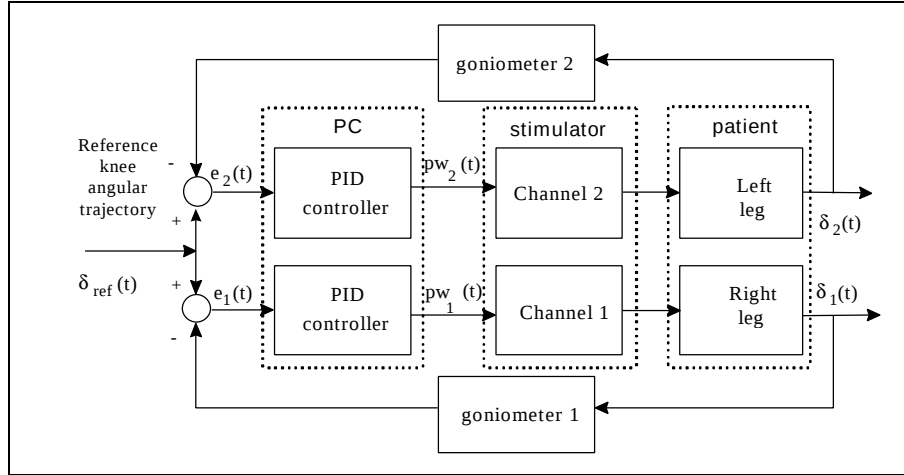


Fig.2 - Block scheme of closed loop controlled FES system.

A digital PID controller is used for each leg of the patient /5/. The knee angular reference trajectory was derived through an optimisation procedure whose target function was the minimisation of knee torque needed to stand up. In order to solve this problem an inverse dynamic model of the entire system (patient plus WRS), able to compute time course of torque necessary to provide a given standing up trajectory, was developed. The result was a modified hyperbolic tangent, opportunely repeated several times to obtain the reference trajectory used for patient exercise (see fig. 3).

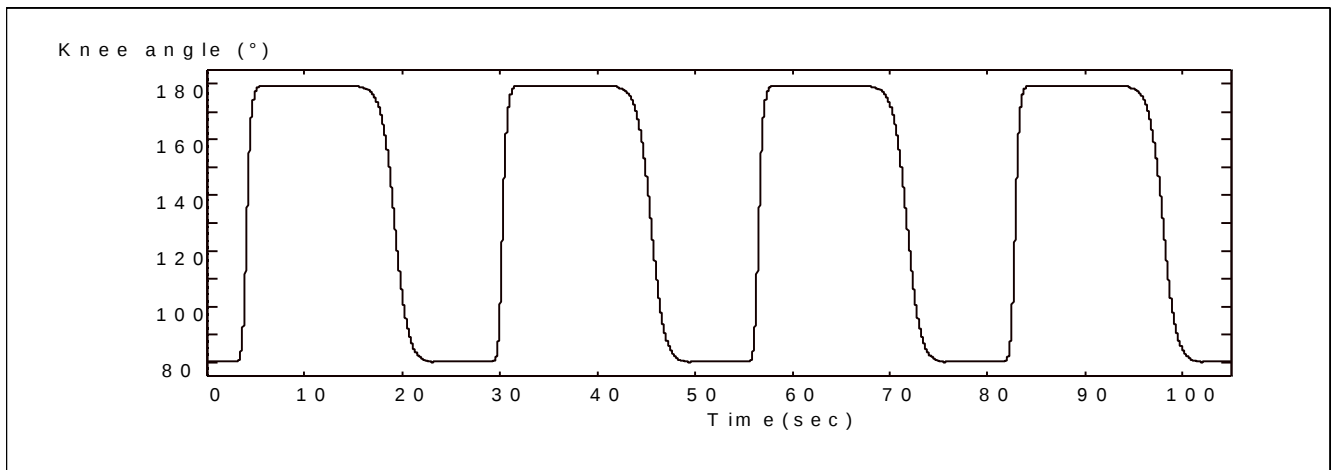


Fig.3 - Reference knee joint trajectory.

Clinical case

This training procedure was applied on one paraplegic patient (male, 28 yrs), with a complete T5-T6 spinal cord lesion since 2 years and without any previous FES experience. The patient was recruited for a rehabilitation program for walking restoration with ARGO and FES. The results here reported are referred to the first four months of training (4 sessions/week and 1 hour/session). In the first weeks the patient was sitting on a table and the controlled stimulation was used to impose a sinusoidal trajectory ($T=2.5$ sec) at both knees alternatively with 2 Kg weight at each ankle (pre-training). The standing up training was started as soon as quadriceps force was enough for the application of the procedure described before.

Evaluations

Before, during and after the training some evaluations were performed to quantify the change in muscle strength, endurance and spasticity level. Maximal isometric knee torque induced by electrical stimulation

($f=25$ Hz, $PW= 500 \mu s$) was measured by means of an isokinetic device (Cybex) with 60° knee flexion. With the same device the fatigue index (FI%) was evaluated, using the following formulas:

$$FI\% = M_{\max} - M_{30''} / M_{\max}$$

where:

$M_{\max}$ = maximal isometric knee torque at the beginning of the test;

$M_{30''}$ = isometric knee torque measured after 30 s of continuous stimulation.

Recovery from muscle atrophy was followed up by measuring thigh circumference and with ecographic examination of Rectus Femoris and Vastus Medialis. Muscle spasticity was tested with Pendulum Tests.

RESULTS

An increase in muscle force and endurance was found during training progress. After four months counter weights were reduced more than 30% respect the initial value, nevertheless the number of standing up movements in one session increased from 4 to 35 (5 series of 7 consecutive sit to stand movements separated by 15 min of rest).

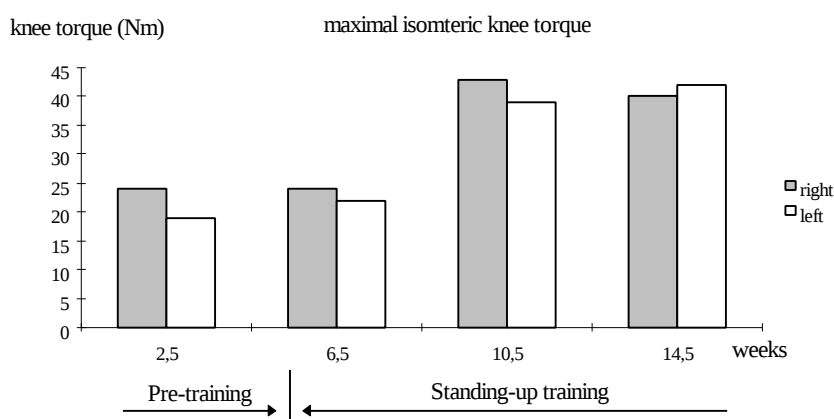


Fig. 4 - Changes in maximal isometric knee torque during the training.

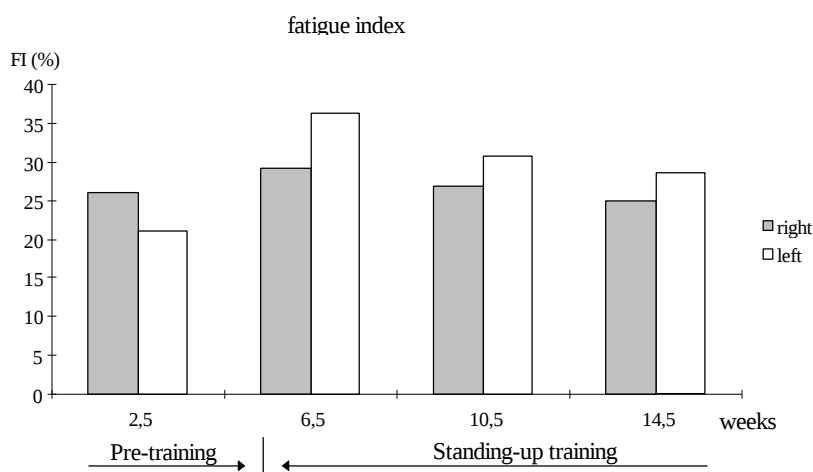


Fig. 5 - Changes in fatigue index during the training.

weights were reduced more than 30% respect the initial value, nevertheless the number of standing up movements in one session increased from 4 to 35 (5 series of 7 consecutive sit to stand movements separated by 15 min of rest).

In fig.4 the histogram of the maximal isometric knee torque is showed, where an increase from 20 Nm to 40 Nm can be found in both legs. The increase started with the specific standing-up training, allowing to suppose a better efficacy than the traditional oscillating training. This hypothesis can be confirmed only with a larger number of patients.

The change in muscle endurance is shown in fig. 5 where a decrease in the fatigue index, meaning an increase of fatigue resistance, is presented mainly in the left leg; an increase of the fatigue index in the pre-training period can be noted, probably due to the different loads applied in the two phases.

In fig. 6 the diameter of the thigh measured 15 cm over the top of the patellae with extended legs is reported. A progressive improvement of muscle conditions (an increase of

about 10% of thigh diameter in both legs) since the first phase of the pre-training can be noted. This data were confirmed by the ecographic study where a growth of about 80% in Rectus Femoris and 20% in Vastus Lateralis of both lower limbs was found.

The Pendulum Test was showing a low level of spasticity in all knee extensors muscle that didn't change significantly during the whole training period.

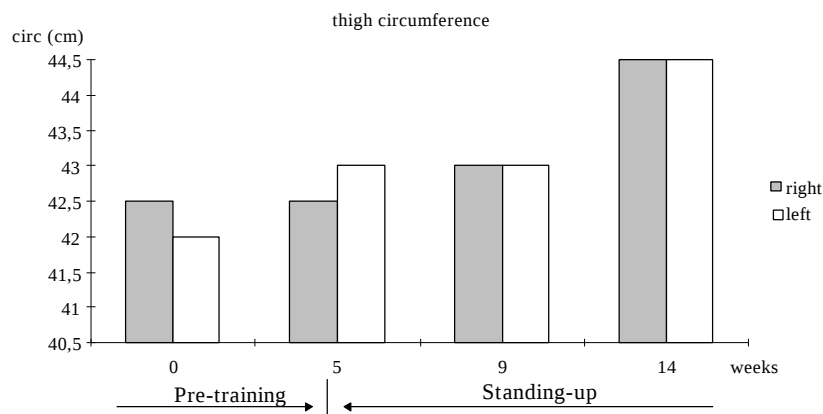


Fig.6 - Changes in thigh circumference during the training.

DISCUSSION

The positive results obtained up to now from the application of this training procedure allow to be optimistic about its efficacy. In particular the increase of muscle volume and maximal isometric knee torque and the improvement of muscle endurance demonstrate its effectiveness on muscle conditioning. From the rehabilitation point of view, the possibility to obtain a FES induced standing-up movements since the very initial phase of the training (when the lower limb muscles are not developing enough torque yet) without overloading the upper limbs and assuring safe experimental condition for the patient, makes this technique promising. It can be supposed that the early restoration of active standing-up/sitting-down movements and standing posture, besides the well known therapeutic benefits of FES training /6/, facilitates the functional use of walking system (FES and hybrid orthoses) by an indirect stimulation of postural control system. Patient's impressions are in this direction.

Moreover the presented procedure can be used for the development of innovative FES control strategies (closed-loop techniques, adaptive control, neural networks, patient driven control, see the accompanying paper of Riener et al.) and their testing on patients in controlled and safe experimental conditions.

We have already started to apply this training procedure on other two paraplegic patients. Further development will be to consider also Gluteus Muscles in the motor scheme.

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JOINT TORQUES DURING FES AND ARM SUPPORTED SIT-TO-STAND OF PARAPLEGIC PATIENTS

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SUMMARY

The sit-to-stand transfer of paraplegic patients using functional electrical stimulation (FES) of the knee extensors and arm support was analyzed in the study. In a group of eight completely paralyzed subjects who were trained FES users, kinematic and kinetic parameters were recorded during standing-up trials. The contactless optical system was used to assess the human body motion. The forces acting on a human body were measured by the multi-axis force transducers. On the basis of the recursive Newton-Euler inverse dynamic analysis the forces and torques acting on the body joints were calculated. Results are given representing joint moments in the lower and upper extremities during the sit-to stand task. The influences of the patient's strength, FES training duration and rising strategy on the joint loading are discussed.

STATE OF THE ART

The ability to rise from the sitting to the standing position is of major importance for impaired persons in order to achieve minimal mobility and independence. Among paraplegic patients, who are candidates for FES usage, the standing-up strategy which employs the open loop stimulation of the knee extensors is well accepted /1/. Within this strategy, patient in the preparation phase brings his body to an initial pose with the upper body leaned forward, arms almost fully flexed in the elbows and supported by the walker frame, while the lower extremities resting at the chair are brought forward toward the chair edge as much as possible and feet pulled backward. For the initiation of rising, the stimulation is triggered by the patient and the body is lifted upward from the initial to the extended position by the help of the stimulated quadriceps muscles and the arm support. The arm support plays an important role. It is unloading the knees while providing sufficient lifting forces and assuring body balance. As the stimulation of the knee extensors is open-loop and on/off triggered with the maximal stimulation amplitudes throughout the rising process, the existent way of standing up is not optimal regarding applied forces and torques in the upper and lower extremities. At the end of the standing-up, when knees are almost fully extended, the excessive knee joint torques cause high terminal velocities in the knee joints what can also results in ligament injuries /2/. Furthermore, overloading of the shoulder joints is additional excessive loading of the upper extremities of paraplegic patients.

Recent research efforts have been concentrated on investigating the closed-loop FES control systems accounting for the rising phases, for the state of the lower extremities or for the voluntary upper body effort /2-5/. While the biomechanics of the standing-up of healthy subjects has been extensively studied /6,7/, the biomechanics of rising from sitting to standing position in paraplegic patients has been investigated only on the basis of small sample groups or even a single patient /8,9/. When using the arm support, the paraplegic's body forms closed loop chain which includes both, the voluntarily controlled upper body segments and the segments of the lower body which are passive or their motion is FES induced. Hence, designing the closed-loop FES control systems should account for the voluntary trunk and arms contributions /10/.

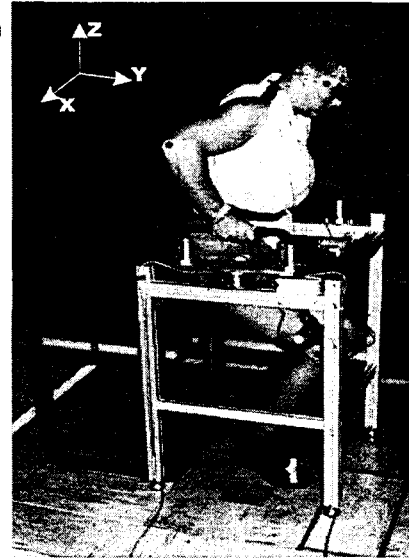
The purpose of this study was to obtain a better insight into the existing paraplegics standing-up process examining a higher number of paraplegic patients. Kinetic and kinematics parameters were measured and joint loads were calculated. Results presented in this paper can be valuable when designing a novel FES standing-up control systems.

MATERIALS AND METHODS

Eight paraplegic patients with different levels of spinal cord injury and with different experiences of FES usage participated in the study. Table 1 is summarizing the patients data.

Instrumentation: A three-dimensional, thirteen segment model of the human body was utilized, embodying feet, shanks, thighs, pelvis, trunk, head, upper arms, lower arms and hands. Each segment of the body had six degrees of freedom in the space, while segmental anthropometric parameters (segment masses, mass centers and inertia tensors) were based on the De Leva study /11/. Measurements were accomplished only for a patient's right side and calculated for the left side, since the human body symmetry during standing-up task was presumed. Kinematics of the body segments movement was assessed by the OPTOTRAK optical system measuring the active markers (infrared LEDs) 3D positions at the 50 Hz sample rate. Markers were attached to the human body joints in a way that two adjoining markers defined 3D position of one segment. Two AMTI force plates were used to determine the ground reaction force vectors acting on the right foot and on the chair. On the figure 1 the measuring set-up is presented.

Figure 1: Paraplegic standing-up measurement setup



Patient	sex	age [years]	height [cm]	weight [kg]	lesion level	post injury time/FES usage [years]
MK	M	23	168	58	Th9	1.5 / 0.2
SB	M	31	183	64	Th10-12	1 / 0.9
BJ	M	23	185	85	Th9	1.2 / 0.5
MT	F	28	171	75	Th4-5	7 / 5
TM	F	19	178	59	Th3-4	5 / 3.5
ZJ	F	57	159	53	Th11	4.5 / 3
KA	M	44	180	74	Th10-11	1.5 / 0.5
ZB	M	22	184	94	Th3-4	3 / 2

Table 1: Data of paraplegic patients participating in the study

Protocol: Subjects were seated on the instrumented seat with the arms resting on the arm support frame. The height of the seat coincided with the height of a wheel chair, while the arm support frame height was adjusted according to the patient's preferences. Subject was asked to take the initial pose and after approximately two seconds from starting the data collection, he was asked to stand up in a preferable way and speed. At least five rising trials were recorded for each participant with 50 Hz sample rate, each trial lasting for 10 seconds.

Data analysis: The signals collected from active markers, force plates and force wrist were interpolated and filtered by the 4th order Butterworth filter with 5 Hz cut-off frequency. The coordinate systems of all sensors were transformed to coincide with the reference coordinate system placed on the floor in the center of the arm supportive frame. From segment position, orientation and anthropometric data, the forces and torques acting on the joints were calculated recursively using the Newton-Euler inverse dynamic analysis /12/. The Newton-Euler inverse dynamic analysis is based on Newton's laws which state that the sum of the external forces acting on a rigid body is equivalent to the time derivative of the linear momentum of the body and similarly, the sum of the external moments acting on a rigid body is equivalent to the time change in the angular momentum of the body. Thus, the human body can be modeled as a collection of constant mass, rigid body segments where for each segment the external forces and moments consist of a net force and a net moment reaction at both proximal and distal joints, and a gravitational force. Additional forces are involved in the segments where interaction with the environment occurs. Ground reaction force vectors acting from the floor on the foot, from the walker on the arm and from the chair on the thighs were all measured and thus, readily used in the analysis.

RESULTS

Results are given in Figures 2 for three representative patients, depicting patient SB by the solid line, patient KA by the dashed line and patient BJ by the dot-dashed line. The figure 2 shows the flexion/extension torques acting in the lower right limb and in the lumbo-sacral joint. In the figure 3 the reaction forces and sagittal plane torque acting in the right shoulder joint are depicted representing the voluntary action of the upper extremities. All the forces and moments are normalized and given in the percentage of the patient's weight (or weight*height product), while the zero moment at the time axis is chosen as the seat-off moment, e.g. the moment when the body leaves the chair. Table 2 lists the force and torque peak values expressed with the standard deviations over all subject's standing up trials.

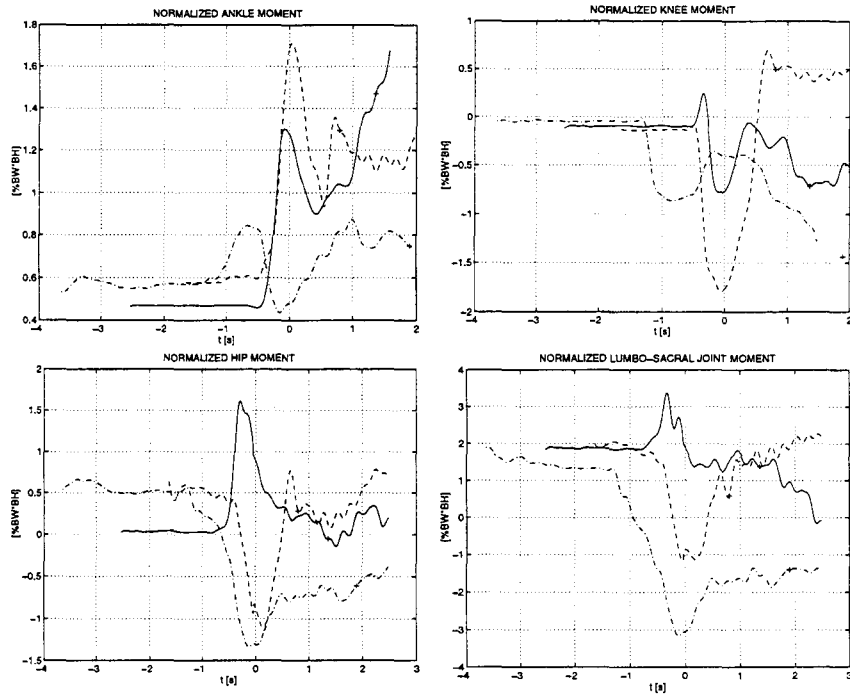


Figure 2: Flexion/extension torques acting in the lower part of the body

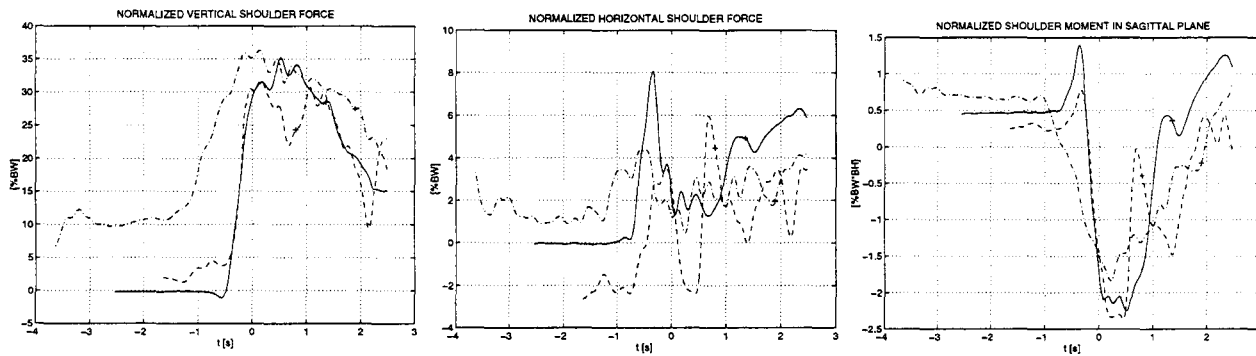


Figure 3: Upper body voluntary standing up activity represented by the reactions in the right shoulder

Peak values	MK	SB	BJ	MT	TM	ZJ	KA	ZB
Ankle moment [Nm]	8.6 ± 0.6	15 ± 0.6	14.1 ± 1.5	15.9 ± 3.9	7.4 ± 0.8	9.8 ± 1.1	18.5 ± 2.1	17.6 ± 1.3
Knee moment [Nm]	-9.6 ± 1.8	-10.9 ± 1.6	-14.1 ± 4.4	-15.4 ± 2.3	-8.0 ± 1.9	-1.3 ± 1.6	-22.4 ± 1.8	-17.4 ± 2.2
Hip moment [Nm]	-9.0 ± 1.6	19.7 ± 3.9	-17.6 ± 7.2	-12.9 ± 2.5	-18.3 ± 3.3	-0.7 ± 0.7	-14.1 ± 3.4	-11.2 ± 2.4
L-Sc joint mom. [Nm]	-18.5 ± 3.8	38 ± 7.2	-40.4 ± 15.1	-18.6 ± 4.2	-27.4 ± 7.4	1.7 ± 5.5	-17.2 ± 6.9	-24.8 ± 8.8
Vert. should. force [N]	237.8 ± 8.9	223.6 ± 13.5	306.8 ± 10.9	279.4 ± 13.6	226.6 ± 15.7	230.9 ± 8.9	235.1 ± 25.6	343.4 ± 13.4
Hor. should. force [N]	22.3 ± 4.9	43.3 ± 7.6	33.8 ± 5.3	44.8 ± 6.6	32.7 ± 9.0	28.5 ± 10.5	36.5 ± 7.0	53.0 ± 12.4
Sagittal shoul. mom. [Nm]	-17.5 ± 6.5	-21.5 ± 4.4	-30.2 ± 2.5	-19.9 ± 4.9	-37.6 ± 8.0	-34.2 ± 4.6	-25.4 ± 4.6	-35.3 ± 5.7

Table 2: Peak values of moments and forces during standing up for eight paraplegic patients

DISCUSSION

Kinematic and kinetic parameters were outlined for a standing up of paraplegic patients. Joint torques in a lower limb and dynamic interactions in a shoulder joints can be useful when designing the simulation of a standing up process. Measurements of paraplegic rising proved that paraplegics stand up in a completely different way than the healthy persons. They employ arm supportive forces to a higher extent than it was expected. It is interesting that in our sample group three groups can be distinguished. First, there are patients whose knee extensors muscles cannot provide enough knee joint torque and therefore they stand up primarily by the help of arm support. Second, regularly FES trained patients make better use of the lower limbs support and hence, unload the upper extremities. Representatives of these two groups are patients BJ and KA respectively. Most interesting is the finding that some patients, to overcome the lack of lifting forces in the lower limbs, use the strategy similar to the healthy persons. They push or pull their upper body forward to gain the linear momentum, which then helps with lifting the body upward. Typical example is the patient SB who stands up with smaller knee torque, with different activity in hip and lumbo-sacral joints, while higher activity in the shoulder joint prior to the seat-off is recorded when generating the momentum.

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ASSESSMENT OF INTACT SUBJECT'S BALANCING STRATEGY

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SUMMARY

The scope of the study was to assess the responses of an intact subject with the knees and hips braced in the extended position to anterior-posterior disturbances. A specially designed device with a stationary platform and a rotational mechanical frame driven by a hydraulic rotary valve served for leg bracing and perturbation implementation. Relations between the kinematics and dynamics of human responses were studied. Correlation between the ankle joint angle and the corresponding ankle joint torque was investigated. Preliminary experiments indicate a linear interdependence resulting in a constant ankle joint active stiffness.

INTRODUCTION

Standing of completely paralysed persons can be achieved by means of long-leg braces, standing frames or functional electrical stimulation (FES). Such standing cannot be successful without the arm support. Functional standing, defined as a stable upright posture which frees at least one upper extremity to manipulate objects, would provide many benefits to the patient. The control of such standing posture must be robust when exposed to sudden perturbations. Paraplegic persons can exercise noticeable control over the upper trunk muscles, however they lack voluntary control of their lower extremities. Therefore, an artificial controller is required for the lower extremity control. The aim of this controller would be to co-operate with the upper trunk voluntary movements in order to achieve a robust arm free standing. The lower extremity controller can be applied to the ankle joint muscles, while the knees and hips are in an extended attitude provided by the long leg braces or FES.

STATE OF THE ART

Hunt et al. /1/ and Murih et al. /2/ achieved arm free standing assisted by an artificial ankle joint controller with the entire body braced in an extended posture, thus treating the subject as a single link inverted pendulum with a FES controlled muscle actuator. Matjačić and Bajd /3,4/ showed a possibility of functional standing by constraining the subject in a double link inverted pendulum structure with voluntary control of the upper trunk muscles and a passive stiffness implemented in the artificial ankle joint, while knees and hips were braced in the extended position.

It is known that an intact subject who is exposed to a sudden perturbation in the posterior-anterior direction typically responds by exercising the ankle or hip balancing strategy or the combination of both /5/. The ankle strategy is normally used when the magnitude of the perturbation is low. By increasing the magnitude of the perturbation the standing subject relies rather on hip and trunk compensatory movements. The trunk flexor and extensor muscle groups are in most paraplegic subjects strong enough to generate necessary balancing torque around the lumbosacral joint. Our aim is therefore to study possibilities of hand free standing in a completely paralysed person where the ankle joint is under FES control of antagonist muscle pairs, while the lumbosacral joint is under patient's voluntary control.

MATERIALS AND METHODS

A special mechanical rotating frame MRF (Figure 1) was developed consisting from a stationary platform and a rotational frame [4]. The subject standing in the MRF with arms folded at the chest can be considered as a double inverted pendulum structure, with one degree of freedom in the ankle joints and the other in the lumbosacral joint (L5 - S1). The purpose of the MRF is to retain the subject legs in the

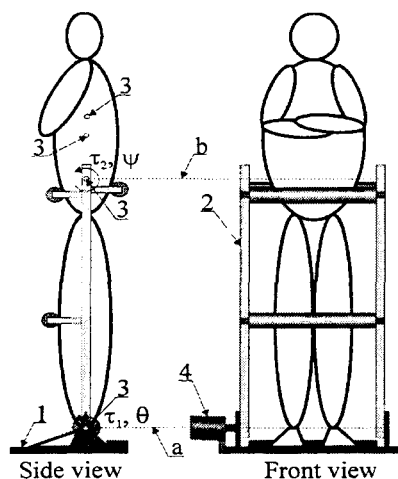


Figure 1 Subject braced in MRF (1- stationary platform, 2 - rotational frame, 3 - markers, 4 - hydraulic actuator, a - ankle joint axis, b - lumbosacral joint axis)

extended position and to provide perturbation through the hydraulic actuator built in the auxiliary ankle joint axis. The frame was made from light aluminium rods mounted on special bearings. The frame consists from two vertical beams which are parallel with the standing subject. Three transversal beams connect the two vertical beams. Two of the transversal beams are positioned in the anterior position of the standing subject, one in the height of the pelvis and the other below the knees. The third transversal beam is positioned posterior to the standing subject in the height of the pelvis. A fourth beam is positioned on the stationary platform, behind the heels of the standing subject, preventing the feet to move backwards. The rotational part of the MRF weights 18 kg. Its moment of inertia around the auxiliary ankle joint axis is 3 kgm^2 . The hydraulic subsystem consists from a hydraulic pump, a servovalve, a rotary valve actuator and two pressure transducers. The rotary valve actuator built in the auxiliary ankle joint axis provides enough torque for implementation of various perturbations in anterior-posterior direction. The hydraulic pump provides the pressure of 60 bars to

the servo valve controlling the pressure difference of the rotary valve. The mechanical rotating frame motion was controlled by a control software running on a personal computer equipped with data acquisition units. From the safety point of view the standing subject was wearing a full-body harness loosely coupled by the ropes to the ceiling.

Kinematics of the movements was assessed by the optical position measuring system OPTOTRAK®. Two infrared markers have been positioned on the rotational part of the MRF, one in the bearing axis and the other on the vertical beam in the height of the subject's lumbosacral joint. The additional two markers were positioned on the subject's trunk, the first one in the midline of the rib cage half way between the iliac crest and the shoulder [6] and the second one five centimetres bellow the first one. The stationary part of the mechanical rotating frame was firmly fastened to the forceplate (AMTI OR6-5-1), enabling reaction forces and torques measurement. The measured forces and torques together with the assessed kinematics enabled determination of moments in the subject's lumbosacral and ankle joints. EMG signals of the right ankle and right trunk side antagonist muscle pairs were measured in order to assure reliable information on the voluntary activity in both joints and to determine latency between the onset of the perturbation and the corresponding subject's reaction.

An intact subject was braced in the MRF device. The pelvis and the feet were positioned in such a way that the lumbosacral joint axis as well as the ankle joint axis of the standing subject intersected the midline of the vertical beam of the bracing system. The ankle joint axis was aligned with the MRF's bearings axis. The subject was allowed to move only in his lumbosacral and ankle joints while his arms were folded at the chest. When no perturbation was applied, a regulation of zero torque in the auxiliary ankle joint was implemented, in order to allow the subject in the MRF device to move freely in his ankle joints. Maximum zero torque regulation error was approximately $\pm 2 \text{ Nm}$. The closed loop torque control cut-off frequency was well above 10 Hz what met our requirements, as the maximal human body

movement frequency does not surpass 6 Hz /6/. The marker trajectories, the time courses of reaction forces and the EMG signals were sampled at 400 Hz and saved for off line analysis.

EXPERIMENT

Three intact male subjects, age 19 to 21, took part in the preliminary experiment. The subject entered the MRF from the rear side after the posterior transversal beam was removed from the frame. Before the experiment the subject was encouraged to assume his most comfortable standing posture. This posture had to be maintained before each perturbation therefore a computer screen was placed approximately 1 metre in front of the standing subject, providing him visual feedback. In this way repeatable initial conditions and consequently comparable results were assured. At the same time the EMG signals, pre-processed with precise differential amplifiers, were presented on an oscilloscope in order to enable the experimenter to estimate the muscular activity in the ankle and trunk antagonists. The perturbation was not implemented until the EMG signal decreased below the value previously assessed as the resting muscle activity.

Responses to eight different types of perturbation were measured (Table 1). Each subject was first given a possibility to familiarise with the perturbed standing. Approximately one hundred perturbations in random order were delivered to each subject before the experimental session started. Each experimental session consisted of eighty perturbations in random order, resulting in ten trials for each perturbation type.

Table 1 : Perturbation parameters

Anterior pert.	Torque	Duration	Posterior pert.	Torque	Duration
1	30 Nm	150 ms	1	30 Nm	100 ms
2	50 Nm	150 ms	2	50 Nm	100 ms
3	30 Nm	250 ms	3	30 Nm	200 ms
4	50 Nm	250 ms	4	50 Nm	200 ms

RESULTS

All three subjects assumed their normal slightly forward inclined standing postures with the ankle joint angle value approximately 3° and the lumbosacral joint angle value approximately -15°. Both angles were measured with respect to the vertical axis. The subjects were able to reject all disturbances in the anterior direction. The subject GM was also able to reject all the disturbances in the posterior direction, while the subject SS failed in rejecting one perturbation of magnitude 50 Nm and duration 200 ms one time. Subject VL failed in rejecting all perturbations of the magnitude 50 Nm and duration 200 ms, while at the magnitude of 30 Nm and duration 200 ms he failed three times.

Figure 2 shows the response of the subject GM to the anterior perturbation of magnitude 50 Nm and duration 250 ms. The instant of perturbation is denoted with the vertical line at the time 0.5 seconds. The anterior perturbation caused an increasing of the ankle joint angle and a decreasing of the lumbosacral joint angle while the posterior perturbation resulted in a decreasing of the ankle joint angle and an increasing of the lumbosacral joint angle. The subject responded by altering the torques in both joints in order to reverse the motion. The average ankle joint muscle latency established from EMG signals was about 80 ms, afterwards it took about 2 seconds for the subject to reassume the initial posture.

The relation between the ankle joint angle and the corresponding ankle joint torque can be expressed by the ankle joint active stiffness value. The active stiffness in the ankle joint can be determined as the ratio between the ankle joint active torque and the ankle joint angle. The stiffness turned out to be constant and independent of the type of perturbation or subject. The stiffness value was found approximately 10 Nm/°. This results agree with the simulation findings by Matjačić and Bajd /3/. They proved that the stiffness

value of 10 Nm/° provides most adequate conditions for disturbance rejection resulting in an increased postural stability.

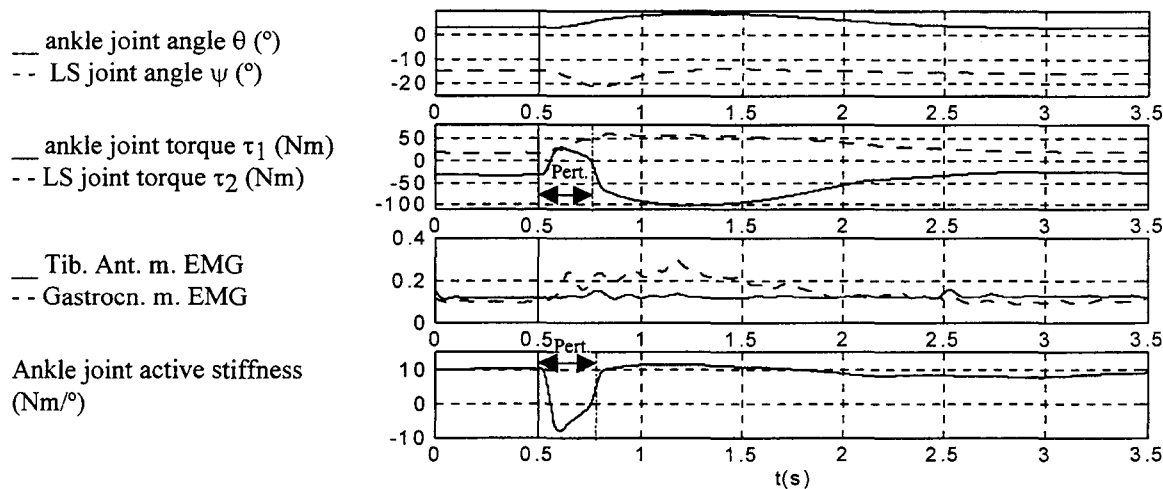


Figure 2 Response to anterior perturbation, magnitude 50 Nm, duration 250 ms

DISCUSSION

An important result of this preliminary investigation is the finding that intact subjects respond to different perturbations in a quite linear manner. The active stiffness applied by all subjects in their ankle joints was constant regardless of the direction, magnitude or duration of the perturbation. This is an important fact in designing the controller for the ankle joint antagonists assisting in the functional standing of patients after SCI. Further experimental work will include more participants as well as various initial postures in order to expand or reject the validity of these preliminary findings.

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EMULATION OF POSTURAL ACTIVITY IN UNDERACTUATED VIRTUAL BALANCING IN ARM FREE PARAPLEGIC STANDING

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SUMMARY

An environment simulating underactuated paraplegic standing and at the same time enabling training of residual trunk muscles of thoracic paraplegic subjects is described. The environment was evaluated by five healthy and one paraplegic subject. The evaluation showed potential therapeutic benefits of the proposed emulation environment for midthoracic paraplegic subjects.

INTRODUCTION

The ability to stand is of great importance for spinal cord injured subjects since it enables performance of functional activities and more importantly it has numerous therapeutic effects [1,2]. A standard technique frequently employed in the rehabilitation environment enabling therapeutic standing exercise of midthoracic paraplegic subjects requires that both lower extremities are firmly fixed in a standing frame. Since in this way stability of a standing subject is assured passively, there is no need for subject's upper body postural activity what makes therapy process static and less attractive.

In our previous work we have proposed and implemented arm free paraplegic standing [3,4]. A subject was standing in a special mechanical apparatus named mechanical rotating frame (MRF), composed from a rotating platform and a bracing system with one rotational degree of freedom (artificial ankle) and a base plate. The artificial ankle is powered by a hydraulic servo valve providing adjustable stiffness of the artificial ankle joint. A subject, standing on the rotating platform, is constrained by the bracing system in such a way that his ankle, knee and hip joints cannot move. In this way a double inverted pendulum mechanical structure was obtained. First joint is the artificial ankle joint which exhibits desired stiffness properties, while the second, lumbosacral joint is voluntarily actuated by trunk flexors and extensors. The standing subject was provided with auditory cognitive feedback giving the information about inclination of the lower link. A subject maintained standing only by the use of voluntary activity of residual trunk muscles employing a control strategy similar to the one used in underactuated robotic systems. We have demonstrated [3,4] that proposed standing is feasible and robust. Additionally, it was observed that after one week of paraplegic subject's standing in the MRF (30 minutes per day) a range of motion (ROM) of subject's spine greatly increased while at the same time the contractures in the lumbosacral joint, primarily due to the shortened iliopsoas muscles, improved. Therefore, standing in the MRF has additional therapeutic effects regarding the motor abilities of paraplegic subject. It restrenghtens the trunk muscles and enlarges the ROM of the lumbosacral joint.

It is of benefit if paraplegic subjects are involved in a program of trunk muscles restrenghtening already prior to standing in the MRF. This could be achieved through various isokinetic exercises. However, we felt that paraplegic subjects should be given a therapeutic environment not only enabling restrenghtening of the trunk muscles and enlarging the ROM of lumbosacral joint, but should be dynamic and attractive enough to raise interest of paraplegic population. We designed and built an environment that emulates underactuated standing in the MRF. In this study it was our aim to investigate whether emulation of underactuated standing resembles actual standing in the MRF device and additionally, to evaluate the role of auditory cognitive feedback during emulated standing.

MATERIALS AND METHODS

Fig. 1. shows a subject standing in the MRF and the mechanical model of the double inverted model in a sagittal plane having only one actuated degree of freedom in the lumbosacral joint. Dynamic equations governing motion of the structure are:

$$T_1 = -m_2 g l_{c2} \sin \psi - (m_1 g l_{c1} + m_2 g l_1) \sin \theta - m_2 l_1 l_{c2} \sin(\psi - \theta) (\ddot{\psi}^2 - \dot{\theta}^2) + (J_2 + m_2 l_{c2}^2 + m_2 l_1 l_{c2} \cos(\psi - \theta)) \ddot{\psi} + (J_1 + m_1 l_{c1}^2 + m_2 l_1^2 + m_2 l_1 l_{c2} \cos(\psi - \theta)) \ddot{\theta} \quad (1)$$

$$T_2 = -m_2 g l_{c2} \sin \psi + m_2 l_1 l_{c2} \sin(\psi - \theta) \dot{\theta}^2 + (J_2 + m_2 l_{c2}^2) \ddot{\psi} + m_2 l_1 l_{c2} \cos(\psi - \theta) \ddot{\theta} \quad (2)$$

where l_{c1}, l_{c2} are distances from joints to centers of masses and l_1, l_2 represent lengths of upper and lower link. The angles (θ - ankle joint, ψ - lumbosacral joint) are measured with respect to the vertical line. m_1, m_2 are masses of both links and J_1, J_2 are the moments of inertia about the mass centers of each link. T_1, T_2 are the net torques acting in the ankle and lumbosacral joint, respectively. In the ankle joint a pure mechanical stiffness behavior is encountered:

$$T_1 = -K \cdot \theta \quad (3)$$

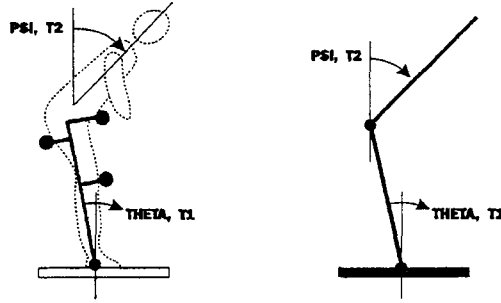


Fig. 1. A person standing in the MRF and the equivalent mechanical model.

The only input to the model is the lumbosacral torque T_2 resulting from subject's voluntary activity. In the theoretical analysis of the closed loop underactuated double inverted pendulum we showed that the equations (1,2) are valid only when certain biomechanical constraints are not violated [3]. The most crucial constraint considers excursions of the center of pressure (COP) under the feet which must remain within the length of the foot.

Fig. 2. shows our emulating environment. A subject is sitting on a chair which is equipped with a potentiometer measuring inclination of his trunk. The potentiometer signal is connected to the A/D converter (Burr-Brown PCI 20001C) of a personal computer (PC). According to the position and acceleration of subject's trunk $\psi, \ddot{\psi}$, the torque in the lumbosacral joint is estimated:

$$\tilde{T}_2 = -m_2 g l_{c2} \sin \psi + J_2 \ddot{\psi} \quad (4)$$

Simulation of equations (1,2) is taking place in PC according to the torque input of the lumbosacral joint $\tilde{T}_2$. The double inverted pendulum movement is animated in real time on the computer screen. Apart from visual information, the sitting subject is additionally provided with auditory cognitive feedback communicating the inclination of the lower link of simulated double inverted pendulum (± 10 degrees is exponentially converted in the auditory signal from 100 - 1000 Hz). The goal of the

sitting subject is to maintain the animated figure in standing position through the appropriate activity of the trunk muscles.

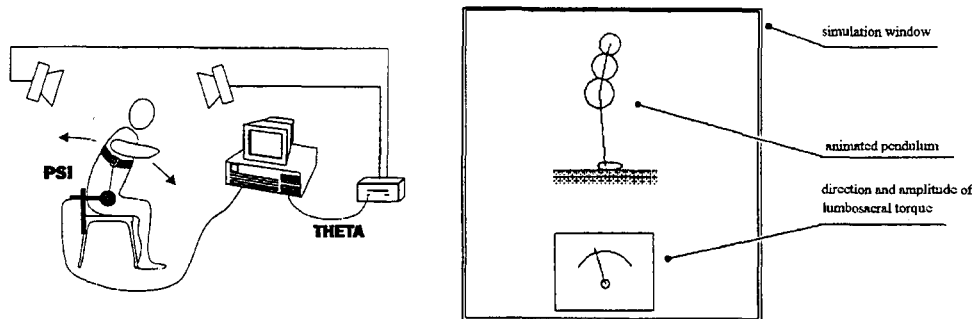


Fig. 2. Experimental environment and a screen of PC displaying animated pendulum and direction and amplitude of the lumbosacral torque $\tilde{T}_2$.

At the beginning of the trial the sitting subject assumes upright posture of the trunk. When the estimated torque $\tilde{T}_2$ is approximately zero, the simulation is started. The sitting subject tries to maintain standing without violating the constraint regarding COP [3/]. When the subject maintained standing of the animated pendulum for 20 seconds, the trial was considered successful.

EXPERIMENTAL PROTOCOL AND RESULTS

Five healthy and one paraplegic subject (34 years old, T-12, 10 years post injury) participated in our investigation that was undertaken in a single day.

In the first introductory part of the experiment all subjects started with balancing of the animated pendulum at the ankle stiffness of $K=15 \text{ Nm/}^\circ$. At such high stiffness value they had little difficulties with the task. We reduced the stiffness value by a decrement of 1 Nm/° and when the subject comfortably balanced at the new stiffness value, the ankle stiffness was reduced again by the same decrement. After half an hour all subjects were comfortable with balancing in the virtual environment.

In the second, evaluation part of the experiment all subjects underwent two sets of trials:

I. Auditory cognitive feedback was provided. Subjects tried to successfully balance in five trials at stiffness value of 10 Nm/° . Then the stiffness value was reduced by 1 Nm/° and another five trials followed. This procedure was repeated until the ankle stiffness value reached 6 Nm/° .

II. Auditory cognitive feedback was not provided. The same evaluation procedure was applied as in the case I.

We were only interested into the successfulness of a particular trial. Fig. 3.a shows mean value and standard deviation of the number of successful trials for the group of healthy subjects for five different levels of ankle stiffness separately for the trials with and without cognitive feedback. Two characteristics can be observed. First, cognitive feedback has noticeable influence on the number of successful balancing trials and second, the number of successful trials decreased with lower values of the ankle stiffness. Fig 3.b shows the results for paraplegic subject which are similar to those presented in Fig. 3.a. Here we have to state that the paraplegic person who participated in this experiment cannot be considered as a completely naive subject since he was involved also in our previous experiment of standing in the MRF [4/]. On the other hand all healthy subjects were naive subjects.

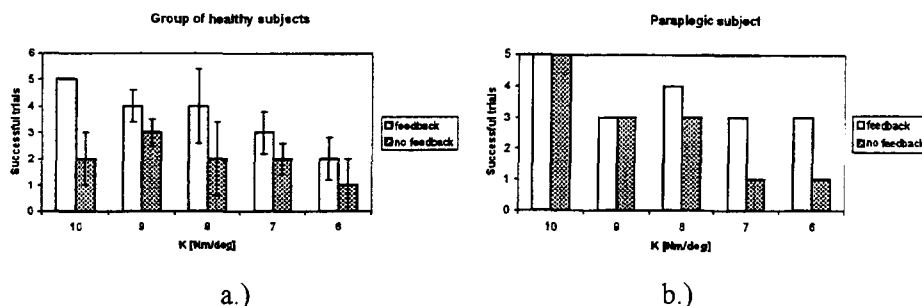


Fig. 3. a.) Mean value and st. dev. of successful trials in healthy subjects (N=5); b.) number of successful trials in paraplegic subject.

DISCUSSION

Comparison of the results between actual standing in the MRF device [4] and virtual underactuated balancing in the presented emulation environment reveals similar performance. In both cases subjects easily balanced at higher values of ankle stiffness (around 10 Nm/°) while similar behavior was observed for lower stiffness values. As in actual standing in the MRF also in this study an improvement of balancing performance can be observed when the auditory cognitive feedback was provided to the subjects. However, there is a significant neurophysiological difference between actual and virtual underactuated standing. In actual standing in the MRF the standing subject receives correct sensory information from vestibular organ while in the case of virtual standing the vestibular information misleads the sitting person. In latter case the balancing subject must ignore the vestibular input and has to rely only on his visual and artificial auditory sensory input. Another problem that was encountered in the emulation experiment was the estimation error of $\tilde{T}_2$ which significantly influenced the performance. Nevertheless, we may conclude that the presented emulation of the underactuated arm free paraplegic standing satisfied the goals stated in the introduction, since it provides interactive and attractive therapeutic environment that can be easily implemented in the rehabilitation institutions.

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EXPERIENCE IN USING KNEE ANGLES AS PART OF A CLOSED-LOOP ALGORITHM TO CONTROL FES-ASSISTED PARAPLEGIC STANDING

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SUMMARY

Using electrical stimulation of lower limb muscles to assist paraplegics to stand has been successful in many centres. However, it does have its problems; primarily the maintenance of stable balance in response to muscle spasms and fatigue, postural changes and external perturbations. These need to be addressed for an FES-based system to be safe for a paraplegic to stand and remove one hand to perform a task. A standing system has been developed for mid-low thoracic complete lesion paraplegics, which implements a closed-loop algorithm. Measurements of the knee angles are used to monitor the stand and changes to these act as an input to the controller, which responds by adjusting the stimulation levels to the quadriceps. The performance of the controller, based on a PID design, is evaluated by subjective assessments of the stand, both when quiet and during physiological and enforced disturbances. Optimisation of the PID algorithm is based on general rules used to calculate initial estimates and from clinical experience. This technique has been used successfully to control standing with 23 paraplegics, 14 of whom have used it at home.

STATE OF THE ART

To stand complete lesion paraplegics using electrical stimulation requires, at the minimum, the quadriceps muscles to be stimulated /1/. If the standing system is open-loop, then this requires that the quadriceps are excessively stimulated to provide a margin of safety, in an attempt to compensate for any disturbances. This causes unwanted hip flexion, because of overflow into rectus femoris, and increased fatigue. The compensation is also, at best, crude. A closed-loop design can improve this, by updating the stimulation levels to the quadriceps in response to changes in the stand and trying to reduce the mean level required for standing. This requires the stand to be monitored and an appropriate controller to be implemented.

Controllers have been advocated which use the ankle angle to control posture, by stimulating the below-knee muscles whilst the quadriceps are stimulated in an on/off manner /2,3/. However, this increases the number of channels for each leg (four if gluteals are stimulated to provide hip extension) and is not considered practical for a surface-based system. The favoured approach is to use knee angle measurements to control the quadriceps, because of the ease in interpretation, using either a finite-state or continuous feedback controller. The finite-state design detects 'unlocked' and 'locked' knees, using these to either switch on the quadriceps stimulation to a pre-set level or switch off/ramp down the stimulation respectively /4,5/. The continuous feedback design uses the error in the knee angle from a desired angle to determine the required quadriceps stimulation to achieve that desired angle. Comparing the two types, a finite-state controller is more robust. Therefore, it is argued that because reliability is more important than accuracy, this is the preferred option /5/. Its disadvantages are that switching on/off stimulation may cause reflex hip flexion spasms and the subject is relied on maintaining a stable posture, usually with hyperextended knees. This increases strain on the knee joint and may limit confidence in removing a hand. With a continuous feedback design the quadriceps stimulation should give a smoother response and one which is more appropriate to the level of disturbance observed, rather than pre-set levels. This type has been primarily based on a proportional, integral and differential (PID) design because of its simplicity in implementation and wide range of adjustment, and has been shown to control knee angle and extension torque /6/.

MATERIALS AND METHODS

Standing procedure

The standing procedure is well established /7/. Standing follows a three month minimum period of FES exercising and before closed-loop standing is attempted, the subject stands open-loop. Standing is achieved by stimulation of the quadriceps, open-loop during get-up/sit-down and closed-loop during standing. It is typical for the gluteals to also be stimulated to provide hip stability. This is in open-loop, the rate of rise being pre-determined, to compensate for fatigue. The subject balances using a wheelchair mounted standing frame /8/. Two programmable stimulators have been used /9,10/.

The stand is monitored by measuring the knee angles, using servo-potentiometers housed in a neoprene knee cuff. When standing is initiated, stimulation only starts if the knee angles are within a pre-determined range - for the system to accept that the knees are sufficiently flexed. When the subject achieves standing, again, the knee angles are checked to be within a range - this time for the system to acknowledge that the legs are sufficiently extended. These safety features also ensure correct operation of the sensors. When standing is acknowledged, the system tries to calibrate the sensors. Calibration is needed because the sensors may not necessarily be put on in a repeatably correct position. It is only successful, if the knees remain adequately extended and if the fluctuation in knee angles is within a narrow margin of one or two degrees. Since the calibrated angle represents the user in 'full-extension', it is reduced slightly by about two degrees, to avoid hyperextension, to give the required angle for the controller to maintain. On a successful calibration, the stimulation levels to the quadriceps come under closed-loop control, until the subject requests to sit. During standing, the subject can depress a switch to recalibrate the sensors. This is used especially if they spasm and maintained an adequate, but different from previous, posture. In this case, if the sensors were not recalibrated then the stimulation levels would change as a result of the angle error.

Controller

The controller implemented in this design is a PID type. Its aim is to maintain the required angle, by using the error in the knee angle to adjust the quadriceps stimulation. It operates the stimulation between a minimum and maximum level and gives a warning signal if it becomes close to maximum. For safety reasons, the rate of fall of stimulation, but not its rise, is limited. A separate controller is implemented for each leg. Typically, the P-term responds to destabilising moments, such as external perturbations or postural changes; the I-term to compensate for slow transients from the knees buckling due to muscle fatigue; and the D-term to control the response to fast transients out of and into lock as a result of quadriceps or abdominal muscle spasms. Optimising the controller is by adjusting the gains for the three terms and finding optimal values for these is based on clinical experience. Initial estimates are selected from open-loop standing results. Generally, the P-term is set to increase the stimulation to maximum if the knee is in about 30 degrees of flexion; the I-term to increase the stimulation to maximum if the knee remains in one degree of flexion for a minute or so; and the D-term to increase the stimulation to maximum if the knee is moving into flexion at around 10 degrees per second.

Evaluation of stands

For a subject to stand independently at home, they must demonstrate that they can repeatably stand safely with a stable posture and take one hand off. Typically, subjects attend weekly for a minimum of three months, where they are trained and the controller is optimised. Evaluating the success of a stand, and therefore by implication whether the control parameters have been optimised, is important but not an easy task. This is confounded as the subject's strength, spasticity, technique or requirements vary. At present, each stand is subjectively assessed as to whether the controller is responding 'adequately' to disturbances. As part of this, the subject may be prompted to take one hand off and reach to a point in space, asked to look over one shoulder or may be 'pushed' in the transverse plane. Evaluation is aided by downloading the data of the knee angles, the error in the knee angles, and its derivative and integral, and the output levels. These can be examined in real-time or afterwards, to determine whether parameters should be changed. It is possible to alter the PID gains whilst the user is standing and this can be invaluable, especially in cases

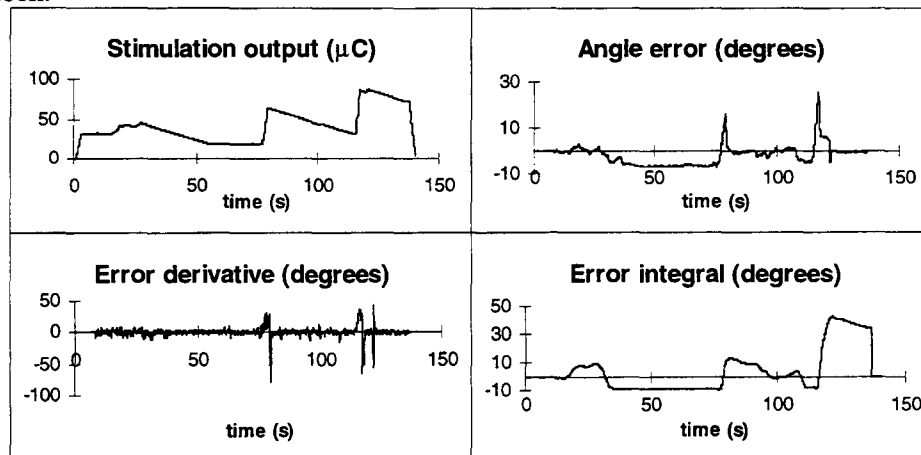
such as trying to reduce the effect from spasms. Standing is further evaluated, by asking subjects who are standing at home to complete a questionnaire every 3 to 6 months. This examines many aspects of FES-standing and exercising and includes questions on the frequency and duration of stands and for what function standing was attempted. The stimulator also logs usage to check subject compliance.

RESULTS

We have successfully stood 23 complete lesion paraplegics using this closed-loop design, with 14 using it at home. Standing at home has been primarily for therapeutic reasons, but eight have used it functionally, such as reaching to a high shelf. We currently have two waiting to progress to home use, four standing at home (three for over five years) and one who is now standing with an implanted lumbosacral anterior root stimulator. The primary reasons for discontinuing are the time required to don/doff the system, the system not providing adequate functional benefits, postural problems from excessive hip flexion and demotivation, despite standing well. Most subjects stand five times every other day, typically between 3 and 15 minutes each but some have reached times of up to 60 minutes. Compared to open-loop standing, the subjects comment that they take less weight through their arms to maintain standing.

Our initial estimates for the PID gains for the controller have been shown to be adequate for most subjects. For those we change, we often find that most of the optimising is time-consuming for the P and D terms. This is because of external disturbances being from different directions and strengths, altering the posture differently each time, and the varied nature of most subjects' spasticity. These need to be closely evaluated, requiring many stands and sessions. The P-term must compensate for disturbances, either into knee flexion or hyper-extension. If the gain is too high, then the system may start to oscillate, with the knees coming in and out of lock, because of over-compensation of the stimulation levels. Generally, spasms result in fast knee angle changes from out of lock. The D-term responds by increasing the stimulation level rapidly, but if the gain is too high, then the excessively high levels may initiate further spasms resulting in instability and increased fatigue. In common with other controllers, the I-gain is much smaller than the gains for the other two terms and one common adjustment we have found is to reduce the gain further to slow down the response of the stimulator compensating for fatigue.

The response below was from a paraplegic with a T10 complete lesion. He often had strong spasms when standing, either with FES or passively in an Oswestry frame. It shows that when he spasmed (78s and 115s), the knee flexed quickly and a high derivative term was produced. The system responded by increasing the stimulation level. As the knees settled into lock again the output fell slowly, controlled by the rate-limiter. Only the left is shown here, but during the same stand the right leg controller produced small controller terms with no significant change in output level, depicting that the right knee was remaining in-lock.



DISCUSSION

It has been shown that knee angles can be an effective method to control paraplegic standing. The sensors have been reliable, though care must be exercised to prevent them from catching on the wheelchair during getting-up. Interpreting the knee angles is relatively easy and general rules have been developed from clinical experience to set the controller parameters. These are considered to be adequate, but optimising these parameters still remains a time-consuming procedure, because stands often differ from each other and the subjects' fatigue or spasm patterns are not predictable. Our main concern is the poor uptake of this system by paraplegics. A recent survey by Salisbury suggested that there is a need for a surface-based standing system, if it was shown to be functional. Our system does not yet meet that, highlighted in the questionnaire by the reluctance of subjects to use it outside of the home and also the limited use within. We believe that the main reasons for this are the time required to don and doff the system, on average 10 minutes, and the reluctance to wear it all day because of the wires interfering with transfers and everyday tasks.

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PROLONGED STANDING IN PARAPLEGIA BY MEANS OF FUNCTIONAL ELECTRICAL STIMULATION AND ANDREWS ANKLE-FOOT ORTHOSIS

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SUMMARY

We have demonstrated the long-term use (6½ years) of an implant for FES standing. One T-10 paraplegic male (CS) is able to achieve safe, closed-loop uninterrupted standing for over 1 hour with the Nucleus FES-22 stimulator (Cochlear Ltd., Lane Cove, N.S.W., Australia). Closed-loop control is achieved by monitoring the bilateral knee angles using electro-goniometers (Penny & Giles Ltd.), resulting in the stimulation time being reduced to less than 10%. Stance stability is achieved by the Andrews' anterior Ankle-Foot Orthosis. Using accelerometers (Analog Devices) for trunk inclination and vertical acceleration, during controlled stand-to-sit, diminishes slamming onto the seat. CS is able to do one-handed tasks including reaching and holding at arm's length a 2.2 kg object.

We have been able to stimulate both femoral nerves at the groin area by surface stimulation for conditioning and prolonged standing, in another T-10 paraplegic male (FR). He has been conditioning his quadriceps muscles daily for 1½ year and is able to produce up to 55 Nm at 45 degrees of knee flexion. With the anterior AFO and closed-loop knee monitoring, FR can stand uninterrupted for over 1 hour and perform one-handed tasks.

STATE OF THE ART

Our ultimate object is to develop a safe, reliable and simple to use aid to daily living for use in spinal injured paraplegic individuals. The aid will complement the use of a wheelchair and is expected to be helpful in overcoming obstacles to wheelchair access. In respect of the latter we are targeting access those unadapted areas such as the doorsteps and bathroom facilities in the workplaces or homes of friends and relatives. In addition, being able to stand up and reach objects or perform prolonged manual tasks at a bench or counter top would be convenient for many workplace and home situations.

Functional Electrical Stimulation (FES) potentially offers some partial solutions to these problems as well as offering concomitant therapeutic benefits with regular use. The restoration of standing using FES in paraplegia represents a starting point to address the above access problems, as it is the precursor to many locomotor activities. The state of the art was reviewed by Kralj /1/ and Davis /2/. Although considerable achievements have been made, there has yet to be developed a safe, practical FES system that is an independent, energy efficient mobility aid for prolonged use at home and in the workplace. The reasons lies in the fact that FES is addressing complex problems requiring not only interdisciplinary knowledge from muscle and nerve physiology and electrical stimulation technology, but also implementation of biomechanical and control principles /3/.

MATERIAL AND METHODS

Closed-Loop FES-22 Implantable Stimulator

The present closed loop system is based on the FES-22 stimulator /4/. The system is capable of delivering a balanced biphasic pulse of 0–4.3 mA amplitude, at a 0–500 μ s pulse width and at 20–50 Hz. The system can accept up to 16 sensors sampled at 100 Hz. The controller is divided in three phases: 1] open loop sit-to-stand, 2] closed loop stand, 3] closed loop stand-to-sit. To initiate standing up and sitting down, the subject can use a remote switch mounted on a hand glove. The current sensors used for closed loop control are: 1] electrogoniometers across both knees (Penny & Giles Biometrics Ltd., Blackwood Gwent, UK), 2] accelerometers on the back at T-6 level (Analog Devices, Norwood, MA, USA). A portable open-loop version of the system is also available for muscle conditioning.

Paraplegic Subjects

Subject CS is a 30 year-old T-10 (ASIA: A) paraplegic male. He was injured in an ATV accident in August 1984. He is 1.78 m tall and weights 100 kg. He was implanted in November 1991 /5/ with a modified FES-22 Cochlear stimulator. CS has been successful in conditioning his muscles and standing with FES /6–8/. CS is married with two children, and is working full time.

Subject FR is a 36 year old T-10 (ASIA: A) paraplegic male. He was injured in a car accident in March 1996. He is 1.70 m tall and weights 72 kg. FR has been successful in conditioning his muscles and standing with FES. FR is a widower with two children, and is self-employed.

Subject Safety When Standing

Standing safety is achieved by using a trunk vest with shoulder straps connected to an overhead standing frame (Maine AntiGravity Systems, Portland, ME). If the subject should fall, then the suspension system will provide enough slack for a 40 degree knee buckle. But further buckling will be prevented. If necessary, a battery-operated winch can lift the subject. The standing tests can be interrupted if any unsafe condition arises or at the request of the patient due to tiredness/fatigue.

RESULTS

Lower Extremity Paralysed Muscle Conditioning

Subject CS is able to exercise his lower extremities both at home and at work using a portable conditioning system, a modified version of the implanted FES-22 system. The exercise protocol stimulates CS's right and left knee extensors and ankle plantar/dorsi flexors alternatively 4 sec on/ 4 sec off, for a total of 20 minutes. After the muscles have been conditioned, Cybex dynamometric testing in the isometric mode has shown that implanted FES stimulation to paralysed muscles has produced bilateral knee extension torque of 45–55 Nm at 30° of knee flexion and 65 Nm at 60° of knee flexion. CS is able to exercise and average of 3 days a week.

Subject FR has been able to exercise his lower extremities at home using a surface stimulator (EMS+2, Staodyn, Tampa, Florida) for 1½ year. He is conditioning his quadriceps (by femoral nerve stimulation just below the groin) and ankle dorsi flexion (by peroneal nerve stimulation) bilaterally daily for 20 minutes. As of December 1997, muscle strength test done on the Biodex dynamometer (isometric mode) indicates that surface stimulation of the right

quadriceps (femoral nerve) is capable to elicit 50 Nm of knee extension at 30° of knee flexion and 45 Nm at 45°.

Closed-Loop FES Standing

FES stimulation through the FES-22 implanted system to the motor nerves of the quadriceps and gluteal muscles has resulted in uninterrupted standing of over 60 minutes for subject CS. This has been achieved with the use of knee-angle goniometer sensors sending information to the PC computer (closed-loop control) and with the Andrews' stabilising Anterior Foot Reaction Orthosis (AFRO), which is an ankle-foot brace. With the knee goniometers sensing for early buckle, the stimulator was found to come 'ON' to correct the buckle between 3-8 % of the standing time. The rest of the stance, no lower extremity muscle activation is required to maintain the upright posture.

For the past year, subject FR is able to stand without knee bracing, with a combination of the Andrews' AFRO and closed-loop surface FES (knees are monitored by the engineer) for over 1 hour uninterrupted and typically for 30 minutes. The stimulation is applied to the femoral nerve bilaterally. Subject FR has been training is achieving the "C" posture and stand with the stimulation 'OFF' for more than 50% of the standing time.

Manual Tasks in the FES Standing Position

Subjects CS and FR are able to perform a variety of one-handed tasks including reaching for and holding at arm's length a 2.2 kg object. This is achieved while there is no activation to the lower extremity muscle. Balance is achieved by upper extremity volitional control.

Stand-Sit Transition

An additional feedback system based on accelerometers and the knee goniometers controls the stand-sit transition to provide a "soft landing". The controller limits the angular velocity of the knees flexing while subject CS is sitting down /9/.

DISCUSSION

We have demonstrated the probability of a 6 year plus, FES implant (Cochlear: Nucleus FES-22 stimulator) and its control of complex stimulation patterns for strong limb movements including knee and hip extension and ankle dorsi/plantar flexion. For prolonged safe standing (30-60 minutes), the system requires an anterior foot-ankle stabilising brace (Andrews' FRO) plus the closed-loop Cochlear FES-22 stimulating system.

We are presently investigating a new, more practical and less obtrusive sensor system to replace the knee goniometers /10/. Also, the stand-to-sit and sit-to-stand transitions are being re-designed to provide smoother motion with less upper extremity support.

With FR's approval, we plan to implant him with a new Cochlear FES implant with portable external controller. The system will make use of the improved sensor system for control of the sit-stand-sit and prolonged standing. With CS's approval, we plan to replace the partially working receiver/implant /6/, so further control of the lower extremities can be obtained.

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STABILITY AND VELOCITY IN INCOMPLETE SCI SUBJECTS GAIT

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SUMMARY

We defined two indexes describing kinematic and dynamic stability and assessed their values in the gait of five different paraparetic subjects gait. The indexes are correlated to the gait velocity to prove the close relationship between overall gate velocity and stability. Based on stability analysis and certain kinematic parameters some possible ways of increasing the average gait velocity are explained.

STATE OF THE ART

In the rehabilitation process of spinal cord injured (SCI) subjects crutches are used extensively to provide necessary forces for maintaining the upright balance and body stability. Such gait pattern is quadrupedal, because the arms with crutches are utilized as the second pair of legs. At least 4-channel functional electrical stimulation (FES) is used for the propulsion of paralyzed lower extremities in case of complete spinal cord injury[1].

Three main drawbacks of such gait are: low average velocity, energy inefficiency and insufficient propulsion forces in the direction of walking. As it is unlikely for the balance problem to be solved in the near future, the FES enabled gait will remain quadrupedal and we are therefore dealing with the problem of how to improve the existing four point gait[2].

Stability, in sense of preventing the subject from tipping over, is a crucial problem in the gait synthesis. The present FES paraplegic gait utilizes a creeping gait pattern known as crawl, which exhibits superior static/kinematic stability properties. A system can remain in a statically/kinematically stable state for an arbitrary amount of time, what results in the gait that can be arbitrary slow but the maximum velocity is limited[3]. A system is in statically/kinematically stable state if the vertical projection of center of gravity (PCOG) on the ground plane is inside the supporting area.

In faster gaits dynamic stability becomes important. The system is in a dynamically stable state when it can recover a statically/kinematically stable state without raising any of the supporting legs or placing on the ground any of the swinging legs; contrary, it is in a dynamically unstable state. The latter requires a walking mechanism to make at least one step more in a certain limited time interval, therefore the system dynamics dictates the step length and cadence and also the average gait velocity. In this case the minimum velocity is limited[4].

In this paper we discuss the mutual dependence of gait velocity and stability from biomechanical point of view.

MATERIALS AND METHODS

FES assisted gait of SCI subjects is much more complicated then a hypothetical walking machine. The gait direction and velocity *changes* almost erratically during the gait cycle. Also the foot – ground contacts are finite area surfaces and not just simple points as usually treated. Therefore we defined a relative index of kinematic stability as:

$$RKS I_1 = \frac{d(PCOG, CS)}{\frac{|d(TSE, LSE)|}{2}} \quad (1)$$

In this index it is important only the distance from PCOG to the supporting area edge in the direction of the instantaneous center of gravity (COG) velocity. Center of supporting area (CS) is the midpoint between leading supporting area edge (LSE) and trailing supporting area edge (TSE). The reference points are placed in the supporting area with respect to the instantaneous PCOG position and gait direction. d in equation 1 denotes the distance between the two points. Distance d in the numerator of the equation 1 is positive if the PCOG is behind the center of supporting area (CS) and vice versa. It is important to stress that all the above defined points but PCOG change if the instantaneous COG velocity changes what in turn also affects the stability index $RKSI_1$ [5]. The system is in kinematically stable state, if $RKSI_1 \in [-1, 1]$.

The knowledge of COG movement and the supporting area shape/size is required to determine the subject dynamic stability. The decisive factor is the maximal hypothetical breaking force, which is limited by the fact that ground reaction force (GRF) origin or center of pressure (COP) is always inside the supporting area and it always points towards COG. If the velocity v_{COG} of the system exceeds critical velocity then the system is in dynamically unstable state. We therefore define simple absolute dynamic stability index:

$$AVI = \sqrt{\frac{g}{z_{COG}(t)}} d(PCOG, LSE)(t) - v_{COG}(t) \quad (2)$$

g is acceleration of gravity and $z_{COG}(t)$ is the height of the COG above the ground level. If the index AVI is positive the system is in dynamically stable state and vice versa.

If we assume the gait is regular than the average gait velocity is kinematically defined as:

$$v = \frac{R}{t_t} \left(\frac{1 - \beta}{\beta} \right) \quad (3)$$

R is stroke pitch, which approximately equals to the step length, β is leg duty cycle, t_t denotes leg swing or transfer time and T is the gait period. The critical value of β for quadrupedal gait is 0.75 [3], which still enables the kinematically stable gait when at least three extremities are on the ground.

RESULTS

The described methods were applied to the gait of five different incomplete SCI subjects. The OPTO-TRAK (Norhtern Digital Inc., Waterloo, Ontario, Canada) motion analysis system provided necessary body segment position data which is then fed into the full dynamic model of crutch supported gait. The results are dimensions of supporting area and COG position and velocity. Calculation of kinematic and dynamic stability indexes is then trivial. The whole analysis was performed for walking on a flat, level and hard surface.

Subj.	Code	Sex	Injury	FES	Time since injury
F.G.	O1	m	C4-5	no	5 months
L.G.	O2	m	C6-7	1 ch. right	3 years
I.F.	O3	m	C5	1 ch. right	6 months
F.V.	O4	m	C6-7	2 ch. right	4.5 months
M.T.	O5	f	T4-5	2 ch. left and right	6 years

Table 1: Tested subjects

Table 1 describes some details on the tested subjects. If single FES channel is used it triggers the flexion withdrawal reflex. If two channels are used the second one stimulates the knee extensors.

Table 2 shows average, standard deviation, median, minimum and maximum values of kinematic and dynamic stability indexes. Table 3 presents mean, minimum and maximum value of kinematic parameters with significant influence on gait velocity.

Subj.	RKSI ₁					AVI[m/s]				
	mean	st. d.	med	min	max	popr	st. d.	med	min	max
O1	0.307	0.325	0.240	-0.385	1.115	2.068	0.730	1.980	0.520	3.782
O2	0.170	0.566	0.078	-0.464	6.116	1.955	0.753	1.916	0.434	4.604
O3	0.061	0.200	0.062	-0.532	0.597	1.648	0.563	1.654	0.337	4.056
O4	0.059	0.245	0.048	-0.589	0.770	1.770	0.741	1.694	0.237	3.603
O5	0.009	0.207	-0.014	-0.539	0.643	2.536	0.921	2.355	0.623	5.691

Table 2: Stability indexes

Subj.	$t_t[s]$			β			$R[m]$			$v_{COG}[m/s]$		
	mean	min	max	mean	min	max	mean	min	max	mean	min	max
O1	0.780	0.680	0.920	0.743	0.710	0.788	0.571	0.506	0.633	0.245	0.125	0.340
O2	1.243	0.760	1.780	0.667	0.597	0.731	0.548	0.470	0.633	0.182	-0.019	0.331
O3	0.759	0.600	0.920	0.790	0.752	0.829	0.353	0.290	0.385	0.137	0.018	0.254
O4	0.570	0.420	0.780	0.797	0.712	0.857	0.444	0.356	0.499	0.200	0.049	0.287
O5	1.278	0.720	2.240	0.830	0.731	0.906	0.299	0.193	0.435	0.051	-0.113	0.183

Table 3: Kinematic parameters

DISCUSSION

Our primary goal is increasing the average velocity in FES and crutch assisted gait and from this point of view we discuss the results.

The relative kinematic stability index RKSI₁ increases with increasing gait velocity, what means that subjects subconsciously compensate their body dynamics. Their COG is on average shifted backward of the center of supporting area with increased gait velocity. This COG shift is small but detected in all tested subjects. An exception to the above mentioned rule is subject O4 who was utilizing a different gait pattern as he was moving forward both crutches simultaneously.

The minimum values of RKSI₁ are never less than -1, what means that the COG is never ahead of the supporting area with regard to the instantaneous direction of walking. Contrary to the normal biped gait such kinematically unstable states obviously never occur in FES assisted gait. But in subjects O1 and O2 the maximum value RKSI₁ exceeds 1 what indicates kinematically unstable states. In such case the COG was behind the supporting area. The rather high maximum value of RKSI₁ is due to very small denominator with regard to the definition in eq. 1. In this particular moment the supporting area length in the instantaneous direction of walking was very small.

The average and minimum value of the absolute dynamic stability index AVI are positive therefore the subjects are always in dynamically stable state. So they are never forced to perform any action and they can walk arbitrary slow. The minimum value of AVI is as low as 0.2m/s. This is the minimum velocity increase required to at least occasionally slip into dynamically unstable state. But an interesting fact is that the minimum value of AVI is not at all correlated to the gait velocity.

We can deduce that kinematic stability and dynamic stability are mutually independent. Therefore the system can be at the same time dynamically stable though it is kinematically unstable and vice versa. This is the case is subjects O1 in O2, as they are according to the RKSI₁ in kinematically unstable state but according to the AVI in dynamically stable state. The average value of AVI is close to 2m/s in all tested subjects. For this amount the velocity should be increased to achieve dynamically unstable states with unchanged gait pattern and supporting area. But the next paragraphs explain why it is not possible to do so.

Stroke pitch R and leg swing time t_t are kinematic parameters directly influenced by the FES system and number of channels utilized and can be therefore changed most easily by adapting the existing stimulation patterns.

However important observation is that the leg duty cycle β is on average close to the critical value of

0.75. This means that it is no longer possible to increase the gait velocity unless β is decreased below its critical value. However this implies that two-point states are introduced in the gait. In such moments only two extremities are on the ground what implies at least kinematically unstable states. In such gait extremity duty cycles β are more than 0.5. Table 4 shows what are actual and theoretically possible velocities for kinematically/statically stable gait ($\beta \geq 3/4$) and for two-point gait consisting including also unstable states ($\beta \geq 1/2$) assuming the stroke pitch R and leg swing time t_t are unchanged.

Subj.	$v[m/s]$	$v[m/s]$	$v_t[m/s]$
		$\beta = \frac{3}{4}$	$\beta = \frac{1}{2}$
O1	0.245	0.244	0.732
O2	0.183	0.147	0.442
O3	0.138	0.155	0.465
O4	0.200	0.260	0.779
O5	0.047	0.079	0.236

Table 4: Assessed and theoretically possible velocities

It is obvious that only the gait with unstable states where $\beta < 3/4$ can result in significantly faster gait. Because kinematic and dynamic stability are mutually independent we can first try to introduce kinematically unstable states in the present FES gait which in most cases consists of kinematically and dynamically stable states. Subjects O1 and O2 demonstrate that this is possible. However this also implies a change in a gait control. In a gait consisting of only stable states then kinematics provide enough information to ensure successful and stable control. If kinematically unstable states are introduced then the control system must be able to recognize at least some basic inertial properties of the body. While if dynamically unstable states are introduced that the control system must be able to deal with full body dynamics and has to operate in real-time.

In our case the control system is SCI subject himself. He is now trained for the gait consisting of only stable states and therefore introducing any kind of unstable states would require a prolonged and new approach to gait training enabling the subjects a new type of control. The task would of course be much more simpler if in the beginning only kinematically unstable states are introduced followed by dynamically unstable states. Kinematically unstable states can already improve the gait velocity but a significant velocity increase and drop in energy consumption would result only from dynamically unstable states.

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PC SUPPORTED EIGHT CHANNEL SURFACE STIMULATOR FOR PARAPLEGIC WALKING - FIRST RESULTS

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SUMMARY

Today Functional Electrical Stimulation (FES) is used amongst others to restore hand and arm function, to restore mobility of the lower extremities, for phrenic pacing and in cardiomyoplasty. Common to all FES-applications is that they require careful set-up of stimulation parameters. To improve these tasks a PC-based software for stimulation parameter evaluation and data acquisition was written. First the described software was used to mobilise paraplegic patients in conjunction with an I2C bus controlled eight channel surface stimulator.

Electrodes were placed on each leg on m. quadriceps and m. gluteus for hip and knee extension and peroneal nerve to elicit flexion reflex. The fourth channel was used corresponding to subjects individual needs.

Stimulation patterns for stand up, walking and sit down could be easily set up and optimised by adjusting up to 128 stimulation parameters in a task specific way.

STATE OF THE ART

Since Kantrowitz demonstrated in 1963 paraplegic standing by quadriceps stimulation several groups concentrate on restoration of lower limb function by means of FES. Some researchers use implantable stimulators and electrodes or external stimulators and percutaneous electrodes while others concentrate on surface stimulation. Usage of implanted components is accompanied by surgical procedures and a stay in the hospital. The advantage is that the system is always ready for use whilst the non-invasive surface stimulation needs every day some time for donning and doffing /1/,/2/.

Most groups that concentrate on surface stimulation use four or six channel stimulators to achieve standing and stepping.

Our group developed an eight channel surface stimulator that allows in conjunction with a PC-software optimisation of a large amount of stimulation parameters to achieve smooth FES-gained movements.

MATERIAL AND METHODS

The introduced stimulation system consists of two modular designed four channel stimulators, a microprocessor system that controls the stimulators and can store different stimulation sequences for distinct tasks, a PC-interface that allows communication with stimulators internal I2C bus via serial port and finally a PC software for easy set-up of stimulation patterns (/3/,/4/).

The idea behind this system is to set-up and test stimulation patterns with the help of a PC-based user interface (UI) and then to download all parameters to the microprocessor for patients personal use.

Stimulator:

During design phase a strictly modular concept was kept (fig. 1). Each stimulation has its own microcontroller (PIC 16C72, Microchip. Inc. Arizona, USA) that takes care of the timing and data acquisition, has its own output stage and offers the possibility to check electrode impedance and to measure certain parameters of the stimulation evoked M-wave. A complete stimulation burst like shown in fig. 2 can be loaded via Inter-Integrated circuit (I2C) bus into the microcontroller. Triggering the channel by either pressing a switch (crutch mounted) or sending the start command via I2C bus launches the shown stimulation burst. In addition various modes for continuous stimulation can be programmed. A start of the continuous stimulation after the burst is important for standing up. Continuous stimulation before and after the burst is necessary to set up proper gait patterns and switching of the continuous stimulation after the burst is used for sitting down.

Stimulation parameters can be set independently for each of the three burst regions (fig. 2) as well as for the continuous mode. Biphasic constant voltage impulses with a peak to peak voltage up to 160V and a pulse width up to 1ms+1ms (with minor restrictions) can be delivered with a maximum frequency of 80Hz.

M-wave parameters and electrode impedance are measured during the second part of the burst and are available after the end of the third part.

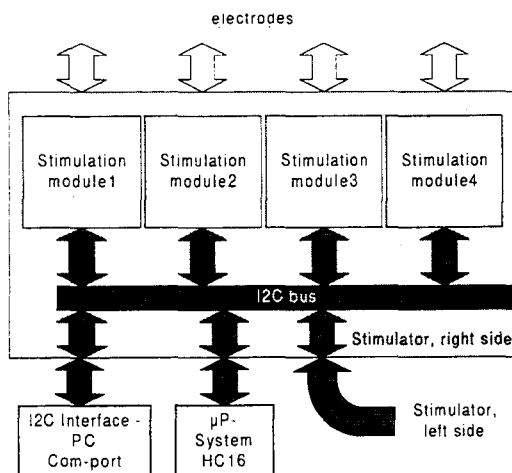


Fig 1: Schematic of one part of the eight channel stimulator

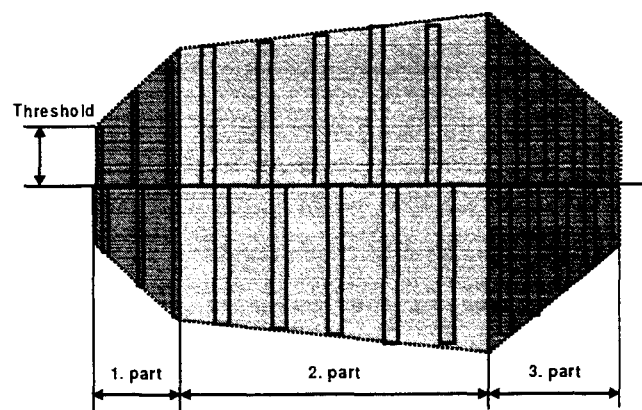


Fig. 2: Three-parted stimulation burst

Microprocessor module

The used microprocessor module is based on Motorola's 68HC16 (Motorola Inc. Phoenix, Arizona, USA). If the connection to the PC is terminated the microprocessor overtakes the I2C bus master function and handles communication with all eight stimulation modules. Stimulation patterns are stored in nonvolatile RAM and transferred to the modules according to the chosen program like standing up, walking and sitting down. A display informs about the current stimulation situation while buttons and a panel coder allow change of stimulation amplitude and several basic parameters. This module is also responsible for collection and storing of M-wave parameters and checking of electrode impedance. All stored data can be transferred via I2C bus to the PC.

PC-software

To create a simple to handle user interface (UI) we decided to use a personal computer as major input device because only a computer screen offers enough flexibility for the UI design.

We chose Inprise Delphi (Inprise Corp. Scotts Valley, CA, USA) as development environment to create a 'Microsoft -Windows' compatible graphical user interface (most PC-users are used to it). Fig. 3 shows a screen shot during set-up of a walking pattern.

The next important goal is the proper handling of the data. We decided to use a standardised database for data management which causes a higher programming effort (although Delphi supports very strongly database management) but on the other hand data can be scanned, sorted, queried and analysed with any standard database software. Expanding of the data structure can easily be done by adding fields or tables to the initial database without effecting the previous structure and consequently preserving file compatibility.

The described system (fig. 4) was used by two male subjects. Both are level T6 paraplegics, use electrical stimulation for muscle training regular for four years and are involved in a training's program for FES walking with six channel stimulators for 3 years.

Stimulation was applied with standard skin surface electrodes. First we used three channels each leg activating m. quadriceps, m. gluteus maximus and withdrawal reflex. Later the fourth channel was applied according to subjects individual needs.

Since this was the first application of the described system on human subjects the FES outcome was evaluated using patient's experience with FES walking and by consulting the medical staff.

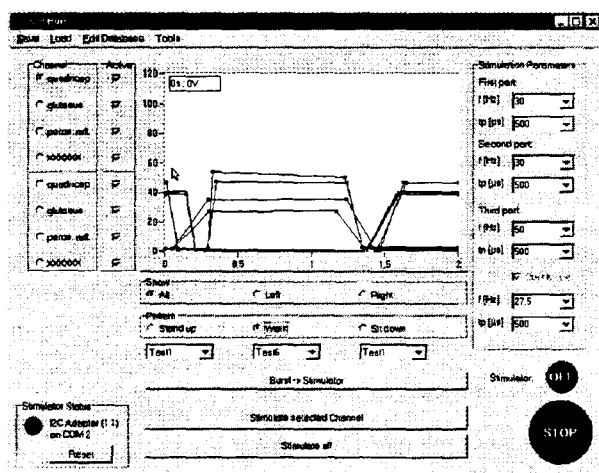


Fig. 3: Screen shot during set-up of walking pattern

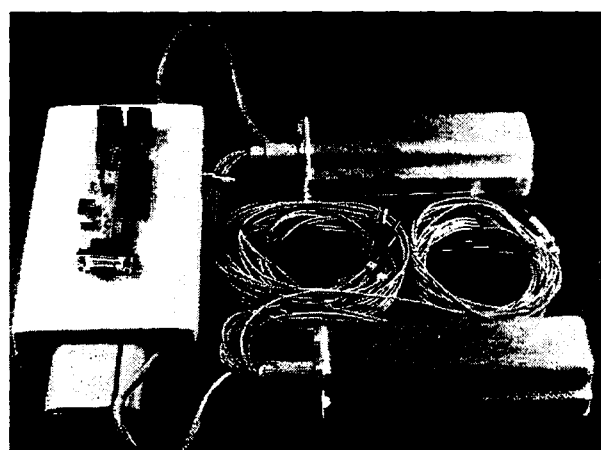


Fig.4: 8 channel stimulator (2 four channel stimulation modules, electrode leads, battery and microprocessor housing, I2C interface

RESULTS

The first sessions with the patients were used to improve the handling of the system. After all hard- and software changes were made the system proofed to be reliable and useful for paraplegic walking. In each of the following sessions we tried to optimise the stimulation parameters for standing up, walker supported walking and sitting down. For each task and channel 16 parameters can be set. That means that 128 parameters can be trimmed to fulfil one of the mentioned tasks. The UI proved to be very useful in this environment because parameters could be optimised in an efficient way and very short time. The first ideas during parameter optimisation were the usage of a higher stimulation frequency during begin of the

movement (1. phase), typically 50Hz and then switching back to less fatiguing lower frequencies, typically 30Hz and optimisation of the duration of 1. phase and 3. phase to achieve smooth movements. Impulse duration was usually set to 0.5ms+0.5ms.

Patients and medical staff agreed that smoother movements and less exhausting walking could be achieved.

Patient 1 showed external hip rotation during stand up phase and also some hip abduction during swing phase. To compensate for external hip rotation and abduction the fourth channel was used to stimulate the adductors of the thigh. After a trial phase and parameter optimisation standing up with nearly constant knee distance and stepping with significant less external rotation of the hips could be achieved.

In patient 2 we tried to improve hip stability by using the fourth channel for stimulation of the longissimus muscles. After a short training's phase the patient showed a more upright posture during standing and walking.

DISCUSSION

The new eight channel surface stimulator allows optimisation of up to 128 parameters for one stimulation sequence. A PC based software proved to be very useful for visual control of the optimisation process. First tests showed that an optimised parameter set helps to gain both smoother and better coordinated movements. The availability of a fourth channel for each leg allows to overcome patient specific weak points in movement. In the future standardised procedures how to apply the additional channel in case of specific problems have to be worked out as well as stimulation parameter optimisation procedures.

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GAIT IDENTIFICATION AND RECOGNITION SENSOR

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SUMMARY

One of the major obstacles in developing reliable walking neural prostheses is poor performance of the sensors which are used for gait phases identification. Improper functioning of these sensors causes wrong stimulation pattern selection and wrong stimulation sequencing of the walking neural prostheses. These malfunctions often cause unstable walking patterns in patients that are using the prostheses. Sensors that are commonly used for gait phase identification are: foot switches, force sensitive resistors (FSRs), accelerometers, pendulum resistors and goniometers. Since none of these sensors is capable of identifying gait phases with accuracy greater than 95 %, a decision was made to develop more reliable gait identification sensor.

A new gate identification sensor, which consisted of three FSRs, an inclinometer and a rule-based observer, has been proposed. Every 50 ms from the FSRs and the inclinometer readings the proposed sensor identified one of the following gait phases: heel off, swing phase, heel strike and mid stance. The experiments conducted with able-bodied and disable subjects showed that the proposed sensory system detected the above gait phases with reliability greater than 99 %. This foot sensor was capable of distinguishing walking sequences from weight shifting during standing, and it did not give false gait annunciation when the instrumented foot was sliding during standing.

Our future research is aimed at further improving the foot sensor packaging, and sensor's robustness to different environmental conditions and shocks.

STATE OF THE ART

In order to design a walking neural prosthesis, which can automatically detect gate phases and accordingly select stimulation sequences, one has to have a reliable gate recognition sensor. One of the first foot sensors proposed was a heel switch [1] which was used to detect the heel strike during normal gate. Advanced walking neural prostheses require information about other gate phases in addition to heel strike. Hence, the heel switch is not an appropriate sensor for this application. Second approach suggests that at least 3 FSRs, placed in a shoe sole, can be used to detect the most important gate phases [2, 3]. Experiments conducted in our laboratory clearly showed that the FSRs alone cannot reliably detect gate phases. This system has a number of problems, out of which identifying weight shifting during standing as walking pattern is probably the most severe one. In order to resolve this problem some researchers proposed using goniometers, in conjunction with FSRs,

which are attached to hip, knee or ankle joints [4, 5]. Experiments conducted in our laboratory demonstrated that goniometers and FSRs together do not provide reliable gait identification. In particular, this sensor configuration generated wrong gait identification when subjects were making short brakes or rests during walking. Since none of the existing foot sensors is capable of identifying gait phases with sufficient accuracy, a decision was made to develop more reliable foot sensor.

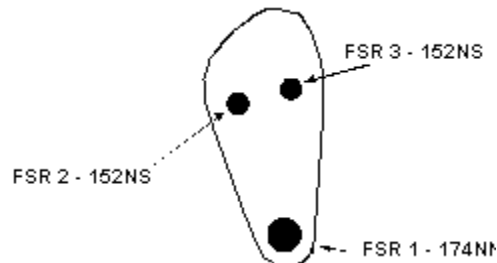


Figure 1: Position of the FSR's in the shoe sole

MATERIALS AND METHODS

The proposed foot sensor consisted of three FSRs, an inclinometer and a rule-based observer. One 174NN and two 152NS FSRs, manufactured by Interlink Electronics Inc. [6], were used to measure forces generated by subject's heel and metatarsal bones during walking. The FSRs were placed in the shoe sole as indicated in Figure 1. Time response of the FSRs was 2 msec.

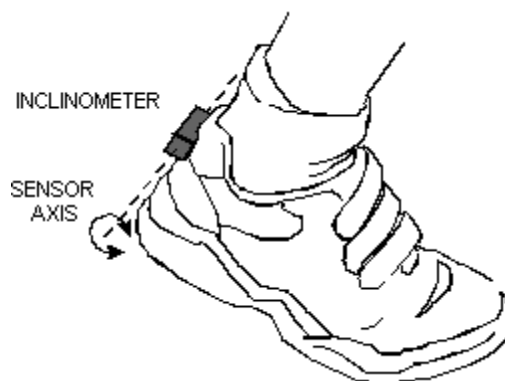


Figure 2: Position of the inclinometer

In house developed inclinometer was used to measure relative position of the heel with respect to the walking surface. The inclinometer consisted of a gyro sensor ENC-05A, manufactured by Murata [7] (see Figure 2), and an integrator which calculated the position of the heel from the raw gyro data. The gyro was attached to the shoe heel and its sensory axis was parallel to the walking surface (see Figure 2). The time response of the inclinometer (combined time response of the gyro and the integrator) was 30 msec.

The rule-based observer was designed to identify mid stance, heel off, swing phase and heel strike gate phases, and was implemented using Hitachi SH7032 evaluation board. The proposed observer functioned as follows. Once the sensor was turned on, a subject instrumented with the sensor had to stand still for one second before it

made the first step. During this period of time the observer automatically reset FSRs' and inclinometer readings and set them to initial values (FSRs = ON and inclinometer angle = 0 deg). After the reset, the rule-based observer shifted into gate recondition mode described in Figure 3. Note, except for mid stance, all other gate phases could be identified only if the previous gate phase was successfully identified. This feature was introduced in order to prevent false gate phase identification. In addition the observer's algorithm was enhanced with an adaptive routine which compensated for FSRs' drifts. Time constant of this algorithm was 11 sec.

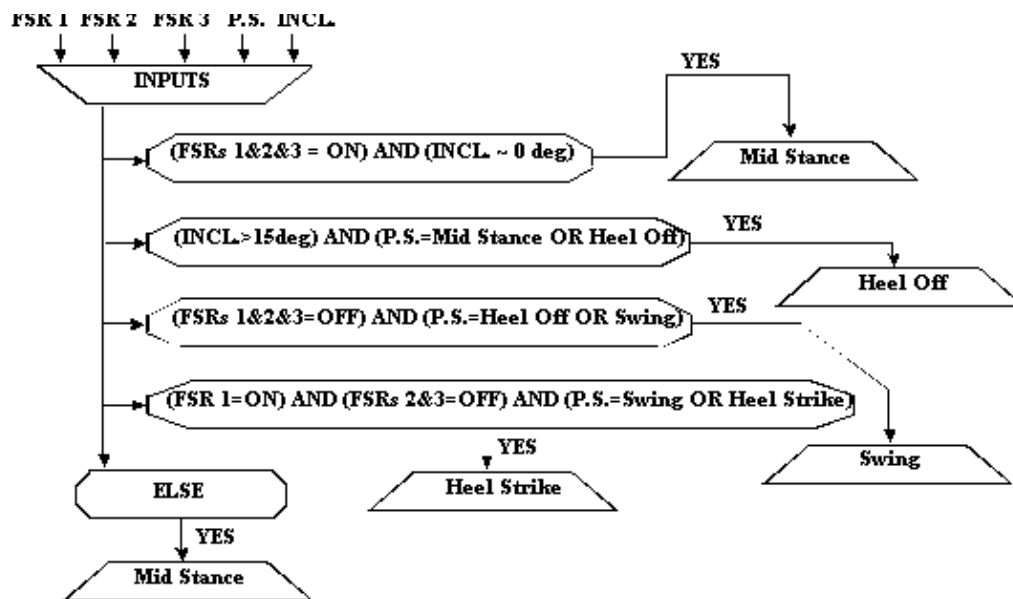


Figure 3: Observer's gate recognition algorithm (INCL. represents the inclinometer angle in [deg] and P.S. represents the previous state of the sensor)

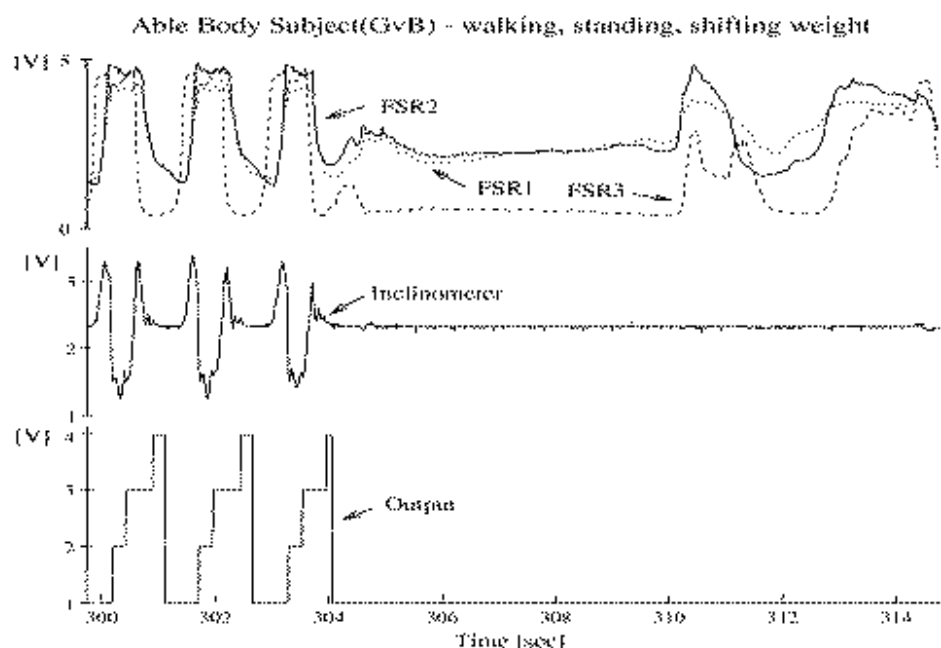


Figure 4: Gait pattern recognition - intermittent walking of an able body subject

RESULTS

Preliminary experiments performed with 10 able-bodied subjects and 10 disabled subjects showed that the proposed foot sensor can identify mid stance, heel off, swing phase and heel strike with reliability greater than 99 %. The proposed foot sensor was capable of distinguishing walking sequences from weight shifting during standing, and it did not give false gait annunciation when the instrumented foot was sliding during standing. It is important to mention that subjects that were trained to use the sensor achieved better results than the subjects which used the sensor for the first time. Representative experimental results obtained with the proposed sensor are given in Figure 4.

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APPLICATIONS OF GYROSCOPIC ANGULAR VELOCITY SENSORS IN FES SYSTEMS

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SUMMARY

Goniometers, accelerometers and footswitches have for many years been recognised as useful sensors in FES systems where some aspects of gait are being measured. However, each has its own drawback –specifically, goniometers are often fragile, require differentiation when measuring velocity and can be expensive, accelerometers are sensitive to gravity and do not measure rotation, and use of footswitches can lead to the incorrect detection of gait events e.g. beginning of stance phase. More recently industry has been using a newer kind of sensor, measuring angular velocity, which utilises a piezoelectric gyroscopic effect to provide accurate measurement. Other studies, with similar gyroscopic sensors, have shown that when measuring gait the results compared exceptionally well with an optical marker (Vicon™) system. In this study, the use of such a gyroscopic sensor in FES systems is being examined. To date, a single sensor has been used to detect the stance and swing phases of gait in real time (providing a sensor that could be used in a simple system to reduce foot-drop), and three sensors have been used for the measurement of joint angles during gait. Results have been favourable, demonstrating that the sensor is worthy of further investigation.

STATE OF THE ART

The gyroscopic sensor offers a number of considerable advantages over other types, due to both its construction and performance. Firstly, it is small, lightweight and easily attached to the leg. It also contains no moving parts, and is therefore very robust. Secondly, due to the employment of the Coriolis force (generated when a rotational velocity is applied to an oscillating body) a rapid response (up to 50 Hz) and high sensitivity (virtually down to 0 Hz or DC) are obtained. The sensor directly measures rotational velocity, and is thus ideally suited to the movement of limb segments (accelerometers measure linearly). Finally, sensor position upon the limb segment is not as critical as that for goniometers, and donning/doffing is more straightforward. The use of gyroscopic sensors for the measurement of gait has been compared favourably with an optical marker (Vicon™) system (correlation coefficient 0.995 [1]).

Accelerometers and tilt sensors have previously been assessed as sensors to reliably detect gait events, as part of a system to correct foot-drop [2,3]. Whilst assessments have shown that these sensors may offer some improvement over foot-switches, the ease with which the gyroscopic sensor can measure both temporal and spatial information may allow it to offer optimum accuracy.

MATERIALS AND METHODS

The current system comprises of three sensors (muRata ENC-05E), a three channel instrumentation amplifier and a PC (Pentium 90) containing a multi-channel data acquisition card, sampling each channel at 100 samples/second. Currently, software has been developed to a) detect the swing and stance phases of gait using one sensor, and b) calculate lower limb joint angles during gait using all three sensors. Figure 1 shows a block diagram for the current system.

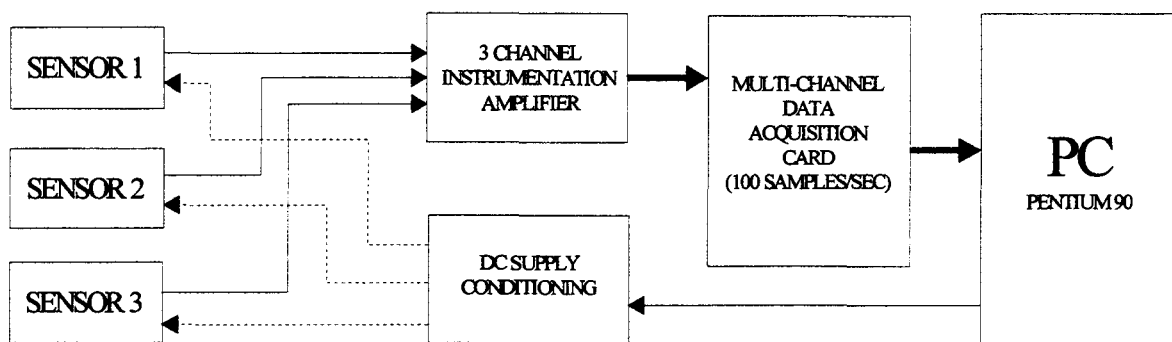


Figure 1 Current System Block Diagram

Gait Event Detection

By placing one sensor on the foot, just above the metatarsals, it has been shown that sufficient information is produced by the sensor to allow the detection of heel-contact and toe-off in real time (to date with able bodied subjects only), to provide a simple system to reduce foot-drop. Detection is achieved using a syntactic algorithm, which identifies certain recurrent trends in the gait cycle. Figure 2 shows the angular velocity measured over two strides for an able-bodied subject, and the vertical loading of a force platform (the y-axis shows a measured voltage which is proportional to both the angular velocity or the vertical load from one foot).

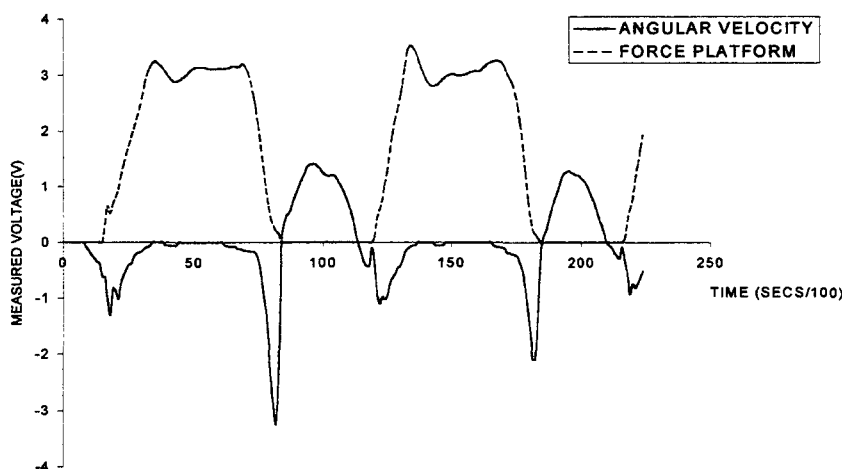


Figure 2 Angular Velocity and Force Platform Data during Two Strides

In Figure 2 the angular velocity data shows that within each gait cycle, two negative peaks occur after a zero crossing. This is followed by a single positive peak, which the detection algorithm detects first. After this a zero crossing from positive to negative identifies heel-contact; later a second zero crossing in the opposite direction identifies toe-off. A force platform instrumentation response delay of approximately 50ms exists (at 1Hz).

Gait Analysis

In order to measure joint angles of the lower limbs during gait, three sensors are required for each limb segment (thigh, shank and foot). Since it is angular velocity that is measured, accurate positioning along each segment is not required; it is only the correct orientation of the sensor that must be adhered to.

Initial studies involving integration of the sensor output showed that a small variation existed between measurement in one direction and the other, due to hysteresis of the velocity measurement. With the sensor moving backwards and forwards between two fixed points, it was noted that a constant drift occurred in the displacement data. Although this drift remained constant through any number of oscillations, the error would change when the sensor was subjected to an abnormally high level of acceleration (e.g. a direct collision with a stationary object). This would result in a new, random drift factor. However, since the data obtained from gait analysis was periodic, it was possible to make use of this in an algorithm and correct the drift. By summing each data sample over a complete gait cycle (before integration), it was possible to determine the amount of drift that was occurring (e.g. if the drift factor was zero, the sum of data samples would also be zero). This total was then divided by the number of samples within that cycle and finally subtracted from each sample. The procedure is identical (in the velocity domain) to subtracting correspondingly greater and greater values in the displacement domain.

In order to provide joint angles, the difference in data from sensors either side of a particular joint is calculated (after integration). Thus ankle joint angles are produced from the difference in the shank sensor's data and the foot sensor's data, knee joint angles from the thigh sensor and the shank sensor, and hip joint angles from the thigh sensor only (this assumes that the trunk remains vertical).

RESULTS

Gait Event Detection

Figure 3 shows the measured angular velocity and the vertical loading of a force platform (as in figure 2), along with the algorithm's prediction for two strides (again, y-axis voltages are proportional to the angular velocity and force platform load). It can be seen that, with 5V representing stance phase and 0V representing swing phase, there is a reasonable correlation between the algorithm's prediction and the loading/unloading of the force platform.

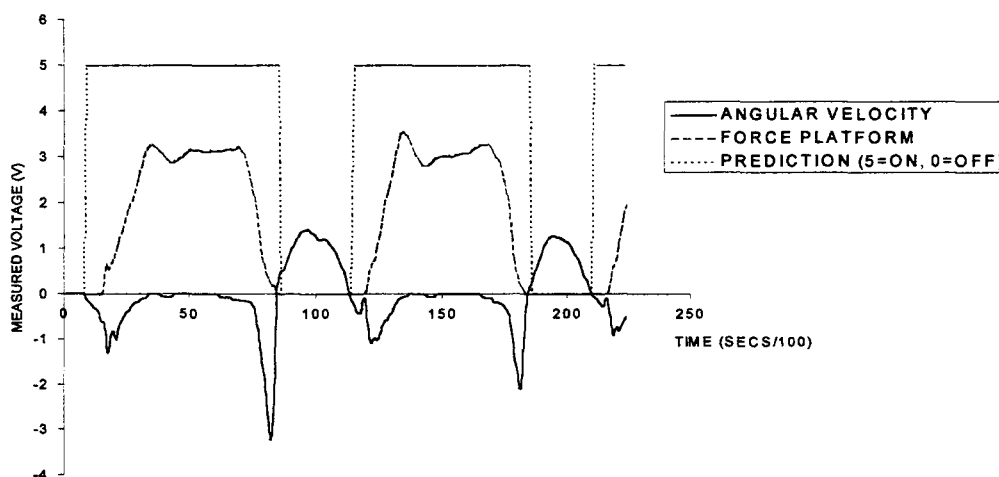


Figure 3 Angular Velocity, Force Platform Data and Algorithm Prediction during Two Strides

Although, the system has not yet been tested on hemiplegics, and more work is required to find the optimum time for stimulation on/off times, these results show that the gyroscopic sensor may offer considerable potential for use in a foot-drop correction FES system.

Gait Analysis

A number of gait trials were performed, with measurements made both by the gyroscopic sensor system and a MacReflex kinematic system (sampling at 60 samples/second). Empirical comparisons have shown a good correlation between the two measurements, with a greater level of information being captured by the gyroscopic sensor system. This was due to both its higher sampling rate and the fact that the kinematic data is often passed through a low-pass filter, which can remove some required information. Figure 4 shows measured joint angles of the thigh, knee and ankle during two strides of an able-bodied subject (angles shown in the y-axis are relative only).

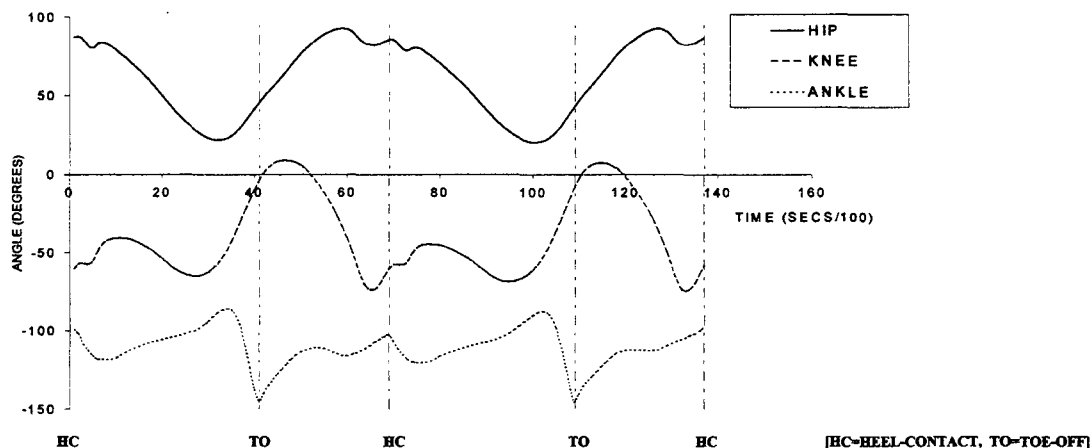


Figure 4 Joint Angles of the Thigh, Knee and Ankle during Two Strides

DISCUSSION

The success of these applications demonstrates the potential of the gyroscopic sensor to become an extremely useful tool as a sensor for FES systems. However, the gait event detection system now requires further tests to ensure that the algorithm maintains reliability when used with more varying gait styles –particularly pathological gait; similarly the gait analysis system requires further tests to ensure its validity is maintained.

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USING NEURAL NETWORK TO GENERATE OPTIMUM FES GAIT CONTROLLERS

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SUMMARY

In functional electrical stimulation (FES) systems for restoring walking in spinal cord injured individuals hand switches are the preferred method for controlling stimulation timing. Neural networks have been used to 'clone' this expertise. A simple three-layer neural network has been used to replace the switch. Twenty-two 'virtual' kinematic sensors and ten physical force sensors were used to generate all the sensor combinations for the controller and the optimum sensor set was found for different individuals. The sensor set comprising three sensors showed a good performance. Each individual has an optimum sensor set pattern. One or two key sensors dominated the optimum sensor sets, it showed the importance of these sensors for each subject. After a few months, the system was still very robust and provided an accuracy of more than 90%. The accuracy of these controllers was more favourable than the traditional heel switch controller.

STATE OF THE ART

In Functional Electrical Stimulation(FES) control systems, artificial intelligence(AI) has been used to produce feedback controllers to assist paraplegic walking /1/. For FES systems, where a hand switch is used to trigger the stimulation, the user through practice becomes an 'expert' in controlling the timing of stimulation. It is possible to use different methods to 'clone' this expertise using either 'hand-crafted' rules or AI. Using AI an optimum robust controller can be generated automatically. AI systems such as Inductive learning (IL) /2/ or artificial neural networks (ANN) /3/ have been used to produce control models for FES systems to replace hand or heel switches. A simple three-layer ANN model can be used to generate a good controller /4/.

Sensors which are used to provide information for the controller range in complexity from simple heel or hand switches to goniometers or accelerometers /5/. There are two basic problems connected with the selection of sensors: the type of sensor to be used and the optimum location of the sensor on the limb. The choice of sensors has been based on the availability of actual sensing devices and the experts understanding on the sensor's optimum location. A large number of kinematic signals can be simulated from 3D data collected from a motion analysis system. These 'virtual' sensors (goniometers, gyroscopes, inclinometers and accelerometers) have been simulated and have shown a good correlation with their physical counterparts /5/.

We have used a three-layer neural network with continuous differentiable function to generate optimum FES gait controllers. The sensor sets comprised of twenty-two 'virtual' kinematic sensors and ten physical sensors recording crutch forces and foot floor contacts were used. The aim of this paper is to determine the optimum sensor set pattern in different individuals and to evaluate the robustness of the optimum controller over time.

MATERIALS AND METHODS

The gait of two incomplete spinal cord subjects(subject A and subject B) was used to design the optimum neural network controller. Their principle gait deviation was drop foot and a single channel of stimulation on the peroneal nerve was used to stimulate the flexion withdrawal response during walking. They both were experienced FES users and used a hand switch to control the timing of the stimulation. They used a pair of crutches to assist walking.

Thirty-two sensors with 'virtual' kinematic sensors and force sensors were used to develop the optimum controller. Twenty-two 'virtual' kinematic sensors were simulated from 3D data collected from an infra-red motion analysis system(VICON). These sensors comprised of *goniometers* on hip and knee joints, *accelerometers*, *inclinometers* and *gyroscope* on thigh, shank and crutch segments. All signals were filtered by a 4th order anti-causal butterworth filter and data was sampled at 50 Hz.

Since the 'virtual' sensor could not simulate force and pressure signals, physical sensors were used. Ten physical sensors were used and synchronised with the virtual sensor set, which comprised of four force sensitive resistors(FSR) (placed underneath the heel, big toe, head of the first metatarsal and head of the fifth metatarsal) and strain gauges (mounted on the crutch tip for measuring the axial force). Data was sampled at 50 Hz with a 12 bit A/D converter.

An ANN program was designed which used all the sensor combinations and constructed a three-layer(input-hidden-output) neural network model for each combination. It has been shown that 5 hidden nodes are adequate to generate a good gait controller [4]. Combinations of up to three sensors were evaluated and optimum sensor set pattern was analysed for each subject.

The data were collected from the incomplete spinal cord injured subjects walking in a straight line at their preferred speed. The optimum sensor sets were found from the first experiment session and compared the performance with the simple heel switch control system. In order to test the robustness of the system, the same experimental procedure was repeated after four and six months for subject A and after two and four months for subject B. The ANN models from the first session were used to test the controllers' performance over a period of time.

RESULTS

The three-sensor combinations were used to evaluate the performance of ANN controller and the optimum sensor set pattern. The results showed that neural networks with a small number of sensors could produce a controller with a higher degree of accuracy than a traditional heel switch controller (fig 1). Different individuals required different optimum sensor sets to adapt to their walking gait.

Table 1 shows the 10 best sensor combinations for subject A and B. For subject A, the best sensor set comprised of a strain gauge on right crutch(S1), an FSR under right heel(S6) and a goniometer on right hip(S11). The optimum sensor sets were dominated by the FSR under right heel(S6). The average accuracy of these 10 sensor sets was 96% and the accuracy of the simple heel switch system was 82%. The top five sensor sets were used to evaluate the robustness of the system. After four months and six months, the average accuracy of these five sensor sets was 91% and 91% respectively and the accuracy of the simple heel switch system was 85% and 75% respectively (fig 1a).

For subject B, the best sensor set comprised of an inclinometer(S23) and a gyroscope(S29) on the anterior aspect of right shank and an FSR under right toe(S4). The optimum sensor sets were dominated by the FSR under right toe(S4) and the inclinometer on the anterior aspect of right shank(S23) (table 1). The average accuracy of these 10 sensor sets was 97% and the accuracy of the simple heel switch system was 75%. The top five sensor sets were used to evaluate the robustness of the system. After two months and four months, the average accuracy of these five sensor sets was 94% and 92% respectively and the

accuracy of the simple heel switch system was 82% and 71% respectively(fig 1b). The ANN controller using the optimum sensors had a higher accuracy than simple heel switch system and the performance can be maintained for a long period of time with accuracy more than 90% after few months.

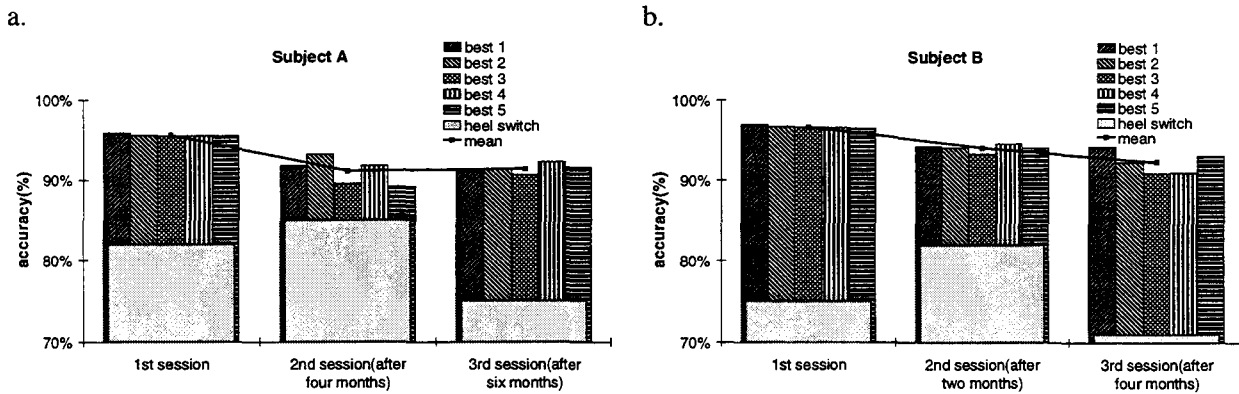


Figure 1 : Comparison between the simple heel switch system and the optimum sensor sets derived from the ANN for subject A and subject B. The 5 best sensor sets and their means was plotted for the first experiment session and another two sessions after few months. The accuracy of heel switch system is plotted for comparison.

		SG				FSR								goniometer				accelerometer				inclinometer				gyroscope							
Subject A		RC	LC	RM	RO	RL	RH	LM	LO	LL	LH	RH	LH	RK	LK	RT	LT	RS	LS	RC	LC	RT	LT	RS	LS	RC	LC	RT	LT	RS	LS	RC	LC
MODEL	ACCURACY(%)	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12	S13	S14	S15	S16	S17	S18	S19	S20	S21	S22	S23	S24	S25	S26	S27	S28	S29	S30	S31	S32
BEST 1	95.84%	###					###								###																		
BEST 2	95.61%					###	###								###																		
BEST 3	95.55%	###					###																			###							
BEST 4	95.53%	###					###															###											
BEST 5	95.51%					###	###																			###							
BEST 6	95.49%					###	###																###										
BEST 7	95.41%					###	###							###						###													
BEST 8	95.39%	###					###										###																
BEST 9	95.39%						###							###																			
BEST 10	95.36%						###																###										
Subject B		RC	LC	RM	RO	RL	RH	LM	LO	LL	LH	RH	LH	RK	LK	RT	LT	RS	LS	RC	LC	RT	LT	RS	LS	RC	LC	RT	LT	RS	LS	RC	LC
MODEL	ACCURACY(%)	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11	S12	S13	S14	S15	S16	S17	S18	S19	S20	S21	S22	S23	S24	S25	S26	S27	S28	S29	S30	S31	S32
BEST 1	96.99%					###	###																										
BEST 2	96.75%					###	###										###							###								###	
BEST 3	96.63%					###	###								###	###									###								
BEST 4	96.59%					###	###																		###		###						
BEST 5	96.55%					###	###							###	###										###		###						
BEST 6	96.51%					###	###			###															###								
BEST 7	96.43%					###	###							###											###								
BEST 8	96.43%					###	###															###			###								
BEST 9	96.39%					###	###																		###								
BEST 10	96.35%					###	###																		###								

Sensor are coded by two characters, X and Y (XY)
X: R= right Y: C= crutch M= medial L= lateral T= thigh
L= left O= toe H= heel S= shank

Table 1: The best 10 optimum three-sensor sets for subject A and subject B. The symbol '###' labels which sensors were used in the corresponding sensor set. The shaded areas show the dominant sensor for each subject.

DISCUSSION

Ideally, in order to select an optimum sensor set a large number of sensors(different sensor types and different sensor positions) should be used at the same time. More complex sensors and larger sensor sets have been developed for FES control, like an integrated system using two accelerometers and a rate gyroscope/6/. With the technique of generating virtual sensors, any proposed sensor combination can be tested prior to implementation. Thirty-two sensors comprised of both virtual kinematic sensors and physical force sensors were chosen to generate all the possible sensor combinations for the controller. The types of sensors consist of strain gauge, FSR, goniometer, accelerometer, inclinometer and gyroscope, and covered all the lower limb segments and crutches.

In recent years artificial intelligence techniques have been used to detect subject intention for automatic FES control, such as Inductive Learning and Artificial Logic Networks. We have developed a FES control system using a three-layer neural network with five hidden nodes. This simple structure produced good controllers giving an accuracy of 96% and 97% for subject A and subject B respectively. After few months, the system was still very robust, it provided an accuracy of 91% and 92% for subject A and subject B. The accuracy of these controllers was more favourable than the traditional heel switch.

Different subjects may have different optimum sensor sets depending on their lesion level, their style of gait and the walking aids used. Each individual has an optimum sensor set pattern. One or two key sensors dominated the optimum sensor sets, it showed the importance of these sensors for each subject. For implementation one would need to develop controllers suited to that particular individual. Using this system, controllers can be developed automatically and the optimum sensor set could be found for any subject.

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AN AUTOMATIC ON-LINE LEARNING NMES SYSTEM FOR GAIT SWING RESTORATION

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SUMMARY

Control systems for gait restoration in spinal cord injured (SCI) subjects must be closed-loop, adaptive, and must conform to each subject's needs. Toward these ends, Sepulveda *et al.* /1/2/ recently developed an artificial neural system which was useful but relied on human intervention for activation of on-line learning. This work presents an updated, automatic strategy which was designed to control gait swing with neural controller adaptation taking place both off-line and on-line. The automatic on-line scheme compared angular data generated by means of NeuroMuscular Electrical Stimulation (NMES) with data from a normal human being. Low correlation coefficients between NMES-generated and normal trajectories lead to *punishment* of the neural controller. High correlation coefficients resulted in neural controller *reward*. The automatic scheme was found to work better than human-activated on-line learning only when *punishment* needed to be applied.

STATE OF THE ART

Many attempts have been made to restore lost motor function since the work of Liberson in 1961 /3/. Significant work has been done by exploring the withdrawal reflex elicited by stimulating the common peroneal nerve /4/5/6/. Hybrid systems have been produced as well /6/7/8/9/. With regard to control issues, open loop /10/ and closed-loop systems /11/12/13/14/ have been produced - preference being currently given to the latter, closed-loop approach. Some systems have included stimulation controlled by biological signal triggers /15/ though most devices use artificial sensors such as force transducers and electrogoniometers. However, in spite of all attempts to date, progress towards restoration of locomotion has been slow. Control difficulties arise from the neuro-musculo-skeletal system's high non-linearity and time-variance. In addition, suitable modeling of human locomotion, including neuromuscular and skeletal elements, remains an illusion /16/. To deal with this situation, control schemes should explore the use of fuzzy logic and/or artificial neural networks. In light of this, the present work demonstrates the use of simple artificial neural networks for control of reciprocal gait by means of NMES. The system consisted of a two-channel stimulation device controlled by a computer-based neural network. Two electrogoniometers were used for gathering feedback data from two leg joints. The adaptive scheme included off-line and on-line learning. On-line learning consisted of positive and negative reinforcement activated both by a human operator in a clinical setting, and by an automatic algorithm in simulation mode.

METHODS

A three-layer artificial neural network was used for adaptive control of gait swing generated by neuromuscular electrical stimulation (NMES) in a spinal cord injured subject. The subject from whom clinical data were obtained was a 32 year old male with a Brown Sequard lesion at the C5/C6 level (Frankel grade D). Two stimulation channels were used: 1 - left femoral nerve; 2 - left common peroneal nerve. In the clinical tests, two Penny&Giles flexible goniometers were used for monitoring left knee and ankle flexion/extension angles, respectively. Network inputs consisted of knee and ankle goniometer signals. Output values were proportional to changes in the NMES Pulse Width (PW) applied to the femoral and common peroneal nerves, respectively. The artificial neural controller was based on an Operator Model /2/ (Figure 1). As such, an artificial neural network was trained to

substitute an expert human operator who was previously responsible for making changes in stimulation parameters based on the observed motion.

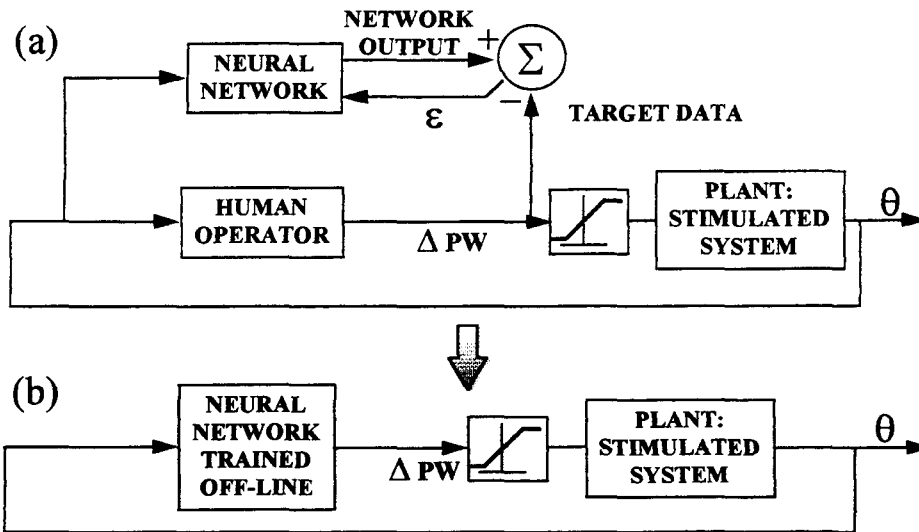


Figure 1 - Operator modeling with an artificial neural network trained off-line. (a) The human operator made changes on the pulse width (PW) based on the angular data generated by means of NMES. Then, an artificial neural network was trained with data concerning the recorded angles and the decisions made by the operator. (b) Once the neural network was trained to 'mimic' the operator, it took charge of stimulation parameter control.

On-line learning was activated in automatic mode (Figure 2). When the generated step correlated well with normal trajectories, *reward* was applied: an enhanced supervised backpropagation [2] scheme was executed with desired outputs corresponding to leaving PW values unchanged. However, when the generated angles did not correlate well with normal trajectories, *punishment* was applied. Correlation coefficients were calculated by comparing measured angles with angular data from an average normal male. For testing purposes thus far, PW changes produced by the on-line learning scheme were compared to those generated by a neural network trained off-line only.

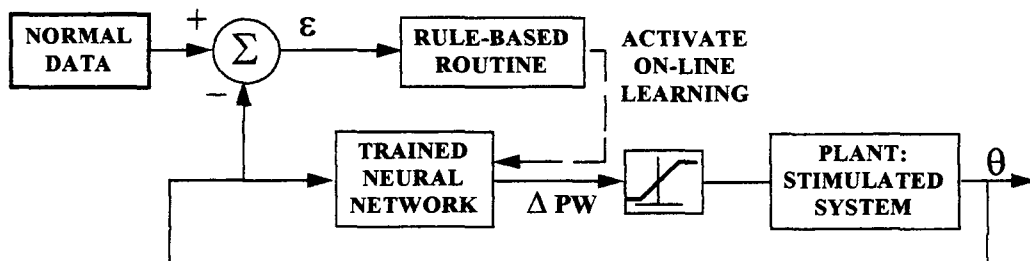


Figure 2 - Automatic on-line learning scheme. Generated trajectories were compared to data from a normal male [17] by means of correlation coefficient calculations. Whenever coefficients were low, *punishment* was applied to network, whereas *reward* was applied when correlation values were relatively high.

RESULTS AND DISCUSSION

While a few steps are generated by means of NMES, there is a combination of PW values which will lead to an almost ideal movement pattern. These ideal values change every few steps (20 steps are usually enough to require different ideal values). However, the PW values set up by the controller (be it

human or artificial) are rarely ever equal to ideal values. Ideal values for a given range of steps can be obtained in a clinical trial. Later, using the clinical data in a computer simulation, estimates can be made with regard to the quality of the PW changes made by the controller before a step is taken. The idea is to compare the absolute distance between updated and ideal PW values based on data from the latest step. This distance, or deviation, will decrease if the controller makes the right decision. Below, (Table 1) there is a comparison between PW deviation changes (from ideal values) obtained clinically using human-activated on-line adaptation, and in simulation mode using the automatic scheme shown in Figure 2 above. The results are average values obtained from an eight-step sequence.

ON-LINE SCHEME	PUNISHMENT $\Delta dev $		REWARD $\Delta dev $	
	Channel 1 (μs)	Channel 2 (μs)	Channel 1 (μs)	Channel 2 (μs)
Human-Activated	-496	43	35	-65
Automatic	-476	-12	210	95

Table 1 - Average changes in PW deviation values, $\Delta|dev|$, for *punishment* and *reward*. Negative values denote a deviation reduction with respect to ideal PW values. This means that the predicted PW changes would bring the applied PW closer to ideal values. Positive values indicate withdrawal from ideal PW values, and, thus, performance worsening.

As can be seen in Table 1, when *punishment* was applied, the use of both human-activated and automatic on-line learning schemes lead to a marked reduction in deviation values for channel 1 (as evidenced by the large negative values in $\Delta|dev|$). For channel 2, the automatic scheme generated a small deviation reduction, whereas use of the human-induced scheme lead to a slight deviation increase. Thus, when *punishment* was applied, the automatic system behaved at least as well as the human-activated scheme. On the other hand, when *reward* was applied, the automatic system's performance was markedly worse than that of the human-activated scheme for channels 1 and 2.

CONCLUSION

According to tests, the automatic on-line learning strategy presented here is an improvement over the original, human-activated system. The strategy is promising and should soon be submitted to clinical tests for a further evaluation.

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Influence of acute physical exercise on twitch response elicited by stimulation of skeletal muscles in man.

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SUMMARY

In sport and medicine it is of the great importance the biomechanical characteristics - force and velocity of skeletal muscles. These characteristics are significantly influenced by acute physical exercise. The problem is how to access the influence of the exercise by simple and non-invasive measurement method. The two main contractile properties, relative force and velocity, of the biceps brachii muscle were assessed by measurement based on magnetic displacement sensor measuring the muscle belly response. The measurements were performed in set of 10 healthy male individuals from 21 to 32 years old. Bipolar electrodes are applied in order to elicit single muscle response. The time response of muscle contraction are analysed, typical parameters are extracted and evaluated by statistical methods. Variability of the new method is compared to method that is widely used. With proper evaluation of the measuring results influence of measuring errors can be lower. It has been estimated by previous study that variability of displacement sensor with electrical stimulation (ES) is 15-33% and 5-16% for maximal voluntary contraction (MVC). The measurements were performed before exercise and repeated 2, 4, 6 10 and 20 minutes after physical exercise. The maximal fatigue due to exercise of biceps brachii muscle were achieved by dominant concentric volitional contraction of m. biceps brachii in condition when the arm is load by weight of 6 kg. The time of exercise slightly varied in each individual. The fatigue was achieved after about 3 up to 5 minutes of activity.

The threshold of stimulating voltage, contraction time, sustain time, and half relaxation time are analysed as parameters of responses. The results show significant increasing of stimulating threshold voltages and decreasing of contraction time and sustain times. In half relaxation time are not detected significant changes. In time interval between 5 and 7 minutes the parameters are achieved the stationary value.

This result and the method proposed might be relevant as a procedure of the on line follow up of sportiest during a process of active training and it might give the valuable data to trainer how to plan the process of warming up before of competitions.

STATE OF THE ART

Acute physical activity can have various effects on skeletal muscle, ranging from subcellular damage of muscle fibres to stretch-induced muscle injuries – strains. Symptoms associated with delayed-onset muscle soreness are an increase in plasma enzymes (e.g. creatine kinase), myoglobin and protein metabolites from injured muscles; structural damage to subcellular components of muscle fibres; and temporary increases in muscle weakness, as reported in references /1,2/. Most of the symptoms are possible to investigate by invasive techniques and therefore are not suitable for daily use in active sportsmen. It is the purpose of the proposed non-invasive biomechanical method to estimate the range of time parameter changes in twitch response due to acute exercise.

Physical activity activate both metabolic and mechanical events that may damage muscle and lead beside to metabolic factor to changes of biomechanical properties of the skeletal muscles. Because eccentric contractions are associated with high forces and possible damage in acute experiment the dominant concentric volitional exercise has been applied in order to avoid possible muscle damage.

MATERIAL AND METHODS

A simple method for the measurement of skeletal muscle contraction has been used /3/. The method is based on the assumption that radial muscle belly displacement detected by a magnetic sensor is proportional to muscle force. By muscle belly displacement is meant the globulisation or the rounding of the muscle surface due to contraction. The procedure has been evaluated in healthy subjects /3/, subject after above knee amputation /4/ and denervated pretibial muscle group. It has been shown that the method can be applied as a substitute for mechanical brace measurement systems that are based on force transducers. With the method proposed one can measure the action of a single muscle within a given muscle group.

The transducer is mechanically constructed on a supporting frame with a micromanipulator for the precise positioning of the displacement transducer directly on the belly of the muscle. Subject is sitting or lying on a table during the experiment.

Ten healthy subjects, aged 21 to 32 were measured by the system in isometric conditions during the experiment the subjects sat comfortably on a special chair. The forearm was fixed to the mechanical brace with an initial elbow flexion of 90 degrees. The displacement sensor was positioned at the surface of the belly of the m. biceps brachii where the maximal enlargement (globulisation) of the belly was observed if the muscle contracted. This position needed to be determined individually because of individual anatomical differences. In the experiment single-twitch stimuli were used in order to study the dynamic response of the muscle. The stimulation was providing cutaneously by two surface electrodes (radius of 5 cm). The positive electrode was placed over the muscle up to 5 cm above the measuring point and the negative one up to 5 cm below the measuring point. The duration of the stimuli was adjusted to 1 ms and the voltage amplitude was gradually increased from up to 40 V above threshold muscle contraction response.

RESULTS

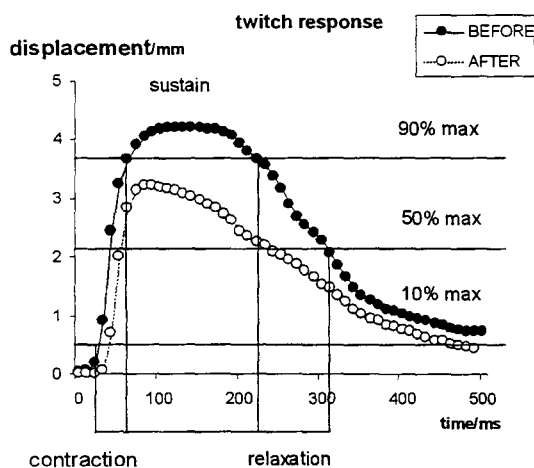


Figure 1. Changes in twitch responses muscle biceps brachii before and after physical dominant concentric exercise. Delay, contraction, sustain a relaxation time are extracted from the time response on single electrical stimuli (duration 1ms, amplitude 40 V above e threshold). These parameters are statistically evaluated for set of 10 healthy individuals

A typical changes in twitch muscle sponses before (filed dots) and after physical dominant concentric exercise (non-filed circles) are shown in Fig. 1. Delay, contraction, sustain an relaxation time are measured as time intervals between moment when the response has the value of 10%, 50% and 90% of maximal displacement. Maximum response was measured at single electrical stimuli (duration 1ms, amplitude 40 V above threshold). These parameters are statistically evaluated for 10 healthy individuals. From the time curves it is evident decreasing of maximal response after exercise, shortening of contraction time and sustains time. The half relaxation time is not changed significantly. The measurements were performed before exercise and repeated 2, 4, 6 10 and 20 minutes after physical exercise of m. biceps brachii in condition when the arm is load by weight up to 6 kg. The time of exercise slightly varied in each individual. The fatigue was achieved after about 3 up to 5 minutes of activity.

The results show significant increasing of stimulating threshold voltages and decreasing of maximal displacement. In time interval between 5 and 6 minutes

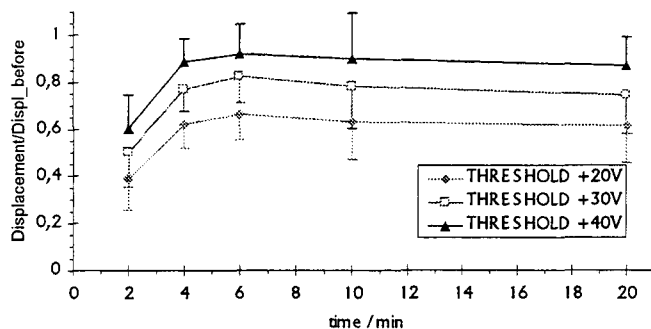


Figure 2 Changes in normalised displacement 2, 4, 6 10 and 20 minutes after physical exercise of *m. biceps brachii*. Threshold voltages are determined for each subject individually.

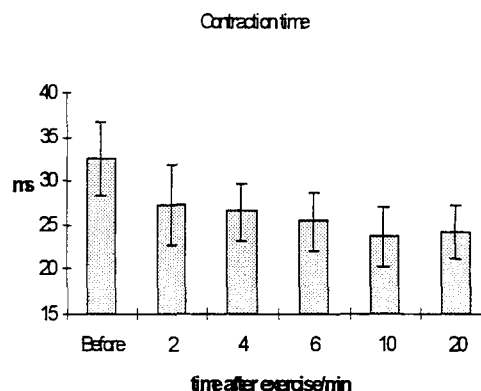


Figure 3. After dominant concentric exercise the contraction time is significantly shorter for about 20%. ($p < 0,05$, $n = 10$, with a Student's *t*-Test, Paired)

the parameters are achieved the stationary value as illustrated in Fig 2. Contraction time is supposed as an important parameter describing the biomechanical characteristic of skeletal muscle. We found that this Parameter varied significantly for different muscles from 20 ms for *m. vastus lateralis* and to up to 60 ms in *m. biceps femoris*. In case of *m. biceps brachii* the average Contraction time is about 32 ms. After dominant concentric exercises the activation time is significantly declined for about 20%. ($p < 0,05$, $n = 10$, with a Student's *t*-Test, Paired). Fig. 3.

After acute exercise of *m. biceps brachii* the sustain time is in all individuals significantly declined ($p < 0,05$, $n = 10$, with a Student's *t*-Test, Paired) Fig 4.

One may assume that the sustain time is accompanied with the active process of crossbridge cycling, the possibility of interaction between the crossbridges and the thin filaments increases by volitional exercising. The net result is the changes in activation and sustain time. Beside these effects no significant changes were detected in half relaxation time.

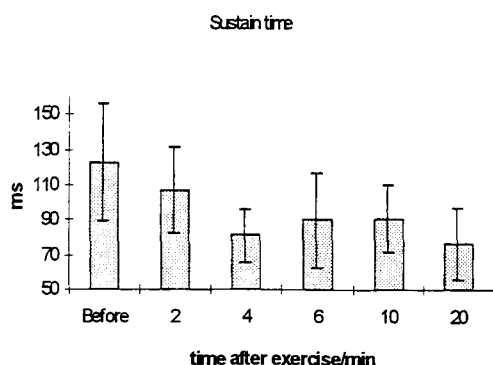


Figure 4. After acute exercise of *m. biceps brachii* the sustain time is in all individuals significantly declined for about 25%.

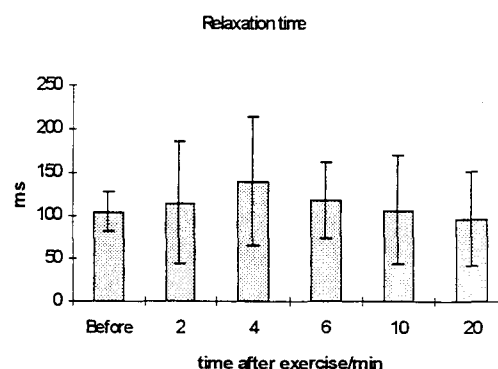


Figure 5. Half relaxation time does not changed significantly after acute exercise of *m. biceps brachii*.

DISCUSSION

These experimental findings are not in agreements with our expectation. After acute exercising and therefore a fatiguing contraction is usually reported an increasing of Contraction time and sustain time, and prolongation in the relaxation time of a twitch. The twitch duration is usually increased after fatigue. This is presumably associated with biochemically mediated reduction in relaxation rate. In our experiment it is possible that short lasting volitional concentric dominant movement is not enough fatigable to elicit expected effects in twitch response.

The next possible, perhaps the most reasonable reason for the contradictory results in twitch duration is posttetanic potentiation. The magnitude of the twitch force is extremely variable and depends on contraction history of the muscle. The posttetanic potentiation of twitch response can be substantial and can be elicited by both voluntary contractions and electrical stimulation. Potentiation of submaximal force occurs in all three types of motor units (Types S-slow, FR-fatigue resistant and FF- fast fatigue). When motor units were activated with a stimulus that elicited a submaximal tetanic force, the average potentiation was greater among the fast-twitch motor units then in the slow-twitch motor units (Gordon, Enoka, Stuart, 1990). Because posttetanic potentiation and fatigue occur concurrently, beginning from the onset of contraction; the twitch response after exercising depends on distribution of different motor units in particular skeletal muscle. For the experiment proposed in m. biceps brachii we might conclude that particular skeletal muscle consist dominantly of fast-twitch motor units. This is in agreement with data obtained by the histological examinations.

In the next experiments we have to repeat the same protocol of measurement in the muscle which typically consists of types S and FR motor units (i.e. m. biceps femoris). We can conclude that the method based in detection of muscle belly displacement is a simple and non-invasive way, suitable for the study of contractile properties of practically any skeletal muscle in man.

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The comparison of dynamic characteristics of skeletal muscles in two groups of sportsmen – sprinters and cyclists

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SUMMARY

Two homogeneous groups of elite sportsmen - eight sprinters (60-100m) and eight cyclists (road) – are selected. It is assumed that biomechanical characteristics – contraction parameters of various skeletal muscles are significantly different in both groups. The expectation is based on hypothesis that muscles in sprinters are faster than those in cyclists. The question is how to access and evaluate the time and velocity parameters as responses to a single twitch electrical stimulation.

A simple and non-invasive measurement method has been used. Typical contractile properties: contraction time, sustain, and half relaxation of six muscles are considered. (m. biceps brachia, m. vastus lateralis, m. rectus femoris, m. erector spinae, m. biceps femoris and m. gastrocnemius). The proposed technique is a useful tool for studying contractile properties of skeletal muscles in sportsmen. Muscles were assessed by measurement based on magnetic displacement sensor, measuring the muscle belly response. The muscle response to single twitch electrical stimulation was measured. The pulse width was 1 ms and voltage of stimuli was adjusted up to 40 V from threshold of contraction and respectively. Bipolar surface electrodes were applied in order to elicit single muscle response. The time responses of muscle contractions were analyzed. The contraction time, sustain time, and half relaxation time were taken into account as representative parameters of the records. The results show significant differences (sometimes in range of up to 100 percent) when all parameters are compared among different muscles. Between groups of cyclists and sprinters the significant difference is obtained in contraction time and no significant difference in other parameters. The results answered the question how muscles significantly differentiate in sprinters and cyclists.

STATE OF THE ART

An important characteristic of a motor system is its adaptability. When subjected to an acute or chronic stress (training), the motor system can adapt to the altered demands of usage. These adaptations can be extensive and have been shown to affect most aspects of the system, both morphological and functional. Sports physiologists have always been interested in the study of muscle adaptations which are the result of a long and targeted training process. In elite sportsmen the morphological and functional muscle characteristics are a combination of their inherited and specifically targeted cumulative changes in the training process, which makes them a very interesting target group. But the study of contractile muscle characteristics in sportsmen has usually been very difficult because adequate methods have so far not been available. For this reason we have designed and tested a new noninvasive method for the study of contractile properties of six muscle groups. Using a new method, the action of a single muscle within a given muscle group can be measured. Two homogeneous groups of elite sportsmen were selected (cyclists and sprinters), which are different in the type of chronic adaptations and their inherited characteristics. We would assume that these differences also pertain to contractile properties of the tested muscles. The above mentioned method could also be useful in the study of chronic and acute adaptation influences on contractile muscle properties in humans.

MATERIAL AND METHODS

A simple method for the measurement of skeletal muscle contraction has been used /1/. The method is based on the assumption that radial muscle belly displacement detected by a magnetic sensor is proportional to muscle force. By muscle belly displacement is the globulisation or the rounding of the muscle surface due to contraction. The procedure has been evaluated in healthy subjects /1/, subject after above knee amputation /2/ and denervated pretibial muscle group. It has been shown that the method can be applied as a substitute for mechanical brace measurement systems

which are based on force transducers. With the method proposed one can measure the action of a single muscle within a given muscle group. The transducer is mechanically constructed on a supporting frame with a micromanipulator for the precise positioning of the transducer directly on the belly of the muscle. The subject is sitting or lying on a special table during the experiment.

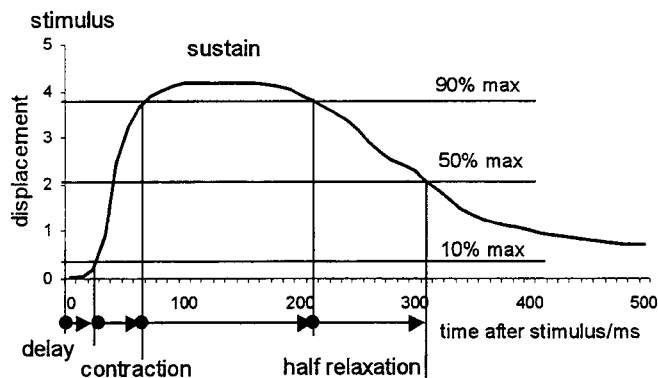


Figure 1. Time parameters definition in typical twitch response

maximal enlargement (globulisation) of the belly was observed if the muscle contracted. In the experiment single-twitch stimuli were used in order to study the dynamic response of the muscle. In response (time displacement curve) three parameters were observed (Fig. 1): contraction time, sustain time and half relaxation time. The stimulation was provided cutaneously by two surface electrodes (radius of 5 cm). The positive electrode was placed over the muscle up to 5 cm above the measuring point and the negative one up to 5 cm below the measuring point. The duration of the stimuli was adjusted to 1 ms and the voltage amplitude was gradually increased from up to 40 V above threshold muscle contraction response. The impulses were generated by the Grass S88 stimulator with isolation unit. The significance of differences between time parameters of both groups was tested by the two-sample Student's t-Test. A *P*-value lower than 0.05 was considered statically significant.

RESULTS

In comparison between cyclists and sprinters three parameters were observed in six different muscles. The comparison of contraction time (Tab. 1 and Fig. 2) shows that statistically the following muscles are significantly different: m. gastrocnemius ($p < 0.001$), m. rectus femoris ($p < 0.01$), m. biceps brachii ($p < 0.05$) in m. erector spinae ($p < 0.01$). The difference in vastus lateralis is not significant while it is not obtained in biceps femoris.

The comparison of sustain time (Tab. 2 and Fig. 3) between cyclists and sprinters does not show a statistically significant difference in the observed muscles. In half relaxation time (Tab. 3 and Fig. 4) the difference exists only in Erector spinae ($p < 0.05$).

DISCUSSION

Our objective was to find out whether the method which measures muscle belly displacement was suitable for the study of contractile properties in different muscle groups and for the comparison of different sportsmen regarding to the type of chronic adaptations which these sportsmen are exposed to. Training adaptations are specific to the cells and their structural and functional elements that are overloaded /3/. If an individual performs a strength-training program, only this characteristic (strength) and not others (e.g., endurance) will exhibit an adaptation /4,5,6/.

The results of our measurements show that there are significant differences in contractile properties of different muscle groups between individual muscles of the same subjects (minimum contraction time 17.4 ms and maximum contraction time 54.5ms) or two groups of subjects (cyclist and sprinters). Significant differences in contraction time are the result of variation in enzyme myosin ATPase, the rate at which Ca^{2+} is released from and taken up by the sarcoplasmic reticulum /7/ and the architecture of the muscle.

In comparison between cyclists and sprinters significant differences in contraction time were observed. The exception was biceps femoris. And there was a slight (nonsignificant) difference in vastus lateralis. The remaining two observed

parameters do not show significant differences except in erector spinae in the case of half relaxation time. The greatest difference between the two groups was observed in the muscle gastrocnemius which is considered to be among the slowest /8/. The explanation for relatively small differences in muscles with short contraction time is most probably the fact that conventional stimulus waveframes are known to preferentially activate large diameter motor units in contrast to the small-to-large recruitment order that occurs with voluntary activation /9/. Therefore the participation of slow fibers in the measured muscles is "not detected" because the contraction amplitude is considerably smaller (20 times) and contraction time longer /10/. As a surprise comes a relatively short contraction time in erector spinae in sprinters. The data obtained in general, healthy population indicate that it is a slow muscle /11/, but almost no data in sportsmen are available for this muscle.

The above mentioned method seems suitable for the study of individual muscles and comparison of the same muscle in different subjects. In the future it could enable us to draw an atlas of individual muscle fiber types distributions (contractile properties) in different important muscles for various groups of sportsmen.

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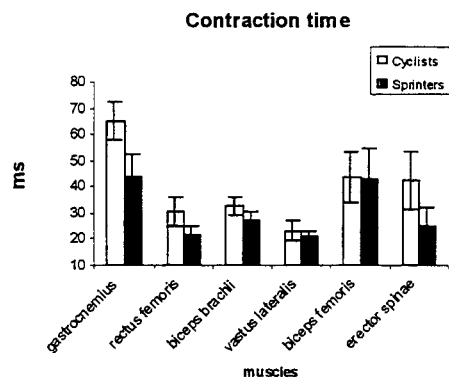


Figure 2. The comparison of twitch contraction time among different muscles

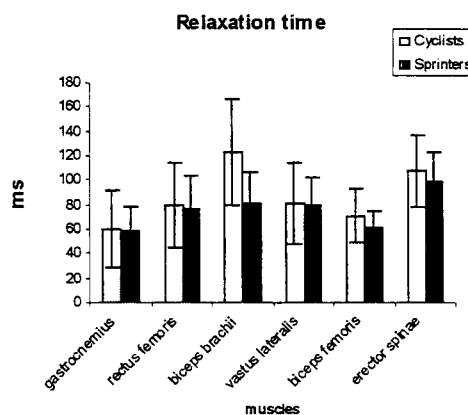


Figure 3. The comparison of twitch half relaxation time among different muscles

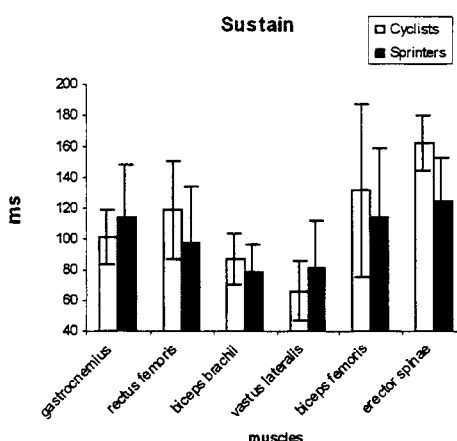


Figure 4. The comparison of twitch sustain time among different muscles

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Table 1.

CONTRACTION TIME (ms)				
muscles	cyclists		sprinters	
	mean	SD	mean	SD
m. gastrocnemius	65,2	7,0	43,3 *	9,4
m. rectus femoris	30,7	5,3	21,9 **	3,0
m. biceps brachii	32,5	3,3	27,5 ***	2,9
m. vastus lateralis	23,3	3,9	20,7	2,0
m. biceps femoris	43,6	9,6	43,2	11,5
m. erector spinae	42,0	10,9	25,3 **	6,7

* $P < 0.001$; ** $P < 0.01$; *** $P < 0.05$

Table 2,

SUSTAIN TIME (ms)				
muscles	cyclists		sprinters	
	mean	SD	mean	SD
m. gastrocnemius	100,9	17,9	114,5	33,4
m. rectus femoris	118,7	31,7	97,4	36,3
m. biceps brachii	87,2	16,5	78,4	18,1
m. vastus lateralis	66,3	19,4	81,6	29,9
m. biceps femoris	131,3	55,7	114,5	44,6
m. erector spinae	162,4	17,1	124,9	27,9

Table 3

HALF RELAXATION TIME (ms)				
muscles	cyclists		sprinters	
	mean	SD	mean	SD
m. gastrocnemius	60,2	31,7	58,4	19,1
m. rectus femoris	79,8	34,1	76,3	27,4
m. biceps brachii	123,5	43,3	81,4	24,8
m. vastus lateralis	80,8	33,0	79,5	22,0
m. biceps femoris	71,0	21,9	61,9	13,5
m. erector spinae	107,6	29,3	98,9 ***	24,8

*** $P < 0.05$

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ELECTROMYOSTIMULATION TO PREVENT MUSCLE ATROPHY IN MICROGRAVITY AND BED-REST: PRELIMINARY REPORT

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SUMMARY

Long term flights in microgravity cause atrophy and morphological changes of skeletal muscles. Training with mechanical devices is performed to inhibit these degenerative changes. Efficient training requires time to exercise and space for the training devices, both lacking in long term space flights.

The objective of our project is development of a passive training method to preserve muscle mass and fiber composition with minimal impairment to the cosmonaut. We want to adapt functional electrical stimulation (FES) for this application, as it is an established method to support muscle training in sports and rehabilitation.

An experimental study is planned to investigate different strategies of automatic skeletal muscle training. During a bed rest-study the effect of FES on lower extremity muscles of healthy volunteers will be evaluated. Subjects are divided in three groups, one with 1 second on / 2 seconds off cyclical tetanic contractions at 20 to 30% of maximum tetanic muscle force during 12 hours per day, one with additionally maximum tetanic contractions during two minutes per hours, and one control group. Synchronous activation of antagonists of thigh and lower leg should prevent from uncoordinated movements. Suitable 8-channel stimulation devices and electrodes had to be developed providing safety, reliability, easy handling, and minimal sensible discomfort.

Regular biopsies, electromyography, dynamometry and tonometry will give insight in morphological changes of muscles and prove efficacy of the stimulation. Response of the circulatory system will be monitored by measuring heart rate variability.

The method and the developed devices should serve as countermeasure means to prevent muscle atrophy for both cosmonauts in space and long-term bed-rest patients.

INTRODUCTION

In the course of evolution all living organisms men, animals, plants down to a single cell are fundamentally effected by the earth gravitation field. It took millions of years for man to withstand gravitation and to achieve erect position. Locomotion is the translation of the center of gravity through space along a path requiring the least expenditure of energy. In microgravity a decreased activity of postural muscles exists and leads to atrophy of antigravitational muscles during long duration flight. It is known that already after 5 to 6 days in space, deficit in man and rodent muscle activity occurs. Not all of more than 600 skeletal muscles of humans are involved to the same extent. It is evident that in weightlessness mainly the leg musculature responsible for locomotion and posture is reduced in activity and reliance. To minimize muscle atrophy as well as orthostatic hypotension and reduction in blood volume, physical activity and daily training is used as countermeasure.

Various devices to implement these countermeasures aboard the space station MIR and on all sky lab missions, have favorably influenced the health of the Cosmonauts and Astronauts. During the Austro-Russian space mission " AUSTROMIR " in 1991 the dynamoergometer "

MOTOMIR " was used for the first time [1]. Daily two exercise sessions on a cycle ergometer are recommended during the Russian space-flight on a 3 day on/3 day off schedule. Each session lasts for approximately 75 minutes. In addition a treadmill has been used during the Skylab mission with a daily training period of 1 1/2 hours to keep crew members in shape. The tendency to extend the active aerobic training during long space flight missions to 320 minutes daily raises the caloric intake, shortens the operational activities and reduces the motivation for the crew members. Three facts have to be considered contraproductive. The limitation for an active muscle training during a long term space mission in terms of time and space needs the consideration of an automatic support.

Established data exist on considerable impairment of neuromuscular function, reduced force development and endurance which effect more the lower limb muscles and less the upper limb. Prolonged exposure to microgravity leads to numerous changes and disturbances in human organism. Besides disorientation, a shift of body fluids from lower part towards the head occurs quickly. Increase of muscle excitability and reduction of muscle tonus has been found already after 2-5 days in space.

EMG examinations revealed a significant shift towards higher frequency spectrum, which means that a greater reduction in slow twitch fibers (Type I) was found compared to fast twitch muscle fibers (Type II). On the other hand Convertino [2] reports a greater reduction in cross-sectional areas (CSA) of type II than in type I fibers in both spaceflight and ground-based experiments. The alterations in the nervous, cardio-pulmonary -, musculoskeletal -, hematological -, vestibular - and immune - system lead to a phenomenon which is called, space-adaptation-Syndrome.

Up to now few references indicate that FES has not been widely used in space programs and deserves further exploration and testing [2]. To further investigate the influence of myoelectrostimulation in microgravity a cooperation with the Institut of Biomedical Problems (IBPM) in Moscow was started and the following protocol worked out.

MATERIALS AND METHODS

Experimental setup:

A 60-days bed-rest study is planned. Orthostatic hypokinesia in 6°-head tilt down position provides simulated conditions of microgravity. The efficiency of two different stimulation patterns and training regimes is investigated and compared with an unstimulated control group. Each of the three groups consists of three individuals. FES is applied to muscles of both lower extremities. The data of six legs per group are collected for statistical analysis.

To perform the FES-training stimulation electrodes are placed on the skin above the quadriceps femoris muscles, the hamstrings, the tibialis anterior- and peroneal muscles and the triceps surae muscles. Synchronous stimulation of the antagonistic muscle groups shall prevent from joint movements.

Stimulation is performed during 12 hours per day with periods of one second "on" and two seconds "off". The intensity level is adjusted to 20 - 30% of the maximum tetanic force. Muscles are trained with either continuous low level stimulation only (Group I) or additional periods with maximum tetanic contractions during two minutes every hour (Group II).

Stimulation device and parameters:

The device consists of electrode trousers carrying EMG- and stimulation-electrodes for the eight channels and two interconnected 4-channel stimulators carried in thigh pockets. After donning the system a programming routine checks the electrode impedance and detects all threshold and saturation levels by amplitude variation of single stimulation impulses (biphasic rectangular, 1ms pulsewidth) and recording the evoked EMG reaction. As the peak amplitude of the EMG correlates with muscle force this procedure estimates the nearlinear working range of the stimulation amplitude. The intensity levels needed for training 20 to 30 % as well as 100 % of maximum tetanic force are decided for all eight channels. Now the system begins with

automatic training. The stimulation frequency is 25 Hz for basic training and 50 Hz for the additional maximum contractions in the alternative training regime. During the whole training electrode impedance and EMG-reaction are monitored for each single stimulation impulse to identify electrode problems and early signs of muscle fatigue.

Evaluation:

Evaluation of subjects is done in accordance with the standard protocol of the Moscow Institute for Biomedical Problems (IBMP) which has been used in former bed-rest-studies. This standard protocol consists of physiological and morphological examinations. In our study specific tests related to FES are added.

A. Physiological examinations

- Isokinetic dynamometry
- Tendometry
- Measurements of muscle stiffness
- Running test on a treadmill
- Veloergometric aerobic test
- Orthostatic tolerance test

B. Morphological examinations:

- Needle-biopsies from the vastus lateralis muscle and the lateral gastrocnemius head
- Histochemical, immunohistochemical and enzyme histochemical staining and capillarisation.
- Electronmicroscopic investigation

C. FES related tests:

- Amplitude, pulse width and frequency gains (isometric force measurement)
- Heart rate variability (rest, onset of stimulation, training)

Subjects are investigated at the beginning of the study, after 30 days and at the end of the experiment. Muscle biopsies are taken at the beginning and the end of the experiment only.

The study and the examinations will take place in Moscow. The stimulation devices and related measurement equipment are developed and reproduced in Vienna. Part of the morphological investigation will be done by the Institute of Anatomy of the University of Vienna. All data will be collected and processed in close cooperation between the Russian and the Austrian partners.

RESULTS

Up to now the project was focused on technical and technological research and development. A practical solution was found for the electrode trousers. After putting them on like normal trousers placement of the electrodes to the skin is simplified by a construction of two flexible flaps carrying electrodes and protection foils that are alternatively exposed to the skin.

Most of the circuitry of the stimulator has been developed and tested as EMG- and impedance-recording, stimulation output stage, microcontroller for impulse generation (one for each output), coordinating microcontroller, power supply, display, control elements and BUS-interface. Under construction is miniaturization of the circuitry to a size of 10 versus 16 cm, development of the case, completing of microcontroller- and personal computer (PC) - software for routine operation of the stimulator, data exchange and data processing in a laptop-PC that is also prepared for automatic evaluation procedures (FES-related tests).

The most complex problem to solve was on-line EMG-measurement (amplitude in the order of mV) during stimulation with impulses of up to 100 V in the immediate vicinity of the recording electrodes.

All technical solutions were tested in experiments on ourselves.

DISCUSSION

To substitute the muscular load of terrestrial conditions during long term space flights exercise and training programs are required. The training and the devices consume extensively time, weight and space and an alternative would be helpful. The objective of our project is to develop a method to avoid or at least reduce changes in the skeletomuscular system caused by microgravity with minimal impairment to the cosmonaut.

Morphologically microgravity causes a loss of muscle mass and a reduction of Type I muscle fibers, which are responsible for muscle tone and posture above all. It is common knowledge that chronic FES tends to transform Type II to Type I fibers an effect which should be useful to compensate the loss of type I fibers in microgravity. The level of 20 to 30% of the maximal tetanic contraction force was selected to achieve substantial training at minimal sensible inconvenience. Simultaneous stimulation of antagonistic muscle groups should prevent from unpleasant movements. Synchronous stimulation of the antagonists at low level intensities might be used without interfering other activities and daily work. The second regime with additionally maximum tetanic contractions is less comfortable but might be more effective concerning the preservation of muscle power. However, two training regimes were selected to obtain first data in a new application of FES. The results may recommend a modified regime or a combination of FES with conventional training methods. An exact simulation of terrestrial muscular activity cannot be expected from surface stimulation and fiber type composition and distribution of stimulated muscles will differ from normal condition. This effect is known to be totally reversible within several weeks under normal conditions.

Assumed the technique proves to be effective the application should be extended to the trunk and neck muscles to preserve posture of the cosmonauts. Terrestrial applications in medicine can be expected, as long term immobilization causes morphological changes in skeletal muscles, similar to microgravity.

ACKNOWLEDGMENTS

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LONG TERM FOLLOW UP OF 160 USERS OF THE ODESTOCK DROPPED FOOT STIMULATOR

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SUMMARY

The Odestock Dropped Foot Stimulator (ODFS) is a foot switch controlled single channel neuromuscular stimulator for correction of dropped foot in subjects with upper motor neurone lesions. Following a randomised controlled trial the ODFS was recommended for use in the National Health Service and led to the establishment of a clinical service. Performance using the device is assessed by measurement of walking speed over 10 m and physiological cost index (PCI). A questionnaire was also sent in a single mail shot to all 291 subjects who had used the ODFS (58% current users, 42 % past users). The questionnaire attempted to ascertain, from the users perspective, the reasons for using or discarding the ODFS, the profile of its use, if there was any change in the use of assistive devices and give feed back on the service provided by the department.

STATE OF THE ART

Approximately 100,000 people in the UK suffer their first stroke each year of whom over 80% survive (1). Of those who survive, approximately 75% will have a reduced quality of life. Although there are no statistics on how many stroke patients suffer from a dropped foot, 12,000 would be a conservative estimate (2). Patients with other neurological conditions may also suffer from a dropped foot, including multiple sclerosis (MS), incomplete spinal cord injuries (SCI), cerebral palsy (CP.), and traumatic brain injury (TBI). Functional Electrical Stimulation (FES) for the correction of dropped foot, following upper motor neurone damage, has been used since Liberson's work in the late 1950's and early 1960s (3). However, its use in clinical practice has not been common in this country. The Odestock Dropped Foot Stimulator, (ODFS) is one of the few FES systems in clinical use in the UK. At the time of writing in excess of 400 people had used the ODFS. The longest duration of use of the stimulator is six and a half years and this patient is still using the system.

The ODFS is a single channel, foot switch triggered stimulator designed to elicit dorsiflexion of the foot by stimulation of the common peroneal nerve, (max. amplitude 80mA, 300µs pulse, 40 pps). Skin-surface electrodes are placed, typically, over the common peroneal nerve as it passes over the head of the fibula bone and the motor point of tibialis anterior. The rise and fall of the stimulation envelope can be adjusted to prevent a stretch reflex in the calf muscles and to prevent a foot flap due to the premature ending of dorsiflexion.

The ODFS was the subject of a randomised controlled trial in which 32 stroke patients who had had a stroke for in excess of 6 months were allocated to a treatment group who used the device and received 12 sessions

of physiotherapy and a control group who only received physiotherapy (4,5,6). After three months of use the treatment group showed a statistically significant increase in walking speed of 16% and reduction in the Physiological Cost Index (PCI) of 29% when the stimulator was used while no changes were seen in the control group⁵. No significant 'carry-over' effect was seen although a trend was present. Users of the ODFS showed a continuing reduction in quadriceps spasticity which was only seen in the control group while physiotherapy continued⁶. The treatment group also showed a reduction in depression score on the Hospital Anxiety and Depression index suggesting an improvement in quality of life. The trial results were presented to the South and West Regional Health Authority Development and Evaluation Committee who subsequently recommended the ODFS for use in the National Health Service.

This paper details the walking speed and PCI results from a much larger patient group who received the ODFS administered as a clinical service and presents the results of a questionnaire sent to 291 users of the ODFS.

MATERIALS AND METHODS

Patient Selection

All patients were referred by their consultant or general practitioner and assessed for their suitability for treatment at an assessment clinic. Patients were judged to be suitable for treatment if their dropped foot was due to an upper motor neurone lesion and was corrected by electrical stimulation. Patients were able to move from sitting to standing unaided and able to walk at least 10 m with appropriate aids. Patients had to be able to have at least a basic understanding of the ODFS and its intended use and have access to assistance from a carer, if required. Tolerance of the sensation of the stimulation was essential. While patients with other upper motor neurone lesions have used the ODFS, this paper details the results from those with stroke and MS.

Methods

After the ODFS is fitted the patient is seen the following day, after six weeks, after a further three months and then every six months as long as they continue to use it. Walking speed and PCI, which is an indication of the amount of effort expended, are measured at every appointment. The patients are asked to walk briskly over a 10m course with 1m at either end for acceleration and deceleration. Patients normally walk this course three times with stimulation and three times without, the order of stimulation / nonstimulation being varied to compensate for any fatigue. The mean speed and PCI for stimulated and non-stimulated walking is calculated. PCI being the change in heart rate (b/min) / walking speed (m/min). The heart rate was measured using a Polar Heart Rate Monitor. The data in this study were obtained retrospectively from the records of these routine measurements kept in the patients notes.

A questionnaire was sent to all current and former users of the ODFS, 168 and 123 respectively. A stamped addressed envelope was included to facilitate their return. The questionnaire consisted of 16 questions which sought to determine what advantages the ODFS gave; when, how and where it was used, if it made any difference to the patients use of other aids, whether the instructions, both verbal and written were satisfactory and whether the repair/advice service we were providing was responsive. Those who had stopped using the stimulator were asked why they had stopped.

RESULTS

Walking Speed and PCI

The results presented here are those obtained on patients at the time of the initial fitting of the ODFS and at the assessment four and a half months later. The same definitions are used throughout.

NSI Initial measurements without the ODFS, SI - initial measurements with ODFS

NSF - Measurements at the 4¹/₂ month assessment without, SF - 4¹/₂ month with ODFS
 NSF-NSI the carry - over effect, SF-NSI total orthotic benefit, SF-NSF continuing orthotic effect. All figures are given in percentages with a negative figure showing a reduction and a positive figure an increase.

	Stroke n=111		MS n=21	
	Speed	PCI	Speed	PCI
Carry over	+14%, p<0.01	-19%, p<0.01	-7%, p>0.05	+16%,p>0.05
Total orthotic effect	+27%, p<0.01	-31%, p<0.01	+10%,p<0.05	-8%, p<0.05
Continuing orthotic effect	+12%,P<0.01	-15%, p<0.01	+16%,p<0.05	-24%,p<0.05

Questionnaire - current users

107 replies were received from the 160 questionnaires that were sent out.

Usage:- 70% use the ODFS four or more days per week, 60% more than 9 hours per day, 72% walk between 10 and 500m and 60% for every activity, mean time to put on nine minutes, mean time used 19 months

Main reasons for use:- less effort 45% (MS 67%), less likely to trip 24%, able to walk further 14%

Supplementary reasons:- more confident 79%, less effort 78%, walk further 70%, less likely to trip 70%. walk faster 62%.

Use of aids:- 18% less assistance from others, 22% reduced use of walking stick, 29% stopped or decreased use of AFO, 18% stopped or decreased use of wheelchair.

Problems:- Electrode positioning 44%, Unreliable equipment 38%, skin allergy 22%.

Satisfaction with clinical service:- ODFS well explained 96%, good written instructions 87%, prompt repair service 88%.

Questionnaire - former users

53 replies were received from the 123 questionnaires that were sent out

Main reasons for stopping:- Walking improved so not needed 19%, could not find the correct electrode position 11%

Supplementary reasons for stopping :- electrode positioning 34%, too much bother 26% deteriorating physical condition 21%, increased spasticity 19%, not sufficient benefit 17%, unreliable equipment 17%.

N.B. All percentages given are calculated on the questionnaires returned, i.e. 107 for the current users and 53 from the past users.

DISCUSSION

The stroke patients in this larger study show a greater orthotic benefit from the ODFS, with the walking speed increasing by 27%, compared to 16% in the original trial. Also whereas there was a trend towards a 'carry-over effect' in the original trial this study showed a statistically significant effect (7). The MS patients did not demonstrate a similar 'carry-over', presumably due to the nature of the disease process. However, they did have a large continuing orthotic effect. More significant to the users than the increase in walking speed may be the reduction in PCI when using the ODFS. This is demonstrated from the questionnaire results in which the most cited main reason for using the ODFS was the reduction in effort (45%). This reason was more often cited by MS users (67%) and agrees well with the reduction in PCI at the 4¹/₂ month assessment. In the authors experience MS patients are often more tenacious users of the ODFS and have a lower drop out rate.

The feedback on the level of service we are providing is encouraging and the low drop out rate we have experienced clearly demonstrate the need for FES based orthoses to be provided as part of a clinical treatment and not just as an electronic device to be given to the patient to take away. If the continual support and follow up is not provided the vast majority of stimulators will find their natural home at the back of a cupboard. We are facilitating the establishment of other clinical services in the UK following the model we initially started in Salisbury and successfully established in Birmingham.

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COMPARISON OF FOOT-SWITCH AND HAND-SWITCH TRIGGERED FES CORRECTION OF FOOT DROP

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SUMMARY

FES system for the correction of foot drop is traditionally triggered by a foot-switch located under the heel of the affected leg. The stimulation of the dorsiflexors is turned on as the heel rises and unloads the switch and off as the heel strikes the ground at the end of the swing phase. The foot-switch is frequently replaced by a hand-switch, that is a push-button built into the handle of a crutch. By pressing and releasing the push-button, patient can turn the stimulation on and off, respectively, thus having voluntary control over the timing of the stimulation. The aim of this study is the comparison of these two approaches. The basic kinematic parameters of subjects walking with the help of FES, controlled first by the foot-switch, and second by the hand-switch, were assessed and case studies are presented.

STATE OF THE ART

Foot drop, classified also as the excessive ankle plantar flexion, is most apparent and clinically significant in mid swing, initial contact and loading response /1/. During swing, the floor clearance is the problem. With only one channel of electrical stimulation applied to the peroneal nerve, the dorsiflexion of the foot can be achieved, lifting the toe of the swinging leg clear of the ground, thus enabling limb advancement. In order to achieve as normal gait as possible, the timing of dorsiflexion should be similar to that of an intact subject. In intact subject's free walking, the dorsiflexor muscle activity starts in pre-swing, which is just after the contralateral limb initial contact. During mid swing muscle action becomes minimal and in terminal swing the intensity gradually rises again to position the foot for stance /1/. The dorsiflexor muscle activity starts just after the intensity of action of the ankle plantar flexor muscles drops to zero by the onset of pre-swing. Since ankle plantar flexors are the antagonist muscles, an early stimulation of dorsiflexors may interfere the roll-off of the affected leg.

Foot-switch:

FES system for the correction of foot drop is traditionally triggered by foot-switch located under the heel of the affected leg. The stimulation of dorsiflexors is turned on as the heel rises and off as the heel strikes the ground or after fixed maximum stimulation time, whichever is the first. This approach has some drawbacks. First, the triggering of stimulation is slightly early, requiring some time delay between the heel rise and the beginning of stimulation /2/. Since the adequate time delay varies with respect to walking speed, a fixed time delay is not optimal. Similarly, the time delay after the heel initial contact, which ensures prolonged dorsiflexor muscle activity to provide shock absorption, should not be fixed, which is the case in foot-switch triggered systems.

There are also difficulties with foot switches, which are prone to erratic behavior and cable breakage. They cannot be used when walking barefoot and may function differently in different shoes or when walking over different terrain /3/. Another problem is negotiating the stairs, especially descending, because the dorsiflexion of the foot by the stimulation makes subject unstable /4/, so stimulator is better turned off on the stairs. Ankle plantar flexion tone or ankle plantar flexion contractures in some spastic patients also make the foot-switch useless, because the supporting weight on the heel is too low to

activate the foot-switch properly. These patients are excluded from use of foot-switches, nevertheless, they might benefit from drop foot FES system with another trigger source.

Hand-switch:

Kralj and Bajd [5] introduced a hand-switch in paraplegic patient's gait. This is a push-button built into the handle of a crutch, used as a simple manual trigger source. By pressing and releasing the push-button, patient can turn the stimulation on and off, respectively. Patient has voluntary control over the timing of stimulation, which can be adapted to various speeds of walking and account for some internal or external perturbation, e.g. fatigue of the muscle or environmental obstacles. There is no need to turn the stimulator off when negotiating stairs. Patient can walk over a different terrain, in different shoes or even barefoot. However, it is not difficult to realise that only the patients using at least one crutch could benefit from the use of the hand-switch.

When using the hand-switch, some conscious effort is needed to press and release the pushbutton properly. We believe that this effort is negligible, as the effort, for example, to move the crutch forward to prepare it for the next step. We also believe that preserved sensations of foot drop patients are sufficient for them to determine the right time to trigger the stimulation.

It should be noted that some patients may have difficulties with pressing the push-button due to the lack of muscle control also in hand. Commonly, the push-button is built into the crutch of the affected side. However, the pushbutton built into the opposite crutch should not hinder the patient to walk using hand-switch.

MATERIALS AND METHODS

We compared the use of hand-switch with foot-switch to trigger the peroneal FES system. The basic kinematic parameters of foot drop patients were assessed in two trials. In the first trial, the patient was walking with FES controlled by foot-switch and in the second controlled by hand-switch. In the second trial, the time of triggering of the hand-switch and also the test foot-switch was assessed, in order to compare these two control approaches.

The measurement system comprised a distance meter, goniometres (Penny & Giles) and measuring shoes with four switches located under the heel, the toe, the first and the fifth metatarsal. The same commercial peroneal stimulator (Mikrofes, Gorenje) was used in both trials (with "stimulation on" time delay of approx. 30 ms, "stimulation off" time delay of approx. 150 ms, and maximum stimulation time of 3s). The threshold of the foot-switch used was approximately 30 N.

From the measured data the basic kinematic parameters (stride time and length, left/right step time and length, speed and cadence) were calculated over a series of strides for both trials.

RESULTS

The basic kinematic parameters were assessed in two tetraparetic patients walking first with help of FES system triggered by foot-switch and second triggered by hand-switch.

Case reports:

Case 1: A 21-year-old female with C6/C7 tetraparesis, injured in traffic accident four months earlier. In her rehabilitation she used 2-channel surface electrical stimulation triggered by hand switch for two months, then she switched to 1-channel FES for the correction of foot drop, controlled by foot-switch. She was walking with aid of both crutches.

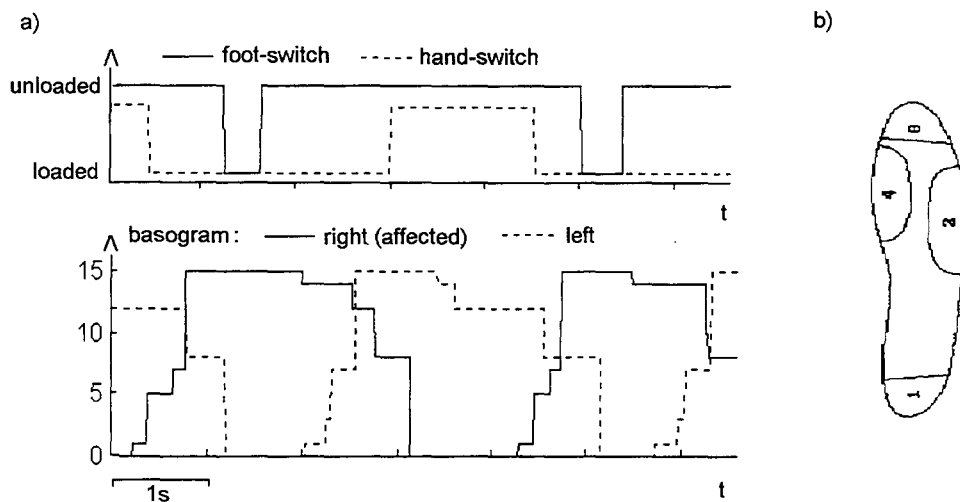


Figure 1. The timing of the foot-switch and the hand-switch during the gait cycle a), location and "weight" of switches under the right foot b).

When walking with FES triggered by hand-switch, inconsistent switching of test foot-switch was observed. Foot-switch did not trigger in 10 out of 17 strides and was prematurely unloaded after successful loading at the heel contact (Fig. 1). This caused an early start of stimulation and consequently, the stimulation ended after the fixed maximum stimulation time (3s), instead at the next heel contact. In fact, the stimulation started in the single stance phase of the affected leg when stability is crucial.

The patient's speed of walking was low (approx. 0.1 m/s) and her stride time was long (approx. 5 s). The hand-switch was pressed 1.1 s after the heel rise on average with the standard deviation of 0.3 s, and released 0.2 s after the initial contact of the foot with the standard deviation 0.1 s, which indicates a consistent triggering of the stimulation.

An increased stride length (0.55 m vs. 0.41 m) and increased dorsiflexion during the swing phase of the affected leg were observed, resulting in increased speed of walking (0.11 m/s vs. 0.08 m/s), compared to foot-switch controlled walking.

Case 2: A 63-year-old male with C4 tetraparesis, injured at work 18 months earlier. In his rehabilitation he used 1-channel FES for the correction of foot drop, controlled by the foot-switch. He was walking with the aid of both crutches.

When walking with FES triggered by hand-switch, the test foot-switch did not trigger in 20 out of 32 strides, and was prematurely unloaded after successful loading. The patient's speed of walking was approx. 0.3 m/s with stride time of 2.4 s. The hand-switch was pressed 0.4 s after the heel rise on average with the standard deviation of 0.2 s and released 0.1 s after initial contact of the foot with standard deviation of 0.2 s. The triggering of the hand-switch was considered not to be adequate in four strides (two delayed and two unwanted releases of the push-button). However, no significant difference in basic kinematic parameters was observed compared to foot-switch controlled walking.

DISCUSSION

The possibility of using hand-switch instead of foot-switch as the FES trigger source was investigated. The unsuitableness of foot-switch was demonstrated for two patients with ankle plantar flexion tone. When using the hand-switch, they were able to control the stimulation properly. The hand-switch proved to be more reliable and could also be used by other foot drop patients walking with aid of crutches to overcome the problems associated with foot-switches. Nevertheless, the hand-switch also needs to be hard-wired to the stimulator, which may be the reason, why it is not used more often.

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ADAPTIVE RESTRICTION RULES PROVIDE FUNCTIONAL AND SAFE STIMULATION PATTERN FOR FOOT-DROP CORRECTION

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SUMMARY

Here we report on our advances in sensory feedback data processing and control system design for FES-assisted correction of the foot-drop problem. Detection of heel-strike and impaired leg's foot-lift are prerequisites for successful FES use in the foot-drop correction. It has been suggested that afferent neural signals, such as those recorded from Sural or Calcaneal nerves, carry mainly cutaneous information and can be used as sensory feedback signals in fully implanted FES-systems [1]. Heel-strike, which is important for determination of the stimulus duration, is easy to detect in the rectified and bin-integrated electroneurogram (RBI ENG). At the same time, detection of foot-lift, which is important for the start of the stimulation, is more difficult to detect. Firstly because the slower change of skin stretch reduces the firing rate of cutaneous receptors, and secondly because of the larger influence by the unwanted nerve signal resulting from the activation of cutaneous receptors by socks, footwear, and bending in metatarsal joints. We have applied two methods of signal purification on the RBI ENG (i.e. optimized low-pass filtering and wavelet de-noising) before training Adaptive Logic Networks (ALNs). ALNs generated stimulation control pulses which correspond to the swing phase of the impaired leg when dorsal flexion of the foot is necessary to provide safe ground clearance. However, the obtained control signal contained sporadic stimulation spikes in the stance phase, which can collapse the subject, and infrequent broken stimulation pulses in the swing phase, which can result in unpredictable consequences. We have shown previously that restriction rules generated on the training data set and fixed during the real-time use can eliminate critical errors of the control system within certain limitations [2]. In this study we have introduced adaptive restriction rules (ARR), which are initially trained as previously reported, and then dynamically adapted during the use of the system. Our results suggest that ARR provide safer and more reliable stimulation pattern than fixed restriction rules.

STATE OF THE ART

Functional electrical stimulation (FES) can assist hemiplegic patients by stimulating the peroneal nerve in the swing phase of the affected leg and thereby providing dorsiflexion of the foot. Systems based on surface stimulation and controlled by heel switch located in the shoes have been most successful, even if the performance was not optimal. Major obstacles in better acceptance of these systems are: 1) complicated daily donning and doffing of the FES system, 2) need to position electrodes precisely to produce correct movement of the foot, 3) surface stimulation can be uncomfortable, at required stimulation levels and may produce skin irritation, and 4) the sensor detecting heel-strike and thus controlling the stimulator, is cosmetically undesirable and is exposed to adverse conditions causing frequent failures. Fully implanted stimulators can resolve the first three problems, however, once the stimulator is

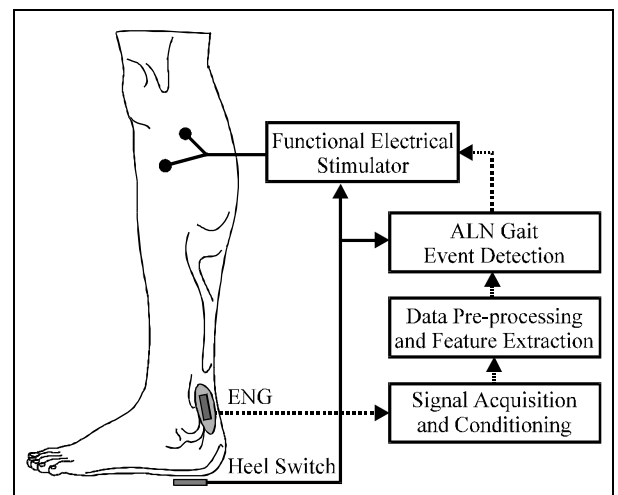


Figure 1. Experimental setup for development of control system for correction of foot-drop problem based on sensory feedback.

implanted it would be desirable to have sensory feedback also generated from implanted or natural sensory sources. Using afferent neural signals, recorded from peripheral sensory nerves (innervating foot areas of interest), was proposed as a solution to increase the detection performance in foot-drop applications and solve problems with external sensors /3/. In our previous work we demonstrated potential of using Adaptive Logic Networks (ALNs) and Restriction Rules (RRs) for gait event detection and FES control /2/. In this study we introduced dynamic adaptation of the restriction rules which provides wider range of operating conditions for safe use of the FES system.

MATERIALS AND METHODS

Experimental setup for this study is schematically illustrated in Fig. 1. In addition to traditional FES system for foot-drop correction (solid lines), we recorded and processed sensory nerve signal - electroneurogram (ENG) from the Sural nerve in the affected leg (dashed lines). The experimental part of the study was performed at the Center for Sensory-Motor Interaction, Aalborg University, Denmark, while data processing took place in the Laboratory for Advanced Assistive Technology, University of Alberta, Canada. Data acquisition is thoroughly described in /1/. The implant and recording experiments are therefore only briefly described here. A 35 year old male subject with spastic hemiplegia, was implanted with a 30 mm long tri-polar whole-nerve cuff on the Sural nerve approximately 7 cm proximal and 3 cm posterior to the lateral malleolus. The three wires were lead subcutaneously to an exit point approximately 25 cm proximal to the lateral malleolus.

The neural signal was amplified with a total gain of approximately 100 dB, band-pass filtered between 800 Hz - 3.6 kHz and rectified and bin-integrated (RBI) into 10 ms bins (top trace in Fig. 2). The data used in this study were recorded during FES-assisted walking with surface stimulation of the deep peroneal nerve, which caused dorsiflexion of the ankle during the swing phase. For ALN training purpose we manually created a target FES-control signal (bottom trace in Fig. 2). The heel-strike information was clearly indicated in the ENG signal by a burst of neural activity. Foot-lift was indicated by a smaller burst followed by reduced activity in the ENG. A heel-switch was used to confirm heel-strike timing, however it was not very useful in determining foot-lift. Two representative data sets were selected for this study, recorded on day 38 after implant with the subject walking barefoot on the floor in the lab area. The length of each data set was 60 sec, equivalent to approximately 32 gait cycles.

To create control algorithm for FES-assisted walking, we used ALNs, a machine learning method for supervised learning based on multilayer perceptron. In all initial ALN evaluation experiments we calculated the performance as the percentile of correctly predicted samples in the ALN output signal /4/. Implementation of ALNs involves splitting the data set into training and test data sets and the ALN performance was measured on both data sets, the first one representing the quality of the training, and the second one representing its generalization. Due to the binary character of the output signal, obtaining an error close to or larger than 50% was considered a random ALN performance.

Optimized feature extraction and ALN training parameters were as follows: **a)** To increase signal-to-noise ratio of the RBI ENG, two methods were compared: low-pass filtering and wavelet de-noising. Although wavelet de-noising has the advantage of selectively removing low energy signal components regardless of their frequency, low pass filtering, which has lower computational demands in real-time implementation, was selected for signal pre-processing. In the rest of this study the first order Butterworth filter with 6.5 Hz cut-off frequency was used. **b)** Expanding the ALN training domain from using only original ENG

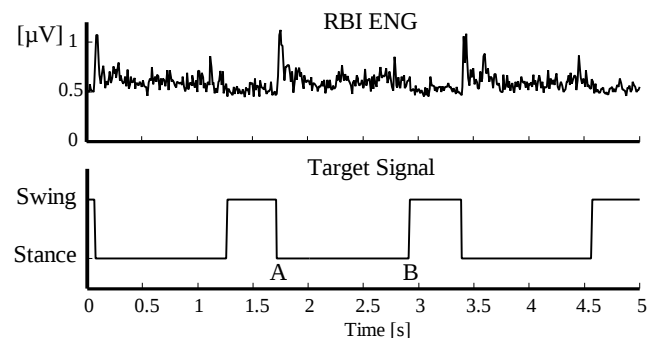


Figure 2. An example of RBI ENG recorded from the Sural nerve, and manually created target signal used for ALN training. Transitions between stance and swing phases are referred to as heel-strike (A) and foot-lift (B).

signal samples to original plus two previous samples (5th and 10th) resulted in the best ALN training performance. **c)** Minimum of ten gait cycles were necessary for successful training, we used fifteen. **d)** ALN training parameters were: five layers, 0.15 learning rate, and fifteen epochs.

A new measure of evaluating the ALN output was introduced. In addition to calculating the actual percentile error, which does not reveal information about the type of error, the output signals were assessed by calculating the frequency distribution of transition duration (TD). This distribution was calculated by counting the number of samples between each transition. This approach was selected due to the periodic nature of the gait. Comparing the TD distribution of the ALN output to the distribution of the target signal revealed information of its functionality (Fig. 3).

For elimination of functional errors /2,5/, different methods using restriction rules were investigated. In the first method we eliminated transitions shorter than a specified duration (blanking), while in the second method we applied a moving average filter followed by a threshold (smoothing). Both methods eliminated short duration transitions, however they introduced a small delay in the output signal. This delay was considered to be negligible for foot-drop correction. Each method was tested individually as well as combined with the other one.

The restriction rules used in this study were a modified version of the rules described in /5/. The equation below illustrates the concept.

$$(\bar{P}_{st} - 2 \cdot s_{st}) < P_{st} < (\bar{P}_{st} + 2 \cdot s_{st}); P_{bs} > \bar{P}_{bs} - 2 \cdot s_{bs} \quad (1)$$

where P_{st} is stimulation period (swing) and P_{bs} is period between stimulation (stance).

We developed adaptive restriction rules (ARRs) by calculating the mean and standard deviation for stance and swing phases and used them to eliminate control signal transitions considered to be ‘out of range’ for this particular user. The modifications consisted of continuous adaptation of the rules to current gait as the ALNs were evaluated on new data. A buffer containing transition duration information on stance and swing phases during the previous fifteen gait cycles was used to store and to calculate new mean and standard deviation values for the restriction rules. The buffer was updated following each transition in the output from the restriction rules.

RESULTS AND DISCUSSION

Figure 3 illustrates TD distributions of the target FES control signal, ALN output and the ALN output processed by the adaptive restriction rules. Most of the swing phases were detected correctly by ALNs, while most of the errors occur in the stance phase (Fig. 3B). Almost none of the complete stance phases were detected. For both stance and swing phase a large number of short duration transitions (i.e. 1-3 samples) were present (not shown). All this indicated that additional processing of the ALN output was necessary before the signal could be used to control a

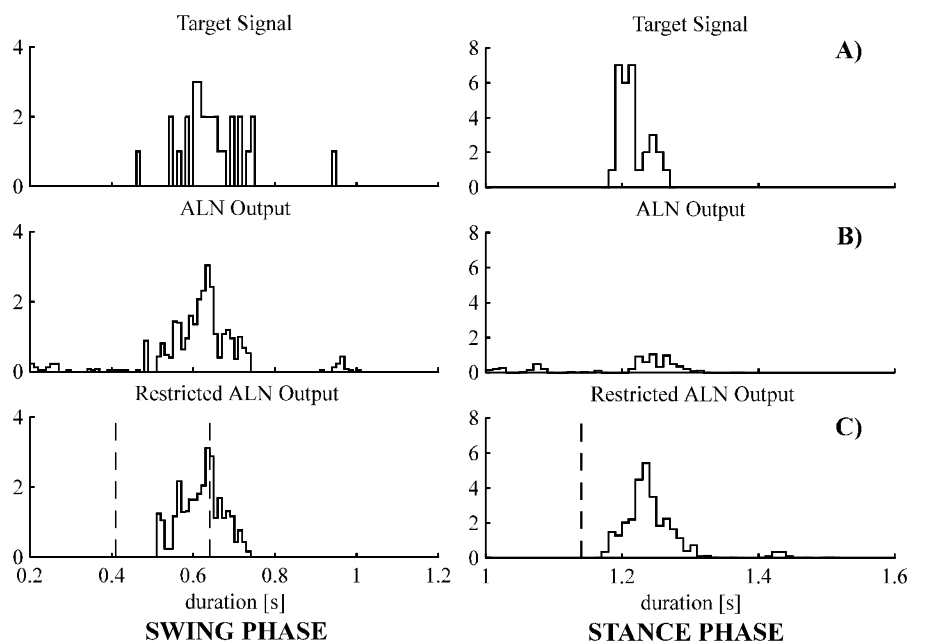


Figure 3. Distribution plots of swing and stance phase transition duration for target control signal (A), ALN output (B), and ALN output processed by adaptive restriction rules (C).

stimulator. Blanking method was the most successful in eliminating short transitions as well as in restoring complete stance phases prior to applying statistical restriction rules.

Applying adaptive restriction rules removed short duration transitions from both stance and swing phases and altered the TD distribution to resemble the distribution of the target signal (Fig. 3C). Dashed lines illustrate initial acceptance margins calculated from the training set using (1). If the restriction rules were not gradually adapted to the test data almost half of the swing phase pulses (i.e. stimulation pulses) would be shortened to the upper limit of the acceptance range. Some of the transition durations were clipped during the adaptation period, which resulted in their higher accumulation at the initial upper limit for the swing phase.

Results from applying ALNs and adaptive restriction rules are illustrated by an example of off-line test in Figure 4. All of the swing and stance phases in the restricted ALN output were complete and of similar duration to the original, which demonstrates potential of this approach for safe operation of the FES control system. As a consequence of using blanking for short transition elimination prior to applying the restriction rules, all transitions are delayed. At sampling rate of 100 Hz, 20 to 30 ms delay is considered to be negligible for overall performance of the foot-drop correction system.

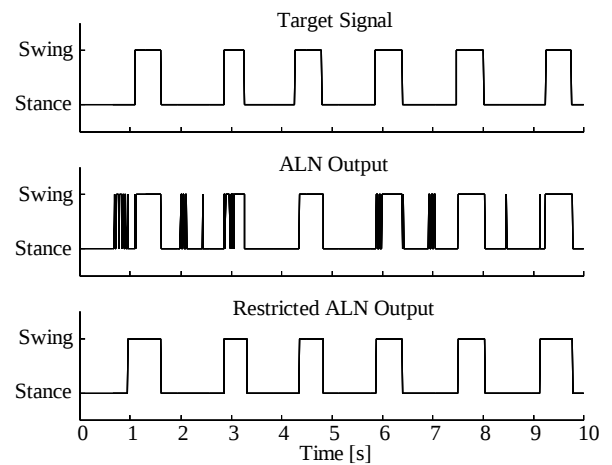


Figure 4. An example of the target FES control signal, its prediction by ALNs, and the ALN output processed by adaptive restriction rules.

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EVALUATION OF A PORTABLE TELEMETRIC FNS DEVICE IN A 3-D MOTION ASSESSMENT SYSTEM

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SUMMARY

A telemetric multi-channel system for functional neuromuscular stimulation (FNS) has been developed and applied in an attempt to reproduce movement. A post stroke hemiparetic patient was asked to perform foot dorsiflexion in a video based motion analysis laboratory. At the same time, EMG data of relevant muscles (tibialis anterior and peroneus tertius) was being acquired. Muscle firing sequence and timing were obtained from the EMG and then used to determine a set of parameters for the FNS system. EMG data was taken from the non-paretic side and the FNS was applied to the affected side, allowing a comparison between foot dorsiflexion trajectories with and without FNS. Such comparison was performed with the aid of the video based motion analysis laboratory. The stimulation parameters are defined by the user on a personal computer connected to a radio transmitter, which transfers them to a radio receiver on the portable, 4-channel, microcontrolled FNS system. The main advantage of a portable telemetric FNS system is the added autonomy for the patient to move in the rehabilitation centre.

STATE OF THE ART

Since 1791 the relationship between electricity and muscular contraction has been investigated¹, developing many studies on electrical stimulation and muscular physiology. Nowadays, several works are under development in the FNS field, mainly in implanted stimulators, a technology still inexistent in Brazil^{2,3,4}. Most of the works apply to the use of FNS with implanted electrodes in spinal cord injured patients. Kagaya et al⁵ applied FNS in two complete paraplegics and they were able to stand up smoothly based on stimulation data obtained from normal subjects. Movement was quantified through electromyography joint angles and floor reaction forces. This information can be provided by a motion analysis system. Investigations about temporal-distance variables⁶, type of gait control⁷ and effects of specific drugs in hemiplegic patients^{8,9} are some of the applications of the use of cinematography, force platforms and electromyography during movement.

According to Andersen et. al¹⁰ there are few studies about ankle dorsiflexion and plantarflexion. To fulfill this deficiency, ankle dorsiflexion with FNS in a spastic hemiparetic patient has been studied with the aid of a motion analysis system.

MATERIALS AND METHODS

A portable telemetric functional neuromuscular stimulator has been developed. The system includes a radio transmitter connected to a microcomputer and a battery-operated portable module connected to the patient through surface electrodes. The operator defines the stimulation waveform

parameters on the microcomputer. These parameters are transmitted to the portable module through the radio link. The equipment generates stimuli in electrical current using biphasic rectangular pulses and PWM. Error detection techniques are used to validate the parameters and commands received. On the portable module, user interface is provided through a LCD and LEDs.

The Motion Analysis Corporation system installed in the Rehabilitation Medicine Division of Clinical Hospital, Faculty of Medicine of the University of São Paulo was used for a quantitative analysis of obtained trajectories. This system integrates six video cameras and a surface electromyography device with computer hardware and software devised for biomechanical analysis.

A 46 year-old left hemiparetic female subject with braquialis predominance was evaluated in this study. Her condition is associated to a stroke occurred during a decompression of the trigeminus nerve. The selection criterion was her present rehabilitation program, which includes regular FNS application to the tibialis anterior.

The subject was seated, allowing freedom of movement to the ankle joint avoiding contact to the ground. EMG signals of the tibialis anterior and peroneus tertius¹¹ of the non-affected side were acquired during voluntary dorsiflexion. Muscles firing sequence and timing were obtained from these signals defined the stimulation parameters to be applied to the affected side of the patient. The video system provided kinematic movement analysis in both situations.

RESULTS

Figure 1 depicts EMG signals of the selected muscles during voluntary dorsiflexion of the non-affected lower limb of the patient. The stimulation waveform timing was extracted from the analysis of these signals. These signals reveal a slight difference in muscle contraction time, the action of tibialis anterior being longer. Therefore, stimulation waveform parameters provided a 0.2 ms longer contraction time to the tibialis anterior. The maximum pulse width applied to the peroneus tertius was 200 μ s, while for the tibialis anterior it was 125 μ s.

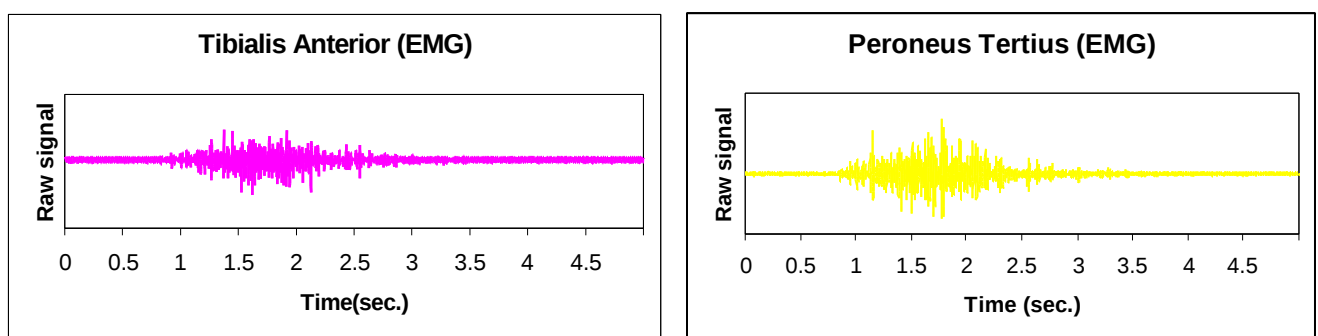


Figure 1 – Raw myoelectric signals from selected muscles of non-paretic side during voluntary dorsiflexion.

The dorsiflexion obtained on both sides can be compared by the analysis of trajectories (Figures 2 and 3). An important reduction of rotation was noted on the affected side as compared to the non-affected one. However, the paretic side presented an increase in abduction. These differences occurred due to the equinovarus pattern of the patient, which induced an abduction movement and limited rotation. Considering eversion as a complex movement involving rotation and abduction, the FNS reproduced movement was reasonable. Further research involving alternative muscle groups should be developed.

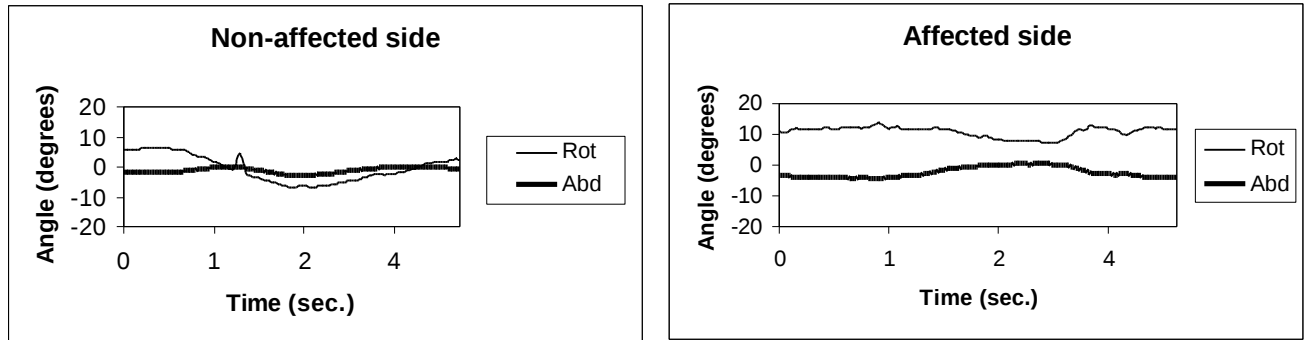


Figure 2 – Thick lines represent abduction angle during voluntary dorsiflexion of the non-affected side and FNS induced dorsiflexion of the affected side

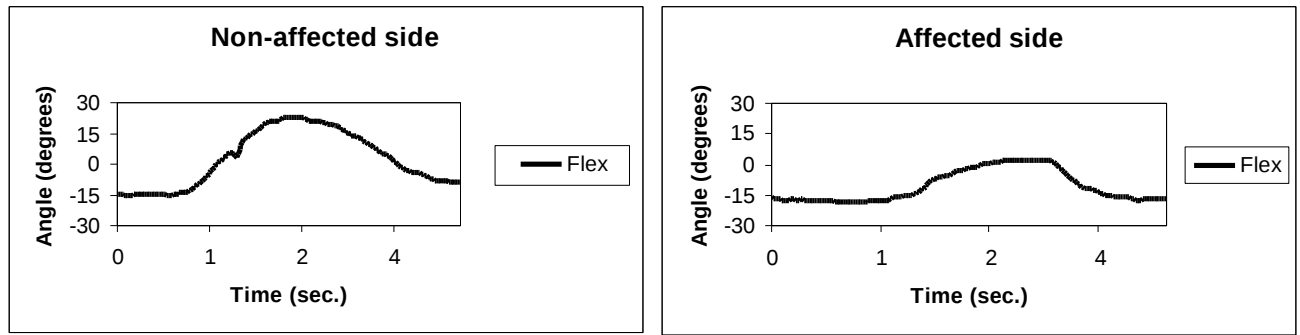


Figure 3 – Ankle flexion angle during movement of non-affected and affected sides. Positive values refer to dorsiflexion angles.

Angles (degrees)	Non-affected side		Affected side		Percentage in relation to non-affected side
	Max	Min	Max	Min	
Ankle Rotation	6.30	-7.05	13.70	6.92	50.8%
Ankle Abduction	0.27	-3.01	0.31	-4.91	159.1%
Ankle Flexion	23.00	-15.17	2.35	-21.50	62.5%

Table 1- Maximum and minimum ankle angles.

In a quantitative approach (Table 1), the induced dorsiflexion resembled the voluntary movement with restrictions, which are partially justified by some factors like: postural pattern, no previous conditioning of the peroneus tertius and the use of superficial electrodes that limited the muscle selectivity. The Table 1 percentages were obtained from the differences between maximum and minimum angles.

DISCUSSION

Results reveal that the proposed approach can be used to evaluate the portable telemetric FNS device. In general, the movement was reproduced but in a minor scale.

Obtained foot flexion was encouraging. Further efforts should be aimed at the selection of additional muscles involved in the desired movement considering that the FNS device provides two extra stimulation channels.

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"THE UTILIZATION OF THE FUNCTIONAL ELECTRICAL ORTHOSIS - KM25 IN REHABILITATION OF HEMIPARETIC PATIENTS"

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SUMMARY

Orthosis are therapeutics devices of functional aid used in Rehabilitation Medicine. In the last few years, a great progress has been achieved in gait rehabilitation because of the association of the functional electrical stimulation (FES) to conventional orthosis. The functional electrical orthosis (FEO) KM25, developed about five years ago, is an external system with one channel of stimulation triggered by one switch that provides electrical pulses on ankle dorsiflexors muscles, correcting the dropped foot during the swing phase of gait. The parameters of the stimulator are: frequency between 10 to 90 Hz, pulse width from 0.2 to 0.6 ms, intensity from 0 to 100 V, attack and descent time of 0.2 ms and maximal stimulation time of 7 seconds. The authors describe the stimulator blocks diagram, the application methods and the FEO- KM25 indications. The physiological effects caused by FES during locomotion and the results of using the FEO- KM25 in eight hemiparetic patients at a Rehabilitation Hospital were approached.

STATE OF THE ART

The Functional Electrical Stimulation (FES) is an electrotherapy modality applied on plegic or parietic muscles that have suffered superior motor neuron injuries, aimed at executing functional movements. For locomotion, the objective of using the functional electrical orthosis (FEO) is to provide, besides articular stabilization (what can also be supplied by conventional orthosis), other effects generated by the use of FES, such as production of effective muscular contractions, augment circulation and stimulation of new spinal cortical routes /1,2/.

The authors designed the FEO- KM25 together with the Chairman and Physiatrist-in-Chief G.A. Fonseca, at Arapiara Hospital, in Brazil in 1992 /3/. This article describes the FEO- KM25, the methods for its use, the physiologic effects, the indications and the achieved results on eight hemiparetic patients.

MATERIAL AND METHODS

The conditions to enter the gait program were: patients suffering from spastic hemiparesis with partial control of hip and knee muscles, lack of dorsiflexion on the foot and response to the contraction of the anterior compartment muscles of the leg with the use of FEO- KM25.

The FEO- KM25 (Fig. 1) is an external device composed of an electrical stimulator, a sensitive insole and a pair of surface electrodes. It weighs 81.50 grams, has dimensions of 95x60x23 mm, is powered by a 9-volt battery and is composed of six blocks, described as follow (Fig. 2).

Interface Block - its function is to eliminate noises from the electrical contact and to put the power controller into action; **Power Controller Block** - it allows the variation of the tension level applied to the voltage elevator block through the power adjustment; **Voltage Elevator Block** - it produces an alternate tension with frequency, pulse width and intensity determined by the oscillator, timer and power controller

blocks, respectively; **Oscillator Block** - it generates a frequency between 10 and 100 Hz, through the rc circuit; **Timer Block** - it receives the frequency from the oscillator block and produces consecutive pulses of equal intensity, and time duration adjustable between 0.2 and 0.6 ms. **Automatic Switch Off Block** - it is responsible for inhibiting the interface block, operation which takes effect seven seconds after the last command of the insole.

Each pulse has two semicycles: one of positive amplitude and the other of negative amplitude. The period of attack and decent is 200 ms. The sensitive insole has two conductors separated by an insulating material and presents several points of contact along the plantar surface. The surface electrodes are made of conductive silicon and have an area of 4.91 cm².

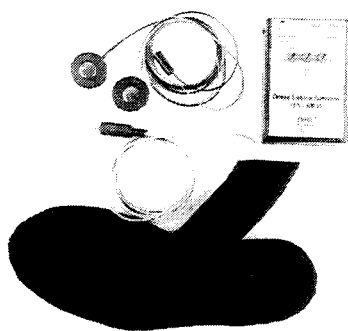


Fig. 1 - The FEO-KM25

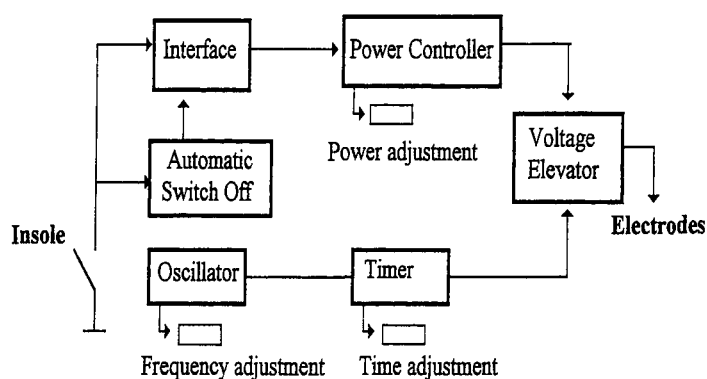


Fig. 2 - Blocks diagram of the FEO - KM25

The parameters of the pulse train were defined according to the muscular contraction response of each patient. The first electrode was placed behind the lateral head of the fibula and the second was placed on the anterior compartment of the leg.

The patients have used the FEO- KM25 for a period of eight weeks, and then submitted to a comparative observational evaluation of the gait with and without the FEO- KM25 through the system of describing the phases of gait developed at Rancho Los Amigos Medical Center. It was measured the indirect energetic consumption of gait through the Physiological Cost Index (PCI), and with one of the patients it was used the cinematic study through the Vicom 370 system, with six infrared cameras 60 Hz, two video cameras and three AMTI force plates.

RESULTS

The observational evaluation of the gait shows that the FEO- KM25 has provided the dorsiflexion of the paretic ankle during the swing phase in all eight patients (Fig.3), in spite of the age range (nine to 66 years old) and the time between pathology and beginning of FES therapy (three months to 13 years).

Fig. 3 - Group of hemiparetic patients in study and PCI during the gait

Patient				Time of pathology start use FEO-KM25	Dorsiflexion/FES during swing	PCI (bat/m)	
Name	Age	Sex	Hemiparesis			Free Gait	Gait with FEO-KM25
LHEC	13	M	L	10 years	+	0,57	0,50
TOM	09	M	R	04 years	+	0,19	0,08
FCNS	15	M	R	13 years	+	0,12	0,10
EFP	66	F	R	11 months	+	0,30	0,27
CDF	14	M	L	04 months	+	2,22	1,46
HRFZ	32	M	L	14 months	+	1,14	0,83
ESF	32	F	R	03 years	+	0,13	0,06
SAC	54	F	L	03 months	+	1,31	0,49

The test of energetic consumption measured in all patients showed evidence of a significant reduction in the PCI ($p=0,005$) of the patients using the FEO - KM25 compared to the PCI in the free gait (Table 1).

Table 1 - PCI during the gait with and without the use of the FEO - KM25

Use FEO KM25	PCI			p
	Low	High	Media	
No	0,12	2,22	0,75	0,005
Yes	0,06	1,46	0,47	

Note: $p=0,005$ - Friedman test

In the comparative cinematic evaluation of the gait of one patient (TOM) it has been observed that during the free gait the patient presents a right plantar flexion of 10° in the initial contact phase and during the swing phase as well. During the gait with the FEO - KM25 it has been observed that the initial contact phase was achieved with a dorsiflexion of 10° as well as in the swing phase (Fig. 4).

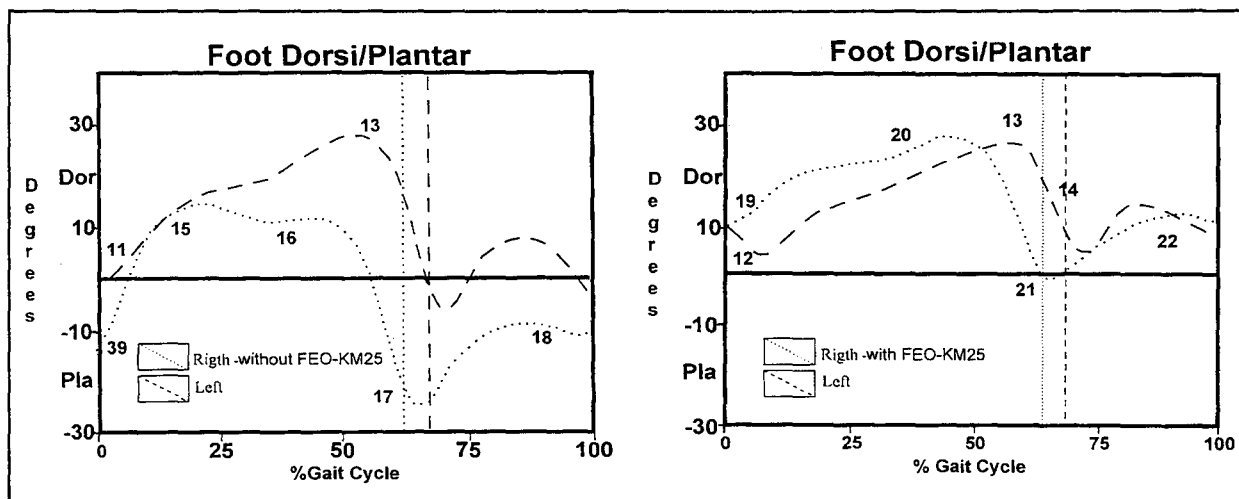


Fig. 4 - TOM kinematic data. Analysis of foot motion in sagittal plane with and without FEO-KM25. The vertical lines separate stance phase from swing phase. Foot contact occurs at 0% of gait cycle.

DISCUSSION

We know that the incidence of patients with hemiplegia in Brazil is high, sometimes occupying half of the beds in Rehabilitation Hospitals /3/. Kralj A *et al.* have shown through a twenty-year study that in 2,500 hemiplegic patients using FES for the gait, 60% needed only one channel of stimulation /5/. Histologically, we know that the plegic muscles atrophy from superior motor neuron injury is selective and predominantly from type II muscular fibers /4/, and that physiologically the muscular fibers have great capacity of morphologic adaptation, depending on the type of enervation they receive /6/. Greve JMD *et al.* have demonstrated that the use of FES increases the amount of type II fibers, which makes evident the improvement in the gait for patients using electrical orthosis /7/. Hazlewood M. E. *et al.* have used FES for the gait of patients with hemiplegic cerebral palsy with frequency of 30 Hz, 0.1 ms of pulse width and stimulation period of 7 seconds, and they have observed a significant increase in the anterior tibial muscle strength of patients using FES /8/. Malezic M. *et al.* have used FES for the locomotion of hemiparetic patients with frequency of 20 Hz, pulse duration of 0.2 ms and current intensity between 50 and 90 mA, and they have also demonstrated a improvement in the cadence, speed and distance achieved by these

patients /9/. Carmick J. *et al.* describe a PCI reduction of up to 70% during the gait of hemiparetic children using FES /10/.

The FEO- KM 25 is indicated to hemiparetic patients who have suffered superior motor neuron injury and present partial control of the hip and the knee. Due to several physiological effects, an evaluation by a specialist and a medical follow-up is essential.

CONCLUSION

The use of functional electrical orthosis to help during the gait is nowadays a tendency in Rehabilitation Medicine. We know that the electrical orthosis, besides articular stabilization, provide a decrease in the energy consumed in the gait and an increase in the speed, cadence and distance achieved by patients using this devices.

The FEO- KM25 has shown to be an effective device to be used with hemiparetic patients who have suffered superior motor neuron injuries, promoting the articular stabilization of the ankle during the swing phase of the gait and also a larger economy in the energy consumption for the locomotion of these patients.

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Computer simulation of field distribution and excitation of denervated muscle fibers caused by surface electrodes

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SUMMARY

In the last 25 years research in functional electrical stimulation (FES) of denervated skeletal muscle has mainly been dealing with experiments to empirically get the right stimulation parameters (amplitude, pulse width, frequency, impulse shapes, ...) and proper electrode design and configuration.

In the course of the study, two submodels has been developed and combined: 1) finite element modelling of the electrical potential distribution in 2-D human thigh and 2) a Hodgkin & Huxley type model to calculate fiber excitation and action potential (AP) propagation.

The theory of the electric field is well known, but it is difficult to calculate the field in living tissue, since the conductors involved have different areas of conductivity, furthermore the field depends on direction of muscle fibers (MFs) and intramuscularly fibroblasts. In order to determine the activation for each muscle fiber (with the help of the activating function), the direction of each muscle fiber (MF) has to be known and the electric field along the fiber has to be calculated as a function of the applied electric current and potential at the electrodes, respectively. The excitement of the MF varies in a wide range, dependent on the active and passive membrane parameters and the intracellular and extracellular medium.

Persisting denervation leads to a decay of muscle cells and a partially substitution by fibroblasts occur. Therefore the electrically activation of the tissue growth more difficult and biphasic stimulation pulses up to 200ms in duration and 60-100V amplitude are needed to cause a contraction of the denervated muscle. An example shows the field distribution and the stimulated activity and propagation of the AP in one representative MF of a well trained M. rectus femoris.

Clinical investigations by Kern /1/ showed that involution of atrophy and consequently reduction of required impulse duration can be achieved. Shorter stimulation impulses enable higher stimulation frequency and hence near normal tetanic muscle contractions.

STATE OF THE ART

Excitation of denervated skeletal MFs depends either on electric field distribution in muscle tissue or on membrane properties and the microscopic morphological features of muscle cells. No useful model of the electric field in human thigh has been calculated up to now. But with the potential distribution along one MF the activating function (AF) /2/, like Rattay calculated along a nerve fiber, can be determined.

A useful membrane model /3/, caused by the use of voltage-clamp techniques, is available and the early model study of Adrean & Peachey /4/ showed that the transversal tubular system (T-system) exerts an important loading effect in the form of a tubular outlet current.

The whole simulation of the combined models is necessary to quantitatively observe all the processes which happen during FES and to optimize the effects caused by the applied voltage.

MATERIALS AND METHODS

The electric field

For FES of den. muscle a specific electric field around each MF is required, which is applied by a pair of electrodes and an appropriate stimulator.

For the model of the electric field, atrophy essentially means that combined with the decrease of the muscle cross-section an increase of the muscle surrounding fat and intramuscularly fat will occur [1]. To reach MFs in deeper regions, current has to be strong enough but causes tissue damaging maximum current densities, which give a border of the system. A surface stimulator for denervated quadriceps femoris has to generate biphasic pulses of 10-200ms duration and 0-100V amplitude, applied by two large electrodes (200-250cm²) arranged like shown in Fig. 1.

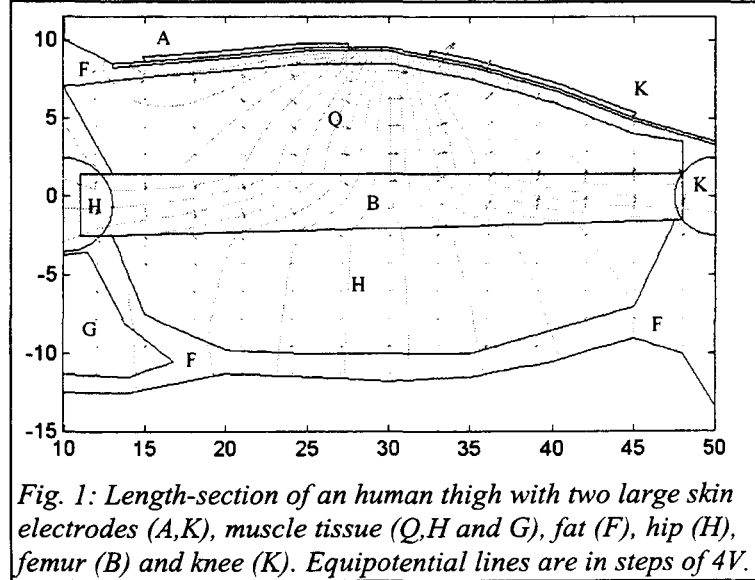


Fig. 1: Length-section of an human thigh with two large skin electrodes (A,K), muscle tissue (Q,H and G), fat (F), hip (H), femur (B) and knee (K). Equipotential lines are in steps of 4V.

Fig. 1 was calculated with the help of the Matlab PDE-toolbox and shows a length-section of the thigh with two large skin electrodes. The stimulation pulses are biphasic rectangles of 30ms duration and 80mV amplitude [1], therefore the calculation can be made under quasistationary conditions.

The denervated muscle fiber

A MF is a cell of tubular shape which essentially consists of the sarcolemma, the transverse tubular system (T-system), the myofibrils and the intracellular fluid. The currents through the ionic channels can be calculated by the method of Hodgkin & Huxley [5]. The proper parameters of different types of MFs can be derived from in vitro experiments [6]. The Hodgkin & Huxley (HH) -model considers the Na⁺-channels and K⁺-channels. For the description of the gating mechanism of these specific channels three parameters m , n and h are used [5]. A hyperpolarization potential caused by the denervation gives a shift of the Na⁺-channel characteristic m^3h towards hyperpolarization.

The description of the membrane current i_m is done by the sum of all currents in point 1 of Fig. 2, which shows a network section of the MF consisting of a system of electric circuits for the sarcolemma and the T-system connected by resistors (R_e , R_i), and yields to

$$i_m = i_{ion} + i_T + C_m \frac{dV}{dt}. \quad (1)$$

The ionic current over the membrane resistance R_m consists of the sodium current i_{Na} , the potassium current i_K and the leakage current i_L . This three nonlinear currents (R_m is extremely nonlinear) are described by Hodgkin & Huxley [5].

The current flowing out of the T-system i_T results from the potential difference between the membrane potential V and the outermost (at radius a) tubular potential $V_T(a)$, which causes a current over the access resistance R_S of the T-system. The tubular potential can be determined from the differential equation [7]

$$G_{L,T} \left(\frac{\partial^2 V_T}{\partial \rho^2} + \frac{\partial V_T}{\rho \partial \rho} \right) = c_T \frac{dV_T}{dt} + i_{ion,T}, \quad (2)$$

where C_T is the capacity of the T-system (Fig. 2). The calculation of the ionic currents of the T-system $i_{ion,T}$ over the resistance R_T (Fig. 2) is analogue to those of the sarcolemma with corresponding parameters. $G_{L,T}$ denotes the lumen conductivity of the T-system and ρ is the fiber radius.

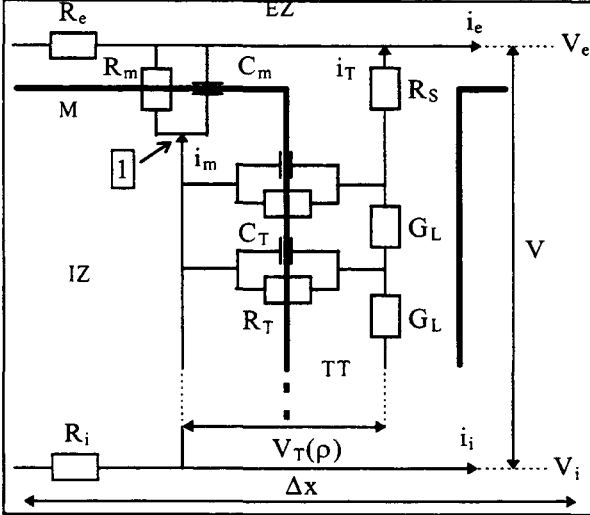


Fig. 2: Network section Δx of the MF, consisting of the sarcolemma (M), the T-system (TT), the extracellular (EZ) and the intracellular (IZ) space. The electric circuit for the sarcolemma and the T-system consists of the nonlinear HH-resistance R_m , the membrane capacity C_m and the nonlinear HH-resistance R_T , the capacity C_T connected by the lumen conductivity G_L , respectively. i_T denotes the current coming out of the T-system over the access resistance R_s . The extracellular potential is denoted V_e , the intracellular potential V_i and the tubular potential V_T . i_m describes the ionic current over the sarcolemma. i_e and i_i are the extra- and intracellular current over the resistors R_e and R_i , respectively into the next compartment Δx .

The propagation of the AP is determined by [3/

$$\frac{d}{4\rho_i} \left(\frac{\partial^2 V}{\partial x^2} + \frac{\partial^2 V_e}{\partial x^2} \right) = \frac{\partial V}{\partial t} + i_{ion} + i_T. \quad (3)$$

The right part of (3) is described by (1). The left part consists of the fiber diameter d , the intracellular conductivity ρ_i , the second derivation of the transmembrane and the extracellular potential V and V_e respectively to the fiber length x .

$V_e(x)$ will be calculated as a function of the tissue depth with the assumption that the fibers of the M. rectus femoris are parallel with the surface of the quadriceps Fig. 1. The AF follows to estimate the stimulating effect of the applied electric field as a function of x and the influence by the extracellular potential $V_e(x)$ becomes

$$f = \frac{d}{4\rho_i} \cdot \frac{\partial^2 V_e}{\partial x^2}. \quad (4)$$

The AF concept [2/] was used by many workers to calculate the recruitment of nerve fibers, and it is also useful to simulate the electrically stimulated MF.

(3) can not be solved in an analytical way, thus the solution has to be found numerically. For example Adrean & Peachey [3/] and Adrian et al. [4/] used Runge-Kutta and Henneberg & Roberge [7/] and Reichel et al. [8/] Crank-Nicolson, respectively.

RESULTS AND DISCUSSION

Fig. 3 shows the propagation of the AP, along one MF, elicited by the electric field in the M. rectus femoris. It can be observed that the fiber requires biphasic pulses shorter than 30ms to get excited. The AF is negative till about 27cm (horizontal position in Fig. 1) and positive afterwards. This causes the first AP at 30cm and propagates in both directions from there. The second biphasic pulse activates the fiber also in the area of negative AF, but propagation stops when the AP crashes the propagation elicited from an other point of the fiber. The third pulse activates the fiber again at 30cm.

Pulse duration depends on state of training by FES after denervation. Three different states of training are considered. The first was a nearly physiological one (Fig. 3) and was calculated as 100%, the others were

calculated with 80 and 60% of muscle mass and fiber diameter of the first. Simulations at this three different states of training showed that about 30ms (100%) to 160ms (60%) biphasic pulses are required to elicit all fibers in the whole M. quadriceps, respectively.

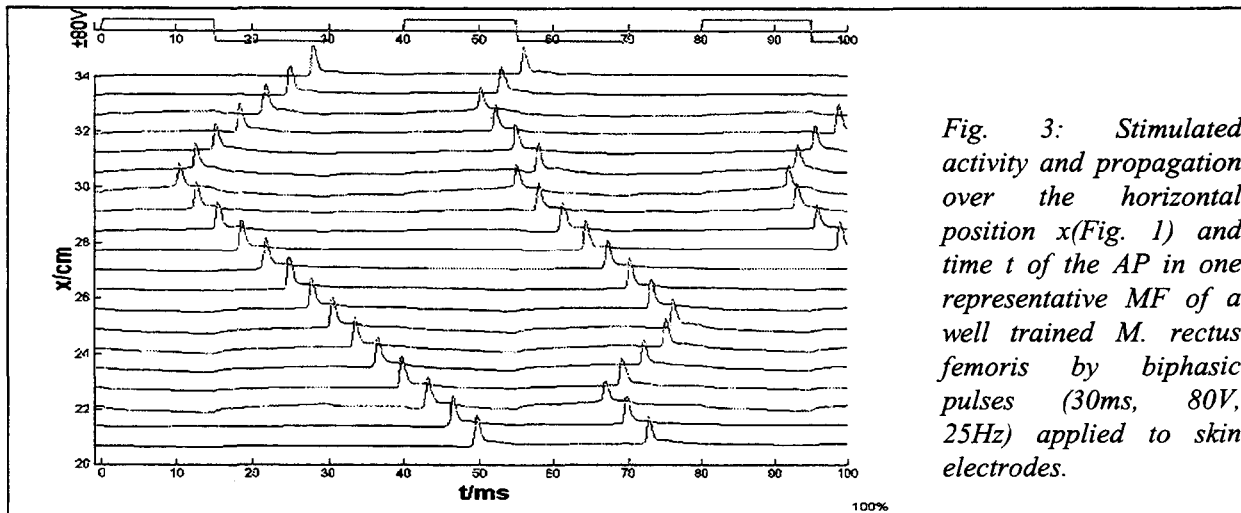


Fig. 3: Stimulated activity and propagation over the horizontal position x (Fig. 1) and time t of the AP in one representative MF of a well trained M. rectus femoris by biphasic pulses (30ms, 80V, 25Hz) applied to skin electrodes.

Since a 3-D model of the thigh has not been simulated, the activation of fibers in M. vastus lateralis and medialis has not been calculated. But stimulation parameter of three denervated patients show that the AF must be equal to them in the M. rectus femoris to cause contraction simultaneously.

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LONG PULSE BIPHASIC ELECTRICAL STIMULATION OF DENERVATED MUSCLE

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SUMMARY

In recent years a number of studies have employed Long Pulse Biphasic stimulation as a treatment for denervated muscle to improve tissue quality and in some cases to improve contractile capability sufficient to restore function. However in the UK, this treatment is yet to be widely adopted clinically. A five subject case study trial of Long Pulse Biphasic direct stimulation of peripheral limb denervated muscle is being conducted and its effect on the tissue evaluated by measurement of muscle bulk, limb blood flow and skin temperature. In cases of partial denervation, trapezoidal shaped pulses are used to minimise sensory and motor nerve fibre recruitment.

STATE OF THE ART

Galvanic, direct electrical stimulation with pulses widths of up to 300ms has been the conventional stimulation treatment for denervated muscle but its popularity has declined with the controversy regarding its effect on nerve growth and muscle re-innervation [1] and the minimal therapeutic benefit observed by many [2]. The latter may be because the frequencies used were limited by muscle fatigue and potential skin damage from non charge balanced monophasic pulses and because of the lack of available home stimulators which precluded regularity of treatment.

More recent studies in Vienna [3, 4] and elsewhere [5-8] have employed biphasic stimulation pulses, consisting of charged balanced negative and positive going impulses in quick succession. With continued daily treatment the muscle has been shown to respond to progressively smaller pulse widths, thereby allowing an increase in frequency and eventually tetanic contractions, typically with pulses of 20-50ms at 10-25Hz. This treatment has demonstrated therapeutic benefits to tissue quality in terms of muscle bulk, blood flow, skin perfusion and temperature, and reduced oedema. By increasing the muscle contractile capability, it also offers the prospect of restored muscle function and perhaps enhanced voluntary recovery, by maintaining the muscle in a state suitable for re-innervation.

In these studies the duration of denervation prior to stimulation treatment is typically at least one year, thereby minimising the effect on any potential re-innervation. However re-innervation has been observed not to be inhibited by stimulation treatment [2, 5, 8, 11] and there is evidence of some forms of stimulation actually enhancing nerve growth [9]. The majority of peripheral limb cases studied have been of completely denervated limbs, stimulation of partially denervated muscle has in some cases been limited by excessive recruitment of local sensory fibres [5, 10]. This may be avoided by gradual increase of the stimulation intensity during the pulse, thereby allowing these intact nerves to accommodate to the stimulus, whilst still causing contraction of the slower responding denervated muscle fibres. Such exponential or linear ramping has been employed for treatment with low frequency monophasic pulses [11], however it remains to be established whether biphasic pulses of trapezoidal shape can result in the tetanic contractions and provide the therapeutic benefits obtained with the rectangular shaped pulses.

CLINICAL BACKGROUND

Salisbury District Hospital encompasses one of the UK's Spinal Treatment Centres and the Medical Physics and Bioengineering Department receives patient referrals for electrical stimulation with a wide range of neurological conditions. In particular, patients with spinal or brachial plexus injuries are assessed for peripheral limb Functional Electrical Stimulation for dropped foot, standing or hand function systems. However some prove unsuitable because of reduced sensitivity of the muscle to stimulation possibly attributable to muscle denervation. In such cases, it may be desirable to selectively stimulate the denervated muscle by direct stimulation with the objective of developing the muscle contractile force and eventually to achieve the functional aim, perhaps in conjunction with indirect stimulation of other muscles. In cases of complete peripheral limb denervation, direct stimulation treatment is more likely to be with the objective of tissue quality improvements. As yet, biphasic direct stimulation has not been employed extensively in the UK because of lack of experience with the technique and the absence of commercially available stimulator units capable of producing the required output pulses and yet suitable for home use by patients.

A previous trial of direct stimulation of peripheral limb muscle denervation with Long Pulse Biphasic pulses and surface electrodes has been conducted at Salisbury District Hospital in which two subjects underwent stimulation with rectangular biphasic pulses of 40ms at 12.5Hz twice a day for up to 15 minutes. Six weeks of treatment of the quadriceps muscles in the subject with a spinal injury, resulted in an increase in muscle bulk of 23%. Eight weeks of treatment of the lower arm of the subject with a brachial plexus injury for 8 weeks demonstrated an increase in muscle bulk of 22% and an increase in resting skin temperature of 3°C, but no significant change in resting limb blood flow. Daily stimulation with monophasic pulses of 30ms at 0.5Hz, produced a weak muscle twitch but no detectable change in these same tissue measurements in either subject over 3 months and 7 weeks respectively [6].

A further investigation of the treatment is planned to apply this experience and that of studies elsewhere to a larger number of subjects, with particular emphasis on the selection of stimulation parameters and the process of their adaptation as the muscle properties alter. Cases of partial limb denervation will be included and the effectiveness of trapezoidal shaped pulses to alleviate sensory and motor nerve recruitment evaluated. Initially, chronic long term cases, at least one year post denervation are being considered to minimise hindering potential re-innervation and concentrating on those where quantitative evaluation measurements can be performed. This experience with the technique will then be applied to cases where a functional outcome is more likely and eventually to acute cases using the Strength Duration curve to determine the progress of any re-innervation. It was recognised that a versatile stimulator unit would be required capable of producing a wide range of stimulation patterns which could be easily adjusted by the clinician as the muscle sensitivity altered and suitable for daily use at home by the patient. However at the commencement of the trial no such unit was forthcoming, commercially or in research circles.

MATERIALS AND METHODS

Five subjects with long term peripheral limb denervation are to participate in a case study based trial with 6 month treatment period and 6 month follow up period. The extent of innervation of the limb is to be determined by the response to stimulation with pulse widths of 0.3 to 300ms. The treatment will be performed by the subject or carer at home and consist of two daily sessions of biphasic stimulation of the selected muscle for up to 30 minutes. The session duration and stimulation parameters will be selected for the individual subject and re-assessed at regular hospital visits especially during the initial period as the muscle sensitivity alters. The effect of treatment will also be evaluated regularly throughout the trial by measurement of muscle bulk using linear array ultrasound, resting limb blood flow by electrical impedance plethysmography, resting skin temperature by Infra-red thermography,

the extent of innervation by determination of the Strength-Duration curve and where appropriate contraction force by dynamometer. These non-invasive measurements are easily performed and their use to evaluate these tissue changes established in a previous trial of indirect stimulation therapy [12].

Stimulator unit

A versatile micro-controller based unit has been developed for single channel stimulation with standard surface electrodes. Stimulation pulse patterns can be entered 'on line' from a PC based LabVIEW package via an opto-isolated serial connection and programmed into the unit for daily independent use at home by the patient. Output monitoring and other sensor data can also be transmitted to the PC for display allowing use in Strength-Duration curve measurement. The unit is portable and powered by an internal, rechargeable battery ensuring mains isolation. Built in safety features and feedback controlled constant voltage output provide protection against electrode peeling, component failure and operator misuse.

Unit specification:

- single channel simulation output of monophasic or biphasic pulses
- stimulation intensity - continuously variable 0-90V (1k Ω parallel 100nF load)
- pulse width (positive and negative impulses, excluding ramp) 1-450ms
- inter-impulse interval (between positive or negative impulses) 1-25ms
- pulse rise/fall time (linear ramp) 0.5 - 250ms
- inter-pulse interval 30ms-12s (33 - 0.083Hz)
- pulse repetition pattern variable
- treatment time limit (adjustable) 0-30min
- endurance (continuous 50mA, 10ms pulses@10Hz) >10hrs
- size 150 x 170 x 55mm
- weight 1.25 kg

A preliminary assessment has been conducted on two subjects with partial lower limb muscle denervation to confirm operation of the stimulator unit and response to the biphasic stimulation, in particular with trapezoidal shaped pulses.

RESULTS

Assessment of a subject, 12 years post T12/L1 spinal injury with lower limb atrophy, has demonstrated that the denervated quadriceps muscle can be selectively stimulated using trapezoidal shaped biphasic pulses (400ms overall impulse time including 200ms ramp time at 0.5Hz). Conversely, rectangular shaped pulses resulted in excessive recruitment of neighbouring innervated muscles which masked the small and rapidly fatigued contraction of the quadriceps. Lower limb sensory denervation was complete in this subject.

The second subject suffers from dropped foot arising from peripheral neuropathy denervation of the Tibialis Anterior three years previously and its subsequent atrophy. Stimulation with trapezoidal biphasic pulses resulted in much less recruitment of neighbouring innervated plantar-flexing muscles than with rectangular pulses but still resulted in a flexion withdrawal contraction of thigh muscles. This, together with the subjects own sensation, limited the practical intensity of stimulation.

This illustrates that response to stimulation varies with the extent of innervation and parameters have to be selected for the individual. Further results from the trial will be presented at the conference.

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**SPINAL CORD STIMULATION (SCS) FOR PERIPHERAL VASCULAR DISEASE:
A CRITICAL REVIEW OF THE EUROPEAN EXPERIENCE.**

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SUMMARY

Bypass surgery is the treatment of choice for patients with severe peripheral vascular disease. Limb salvage rates are around 70% at 3 years and 30% will require a below or above-knee amputation for severe limb ischemia. (1)

The ideal treatment in symptomatic non-reconstructable patients should allow the patient to retain his limb with no or tolerable pain and to maintain a satisfactory level of independence.

Spinal cord stimulation (SCS) is widely used the world over for the treatment of chronic ischemic pain.

STATE OF THE ART

In patients with non-reconstructable severe peripheral vascular disease, conditions become critical when blood supply no longer meets the metabolic demands of the acral skin.

SCS is an effective treatment modality in controlling ischemic pain and improving skin microcirculation and is therefore a technical advance in the field of ischemic pain management.

MATERIAL AND METHODS

Only patients with non-reconstructable vascular disease are potential candidates for a stimulation treatment. There is a formal contraindication for SCS in patients with a clear indication for distal bypass surgery. Other exclusion criteria are progressing ischemia, extensive gangrene and local infection, poor compliance, and short life expectancy.

Surgical Technique: This involves placing a quadripolar lead into the epidural space by performing a percutaneous lumbar puncture (Pisces Quad 3487A, Medtronic). The lead is advanced under radioscopic control to the level of Th 11-12. Midline placement is preferable. Connecting a portable stimulator to the lead allows intraoperative stimulation producing paresthesias in the painful foot or limb. During a trial period of one week the clinical effects are monitored and an implantable pulse generator (Itrel II or III, Medtronic) is placed in a subcutaneous pocket of the abdomen. The usual initial settings are a pulse amplitude varying between 1.0 - 2.5 V, a frequency between 70-120 Hz, and a pulse of 180-450 microseconds.

RESULTS

Ischemic rest pain in vascular disease is an excellent indication for SCS if patients are well selected for this procedure. Patients with intractable ischemic pain due to vasospastic vascular disease are ideal candidates, but patients with ischemic pain due to

arteriosclerosis with or without diabetes, or patients with Buerger's disease may also be good candidates for SCS. The first publication of a larger series was made by the group of Augustinsson et al., who, in 34 patients with peripheral vascular disease, reported excellent or good pain relief in up to 80% of the cases. (2) During the following years similar results were reported from several other centers. The most promising conditions include vasospastic vascular disease. Advanced age, subtotal occlusion of all vessels, severe diabetic disease are negative prognostic factors. Besides the relief of the ischemic pain, several studies have demonstrated that SCS improves the microcirculatory skin blood flow. Two centers studied more in detail the effects of SCS on the capillary blood flow. Jacobs M. et al. (3) assessed capillary density, capillary diameter and red blood cell velocity before and after arterial occlusion in 35 patients treated with SCS and it was shown that relief of ischemic pain was correlated with improved microcirculatory blood flow parameters. Claeys L. et al. (4) studied capillary morphology and red blood cell velocity in 47 patients with significant pain relief under stimulation. This study revealed an increase in the number of perfused capillaries, however, this increase was not significant. Mean capillary red blood cell velocity before stimulation was 0.11 mm/s and increased significantly to a mean value of 0.29 ($p < 0.021$). Other groups have published data of improvement of microcirculation as recorded by laser Doppler fluxmetry, or an increased tissue PO_2 . Sciacca V. et al. (5) demonstrated that laser Doppler flux measurement is an accurate non-invasive method of evaluating changes in microcirculatory flow. Horsch and Claeys (6) studied the effects of SCS on microcirculatory blood flow, using $TcPO_2$ in 237 non-reconstructable patients with severe ischemic pain. After a mean follow-up period of 31,2 months, major pain relief (>75%) was noticed in patients who retained their limbs. Sixty-four patients underwent major amputation despite SCS. Clinical improvement was confirmed by the increase in $TcPO_2$ ($p < 0.02$) from 21.7 to 44.5 mmHg in the patients with limb survival.

The most convincing data to demonstrate the effectiveness of SCS would be a difference in amputation rate between patients who have been treated by SCS and a group of patients who have had only a optimal medical treatment without SCS. Several prospective randomized studies are going on in Europe. The study of L. Jivegard et al. (7) is the first multicenter study evaluating the hypothesis that SCS improves limb salvage in non-reconstructable patients. Fifty-one patients, 41 with limb ischemia and 10 with diabetes, with inoperable severe ischemia were randomized to either SCS and peroral analgesic treatment or peroral analgesic treatment alone. Twenty-five and 26 patients were randomized to the SCS and control group, respectively. The systolic and diastolic blood pressures were measured and indices were calculated. Ischemic pain was assessed using the visual analogue scale and the verbal scale. Macrocirculatory parameters were not different in the two groups during the follow-up period of 18 months. Long-term pain relief was observed only in the SCS group. Significant differences in limb salvage rates between both groups were not noted. The hypothesis that SCS improves limb salvage in these patients was not proven. However, SCS provided long-term pain relief improving life quality of the patient.

Horsch and Claeys performed a randomized-controlled study with one year follow-up in 86 Fontaine stage IV patients with endstage

vascular disease undergoing 21 day intravenous prostaglandin E1 (PGE1) therapy for nonhealing ulcers.(8) Only patients with non-reconstructable vascular disease as proven by angiography were included. Inclusion criteria were an ankle systolic pressure <50mmHg, severe rest pain despite analgetic medication, and presence of nonhealing foot ulcers or dry gangrene. One week after the start of PGE1 therapy, patients were randomized into receiving SCS plus PGE1 (n=45 patients), or just PGE1 (n=41 patients). At 12 months total healing of foot ulcers in the SCS-group was significantly better (69 vs.17%; $p<.0001$) and more SCS-patients achieved an outcome of Fontaine stage II (claudication pain, no rest pain or lesions) (40 vs. 10%; $p=.0014$). Despite this clinical improvement, differences in amputation rates were not observed (minor/ major amputations; respectively 13 vs.15% and 16 vs.20%). Foot TcPO2 increased significantly for the SCS-group (+ 213 vs.-2%; $p<.0001$). Patients in either group whose TcPO2 rose to 26.0 $\pm$ 8.6 mmHg on average were able to heal ulcers or toe amputation wounds. PGE1-patients had temporary TcPO2 elevations of about 33% on average but this was gone by six months. SCS-patients had steady increases in TcPO2, and maintained them at 12 months. Among the SCS-patients, those with baseline TcPO2 $\leq$ 10mmHg had significantly less success at 12 months, this was not observed for the OMT-patients. The regional perfusion index increased significantly, 187 vs. 0%; $p<.001$). The results of the Dutch prospective randomized multicenter study, including 120 patients and comparing SCS versus optimal medical pain treatment, or not yet published.

Complications: Technical complications are reported from a few percent to more than 15%. Breaking of the probe and dislodgement are recognized by a loss or change of the stimulation-produced paresthesias. Replacement of the electrode is mostly successful. Reoperation can be difficult due to fibrosis around the electrode. Electrode dislocation will occur usually within the first 2 months following implantation. About 2% of the patients will develop an infection around the device. Removal of the system and intravenous antibiotics are mandatory. Liquor fistula have been reported but are very rare.

DISCUSSION

Amputation is often the only alternative for pain relief when vascular reconstruction is impossible. Since 1967, SCS has become an accepted technique for the management of chronic pain. The precise mechanisms to explain the effect of SCS on pain and peripheral blood flow still remain uncertain. A neurophysiological explanation is based on the Gate Control Theory of Pain postulated by Melzack and Wall in 1965. This theory of segmental pain inhibition postulates that the stimulation of large afferent nerve fibers in the dorsal columns of the spinal cord prevents the transmission of pain information from smaller diameter pain fibers. Relief of ischemic foot pain might be assisted by improvement of the microcirculatory blood flow resulting from a release of sympathetically mediated vasoconstriction, the inhibition of normal sympathetic activity and the release of vasoactive peptides or prostaglandines. There is also the possibility that SCS may act by releasing neurotransmitters involved in pain modulation.(9) The hypothesis that antidromic activation of afferent fibers causes vasodilation is no longer accepted. The results of experimental work done by Linderoth,

indicates that spinal mechanisms are essential and that antidromic activation of primary afferents is unlikely to account for peripheral vasodilation. Pain relief is definitely assisted by improvement of the microcirculation as shown in different experimental and clinical studies. TcPO₂ and capillary red blood cell velocity showed a significant overall increase in the patients with limb survival following the stimulation.

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EXPERIMENTAL WOUND HEALING WITH ELECTRICAL STIMULATION

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SUMMARY

The effect of alternating current (AC) and direct current (DC) stimulation was studied on experimental pressure ulcer healing in a new monoplegic pig model. The study was conducted in 29 healthy young Hanford mini-pigs. The rate of wound healing, histology, vascularization, collagen formation, microbiology, perfusion, and the mechanical strength of the healed wounds were studied. Normal pigskin was compared to denervated controls, denervated AC, and DC stimulated healed skin. Hind limb denervation was by right unilateral extra dural rhizotomies from L2 to S1 nerve roots. Reproducible uniformly controlled grade 3 or higher tissue ulcers were created. Electrodes were placed distal and proximal to the wound periphery and the wounds stimulated 2 hours per day, 5 days per week, for up to 30 days. Both AC and DC stimulated wounds showed reduced healing time, increased perfusion in the early phases of healing when compared to controls, DC stimulation reduced wound area more rapidly than AC, but AC stimulation reduced wound volume slightly more rapidly than DC. From uniaxial tension experiments to failure, the healed skin stiffness oriented parallel to the principle axis of current flow were reduced by nearly half the values obtained for normal controls. Samples oriented in the perpendicular direction were comparable to normal skin. The electrical stimulation did not reduce the strength of the healing wounds below the non-stimulated controls. The applied current appears to orient new collagen formation even in the absence of neural influences.

STATE OF THE ART

The treatment of pressure ulcers is a major concern for the patient and the health care provider. These wounds are costly in both economic and human value. Pressure ulcers affect the quality of life, may cause pain and suffering, and their cost of treatment reaches an estimated \$1.3 billion each year. To accelerate the healing of pressure ulcers various pharmacological, physical and surgical procedures have been tested. Of all the adjunctive therapies, electrical stimulation is the only one found with sufficient supporting evidence to warrant recommendation by experts for treatment of Stage III and Stage IV pressure ulcers which have been found to be unresponsive to conventional therapy /1/. The results of clinical trials on subjects with Stage III and Stage IV pressure ulcers have been reported to enhance the healing rate of wounds without serious adverse reactions /2,3,4/. The mechanism of healing effectiveness of electrical stimulation, however, has not been reported in humans or in animals with denervated skin that simulate patients with low level spinal cord injuries. To study the healing effect we developed a monoplegic pig model for grade 3 or 4 pressure ulcer (a wound extending to deep fascia or bone)/5/. The major advantages to using this flaccid monoplegic model are the low mortality, the minimal animal maintenance and disability occurring in a condition where tissue susceptibility to pressure ulcer are higher than in spastic tetraplegia .

The objectives of this study were to determine the healing time of pressure ulcers stimulated with AC and DC in comparison to unstimulated control ulcers created on denervated pig skin. Also to determine the vascularity of the healing granulation tissue of the wounds, the relation between stimulating current density and wound healing time and the effect of electrical stimulation on the mechanical properties of healing skin in denervated limb trochanteric pressure ulcer model /6/.

MATERIAL AND METHODS

Hanford mini pigs, 3 months old, weighing 17.8 ± 3.4 kg were used. Hind limb denervation was accomplished by right unilateral extra dural rhizotomies from L2 to S1 nerve roots. Unilateral nerve root transections are less invasive than spinal cord transection, resulting in no bladder and bowel dysfunction. Reproducible uniformly controlled grade 3 or higher tissue ulcers were created by the use of a 6.5 millimeter percutaneous cancellous screw installed in the right greater trochanter of the femur with a 3 centimeter diameter spring compression indenter. Electrodes were placed distal and proximal to the wound periphery and the wounds stimulated 2 hours per day, 5 days per week, for up to 30 days. In AC stimulation a charge-balanced tetanizing current (4 sec on, 4 sec off) with a amplitude of 7-10 mA and a pulse width of 300 μ s was applied at a frequency of 40 Hz. The amplitude was measured and adjusted just below contraction level with maximum calculated virtual current densities reading near 1.5A/cm² depending on the size of the wound. In DC stimulation the current flow was from proximal to distal electrode at a constant amplitude of 0.6 mA with varying virtual current density near 0.2 mA/cm² depending on the wound size.

The selected stimulus regime was chosen to closely reproduce the parameters of clinically applied stimulations in human experiments /2,3,4/. From biopsies of the wound margins the histology and the vascularity of the granulation tissue was analyzed to document the extent of the angiogenesis near the end of the healing process. The surface area and volume of wounds were measured during a three week period after pressure release. A series of measurements were taken to establish the normal and pressure-exposed tissue response to changes in perfusion as indicated by the change in transcutaneous partial pressure of oxygen. Properties of the healing skin were evaluated in uniaxially loaded tension tests until failure using a Chatillon ET 110 testing machine. Skin specimens were oriented parallel and perpendicular to the current flow.

RESULTS

There was no disturbance in bladder and bowel function in any of the animals. The sensory deficit region observed in all animals corresponded to dermatome L2 to S1. Wound uniformity was established by measurement of the initial surface area and volume and their change with time. All wounds healed rapidly including the non-stimulated controls. The wounds initially increased in both surface area and volume. Following the reach of a maximum value, each wound gradually reduced in size as granulation tissue filled the wounds. This gradual decreasing segment was found to fit an exponential function in both surface area and volume. The measured areas and volumes of the wounds after the maximum were fitted to the exponential function and the time constants calculated for each wound. The time constant was the number of days required for 63% reduction of wound size from the maximum.

The stimulation of pressure ulcers accelerated both the rate of wound closures and the rate of wound filling and reduced the variance in the outcome of the healing process. The application of AC or DC stimulation affected the reduction of wound area more than the reduction of the wound volume /table 1/.

In the DC stimulated group there was a trend toward the area time constant being shortest at a current density of $127 \mu\text{A}/\text{cm}^2$, among the AC stimulated group the current density giving the shortest area time constant was calculated to be $1125 \mu\text{A}/\text{cm}^2$.

Table 1 Wound Healing Time Constants (days)

	Wound Area				Wound Volume			
	n	Mean $\pm$ SD	CV	*	n	Mean $\pm$ SD	CV	*
Control	10	12.11 $\pm$ 7.09	0.6	0	8	4.41 $\pm$ 1.68	0.4	0
AC stimulation	11	9.37 $\pm$ 3.9	0.4	23	9	3.59 $\pm$ 0.93	0.3	19
DC stimulation	9	8.69 $\pm$ 2.98	0.4	28	7	3.94 $\pm$ 1.59	0.4	11

* = % Difference from control. CV = coefficient of variance

Gross observations of the healing wounds confirmed the early acceleration of healing. Contraction of the wounds occurred more rapidly in stimulated animals than in the controls. No histologic differences could be discerned between the AC and DC stimulated wounds. At the time of sacrifice, near complete healing, the blood vessel count and the total vascular area was measured from the biopsy specimens by two different experienced observers. The results of these histomorphometric analysis were not uniform between observers. The results indicated that electrical stimulation has minimal or no effect on the vascularity of the healed granulation tissue but most likely improves the number of the blood vessels and the vascular area in the healing tissue. No detrimental proliferative or cytopenic effects resulted from the electrical stimulation. Direct measure of skin perfusion showed an increase in blood flow in the healing process. The biopsy samples obtained at sacrifice showed the tissue concentration of soluble proteins to be not significantly different among the control and stimulated samples. There was a tendency for each pig to grow an increasing number of different bacterial organisms in the wounds of increasing age but no difference in the types of organisms could be detected between stimulated and unstimulated control animals. The study did show that the observed differences in wound healing with selected electric current types are most unlikely to be related to the effect of electric current on the bacterial organisms.

AC and DC stimulated skin and denervated control skin samples oriented parallel to the current flow were not stiffer ($P < .05$) than normal skin. Significant differences were also noted for stress and modulus values; however, the stiffness values did not approach that of normal skin. In general, there were no statistically significant differences among the samples obtained from perpendicular sites. The cumulative effect of electrical stimulation on the mechanical properties of pig skin was not damaging and was comparable to the results obtained from denervated skin alone. In these experiments, the scar tissue of AC and DC treated wounds appeared identical, and differentiation by mechanical means between the healed tissues was not possible.

DISCUSSION

The results showed that the application of electrical stimulation enhanced tissue perfusion in the early phase of healing more significantly with DC than with AC stimulation. These effects confirmed the finding of wound healing acceleration of DC stimulation above the AC stimulation. The shorter wound area time constant for DC than AC stimulation indicated a higher rate of wound area reduction with DC than AC stimulation but AC reduced wound volume more than DC. The studies also confirmed that electrical stimulation may orient new collagen formation in a pattern similar to normal skin even in the absence of neural influences.

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REGENERATION OF THE RADIAL NERVE IN THE DOG INFLUENCED BY ELECTRICAL STIMULATION

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SUMMARY

This study examines the effect of applied biphasic electric fields on nerve regeneration following injury to the left radial nerve of the dog using a method of electromyography. Left and right radial nerves in all animals were crushed with a serrated hemostat. One of the two bipolar stimulating electrodes was positioned just proximal and one just distal according to the injury. Right radial nerves in all animals were treated as controls and they were left to regenerate without electrical stimulation. Electrically treated radial received current across the lesion for two months. The stimulator was positioned and fixated under the skin. EMG activities recorded intramuscularly from left and right m. extensor digitalis communis muscles, elicited by electrical stimulation of crushed left and right radial nerves proximally and distally according to the lesion at the beginning and at the end of the two months stimulation period were compared. A significant difference between EMG activities of left stimulated and right unstimulated m. extensor digitalis communis muscles after two months stimulating period recorded proximally and distally according to the regenerated lesion suggests that the electrical treatment enhanced the progress of nerve regeneration.

STATE OF THE ART

The recovery of muscle function after nerve crush is a complex process involving axon regeneration and re-establishment of nerve muscle connections with recovery of nerve transmission and muscle contractions (1, 2, 3, 5). However, it is difficult to choose a single, reliable and quantitative method for the evaluation of muscle function recovery. It was demonstrated in recent works (4) that chronic monophasic, bipolar stimulation across the nerve crush lesion shortened the overall time necessary to restore muscle force. The purpose of this work was to investigate whether continuous stimulation with biphasic pulses of low current amplitude across the lesion in crushed radial nerve of the dog accelerates the ingrowth of regenerating motor axons into the m. extensor digitalis communis muscle.

MATERIAL AND METHODS

The implantable stimulator

We developed the totally implantable stimulator giving rectangular, biphasic, current stimulating pulses with amplitude of $30\mu\text{A}$. Both, anodic and cathodic parts of stimulating pulse pair were wide 1s. The bulk body of the implantable unit was a 10mm high cylinder with diameter of 29mm. The thick hybrid electronic circuit was covered by a special wax, molded in epoxy resin and enclosed in low pot made of stainless-steel (316L). Finally, the dimensions of the implant body were determined by molding aforementioned composition in epoxy resin using custom designed tool in vacuum unit. Bipolar stimulating electrodes getting out from the

implant were made of 10cm long biomedical wire with 1.5cm long deinsulated ends. At each deinsulated end, two loops with the diameter of 1mm were made. The distance of deinsulated part between loops was within the range of circumference of the radial nerve enabling the nerve trunk to be encircled by the electrode.

Experimental animals

The research was performed on adult Beagle dogs having up to 15kg. Heart rate, respiratory rate and body temperature were recorded, followed by administering premedication agent (medetomidine 40µg/kg i.m. and methadone 0.2mg/kg s.c.). After 20 minutes an intravenous catheter was placed (v. cephalica antebrachii) and urinary bladder was emptied. Operation field was prepared before induction and antibiotics were administered (cefazolin 20mg/kg i.v.). Induction was performed with propofol (0.5 to 2.0mg/kg i.v.). After endotracheal intubation dogs were brought into the operation room and anesthesia was maintained with isoflurane (0.8 to 1.5%) in 100% oxygen (flow 20ml/kg/min). Analgesia during surgery was improved with administering ketamine (0.5 to 2.0mg/kg i.v.) if necessary. After the completion of surgery, isoflurane was withdrawn and oxygenation with 100% oxygen was provided for 5 minutes. Dogs were disconnected from anesthetic machine and brought to recovery room and extubated. Analgesia was provided using opioid agonist methadone (0.3 to 0.5mg/kg s.c. every 6 to 8 hours) during early recovery period.

Axonotmesis

In all four experiments, axonotmesis was performed in the same manner. The skin over the left and right radial nerves was shaved, cleaned and disinfected. Left and right radial nerves were surgically exposed on lateral sides for a length of 4 to 5 cm. The left radial nerve was lifted intact and placed on a pair of dummy bipolar stimulating electrodes having the shape of fork. They were connected to the nerve stimulator, thus delivering the stimuli to the nerve. Right radial nerves were treated as controls and they were left to regenerate untreated. During stimulation of intact radial nerve, EMG activity of the m. extensor digitorum communis elicited by stimulation of mainly α motor fibers were recorded differentially with intramuscular electrodes inserted in the muscle belly, amplified and displayed on an oscilloscope. A common electrode was positioned in the tissue immediately under the skin. About 1cm above the bifurcation left and right radial nerves were then crushed with a serrated hemostat for 3 seconds. With the aim of ensuring as much as possible uniform injury the same hemostat having the same value of compression was used. After the crash, dummy electrodes were moved distally according to the injury and EMG activities were recorded again.

Fixation of stimulating electrodes

Bipolar electrodes were fixated on the nerve in the way of encircling the nerve trunk by deinsulated part of wire and suturing two loops together thus forming ring around the nerve. One of the two electrodes was positioned just proximal and one just distal according to the injury. Therefore, stimulating current passed through the crushed tissue between stimulating electrodes. The bulk body of the stimulator was fixated under the skin by using four O sutures. Two months later dogs were anesthetized again. Left and right radial nerves were exposed and visually inspected. Our inspection was concentrated especially on the stimulated radial nerve. In all cases stimulating electrodes were located at the same sites as they were fixated during implantation. Since stimulators were in function for two months their function was tested. EMG activities recorded intramuscularly from left and right m. extensor digitorum communis muscles, elicited through electrical stimulation of radial left and right radial nerves proximally and distally according to the regenerated lesion were compared.

RESULTS

During the first postoperative week the animals showed good healing of the wounds and tolerated the implant well. As expected, in the case when the pair of stimulating electrodes was moved distally according to the injury, amplitudes of EMG activity were almost of the same value as in the case of stimulation the intact nerve. However, when the pair of bipolar stimulating electrodes was moved proximally according to the injury, amplitudes of EMG activity of the m. extensor digitalis communis were much lower than amplitudes of EMG activity in intact nerve. Fig. 1 shows an intramuscularly recorded EMG activity evoked by stimulation of the whole left radial nerve proximal to the lesion before the treatment with electrical stimulation. It is obvious that low action potentials could be induced to cross the nerve lesion.

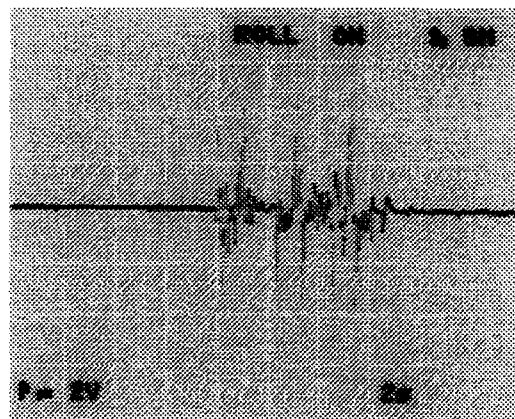


Fig. 1. EMG activity of the m. extensor digitalis communis evoked by stimulation of the radial nerve before stimulation.

Such an absence of activity across the lesion was noted in all animals. Fig. 2 shows an intramuscularly recorded EMG activity of the m. extensor digitalis communis muscle evoked by electrical stimulation of the whole left radial nerve proximally according to the regenerated lesion after the two months treatment with electrical stimulation.

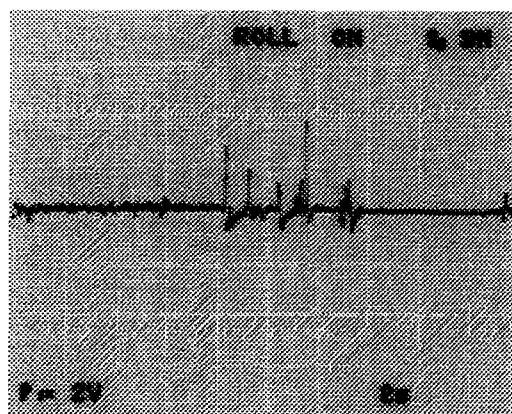


Fig. 2. EMG activity of the m. extensor digitalis communis evoked by stimulation of the radial nerve after two months of electrical stimulation.

DISCUSSION

This study is the first to demonstrate the effects of biphasic electrical stimulation on dog radial nerve regeneration. Our study indicates that accomplished methodology of continuous stimulation of the injured radial nerve of the dog has a positive influence on process of regeneration. Namely, after the two months of stimulation, the amplitudes of compound action potentials of m. extensor digitalis communis muscle are almost of the same as before axonotmesis, but they are significantly lower in the unstimulated radial nerve. Our findings are consistent with those from previous studies involving electrical stimulation of in vivo peripheral nerves. In related studies suggesting that biphasic electrical stimulation enhances the progress of nerve regeneration.

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DEVELOPMENT, ACTUAL STATUS AND THE FUTURE OF EXTERNAL FUNCTIONAL ELECTROSTIMULATION IN TREATMENT OF FEMALE URINARY INCONTINENCE

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SUMMARY

Over the last 30 years, the treatment of female urinary incontinence (UI) with functional electrical stimulation (FES) has become efficient because of technical improvements and new clinical and neurophysiological findings. Thus, vaginal and rectal plugs have achieved a more physiologic shape, the quality of the materials used has improved, and the stimulation parameters have become more appropriate. Clinical and neurophysiological findings that external FES acts through the reflex arch and the micturition centre (S2 – S4) and that the response to electrical stimulation is always physiological (contraction of the pelvic floor muscles and relaxation of the detrusor) have provided new possibilities in the treatment of UI. The patient selection is extremely important when deciding on the FES treatment. Therefore, before the introduction of treatment the patient should undergo clinical and urodynamic examinations to classify the type of UI, and pad tests to determine the degree of UI. FES is applied in the treatment of stress, urge and mixed UI, and provides efficient outcome in 73.9% of patients with stress UI, in 81.8% of patients with urge UI and in 76.2% of patients with mixed UI. The efficient outcome of treatment depends largely on the appropriate patient selection.

STATE OF THE ART

The year 1963 is considered as the beginning of modern mode of treatment with functional electrical stimulation (FES), when Caldwell published his paper "The electrical control of sphincter incompetence" in the Lancet. He used an implantable radio-linked electrical stimulator with the electrodes fixed to the periurethral musculature. However, implantable systems were technically too complicated, and the results were successful in only 50% of cases. In 1968, Alexander and Rowan presented electrical nonimplantable stimulators with a vaginal or anal plug and an external housing for the circuitry and battery. Ever since, functional electrical stimulation has witnessed a swift development in technical and in medical direction.

The technical problems that had to be solved for providing efficient treatment of female urinary incontinence with FES were the following: shape of the vaginal and anal plug that would improve the contact with tissues, finding the most inert material possible for the plugs and for electrodes to prevent damage to tissue and corrosion of electrodes. To avoid corrosion of electrodes, biphasic stimulation was introduced. Besides, the stimulation parameters that proved to provide the most efficient treatment outcome, were determined. Our stimulators, used for vaginal or rectal external application, have the following parameters of electrical stimulation: impulse is rectangular and biphasic, duration of impulse is 1 msec, frequency of impulse is 20 Hz, intensity of current ranges between 35 and 100 mA, depending on the type of UI. Medical knowledge in this area has been improved by numerous clinical, neurophysiological and urodynamic findings. Neurophysiology has contributed the important finding that FES applied on the pelvic floor muscles has a predominantly reflexogenic effect. FES stimulates afferent nerves of the pelvic floor, the impulse continues to the centre in S2 to S4 and returns via efferent fibres to the pelvic floor muscles, which contract. The important clinical and urodynamic finding is that the response of the micturition centre in S2 to S4 is physiological. Its response to the stimulus is the contraction of the pelvic floor muscles and relaxation of the bladder detrusor.

MATERIAL AND METHODS

To evaluate the efficiency of treatment of female UI with FES, 241 patients were enrolled in a retrospective study. All the patients underwent diagnostic procedures to obtain the exact diagnosis of UI. In all the patients a precise medical history was taken and laboratory tests made (urinary test, bacteriological Sanford's test, blood sugar test). The patients underwent a pelvic examination, especially with regard to the problems of genital statics, followed by urologic and neurophysiological examinations (EMG of the pelvic floor muscles), and by multi-channel urodynamic investigations (urethral pressure profile, cystometry, urodynamic stress profile, provocation tests for urge incontinence and uroflowmetry). After making the exact diagnosis of UI, a pad test for objectivization and quantification of urine loss was made at 2/3 and full capacity of the urinary bladder. Only the patients conforming to the criteria of UI set by the International Continence Society were enrolled in the study and underwent further treatment. All these examinations were repeated 3 months after the concluded treatment. In this way we obtained subjective (provided by the patients) and objective evaluations of treatment.

Regarding the diagnosis, the patients were divided into 3 groups: patients with stress UI (n=111), patients with urge UI (n=88) and patients with mixed UI (n=42). The first group consisted only of the patients with mild or moderate stress UI and with normal gynecological status or with a mild utero-vaginal prolapse. The patients with severe stress UI associated with descent or subtotal utero-vaginal prolapse were not enrolled. For these cases, surgery is the treatment of choice.

In the treatment of stress UI, the stimulators for the so-called chronic stimulation were used. Stimulation lasted for 1.5 - 2 hours per day, and had to be continued for at least three months. The stimulation parameters used were as follows: impulse was rectangular and biphasic, duration of impulse was 1 msec, frequency of impulse was 20 Hz, and intensity of current was 35 mA. Idiopathic urge incontinence was treated with acute maximal functional electrical stimulation (AMFES). The parameters used were the same as indicated above, whereas the intensity of current had to exceed 65 mA in case of vaginal application, and 40 mA if applied rectally. The intensity of the applied current should be individualized and should not exceed the threshold of pain. The current was applied 20 minutes per day for 5 consecutive days. The intensity was gradually increased so that the recommended intensity was achieved within 2 - 4 minutes.

In the evaluation of the outcome of treatment, the objective and subjective assessments before and after treatment were considered. The objective assessment of stress UI was provided by pad tests, clinical stress tests and urodynamic stress tests, and by pressure transmission ration (PTR); the subjective assessment was provided by the patients. The objective assessment of urge incontinence was provided by pad tests at provocation tests for urge incontinence and urodynamic changes; whereas the patients provided their subjective assessment.

RESULTS

In case of no urodynamic signs of UI, the negative pad test and the patient's subjective assessment of having no related problems anymore, the patient was considered cured. The patient condition was considered improved, if she subjectively considered to have been cured or that her condition essentially improved, but objectively (pad test and urodynamic investigations) we still found some parameters indicating the existence of UI, although of a milder degree.

Table 1. Results of treatment of stress incontinence by chronic functional electrical stimulation

Outcome	No. of patients	%
Cured	56	50.5
Improved	26	23.4
Unchanged	29	26.1
Total	111	100.0

73.9

Table 2. Results of treatment of urge incontinence by AMFES

Outcome	No. of patients	%
Cured	64	72.7
Improved	8	9.1
Unchanged	16	18.2
Total	88	100.0

81.8

Table 3. Results of treatment of mixed incontinence by AMFES

Outcome	No. of patients	%
Cured	24	57.2
Improved	8	19.0
Unchanged	10	23.8
Total	42	100.0

76.2

On the basis of years of experience of treating female UI with FES, we determined the following indications for FES treatment:

- stress UI - mild and moderate degrees without or with a mild utero-vaginal prolapse
- recurrent stress UI following surgery
- urge UI (motor and sensory type)
- mixed UI (stress and urge)
- vesico-urethral dyssynergia
- frequency

DISCUSSION

The opinions on the efficiency of FES treatment of female UI are divided. The results we obtained in the treatment of mild and moderate stress UI with FES are favourable (73.9% cure and improvement rate). In 1984, Fall achieved a 60% cure and improvement rate, which is almost comparable to our results. However, Doyer et al. (1974) report on the efficient outcome of treatment in only 37% of patients. The aim of FES treatment is not only to increase the strength of the pelvic floor muscles resulting in increased maximal urethral pressure. More important is the reflex stimulation of the pelvic floor muscles, which improves the pressure transmission to the urethra during stressful activity such as coughing. Bo and Talseth (1997) have achieved higher maximal urethral pressure with voluntary pelvic floor muscles contractions than with FES. We, however, have achieved better results with FES than with Kegel exercises (73.9% vs 66.0%) in the comparable group of women with stress UI. In spite of this, we are of the opinion that further prospective clinical, urodynamic and neurophysiological studies are required to clarify this dubious situation, i.e. the efficient application of FES in the treatment of female stress UI. However, we consider the variable outcomes in the treatment of stress UI with FES to be mainly due to the patient selection.

Our results of the treatment of urge UI (motor and sensory type) with AMFES are extremely favourable (cure and improvement rate = 81.8%). These results are in agreement with those of Fall (1984) who achieved even a 90% cure and improvement rate. Urge UI is most frequently treated by drugs (anticholinergics, tricyclic antidepressants, calcium channel blockers). Medical treatment has proved efficient in only 60 - 70% of patients. Unfortunately, medical treatment is associated with numerous contraindications, especially in elderly women. After treatment with anticholinergics, the recurrence of disease has been reported in 50% of patients. After treatment with AMFES, the recurrence of the disease has been registered in 26% of patients only. The recurrent disease is then again treated by AMFES. And, what is more important, there are no absolute, but only a few relative contraindications involved (severe urinary retention and vesico-ureteral reflux). The treatment with AMFES should not be used in patients with a pacemaker or during heavy menstruation and during pregnancy.

We have also obtained extremely favourable outcomes of treatment of mixed (stress and urge) UI (76.2%). Both components of UI are cured simultaneously, and the surgical treatment, that could even worsen the urge component of UI, is thus avoided. Therefore, in the treatment of mixed UI, we consider AMFES the treatment of choice.

In the future, FES will be primarily used for the treatment of urge and mixed UI. Namely, these two types of female UI do not have such an efficient competitive treatment as stress UI (Kegel exercises, surgery). Our hypothesis is based on the fact that medical treatment (anticholinergics) is less efficient than treatment with AMFES, results in recurrent diseases in 50% and has numerous contraindications, especially uncomfortable for elderly women.

CONCLUSION

Over the last 30 years, the treatment of UI with external application of FES, has become ever more recognized and widely used. This mode of treatment is efficient in the treatment of female UI (stress, urge and mixed), exhibits almost no contraindications, and can be used in all women, especially in the elderly ones.

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THREE DIMENSIONAL CHANGES IN THE UPPER AIRWAY DURING NEUROMUSCULAR STIMULATION OF LARYNGEAL MUSCLES

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SUMMARY

During swallowing protection of the airway depends upon adequate glottal closure and laryngeal elevation to prevent the entry of substances into the airway. The purpose of this study was to quantify three dimensional changes in the upper airway during laryngeal muscle stimulation in a canine model. Six animals were implanted with Peterson type stimulating electrodes in the thyroarytenoid muscle in the body of the vocal fold at the level of the glottis and in the superior ventricular portion of the thyroarytenoid along with a reference electrode. Each active electrode was stimulated chronically relative to a distant subcutaneous reference electrode with an implanted Medtronic Xtrell on each side. Stimulation during scanning was continuous on one side only between 4 and 7 Volts with a 100 μ s pulse width at a rate of 60 Hz. CT scanning was conducted on an IMATRON scanner under general anesthesia with and without stimulation of each muscle group. Scans had a 3 mm thickness but were advanced at overlapping 1 mm increments. The surface of the airway was extracted, reconstructed using a region growing algorithm and calculated from isosurfaces. One animal's scans could not be processed because of movement artifact associated with respiration. A three dimensional reconstruction of the upper airway in each of 5 animals quantified changes in tract width and shape with neuromuscular stimulation. Stimulation of the thyroarytenoid muscle produced changes in the supraglottic region as well as the glottis; the glottic wall was compressed medially above and below the glottis. These results suggest that chronic neuromuscular stimulation can effect glottic protection by reducing the glottal opening and may be beneficial for patients with central control disorders affecting airway protection during swallowing.

STATE OF ART

Neuromuscular stimulation has been used in recent years in the larynx for patients with bilateral recurrent laryngeal nerve injury whose airway is compromised because of the inability to actively open the vocal folds for inspiration^{4,5}. However, because many of these patients have suffered prolonged denervation and atrophy of the laryngeal muscles, changes have already occurred compromising the kinematic result. Consideration has not previously been given to using neuromuscular stimulation in patients with normal peripheral nerve function but who have voice and swallowing disorders due to the loss of central control of vocal fold closure for voice and swallowing. Over 16% of persons over 55 years of age are estimated to have dysphagia and over 412,000 patients per year currently require enteral feedings because of risk of aspiration². Half of these patients are unable to control the timing of laryngeal elevation and closure for swallowing as a result of stroke, head injury or neurological disease. The purpose of this project was to evaluate the 3 dimensional shape changes in the upper airway during neuromuscular stimulation in chronically implanted dogs to determine the adequacy of intrinsic laryngeal muscle stimulation for airway protection.

MATERIALS AND METHODS

Implantation and Chronic Stimulation

Each canine was implanted with 3 Petersen type electrodes in the inferior and superior bellies of the thyroarytenoid muscle in the vocal fold and the ventricular fold and a subcutaneous reference electrode placed 10 cm from the larynx. The 3 electrodes were connected to an Xtrel receiver placed in the animal's chest. Each animal was implanted with two such systems, one on the right and one on the left side. Each animal was chronically stimulated on one side only for 8 hours, at 3 s on and 5 s off for 5 days per week. Stimulation parameters were between 3 and 6 V, 60 Hz, with a 100 μ s pulse width.

CT Scanning

Six dogs were scanned under Ketamine or Nembutal at rest and during chronic stimulation in an IMATRON CT scanner. Scans had a 3 mm thickness but were advanced at overlapping 1 mm increments. In each animal, both rest and stimulation scans were completed. During a stimulation scan, the stimulator was turned on at supramaximal stimulation level ($\sim$ 6 -8 Volts) and remained at 60 Hz continuously throughout the scan which lasted approximately 4 minutes. Limited fatigue was noted with continuous stimulation at this rate in these muscles. Stimulation electrodes were programmed for each scan to contrast tract area change during stimulation of the right and left sides and the superior or inferior portions the thyroarytenoid muscles.

Image Processing

The scans were imported into Voxel View (Vital Images, Inc.). In each scan the airway was segmented and the airway were then reconstructed using a region growing algorithm³. The airway walls were then calculated from the isosurfaces (Figure 1).

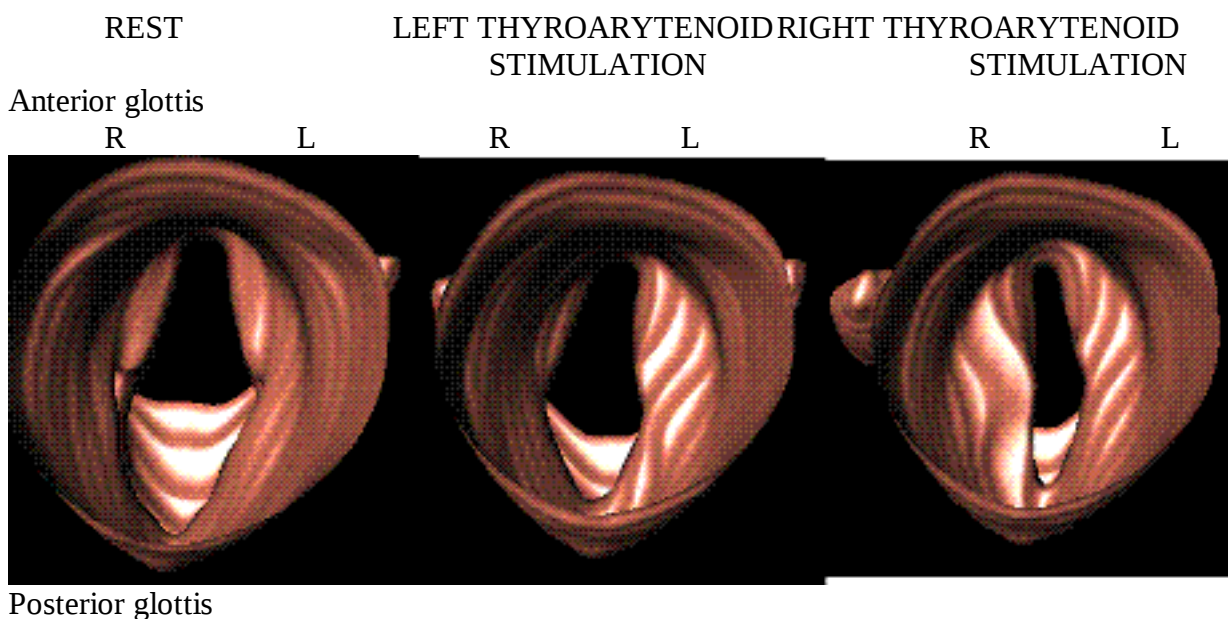


Figure 1. The surface models of the airway walls in one canine from CT scans. The view is from the trachea up through the glottis with the anterior glottis at the top and the posterior glottis at the bottom. The image on the left hand side was made at rest, the middle image was made during left thyroarytenoid stimulation, and the image on the right hand side was made during right thyroarytenoid stimulation.

The level of the glottis was determined by examining the axial slices. The midpoint of the vocal fold on the right and left sides was measured from the axial slice at the level of the glottis to quantify the change in position of each fold independently. The change in vocal fold position between rest and stimulation was then measured in pixels relative to the midline through the glottis from the anterior commissure to the posterior glottis. The area of each axial contour was also quantified in pixels and compared at each level throughout the tract relative to the level of the glottis (Figure 2).

RESULTS

One animal's scans could not be quantified because of movement artifact associated with respiration. Movement artifact could be seen in the other animals to varying degrees but did not interfere with measurement of change in overall tract area when contrasting rest with stimulation.

The change in vocal fold position between the stimulated and non-stimulated condition was examined on a repeated ANOVA with a side factor and a trend ($F=3.783$; $p=0.069$) was found due to a reduced distance from midline with stimulation with no difference in the effect of stimulation between the left and right sides (Figure 2).

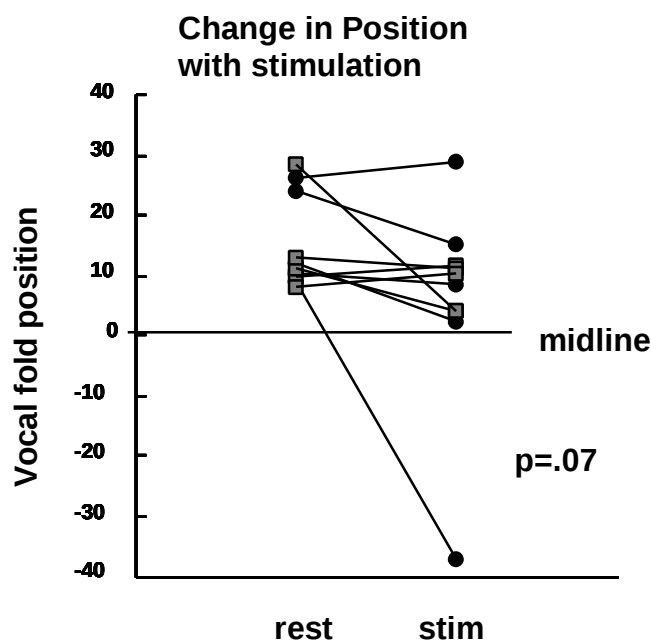
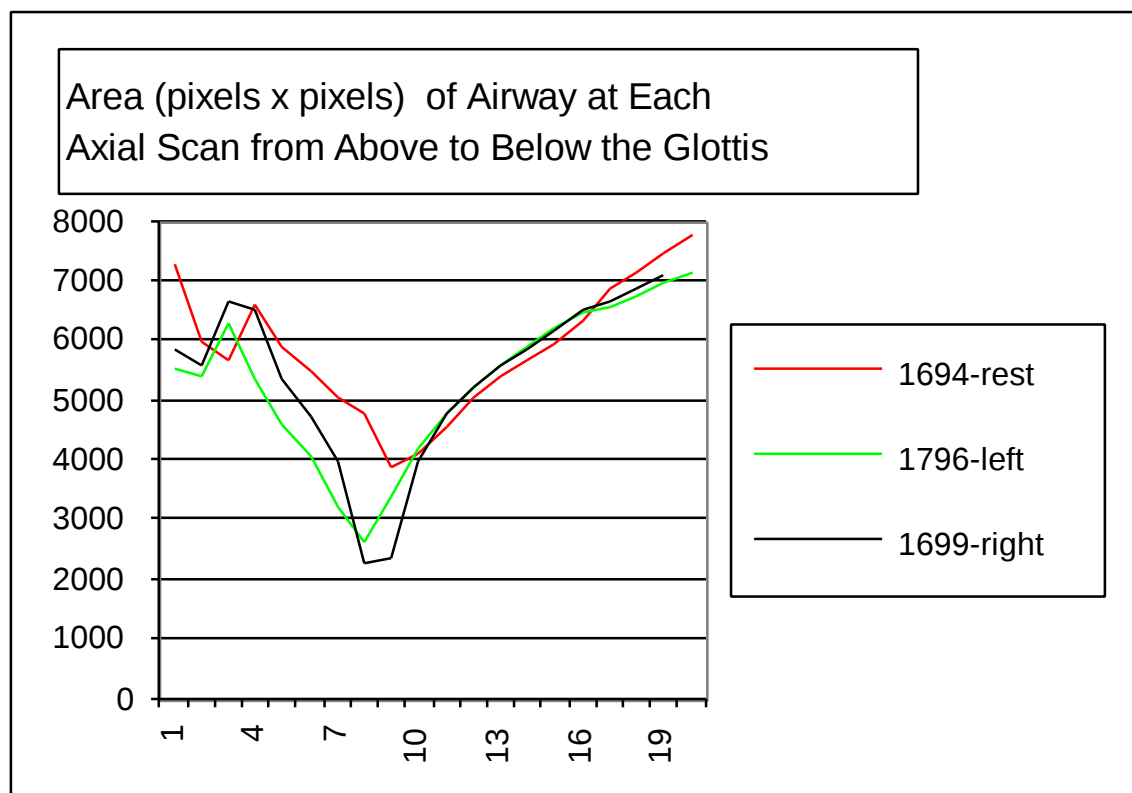


Figure 2. Vocal fold distance from the midpoint in pixels at rest and during stimulation on the left (filled circles) and the right sides (shaded squares).

The area of the airway was computed in pixels squared for each axial slice of each animal at rest, during right thyroarytenoid stimulation and left thyroarytenoid stimulation (Figure 3).



Regions **Supraglottic** **Glottic** **Subglottic**

Figure 3. The area in pixels² measured from each axial scan in one animal at rest, during left thyroarytenoid stimulation and during right thyroarytenoid stimulation. The level of the glottis was most obvious in axial scan 9, however the glottis could be seen in scans 8 through 12. The supraglottal region was the from 8 though 1, the subglottal level was from 12 through 20.

In each of the 5 animals analyzed the glottis was identified. Reductions in tract area were seen not only at the level of the glottis but also throughout the supraglottal region in each animal.

DISCUSSION

The use of CT scanning with 3 D reconstruction was used to examine changes in the upper airway with the use of two measures: the lateral medial position of the midpoint of the vocal fold relative to the midline and the area of the airway opening within each axial slice. Both these measures provided information not available without the use of this technique. Using rigid videolaryngoscopy one can visualize the vocal folds and their change in position. However, calibration of the movement of each fold independently is not possible in distance because of possible superior-inferior movement of the glottis during muscle stimulation. In this study the level of the glottis moved by at least one axial slice, equivalent to between 1 and 3 mm in distance in 2 of the 5 animals studied; therefore videolaryngoscopy would not have been accurate. CT scanning allowed us to quantify the movement of each vocal fold as well as determine the effect of thyroarytenoid muscle stimulation upon the total area both above and within the glottis, both of which are important for airway protection.

A narrowing in the supraglottal region during thyroarytenoid muscle stimulation was found in all the dogs studied. Thus stimulation of the thyroarytenoid muscle altered the degree of glottal opening both within and above the glottis which would assist airway protection during swallowing.

The thyroarytenoid muscle has both a glottal and a supraglottal component in the human and in the canine ¹. The superior portion in the canine, however, has many fewer fibers where a much larger portion of the ventricular fold is composed of cartilage than in the human. Therefore, the degree of supraglottal narrowing could be expected to be greater in the human than found here in the canine. It can be expected that stimulation of both the vocal fold and the ventricular portions of the thyroarytenoid muscle in the human can have a substantive airway protective action with muscle stimulation.

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FOUR-CHANNEL STIMULATOR FOR EXPIRATORY SUPPORTED VENTILATION

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SUMMARY

One proven approach to ventilatory failure using electrical stimulation is by pacing of the phrenic nerve or diaphragm. Another possible approach is to stimulate abdominal muscles in the expiratory phase of respiration. This paper presents a new four-channel surface electrical stimulator intended for use in such expiratory supported ventilation. A cannula style thermocouple sensor enables long-term triggering of synchronised stimulation. The stimulator was designed for use in experimental feasibility studies in order to determine the patient groups that could benefit from this kind of stimulation. Therefore it offers different modes of stimulation and ease of rapidly changing of the stimulation parameters.

STATE OF THE ART

Among different kinds of surface stimulators that have been developed in the past, each is typically designed for a specific application and each requires its own input signals for control of the stimulator to provide appropriate output [1]. Most often, surface stimulators are used in therapy and in restoration of function in the lower and upper extremity such as standing and walking, foot drop correction, hand grasp/release and recently also for cough [2,3].

The stimulator presented in this paper is intended for ventilatory assistance using functional electrical stimulation (FES) of abdominal muscles during expiration. Previous reports of using stimulation in patients with ventilatory failure has been focused on the active inspiratory phase only [4]. During quiet breathing the contraction of inspiratory muscles, predominantly the diaphragm, results in lung volume increase and expiration occurs passively due to elastic recoil. Although commercially available phrenic pacing systems are proven and successful, this approach does require an invasive procedure and in general is not indicated in cases where only short term support might be needed, in which case mechanical ventilation may be used.

On the other hand, FES of abdominal muscles augments the expiratory phase of respiratory cycle to overcome the elastic resistance of the chest. Expiration is deepened under the level of functional residual capacity (FRC) in the area of expiratory reserve volume (ERV), followed by the inspiration due to passive elastic recoil of the chest wall, contraction of the diaphragm and other inspiratory muscles. Thus tidal volume and consequently total ventilation might be increased. Rectus abdominis, obliquus abdominis internus, obliquus abdominis externus and transversus abdominis are the abdominal muscles that we stimulate. Experiments in normal subjects and SCI patients suggested that FES of abdominal muscles could be clinically important in augmenting pulmonary ventilation [5,6].

MATERIALS AND METHODS

Our goal was to design easy-to-use, portable, battery-powered, flow triggered four-channel electrical stimulator. Stimulator will be used in clinical experiments and it will, together with obtained experimental results serve as a good base for further optimisations that will lead to a clinically applicable stimulator.

The structure of the stimulator could be divided in three major parts: sensor and amplifiers, logic and output stages (Figure 1). Logic part of the stimulator enables different modes of stimulation: a) four channel stimulation during each expiration or during every second expiration, b) two channel stimulation in one expiration and the other two channels in the following expiration, c) triggering of the stimulation at the very beginning of the expiration or with a predefined delay.

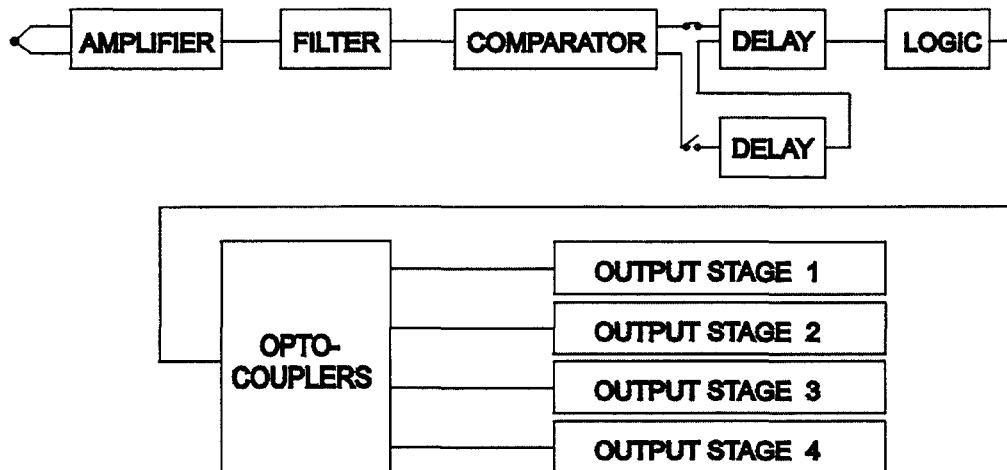


Figure 1: Structure of the stimulator

A reusable thermocouple cannula style airflow sensor gives a voltage proportional to changes in temperature between inspired and expired (hotter) air. In order to obtain a better signal/noise ratio the signal from sensor is amplified and filtered. Due to fluctuations in ambient temperature, different breathing patterns and differences in thermocouples the amplification could be adjusted with a trimer by a physician. We apply a bandwidth filter that suppress signals of the frequencies lower than 0.15Hz and higher than 15Hz. Expiration phase of the breathing that triggers stimulator is determined using an adjustable reference level comparator with hysteresis. Adjustable pulse train duration and delay (if selected) are realized with monostable multivibrator. Using flip-flop, logic gates and jumpers we can choose between stimulation of four (or less) channels in every expiration, in every second expiration or stimulation of first pair of channels in one expiration and the second pair of channels in the next expiration (Figure 2). These logic signals are transmitted through optocouplers to trigger

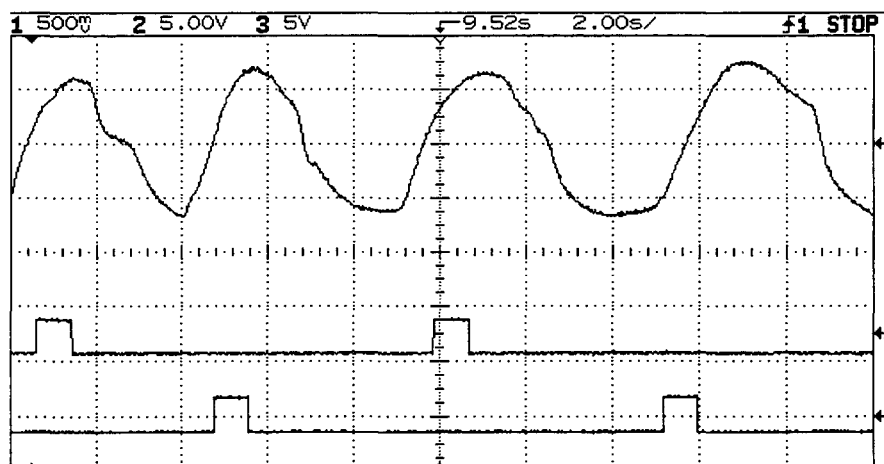


Figure 2: 1) signal from sensor 2) stimulation sequence from first pair of channels
3) stimulation sequence from second pair of channels

the DC-DC converters and output stages. In order to minimize development time and increase reliability we used DC-DC converters and output stages from our commercially available one-channel stimulator (Microfes) for each channel. Therefore each channel has its own DC-DC converter, pulse generator and output stage which provides a perfect galvanic isolation of the channels. Pulse rate (from 15 to 80Hz), duration of pulse train (up to 3s) and the amplitude (up to 100mA) for each of the four channels can be separately adjusted. The output stages give rectangular, balanced, asymmetrical, biphasic current pulses of 150 μ s. Each channel is powered with a single 1.5V battery (or 1.24V NiCd accumulator), whereas the amplifiers and logic require two 1.5V batteries.

RESULTS

A prototype of the stimulator is shown in Figure 3. The size of the is 12cm x 13cm x 4cm with

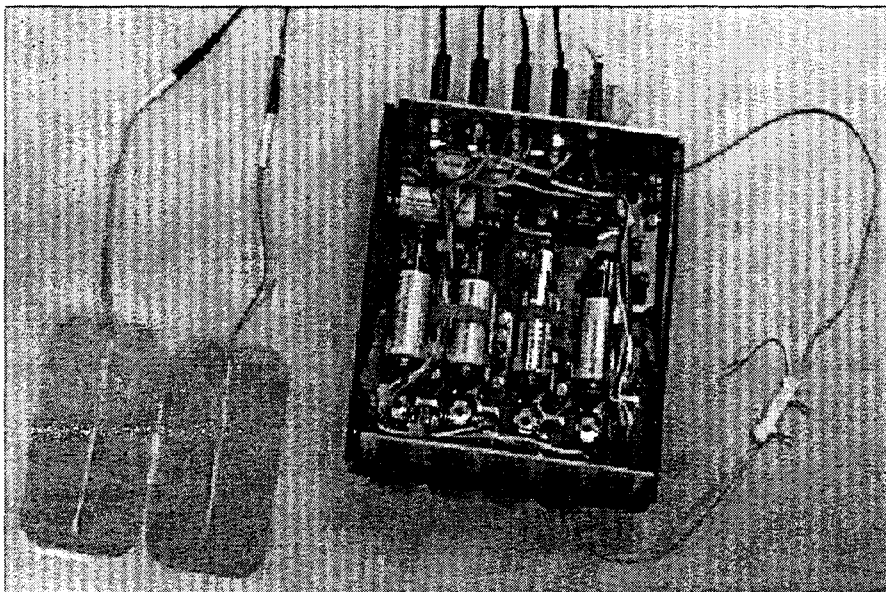


Figure 3: Stimulator with sensor and electrodes

the mass $m=255$ g. Front panel has an on/off switch and four switch potentiometers to turn on and adjust the amplitude of the individual channel. The stimulator has connector for thermocouple sensor and four pairs of electrodes. We decided not to put a special potentiometer on a front panel of a stimulator for changing the pulse train duration because experiments showed that by prolongation of stimulation breathing frequency decreases and therefore total ventilation is also decreased [7]. Optimal choice for a pulse train duration is 1s.

Stimulator has been clinically tested on several healthy subjects. Sensor provides reliable long term triggering of the stimulator and due to its design it is comfortable in comparison to other solutions such as plastic mouthpieces or masks.

DISCUSSION

Stimulator was designed for experimental use and therefore provides flexibility for changes or improvement that will be based on the obtained experimental results. Some other possible sensors should be considered in the future such as thermistors, differential pressure sensors, and others.

It should be stressed that increased ventilation is not the only goal that we would like to achieve with this kind of stimulation. Respiratory muscle training through FES of abdominal

muscles could be of high importance too, especially in patients that are temporarily taken off mechanical ventilator support. Effects of FES of abdominal muscles on respiratory capabilities in quadriplegic patients should be tested as well, since it might help maintain compliance of the lungs and chest wall.

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PRECISELY TIMED FUNCTIONAL ELECTRICAL STIMULATION FOR COUGH ASSISTANCE IN PERSONS WITH SPINAL CORD INJURY

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SUMMARY

Pulmonary complications are the leading cause of morbidity and mortality in persons with spinal cord injuries (SCI) [3]. A significant contributor to these complications is an impaired ability to cough. The impaired cough is due to full or partial paralysis of the abdominal muscles used during forced expiration. Cough assistance methods, including manual compression and functional electrical stimulation (FES) of the abdominal muscles, have been shown to increase cough efficiency in patients with SCI. It is hypothesized that an optimal cough efficiency can be found through experimentation with timing of stimulus delivery. A newly developed, precisely triggered stimulation system, based on established FES technology, will provide the means for clinicians to establish the optimal timing parameters for effective cough.

STATE OF THE ART

There are two types of assisted cough for increasing cough efficiency in SCI patients: the manually assisted cough and the electrically stimulated cough. In the manually assisted cough technique, a caretaker compresses the abdomen in a forceful movement, while the patient controls the upper airway. The second method of assist involves electrical stimulation of the abdominal muscles thorough electrodes on the abdomen. Both of these methods are coordinated between the patient and caretaker on a predetermined count. Although both of these approaches have been shown to significantly improve cough efficiency they have the common disadvantages of imprecise timing and mandatory presence of a caretaker [2][3].

It was hypothesized that cough efficiency can be further improved and ultimately optimized through a computer-controlled system that delivers precisely timed stimulation. The timing is delivered based on monitoring the patient's breathing in real time. In this way, CPFR can be given as a function of time of delivery after epiglottis closure. This type of system presents complementary advantages. It can be developed to provide optimal timing on an individual patient basis. The precise timing system is potentially configurable into an entirely patient controlled system, giving a patient complete independence from a caretaker for cough. A patient would be able to perform a stronger cough as frequently as desired, leading to more effective and regular clearance of the airways, and presumably reduce pulmonary complications.

MATERIALS AND METHODS

This study was approved by the Human Subjects Committee. Figure 1 shows a block diagram of the triggered stimulation system that was developed. The system is controlled by C code on a laptop computer. Patient breathing is monitored by a Fleisch pneumotachograph. An A/D converter receives the analog signal from the pneumotachograph and converts it to a digital value to be processed by the program. When the required breathing conditions are met according to specifications in the software an Empi FOCUS™ electrical stimulator is triggered to deliver the stimulus via four electrodes on the abdomen. All hardware is battery powered.

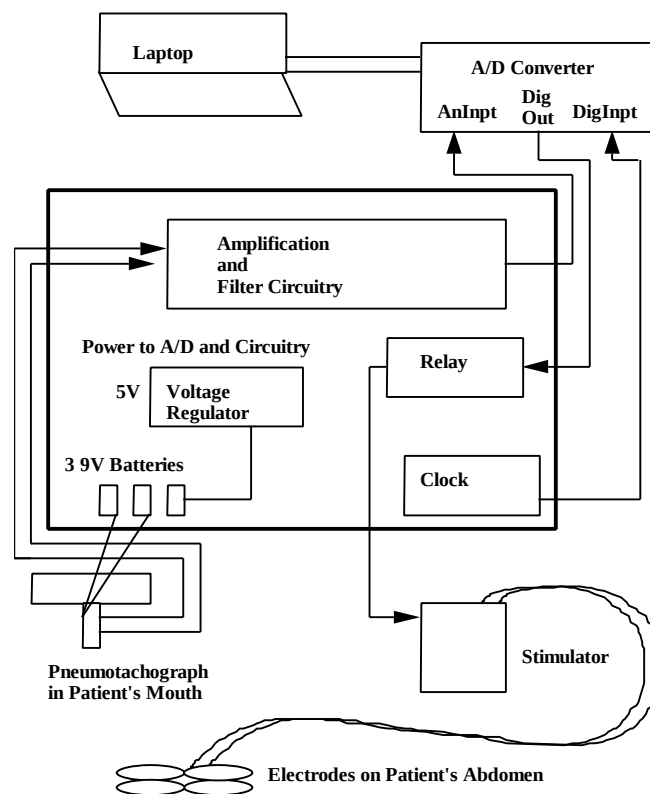


Figure 1.

A photograph of the system in use is shown in Figure 2. The patient rests in a supine position. Four electrodes were placed on the abdomen. The leads from the stimulator were connected to the electrodes. The patient was tested for sensation in the abdomen. The stimulator level was ramped up slowly until an abdominal muscle contraction was clearly visible. If a contraction did not occur, the patient was not used in the study. If a contraction did occur, the patient evaluated the sensation. When a muscle contraction was observed the patient was asked if he experienced any discomfort. If in the judgement of the

investigator the stimulation was effective and the patient reported no discomfort the patient participated in tests of the triggering system.



Figure 2.

The clinician instructed the patient to put the pneumotachograph in the mouth, form a tight seal around the tube with his lips and begin breathing normally. After the patient had several breaths to adjust to breathing through the pneumotachograph, the clinician began acquiring breathing data. The clinician instructed the patient to take a deep breath and cough when ready. The clinician either saved or discarded the data after each cough sequence. Throughout the session, the clinician adjusted the parameters to better serve the patient's unique capabilities or to experiment with the effect of different settings on the cough produced.

RESULTS

The following criteria were satisfied to validate the system: a stimulus was only triggered after a deep inspiration, a stimulus was triggered at the precise time chosen by the user, the stimulus was turned off after the precise duration chosen by the user and one A/D airflow data point was recorded in every clock cycle. The newly developed system allows for precisely timed delivery of stimulation based on epiglottis closure and records patient data during both stimulated and voluntary cough. The delay in delivering stimulus after epiglottis closure was varied on a trial by trial basis during experimentation. Through simple approximations and multiplication of the data by a conversion factor, the recorded cough data was expressed in terms of CPFR in L/min. In this way, the tool will be used to study the efficiency of cough based on stimulus delivery time. This tool will be used to test many patients over a long period of time to find general trends in CPFR improvement and individual patient cough efficiency.

DISCUSSION

In the future, clinicians will use the tool developed in this project to study cough efficacy as a function of stimulus timing. They will be able to compare voluntary coughs with stimulated coughs to examine the benefits of precisely timed stimulation. After testing a large sample of individuals, they will be able to investigate general trends in stimulus delivery timing as it affects CPFR. All types of testing performed by clinicians will serve to provide additional information for refinement and sophistication of the tool. The current state of the system has a great deal of potential for improvement and additional features such as patient control. The technology could be reduced to a smaller, mobile system. Sensors or voice recognition devices could be incorporated to initiate the stimulation process in coordination with a patient's desire to cough. This system also lays the foundation for automation of FES as it is used in other capacities.

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RESTORATION OF FUNCTIONAL ACTIVITIES WITH THE HANDMASTER NMS1

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SUMMARY

The Handmaster NMS1 is an upper limb neuroprosthesis which can be used therapeutically for exercising the paretic upper limb, and for restoring grasp and release. Both can result in functional gains.

In hemiplegia, the therapeutic exercise protocols can reduce spasticity, and increase both active and passive range of motion. Afferent and sensory input during the exercise programs draws the attention of the patient to his paretic limb. These motor and sensory factors often induce the restoration of functional use of the paretic upper limb as an assist to the healthy limb.

In both hemiplegia and quadriplegia, FES-generated hand grasp - release programs are utilized for a variety of functional activities. In quadriplegia the device is used either unilaterally or bilaterally. Bilateral use of the Handmaster enables a far wider range of potential activities.

STATE OF THE ART

Recently upper limb neuroprosthesis technology came of age, passing from R&D to the commercial market. Although it is too early to predict commercial success or failure, the research groups who have struggled over several decades to develop this technology today feel some satisfaction that their hard work is bearing fruit.

Today three neuroprostheses for restoration of upper limb function are commercially available, each in its country of origin: the FESMate system in Japan [1], the Freehand system in the USA [2] and the Handmaster system in Israel [3]. The Tetron Glove [4] may reach the market next year. The lengthy process is underway of technology transfer and market penetration internationally but it will take several years before this process is complete, and upper limb neuroprostheses are available worldwide.

The difference between the technologies used in these systems lies mainly in the degree of invasiveness. The Freehand has implanted stimulator and electrodes with external controller, the FESmate has percutaneous electrodes with external stimulator and controller, and the Handmaster is wholly external.

In functional use for SCI patients suffering quadriplegia, the three systems each deliver muscle conditioning modes and two hand prehension-release patterns: *grasp* or *palmar prehension* and *key grip* or *lateral prehension*.

In addition to SCI [6, 7, 8], other patient groups using the Handmaster system include: Cerebral Vascular Accident (CVA) [8, 9, 11, 13], Traumatic Brain Injury (TBI) [10, 11, 13], Cerebral Palsy (CP), Multiple Sclerosis (MS) and orthopaedic patients after hand trauma/surgery [12]. For these patient groups the device is used mainly therapeutically for FES-generated exercise programs, however in a substantial number of cases the therapy has resulted in a restoration or enhancement of hand function.

Handa et al [5] has also applied the FESMate to ALS patients.

MATERIALS AND METHODS

The Handmaster comprises a portable microprocessor-controlled unit connected through a cable to a hand/forearm orthosis which holds the wrist at a functional angle of extension and delivers the stimulation through five surface electrodes positioned individually for the patient on panels on the inside surface of the orthosis. Extrinsic and intrinsic muscles of the fingers and thumb are activated according to the choice of the clinician during the initial system set-up.

Six selectable modes deliver three therapeutic and three functional programs. The functional programs comprise two hand prehension- release patterns (grasp and key grip) and an open-hand posture.

The therapeutic modes are intended for exercise the hand. The sensory and afferent neurological input is considered an important component in eliciting the therapeutic benefits. Initially treatment duration rises from 30 minutes up to four hours per day, and thereafter averages approximately one hour daily in the long term for maintenance of the therapeutic benefits to the limb. Measured therapeutic benefits resulting from exercise programs include a reduction in spasticity, normalization of posture, and improvement in voluntary movement.

Candidate SCI patients for functional restoration of the upper limb at C5 and C6 lesion levels are given an initial assessment for response of the target FES-activated muscles, and for proximal arm strength and mobility. If appropriate, the Handmaster system is then set up for him. Two weeks' FES muscle conditioning and proximal limb exercises with the Handmaster can be carried out at home. Then follow functional training sessions of number, pace, and duration determined by the therapist and patient. A training video allows the patient to carry out a substantial part of this training process at home. His special problems and needs can be worked out with the therapist.

RESULTS

Functional gains in hemiplegic patients

(i) *Using enhanced voluntary movements of the plegic limb resulting from therapeutic use of the Handmaster:*

Alon et al [13] has shown significant improvement in Frenchay test scores on 18 neurologically stable CVA and TBI patients (6.7% success pretreatment, 31.1% success post treatment).

Numerous individual cases have been reported by patients and families of enhancement or restoration of function to the plegic hand, usually as an assist to the healthy hand. Often the plegic limb which was "disowned" by the patient was spontaneously "rediscovered" and put to functional use as an assist to the non-plegic limb by the patient himself.

(ii) *Using Handmaster to generate hand opening:*

(a) Where insufficient voluntary hand opening but voluntary grasp is present.

(b) To maintain an open-hand posture for use of the plegic hand as a functional assist to the non-plegic hand.

(iii) *Using prehension-release programs in the Handmaster:*

Holding a bag while walking with a cane (cane in the healthy hand).

Sweeping with a broom.

Using a walking frame.

Holding a phone (in the plegic hand) while writing.

Functional restoration in quadriplegia

(i) Unilateral

Simple ADL requiring one hand only is possible, the other arm without hand prehension may be used as an assist to the FES-activated limb. Activities achieved include: eating, drinking, writing, toothbrushing, shaving, ball throwing.

(ii) Bilateral

More complex ADL is now possible, and a more symmetrical and natural-looking approach to life results. Activities achieved include: cutting food using a knife and fork, removing pen tops & lids from containers, simple preparation of food, sports activities such as billiards, baseball batting, weight-training exercises.

DISCUSSION

Patients suffering neurological disorders affecting the upper limb are now being presented a variety of choices:

- (a) Neglect of the limb.
- (b) Traditional passive splinting and/or therapy techniques
- (c) An active neuroprostheses.

His choice is made according to information and recommendations supplied by health care professionals, by the media, by fellow device-users, and by the device manufacturers. His socio-economic position influences the decision, as does personal motivation. We the researchers and developers have pushed neuroprosthesis technology to its present state-of-art to make it as effective, reliable, and friendly a consumer product as possible. We hope that this first generation of devices will succeed, enabling the establishment of the upper limb neuroprosthesis as the preferred choice for rehabilitation of the paretic/paralyzed upper limb and encouraging the evolution of subsequent generations.

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EMG-CONTROLLED HAND OPENING SYSTEM FOR HEMIPLEGIA

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SUMMARY

Some stroke patients can close their hands but cannot open them. In such a case a Functional Electrical Stimulation (FES) to the forearm muscles is effective. It is frequently possible in hemiplegic patients to observe small voluntary EMG signals from impairment limbs. The signals have been often used for a biofeedback training./1/ It is able to train hemiplegic patients to control their muscles. We used the EMG signals derived with surface electrodes as an input interface.

In this study we developed an EMG-controlled hand opening system for hemiplegic patients with a technique which made it possible to stimulate and record with the same surface electrode. Consequently additional electrodes and a wiring for recording the EMG of command input device are not required. The electrodes arranged on the extensor digitorum communis muscle, and the integrated EMG (IEMG) of the maximum voluntary contraction (MVC) was measured. The stimulation intensity was adjusted in proportion to the IEMG, where IEMG of MVC was equivalent to the maximum stimulation intensity with no pain.

Patient could regulate the extent of opening her hand by her voluntary EMG of finger extensor muscles. The system was tested by a stroke patient. As a result, she could open her hand. But in short time use the carry over effect was not observed.

STATE OF THE ART

Functional electrical stimulation (FES) can restore limited control over absent or abnormal function in persons who have suffered from stroke or spinal cord injury. In the hemiplegic patients a fine control of grasping is not required, because they can perform most of daily living activities by their healthy limbs. There are the following requirements to apply an FES system to a hemiplegic patient. 1)It has an expectation of training effect. 2)It does not need for surgery. 3)It is easy for patients to use and to mount the system for themselves in daily living.

It is reported that the electrical stimulations to muscles strengthen contractions, facilitate muscle control, and decrease muscle tone./2/ And a biofeedback of EMG to relearn to control hemiplegic muscles is effective. Several input interfaces for FES grasp system have been reported: 1)shoulder movement, 2)voice, 3)respiration, 4)joystick, 5)hand position transducers, 6)EMG etc./3/ We employed EMG as an input interface for expectations of a training. We developed a technique which made it possible to stimulate and record with the same surface electrode from the following reasons. 1)It was difficult to arrange both the recording electrodes and stimulating ones at a restricted area of a forearm. 2) For the purpose of their learning to control the muscles, the patient require the information of the stimulating muscles. 3)It will be required to be easy to use and mount, because the patients

will use it in their daily living in future.

MATERIAL AND METHODS

The technique to record voluntary EMG from the stimulation electrodes

Figure 1 shows the circuit diagram. The technique was realized by a switching circuit which was placed between a stimulator and an amplifier. S1,S2,S3 in the figure are Photo-Mos-Relay's (AQV216:MATSUSHITA,JAPAN). During the stimulating period the electrodes were connected to the stimulator, while the other period they were disconnected from the stimulator. Immediately after stimulation, the electrodes are polarized, and it resulted in artifacts. Therefore, after the stimulation the electrodes were short circuited with S3 to the ground for 2 ms to discharge it. The EMG signals were fed into an amplifier with a limiter, a band-pass filter, and a computer via an A/D at the sampling frequency of 1kHz. The EMG waveform with the circuit is shown in figure 2. It was recorded from a normal person. The magnitude is about ten times as large as that of a stroke patient. The stimulation was a rectangular waveform with a duration of 0.2 ms, and repeating with 50ms.

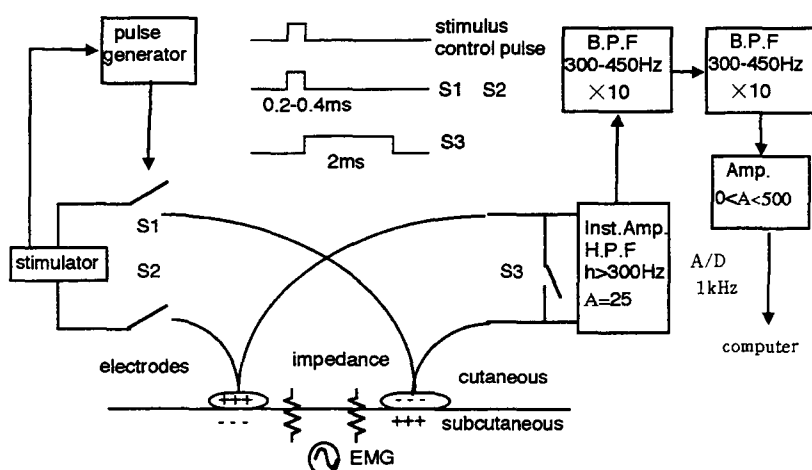


Fig.1 The circuit for recording voluntary EMG from the stimulating electrodes

EMG-controlled FES system

At the computer the signals were differentiated for an elimination of an offset, set a blank period of 25ms to eliminate an evoked EMG, rectified, and integrated by the integration time of 500 ms.

The IEMG of MVC was measured. The stimulation intensity was adjusted in proportion to the IEMG, where IEMG of MVC was equivalent to the maximum stimulation intensity with no pain and IEMG during a relaxation was equivalent to the threshold. The intensity signals were transmitted to a stimulator and it stimulate muscles via the surface electrodes. The block diagram of the total system is shown in figure 3.

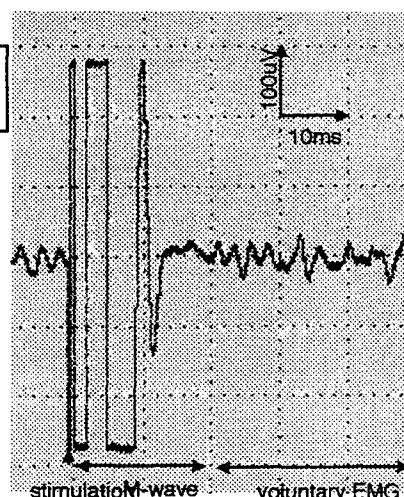


Fig.2 The EMG waveform by the record/stimulation circuit

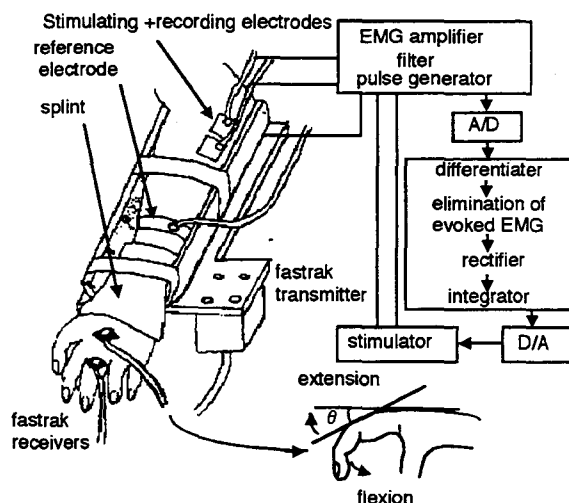


Fig.3 The diagram of the total system

Experiment

A subject is a female stroke patient.(65 years old) She can close her hand a little but cannot open it at all. But small voluntary EMG of the muscles for opening her hand can be picked up. The bipolar electrodes with conductive gel of 3.5 cm*3.5 cm were placed on the extensor digitorum communis muscle (EDC). Her wrist was fixed straight by a sprint lest her wrist should move and do substitution movements. In order to evaluate the extent of opening, the angle θ (Fig.3) between the back of the hand and the proximal phalanx of the middle finger was measured by 3 dimensional magnetic position sensor (FASTRAK:Polhemus).

Protocol

After setting as shown in figure 3, IEMG during relaxing, MVC, threshold of stimulation, and the maximum stimulation were measured. It was defined as each trial that she was directed to open her hand as much as possible during 5-10s, 15-20s, and 25-30s, and during the other time to relax her hand. Then the angle, IEMG and the stimulation intensity were recorded. The above trial for 30 seconds was repeated several times. First trial without stimulation and the next 5 trials with the stimulation were every 1 minute, the last 7 trials without the stimulation were every 3 or 6 minutes. (Fig.5)

RESULTS

Figure 4 shows the angle θ , IEMG, and the stimulation intensity of the 1st trial (without stimulation) and the 3rd trial (with stimulation). Figure 5 shows $\theta_{\max}$ (the maxima of angle θ) and IEMG in each 13 trials.

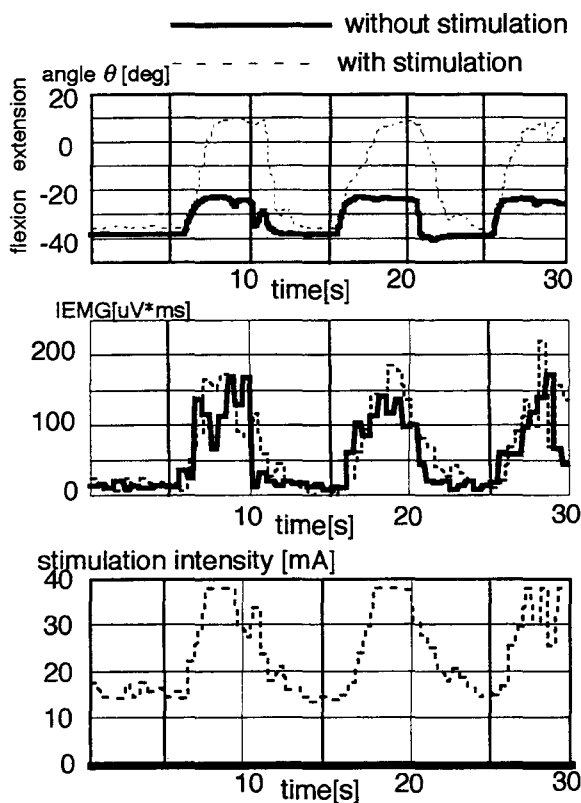


Fig.4 The angle, IEMG, stimulation of 1st and 3rd trials

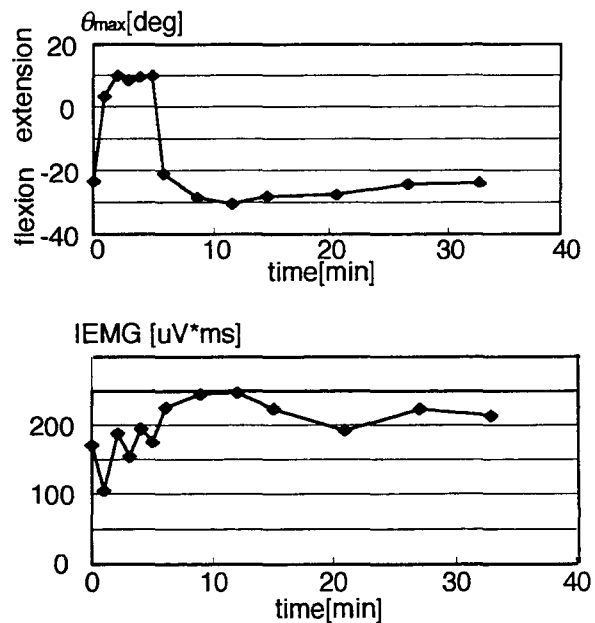


Fig.5 The maximum angle θ and IEMG of each 13 trials

DISCUSSION

It was found that the system could record patient's voluntary IEMG from the stimulating electrodes, and stimulate muscles in proportion to the IEMG magnitude (Fig.4). The system assisted patients voluntary movement, and she could open her hand broader by using the system. The $\theta_{\max}$ with this system was improved about three times larger than that without this system, which was almost equivalent to a normal person.

The time delay from the instruction of opening hand to beginning to open actually is about 500 ms because of the integration time. By reducing the integration time, the oscillation of her hand occurred since it was difficult for her to keep the magnitude of IEMG constant, so it was determined as 500 ms. The patterns of the stimulation (i.e. the integration time, the time constant, etc.) should be considered.

Comparing with the $\theta_{\max}$ and the magnitude of IEMG before and after the stimulation by this system, the $\theta_{\max}$ did not increase, while the magnitude of IEMG increased. The electrodes recorded the cross-talk of the EMGs of the involuntary contracting antagonists. Because EMG of the atrophied EDC was much smaller than those of the antagonists. Further investigations on the size, the shape and the positions of the electrodes are necessary to eliminate the cross-talk.

In order to make it easy for the patient, the system should employ an auto tuning system, a fatigue monitored FES system /4/, and so on.

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EMG-CONTROLLED FES FOR TREATMENT OF THE PARALYZED UPPER EXTREMITY

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INTRODUCTION

Spinal cord lesions at level C5 to C6 lead to loss of hand functions, lesion at C4 to additional functional deficits of the arm. Differences to extent and position of the lesion lead to large differences in the functional failures, usually with partial denervations /1/. To achieve an improvement of functionality and thus a regaining of more independence for the patient with the help of electrical stimulation, a flexible solution is required. A dualchannel-surface-stimulator with dualchannel EMG measurement and variable signal processing was developed and different operation modes were implemented in the microcontroller program. Beside manual or EMG-controlled stimulation a "shoulder control" program for alternating EMG-proportional control of two stimulation channels using one control muscle and a special "feedback"-training program for EMG triggered stimulation were developed. In the following the different operation modes of the stimulator and the results of a patient study for evaluation of the „feedback“ training are described.

MATERIALS AND METHODS

Dualchannel-surface-stimulator with EMG measurement

For EMG measurement and stimulation a dualchannel-surface-stimulator was used. The battery-operated device has two EMG input channels, two stimulation channels (constant voltage) and provides alternatively bi- or monophasic square-wave impulses within the following parameter ranges:

- pulse frequency: 15 - 60 Hz
- pulse width: 50 μ s - 1 ms
- amplitude: 0 - 90 V_{pp}

Operation modes

The dualchannel-surface-stimulator offers four different operation modes, manually controlled or EMG-proportional stimulation, a „shoulder control“ program and a „feedback“-training program.

The „shoulder control“ program for alternating EMG-proportional control of the two stimulation channels uses the signal from one muscle for proportional control of stimulation amplitude and the EMG signal of an additional muscle for selection of the controlled channel. In order to prevent from sudden shift of stimulation amplitude after a channel change, the amplitude-proportional control is not executed until the control signal passes the level, which has determined the last active amplitude of this channel. This control mode was developed particularly regarding the permanent functional use. (Fig. 1).

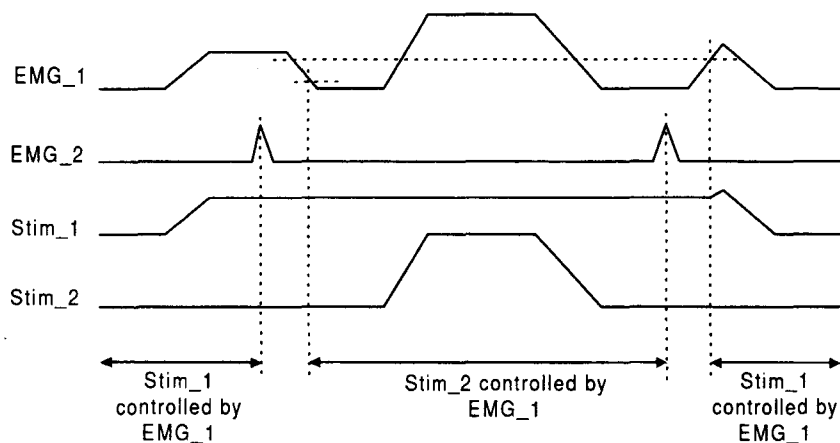


FIGURE 1
Concept of „shoulder controlled“ stimulation

The „feedback“ operation mode supports a special training for patients with partial innervation but weak muscle force. The preprocessed EMG signal of a weak muscle is compared with a trigger threshold. If the signal exceeds the threshold, stimulation of the same muscle is activated for the duration of two seconds (Fig. 2).

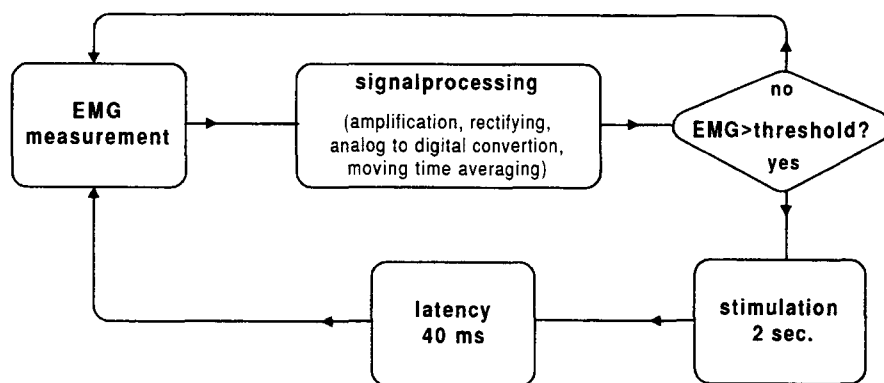


FIGURE 2
Conceptual model of EMG triggered stimulation („feedback“ training)

Stimulation parameters and Electrodes

For the study a pulse width of 500 μ s for each phase of the biphasic impulses was chosen. The amplitude was within the range of 35 - 90 V_{ss}. For the „shoulder control“ program frequency was selected within the range of 20 - 50 Hz, for the „feedback“ training it was determined with 50 Hz slightly above the fusion frequency.

For both stimulation and EMG measurement selfadhesive reusable surface electrodes were used.

Patients

Five patients with spinal cord lesions between C2 and C5 learned to use the „shoulder control“ program.

During a two year patient study 18 patients from two hospitals and one rehabilitation centre performed the „feedback“ training. Two of them suffered from brachial plexus palsy, one from hemiparesis and the others from spinal cord lesion (level C4 to C7). Part of the patients trained two or three muscles, in most cases m. triceps and the wrist extensors.

Measurements and tests

For the documentation of the functional status at the beginning and the end of the „feedback“ treatment period, functional muscle tests (grade 0 - 5 according to the BMRC) and measurements of force, angle, torque, muscle fatigue, and EMG were performed.

The maximum angle of wrist extension/flexion without stimulation and muscle fatigue with automatically triggered stimulation were measured with the help of a special measurement brace (Fig. 3). The angle and force of elbow extension was measured in prone position without stimulation (Fig. 4), the latter with the help of a spring scale. Functionality was evaluated with standardised test exercises, the SOLLERMAN-test and the ADL-test (activities of the daily life).



FIGURE 3

Brace for measurement of angle and muscle fatigue of wrist extension/flexion



FIGURE 4

Angle measurement of elbow extension in prone position

RESULTS

„Shoulder control“ program

One of the five patients who used the „shoulder control“ program had to stop training because of increasing spasm and one could change to „feedback“ training after short regeneration phase. The other three patients showed that this type of control is easy to learn within a short period of time. But hypersensitivity and partial denervation prevented further use of the system, because of no sufficient muscle contraction could be achieved within the bounds of possible stimulation parameters.

„feedback“ training

The results of the patient study showed an average increase of one grade muscle force according to BMRC, within the 28 trained muscles. The angle measurements of wrist extensors/flexors were performed by three patients and showed an increase of 6, 7 and 17.5 degrees. All of them approximately doubled their fatigue resistance.

Angle measurements of elbow extension were performed with 7 patients, force measurements with 8 patients. After the training period an average angle increase of 14.4 degrees and an average force increase of 2.5 Newton were registered. EMG recordings from eight of the 28 trained muscles affirmed the force increase by an accordingly higher amplitude. Increased independence regarding body care, dressing/undressing, taking meals, drinking, as well as activities in the household was proven with the help of the ADL-test in three patients. In one patient improvement of functionality was investigated on the basis of the SOLLERMAN-test. Isometric torque measurements showed a decrease of the deficit (compared to the healthy arm) of 6% AVG torque respectively 1% PEAK torque for the shoulder abduction and 15% AVG torque respectively 23% PEAK torque for the elbow flexion.

DISCUSSION

Three patients showed that „shoulder control“ program is easy to learn within short time, but in these cases only an implantable system maybe capable of achieving sufficient muscle contraction without painful sensations.

The patient study illustrated that the EMG triggered stimulation is able to increase muscle force, to improve proprioception and to support relearning of motions. Almost all patients obtained an improvement of functionality. The majority of the patients was in the first phase of rehabilitation, so that the possibility of spontaneous remission must be considered. Therefore the study has to proceed to obtain results from more patients.

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AN APPROACH USING WRIST EXTENSION AS CONTROL OF FES FOR RESTORATION OF HAND FUNCTION IN TETRAPLEGICS

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SUMMARY

A microprocessor-controlled device (MeCFES) is used for the investigation of the possibility to restore the hand function in C5 tetraplegics with paralysis of the hand. So far three tetraplegics have been testing the system. Myoelectric signals from wrist extension was recorded and used as control signal for functional electrical stimulation of thumb adduction/flexion. The results have shown that the device can improve the hand-function of tetraplegics. In this part of the work a hand function test was designed and used to assess the results.

STATE OF THE ART

As the lack of hand-function is a severe obstacle for activities of daily living, it is an important issue to investigate if and how FES (Functional Electrical Stimulation) can be used to restore or improve the grasp in tetraplegics. At this time there are a few devices on the market for this purpose. One is the Handmaster /1/, consisting of a splint that can be placed on the forearm and contains 5 electrodes for stimulation of the hand/fingers. Different pre-programmed stimulation patterns can be initiated by activating a pushbutton. The device uses surface electrodes for the stimulation. Another system is the Freehand /2/ which is an implanted system for stimulation of the hand-function using shoulder movement as control. An important part of a FES system for grasping is the control. The inherent problem is where and how to interface the user with the system without impeding other movements. It has been shown that myoelectric signals from muscles in the forearm can be used for control of FES to obtain a grip /3/. The controlling muscle must be under voluntary control but can be partly paralysed /4/. The present work is attempting to use the myoelectric signal from voluntary wrist extension to control FES of finger flexion, using surface electrodes. Thus is utilised the synergy between wrist extension and grasping.

MATERIAL AND METHODS

Depending of the level and extension of the spinal cord lesion, tetraplegics can have the ability to perform some wrist extension but no active finger flexion. For this reason they have no or a limited grasp. The hand can be positioned and moved for functional use but the lacking force of the grip is an obstacle for performing some activities of daily living (ADL). The objective of this study is to improve the grasp force by FES. Since grasping often can be synchronised with extension of the wrist it has been found that the wrist extension might be an adequate control source for the FES.

For the investigation a specially designed electrical device was used, referred to as the MeCFES /5/. The MeCFES records myoelectric signals and outputs an electrical stimulation where the amplitude is proportional to the processed myoelectric signal. It consists of an amplifier, a signalprocessor and a stimulator part. The MeCFES is designed as a miniaturised pocket held device. Both recording of myoelectric signals and electrical stimulation occurs through surface electrodes. The amplifier part is specially designed for suppressing stimulation artefacts /6/. By digital processing this signal is converted into a control signal for the stimulator.

In this study the MeCFES is used for letting the remaining wrist extension activity control stimulation of the thumb flexion. The stimulation amplitude is linearly increasing with the value of the recorded myoelectric signal from the wrist extensors. This means that the subject should be able to graduate the stimulation intensity rather than having on/off control.

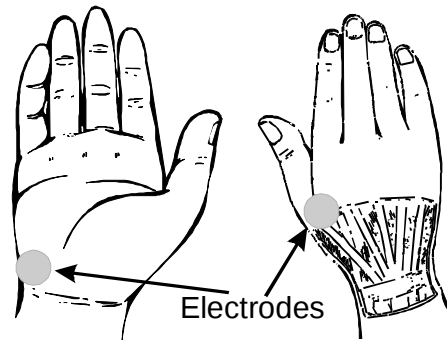


Fig.1. Stimulation Electrode Placing

The myoelectric control signal is detected in a zone over the extensor carpi radialis using common EEG with electrodes approx. 5 cm distance. Due to limited time and human concerns the placement of the electrodes was made as a fast choice fulfilling the criteria of recording sufficient myoelectric signal. The stimulation is applied via 3 cm Ø adhesive electrodes placed over 1st dorsal interosseous m. and over the pisiform bone (Fig.1). For some persons this way of stimulation gives a strong flexion of the thumb and slight flexion of the fingers.

This particular use of the MeCFES is considered adequate for a type of tetraplegia where the characteristics are as follows:

- The muscles are susceptible to FES
- The hand function is absent due to the paralysis but some wrist extension is present
- The person can lift and move the hand according to some ADL tasks
- The hand is adequate for grasping with limited contractures. It must be normally open, have some thumb extension and some finger flexion. Stimulation of the thumb flexion must result in the lateral pinch grip
- Normal cognitive ability to understand and use the function of the MeCFES

In this phase of the study a simple functional test had been used to evaluate the functionality of the system since feasibility plays an important role. (An objective evaluation of force is planned as another part of the study). The functional test comprises eight tasks which are

- I. Lifting and moving CD covers with weighs 100g, 200g and 400g. Lifting and moving a thin book (570g). The items are to be moved from the table into a box on the table.
- II. Taking a cylinder (5cm Ø , 150g) and a ½ l bottle of water (7cm Ø, 500g) and putting them into the box.
- III. The movement of drinking from the bottle.
- IV. Grasping and perform eating movements with a ordinary spoon

The four tests in group I is using the lateral pinch grip (or key grip), which is the direct objective of this use of the MeCFES (Fig.2). The tests in group II and III is intended for evaluating the volar grip (Fig. 3), although the key grip can be used as well. Since the stimulation together with the wrist extension can indirectly augment the volar grip this test is applied too. Finally the test IV can be performed by a variety of different grips but the intention is to use the lateral pinch grip.

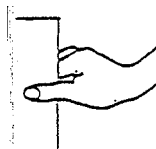


Fig.2. Lateral Pinch Grip



Fig. 3. Volar Grip

The performance of the grip is rated as 0-2 where 0 is given when no grip and lift is possible, 1 is given where the object is lifted and moved but dropped before completion of the task and 2 means a completed task.

In Table 1 the results of the subject's performance are shown in relation to tasks performed without/with the device. In case the same rating is obtained without and with the device, a (+) is indicated in case the task seems to be performed better with the device and a (-) in case the device impedes the function. Some of the tasks have not been applied and these are indicated as NA. This is the case when the person finds impossible in advance to perform the task. The parameters for the signal processing (myoelectric gain, filter parameters, stimulation current etc.) are roughly adjusted before the commencement of the experiments. As with the electrode placement there is not time for fine-tuning since the test persons gets tired or have a schedule. The total experiment including preparing the experiment takes less than 1 ½ hour. The parameters are adjusted such that the control of grip and slip is obtained.

RESULTS

Five tetraplegics were available for testing the device. Three of these had a grasp with such a low force that FES for force augmentation made sense. The results are listed in Table 1. The first two subjects (M,FB) have only tested the device one time while the third (SI) has been testing the device twice (indicated with the number) with one month interval. This person achieved quickly a good understanding of the function of the device and tested it on both hands (indexed with R and L according to right and left hand). The level of lesion for the persons are:

M: C5/6 Complete

FB:C3/4 Incomplete

SI:C5/6 Complete

Table 1. Results of Functional Test (Without/With MeCFES)

Type of grip	Task	M	FB	SI(L,1)	SI(R,1)	SI(R,2)	SI(L,2)
Lateral pinch	CD cover in box 100g	NA	0/2	0/2	0/2	2/2 +	2/2
	d.o. 200g	NA	0/2	0/2	0/2	0/2	2/2 +
	d.o. 400g	NA	0/2	0/1	0/2	0/2	2/2 +
	(Book in box 570g)	NA	0/NA	0/1	0/2	1/2	0/2
Volar grip	5cmØ cylinder in box	2/2	0/0	2/2	2/2 -	2/2	2/2
	7cmØ ½l bottle in box	0/1	0/NA	0/2	2/2 -	0/2	2/2 +
	7cmØ bottle & drink	NA	0/NA	0/0	0/2	NA	0/0
Any grip	Eat with spoon	2/2	1/NA	2/0	2/2 -	2/2 +	2/2

DISCUSSION

These few experiments show that myoelectric signals from voluntary wrist extension can be used for control of stimulation of the thumb to obtain the key grip. In one case, however the volar grip is impeded using the MeCFES. Among the problems are that good myoelectric control is difficult to achieve and that the possibility to use the key grip implies, for the person, new grasp strategies. It has been seen that the flexion of the elbow was accompanied with the presence of myoelectric signals at the recording electrodes. It is uncertain if these signals are spill-over from the biceps/brachioradialis or if the wrist extensors are involuntarily activated too, during the elbow flexion. A theory can be that such involuntary contraction can be a result of the lack of neural/visual feedback from the paretic wrist, as no movement occurs. When the

biceps are activated the person is maybe used to activate all muscles in the zone, unaware that the wrist extensors are activated as well. If this is the case training with the device could eliminate this effect since the MeCFES provides the visual feedback in terms of movement.

The system's control strategy is based on proportional control but during the experiment the stimulation intensity was behaving in an on/off manner. This could be due to lacking the fine-tuning of the parameters and to the fact that the person had only visual feedback of the grip force. The person (SI) which had the best improvement of the grip answered negatively to the question of whether he would use a system like this for daily use if not the design and functionality was significantly improved.

At the time of writing a splint is being designed with built-in electrodes that facilitates mounting/dismounting the system. Since the device gives the possibility for some tetraplegics to grip it will be a useful solution for some tasks. On a longer perspective it can form an attractive component in a more complete neuroprosthesis system that has attractive design and functionality.

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PROGRAMABLE FUNCTIONAL ELECTRICAL STIMULATOR WITH EMG FEEDBACK

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SUMMARY

Electrical stimulation is a widely used method of eliciting functional muscle contraction in spinal cord injured subjects. Portable, four channel, constant current functional electrical stimulation (FES) device described in this paper is programable, battery operated unit with the ability to accommodate surface electromyography (EMG) feedback signal from the activated muscle. This is accomplished through the use of active surface EMG preamplifiers with blanking capabilities. Blanking suppresses the strong stimulation artefact present in the EMG signal during FES. The device is microprocessor controlled. It is programable both internally from the built in keyboard and externally from the host PC based computer via the serial link. It supports simultaneous pulse width and frequency modulation of the stimulation train. The third stimulation parameter, the intensity, can be adjusted manually. Various stimulation profiles can be set, or downloaded to stimulators memory, to provide for different stimulation patterns. The EMG feedback can be used to control the stimulation or as a visual information about the shape of the evoked electrical muscle response. The later is done through the use of built-in graphical LCD.

This stimulator was developed for the study of the correlation between the force and the surface EMG in FES activated skeletal muscle. Possible applications include the study and implementation of closed-loop control of FES using EMG as the feedback signal and for on-line detection of muscle fatigue during FES assisted exercise.

STATE OF THE ART

Electrical stimulation is widely accepted as a dominant way of restoring functional movement in extremities affected by stroke or spinal cord injury /5/. Numerous stimulators have been designed for such a task ranging from simple single channel units to advanced programable multichannel devices /1/-/4/. Common to almost all of them is that they were built for particular type of application. Despite some of the claims stating that the stimulators are flexible and user friendly there are no stimulators that can easily be adapted to a wide spectrum of rehabilitation tasks. Further, some authors use the term programable, to describe the fact that the stimulation parameters can be accessed from the outside by the host computer. At present the best the portable, battery operated stimulators are capable of is following the preset cycle of turning the channels on and off with varying pulse width and/or frequency and accepting the external trigger source. In addition to being truly programable the stimulator described in this paper provides the feedback information about the muscle activation by means of active surface EMG amplifiers.

MATERIAL AND METHODS

The portable, programable stimulator consist of four major subsystems: 1) control unit built around the Motorola MC68HC711E9 microcontroller with on chip RAM, EPROM, E²PROM, 8 channels of 8 bit A/D converters, timer system and RS-232 serial link; 2) constant current stimulator output stage with DC-DC converter; 3) user interface subsystem involving graphics LCD, alphanumerical LCD and the keyboard and 4) EMG feedback part consisting of active preamplifiers with stimulation artefact suppression capability and

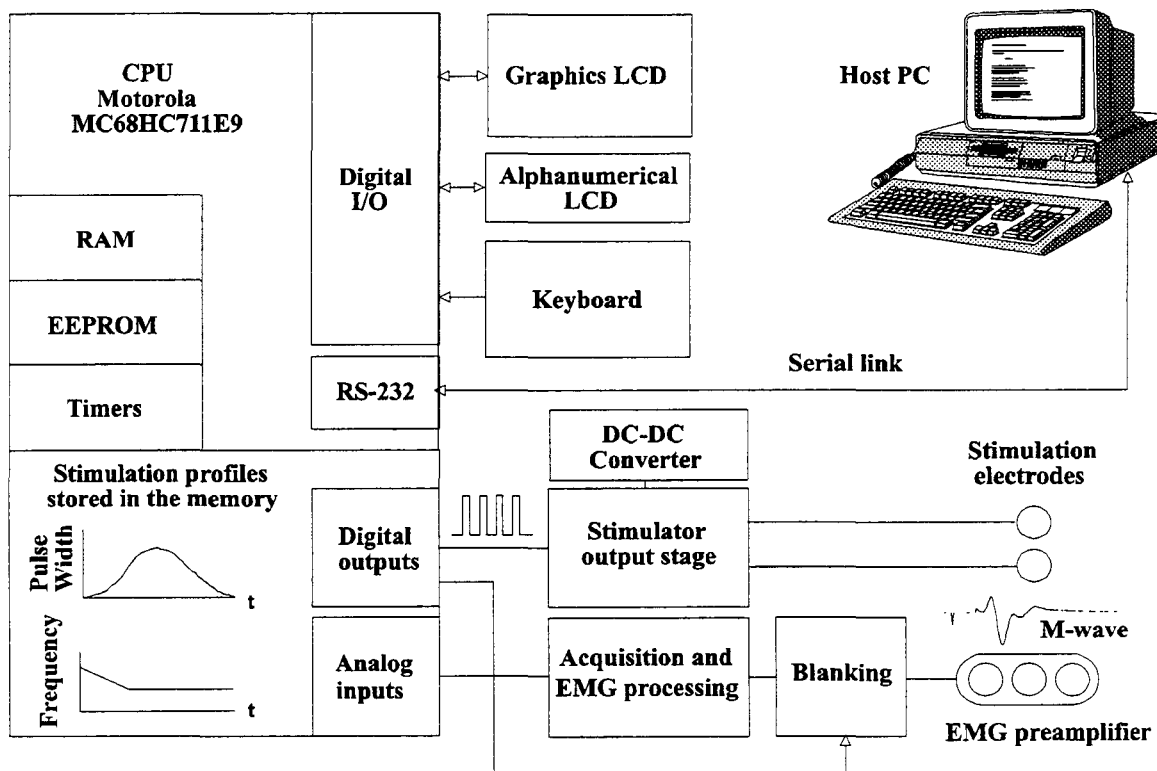


Fig. 1. The portable, programmable stimulator subsystems: 1) control unit built around the Motorola MC68HC711E9 microcontroller; 2) constant current stimulator output stage with DC-DC converter; 3) graphics LCD, alphanumeric LCD and the keyboard for user interface and 4) EMG feedback active preamplifiers with blanking circuitry.

analog processing circuitry (Fig. 1). The stimulator can be controlled and programmed from the host PC computer via the serial connection. The controller board [8] is responsible for generating the stimulation train, displaying the stimulation parameters on the alphanumeric screen and the actual muscle response, called the M-wave, on the graphics display, issuing the control signals for blanking and communicating with the host PC. The stimulation profiles are stored into microcontrollers memory in the form of pulse width (PW) and inter-pulse interval (IPI) pairs for every stimulation pulse. The size of the available RAM memory allows for the minimum of 5 minutes of arbitrary stimulation profiles, for each stimulation channel, as described by different PW and IPI combinations. The size of the acquisition memory allows for recording of up to 15 minutes of processed surface EMG. The stimulator can also be programmed to repeat the pattern or patterns, stored in the memory, any number of times in any combination. Pulse width range is from 10 μ s to 500 μ s with the resolution of 1 μ s. The inter-pulse interval is in the range of 10 ms to 100 ms (corresponding to frequency a range of 10 Hz to 100 Hz), with the resolution of 1 ms. Different stimulation profiles can be downloaded from a host computer through a RS-232 serial link. The same link is used to send recorded data to the host computer for off-line analysis.

The output stage of the stimulator is of a constant current type. The maximum current output was limited to 120 mA. Stimulation pulse train is monophasic. The battery operated high voltage DC/DC converter is galvanically isolated from the control part of the circuitry.

The unique feature of this system is its capability to record evoked or voluntary surface EMG (sEMG) while the stimulation is active. This is achieved using modified Motion Control EMG preamplifiers [7]. The original specifications for this preamplifier are: gain of 350, bandwidth 8 Hz to 26 kHz, common mode rejection ratio (CMRR) 105 dB, and the input impedance of 100,000 M Ω . We modified the circuit by adding a pair of analog switches between the two stages of amplification. When the blanking signal is activate the output of the first stage is grounded through a resistor and capacitor in series and simultaneously disconnected from the second stage. At the same time the input to the second stage is grounded. This prevents the second stage

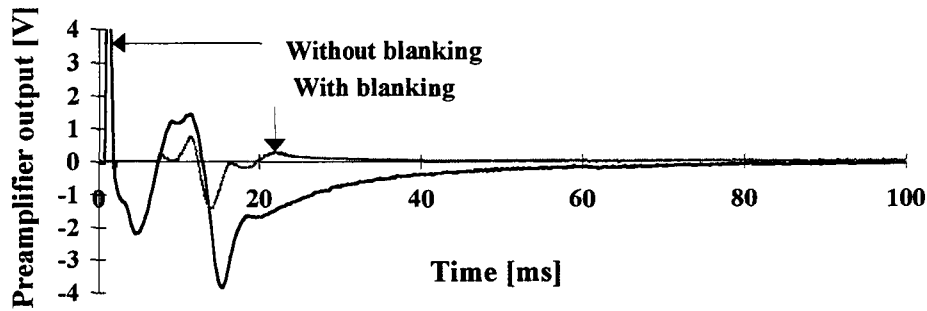


Fig. 2. The M-wave response to the stimulation pulse with and without the artefact suppression.

from saturating and hastens the recovery of the first stage (Fig. 2). The modified preamplifier has a lower high end bandwidth frequency of 18 kHz. The processing of the preamplifier sEMG is performed by an analog board originally developed for a 2-channel long-term spasticity recording system /6/. The sEMG from the preamplifier is filtered through an active second order band pass filter with cutoff frequencies of 12 Hz and 1061 Hz, fully rectified and integrated over a 10 ms time period. The output from the integrator is sampled at the end of each integration period. Analog to digital conversion is performed by the A/D part of the microcontroller with 8 bit resolution.

In terms of user interface the stimulator has built in keyboard for manual entry and editing of stimulation parameters and stimulation profiles. These parameters are displayed on an alphanumeric 2 x 32 character LCD. The feedback information from sEMG preamplifiers is displayed in graphical form on a 256 x 128 dot graphical LCD. This way it is possible to monitor the muscle response in real time. The signals can be displayed cumulatively or single sweep at the time.

RESULTS

Portable, battery operated , programable stimulator was designed and tested as a part of a project for force estimation using sEMG in FES systems. In this application the sEMG was recorded together with the torque from the wrist during isometric wrist flexor muscles contraction. The sEMG was then processed, off-line, in various different ways to establish the best correlation between the force and the accompanying sEMG. One segment of the protocol was dealing with different activation profiles. One example is the staircase type stimulation profile (Fig. 3). Stimulation pulse width was increased from 0 to 500 μ s in 50 μ s increments and

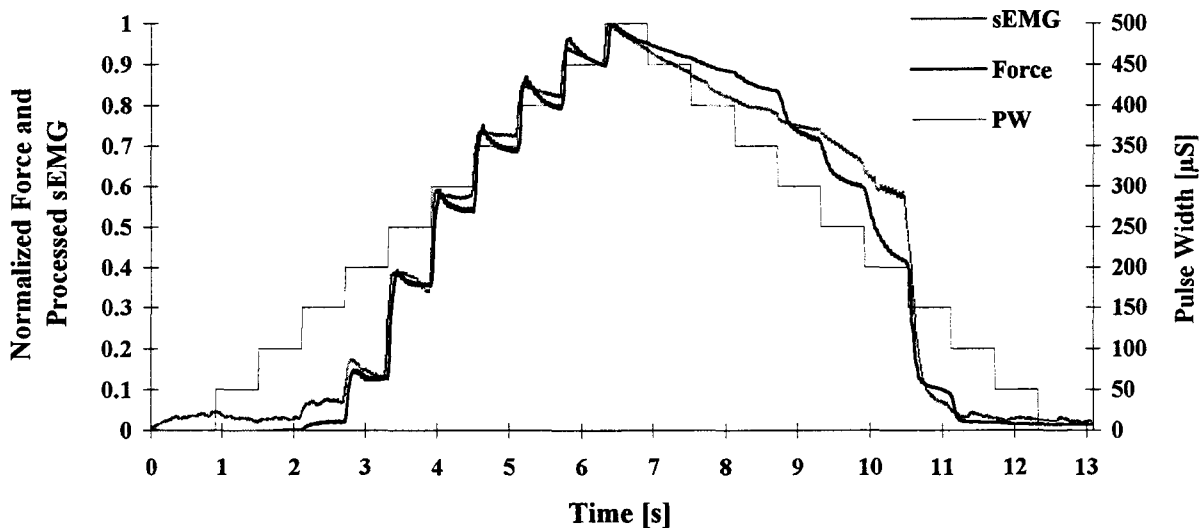


Fig. 3. Normalized force, and sEMG as a response to the staircase like stimulation profile recorded from the wrist flexor muscles of the able bodied subject. The sEMG was processed on-the-fly.

then reduced back to 0 in the same way. The sEMG was filtered, fully rectified, integrated and filtered using moving average filter to establish linear envelope. The processing was performed in real time.

DISCUSSION

A portable, battery operated, programable electrical stimulator with sEMG feedback was developed. The device is capable of simultaneous pulse width and frequency modulation of stimulus train following an arbitrary profile stored in microcontrollers memory. It can be used for a wide variety of applications where the muscle activation has to follow a certain profile. The system also offers the feedback information by recording the sEMG with artefact suppression. This promises to be a valuable feature in closed loop control of functional movement. By introducing the additional on-line processing it would be possible to use this device for muscle fatigue monitoring in FES systems. With all the features described, this system is promising to be a valuable research tool in developing and testing different control strategies involved in the restoration of functional movement in impaired people.

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FORCE TRANSDUCER FOR MEASUREMENT OF GILL MOVEMENTS IN FISH

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SUMMARY

A single channel force transducer intended for measurement and evaluation of the curves of recruitment of fibres in muscles contracting synergistically during respiration of fish was designed, developed and experimentally tested.

The most important requirements in developing of the proposed force transducer were, that transducer should be able to evaluate a force elicited by contraction of the muscles (gill movements), that electrical response should be as linear as possible in whole range of forces, and, that transducer should react fast enough to be able to represent contraction as reliable as possible. The force transducer was made up of full Wheatstone bridge composed of four semiconductor strain gages bonded on especially designed cantilever. The mechanic tension produced by force elicits elastic deformation of the cantilever thus resulting as the change of the output voltage which directly represent an information about mechanical load applied on the cantilever. The completed transducer represented very linear dependence of the output voltage upon the load. Over the nominal range of (0-70)mN the sensibility of transducers is 0.5mV/mN at bridge excitation voltage of 5V.

STATE OF THE ART

The purpose of this work was to develop and evaluate mechanically test the transducer intended for measurement and evaluation of the curves of recruitment of fibres in muscles contracting synergistically during respiration of fish.

MATERIAL AND METHODS

Definition or requirements

The most important requirement in developing of the proposed force transducer was, that transducer should be able to evaluate a force elicited by contraction of the muscles during respiration of a fish. Next important requirement was that electrical response should be as linear as possible in whole range of forces. Final important requirement was that transducer should react fast enough to be able to represent contraction as reliable as possible. According to the aim of evaluating contraction of fish's muscle the data about rise times of involved muscles was considered.

Development

The force transducer was made up of full Wheatstone bridge composed of four semi-conductor strain gages (resistance in ohms: $500.0 \pm 0.3\%$), bonded on especially designed cantilever. The dimensions of the cantilever section intended to bend upon the applied force were defined according to the request of gage's producer and our request to develop transducer that would be enough sensitive to measure elicited forces. Strain gages were bonded according to the procedure described by the producer of strain gages and adhesive, respectively. After bonding of the full Wheatstone bridge equipped with terminals for connection of wires leading to the connector the band was mounted in especially designed tool made of Plexy Glass. The mechanic tension produced by force elicits elastic deformation of the cantilever thus resulting as the change of the output voltage which directly represent an information about mechanical load applied on the cantilever. Of course, the output signal can be amplified and connected to the A/D converter and IBM Compatible Personal Computer.

RESULTS

Static characteristic of the transducer was obtained simply by hanging weights of 5mg on the transducer at the level supposed to be acting point of the forces. It is obvious from obtained characteristic that the completed transducer represented very linear dependence of the output voltage upon the load acted rectangularly on the cantilever. Over the nominal range of (0-70)mN the sensibility of transducers is 0.5mV/Mn (Fig.) at bridge excitation voltage of 5V.

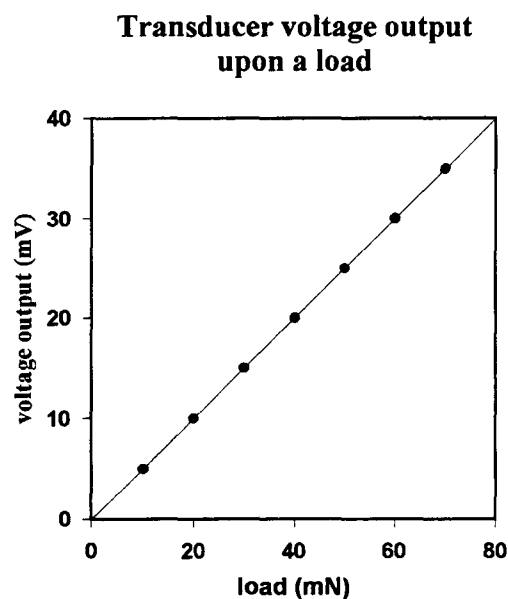


Fig. The transducer voltage output voltage upon the load.

DISCUSSION

According to requirements determined in methods section we can conclude that all aforementioned requirements were met. Thus, the single channel force transducer described above provides evaluation of the curve of recruitment of muscle fibres recording time dependent force elicited by contraction of muscles activated synergistically. Because of it's high sensitivity the system is able to record contraction of only few muscle fibres.

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A THERMO-REVERSIBLE GEL ACTUATOR FOR AN ARTIFICIAL URETHRAL PROSTHESIS.

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SUMMARY

In this work a thermo-reversible polymer gel obtained from free radical polymerisation of poly(vinyl methyl ether) has been characterised. The equilibrium gel length and the gel Young's elastic modulus have been measured as a function of its temperature as well as the contraction time of the material to temperature step changes.

The isometric stress attainable by a PVME gel actuator has been calculated from experimental data as a function of temperature. In the prosthesis working configuration, where the gel temperature is driven by electrical means, the gel actuator has shown to generate a closing pressure around the urethra enough to restore the normal condition of continence in the human body.

STATE OF ART

The development of a soft linear actuator with an intrinsic compliance, similar to that of natural tissues and muscles, may be very important in the solution of the problem of human urinary incontinence.

The mechanism that leads to bladder diversion is a complex process. It is achieved by mean of by two forces: the detrusorial pressure and the urethral contraction. The former one induces bladder diversion, the latter one maintains the urinary continence.

Many pathologies[1] may lower the urethral pressure. In this case it has been shown that an artificial addition of pressure around the urethra, achieved by means of various techniques[2], restores the continence, but it represents an obstacle to bladder diversion and may cause damage to the high urinary apparatus. A better solution is to add a tunable pressure to the urethral one. This is achieved by conventional prostheses where a pressurised fluid filled cap is emptied by means of a hand powered system that makes use of complex micro-mechanical parts. The major drawbacks of such a device come just from the failure of micro-mechanical components and from the ischemic damage (erosion) of the tissue in contact with the prosthesis.

The use of a soft polymeric actuator with an intrinsic compliance close to that of natural tissue may lead to a great improvement of the interaction between the urethral tissue and the artificial device. In fact, even though, the mean pressure of the prostheses cap needed for urinary continence (of order of 40 cm H₂O)[2], is much lower than the diastolic one, the limit beyond which the tissues undergoes ischemic damage, the bad matching between the cap elasticity and the urethral one, generates local excesses of pressure that leads to biological damage in about 10% of the patients. Moreover the simple mechanism of contraction, induced by electrical heating, in a

polymeric gel actuator does not need a complex micro valve system.

In this paper we have synthesised and characterised a polymeric gel that shows reversible volume variation in response to temperature changes of order of few degree Celsius in the range of physiological values.

MATERIALS AND METHODS

The gel material has been synthesised by means of free radical polymerisation of poly(vinyl-methyl-ether) (PVME). Following the method described by Hirasa [3], a sodium alginate- Ca^{++} pre-gel, containing an interstitial PVME aqueous solution at a concentration of 30% by weight, has been submitted to the γ radiation of a Co^{60} source of about 0.91 M Rad/h for 24 hours.

Then samples in form of parallelepiped of various dimensions were cut and let to equilibrate in de-ionised water at room temperature ($20 \pm 1^\circ\text{C}$); hence their dimensions were measured by means of a stereo-microscope (Olympus Zoom Stereo Microscope, Research Instruments Limited).

The equilibrium gel length as a function of temperature and the gel length change following a sudden jump in temperature has been measured by means of a Hall effect isotonic transducer (Biological Research Apparatus, Ugo Basile) connected to a plotter (7090A measurement plotting system, Hewlett-Packard) and to a computer acquisition data system. The temperature was controlled by means of a thermostat (M3, Lauda).

RESULTS

In figure 1 the percentage of equilibrium length variation of a PVME gel sample, with respect to its phase transition length L_c is shown. During the measurements the sample is maintained at thermal equilibrium within a bath of de-ionised water.

The maximum rate of length change per degree Celsius is achieved near the transition temperature ($T_c = 38.9 \pm 2^\circ\text{C}$) and it results $\Delta L / (L_c \Delta T) = 0.062 \pm 0.006^\circ\text{C}^{-1}$.

In figure 2 we report the PVME gel Young's elastic modulus at various temperature. It is worth noting that up to 30°C despite the gel shrinks and its polymeric content increases, it becomes softer and softer, while, after that point, there is a sudden increase of the Young's modulus that continues beyond the transition temperature of 38.9°C .

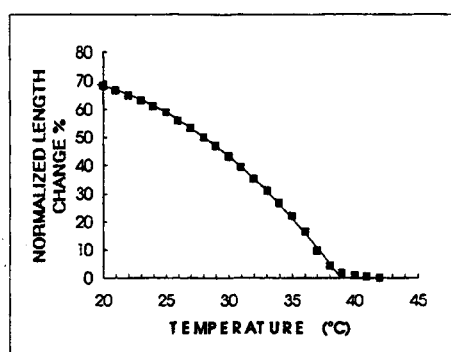


Fig. 1. The PVME gel length as a function of temperature normalised to the fully collapsed one at the transition temperature. The full line is the fit of a quadratic curve obtained by means of a least squares method.

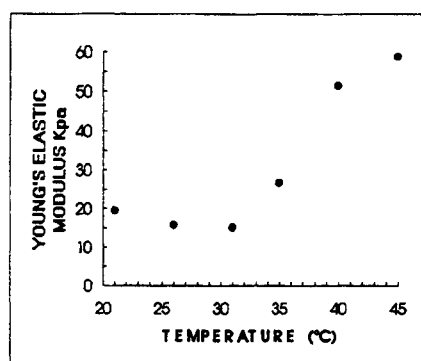


Fig.2. The PVME gel Young's Elastic modulus as a function of temperature.

From data in figure 1 and 2 the stress generated by means of a PVME gel actuator held in isometric condition at its rest length at 21°C is calculated from the elongation of the sample needed to compensate its temperature shrinking and from the gel Young's modulus at that temperature.

The result of calculation is plotted in figure 3. As it can be seen from figure 3, the maximum isometric stress reaches about two tenths of that one of frog muscle as measured by Suzuki [4].

As far as it concerns the gel time response to a temperature step change, it has an exponential like behavior and it decrease as the temperature step increase.

The increase of the gel Young's elastic modulus with the temperature, given in figure 2, agrees with the decrease of gel time response. This fact is well explained by a bi-phasic continuum model [5], where the polymer network (solid phase) moves through a stationary liquid phase. The resulting diffusive-like kinetics has a characteristic time $\tau = a^2/\pi^2 D$ where D is a diffusion coefficient that for a thin gel strip, of a thickness "a", takes the form $D = \mu / f$, where μ is the gel shear elastic modulus and f is basically the inverse of the Darcy's hydraulic permeability with a correction coming from the electro-osmotic coupled Onsager coefficients [5]. Since for gel the Young's elastic modulus E is of order of 2.4μ , the gel time response is inversely proportional to such an elastic modulus by the relation $\tau \approx 2.4 a^2 f / \pi^2 E$.

For a final temperature of 42 °C, that it can be assumed the maximum one for a PVME gel operating in a human body, we obtain an exponential characteristic contraction time of 4 seconds as shown in figure 4.

Given a PVME gel band, as schematised in figure 5, with a thickness Δr , applied around a rigid cylinder with a diameter r (with at ratio $\Delta r/r=0.6$), the generation of inwards radial pressure P following a gel temperature change, by using the tensile isometric stress shown in figure 3, is shown in figure 6.

It can be seen that the generated pressure is higher than the minimum one required to ensure urinary continence that is about 31÷35 cm of water as reported in literature [2].

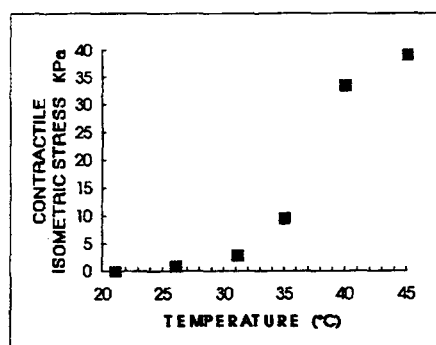


Fig. 3. The Isometric stress generation of PVME gel hold at rest length at 21°C, as a function of temperature

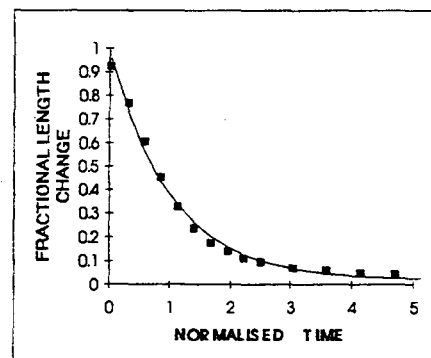


Fig. 4. The Fractional length variation of a PVME gel sample as a function of normalised time t/τ submitted to a temperature step change to 42 °C. The characteristic time τ of exponential decay results $\tau = 4$ s.

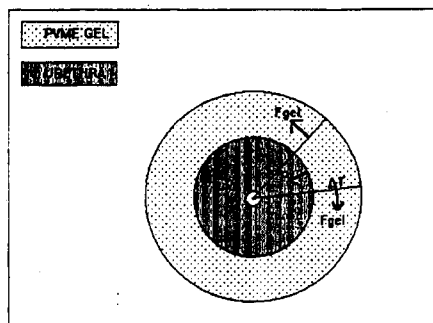


Fig. 5. Schematic configuration of a PVME gel actuator of thickness Δr around an urethra of radius r .

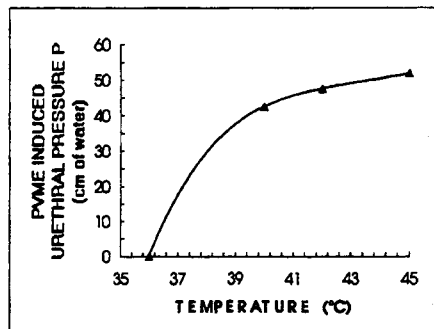


Fig. 6. The pressure p generated by a PVME gel band of thickness Δr (with a null stress at the urethral temperature of 36 °C [6]) as a function of its temperature for a value $\Delta r/r=0.6$. The full line is obtained by a polynomial least squares procedure.

CONCLUSION

In this work we have studied a polymer gel obtained from free radical polymerisation of polyvinyl methyl ether). The material data have been evaluated in order to study the feasibility of a urinary sphincter prosthesis. The gel length change and the gel Young's elastic modulus as a function of temperature has been measured.

The isometric stress generated by the thermo-reversible gel can generate around the urethra a tunable pressure of about 50 cm of water, enough to restore the normal condition of continence in the human body.

The muscle-like softness of the actuator and the simple mechanism of functioning (electrical heating) may avoid the erosion of urethral tissue (8 + 13 % of patients) and mechanical malfunctioning (12 + 22 % failure of implanted prosthesis).

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IMPROVEMENT OF MICROCIRCULATORY SKIN BLOOD FLOW UNDER SPINAL CORD STIMULATION (SCS) IN PATIENTS WITH ISCHEMIC PAIN.

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SUMMARY

Spinal cord stimulation (SCS) was first introduced into clinical practice by Shealy et al. in 1967. (1) A.W. Cook, a neurosurgeon from New York was the first to treat ischemic pain with SCS. (2) The method of stimulation for ischemic pain was revived 10 years later and different clinical reports were published reporting increased distances to claudication pain, relief of ischemic pain and ulcer healing under stimulation, suggesting that SCS improves microcirculatory skin blood flow.

STATE OF THE ART

At present, several studies indicate that SCS relieves rest pain, enhances microcirculatory skin blood flow, and improves ulcer healing in patients with ischemic pain.

MATERIAL AND METHODS

Only patients with ischemic rest pain or non-healing ulcers due to non-reconstructable crural or pedal vessels, are potential candidates for SCS. Classification should be based upon the criteria published in the Second European Consensus Document on Critical Limb Ischemia.(3) There is a formal contraindication for SCS in patients with a clear indication for angioplasty and/or bypass surgery.

Different techniques for the morphological and dynamic evaluation of skin microcirculation are available. There is however no "gold standard" method of measuring microcirculatory skin blood flow due to the complexity of the skin microcirculation. Nevertheless, the following methods are far more accurate than the ankle brachial index and segmental pressures, and it is recommended to use them complementary: 1° **vital capillaroscopy**: a technique with which the blood filling and morphology of the nutritional skin capillaries can be directly and non-invasively evaluated, it enables us also to study the capillary red blood cell velocity; 2° **laser-Doppler flux measurement**: with this technique both nutritional and thermoregulatory skin blood flow are measured. The principle disadvantage is that it is impossible to calibrate the measurements in absolute units and that this technique is very sensitive to artefacts; 3° **transcutaneous oxygen tension (TcPO₂)**: the oximeter utilizes a Clark-type oxygen-sensing electrode. The heating element of the electrode is warmed to 43°-45° C, leading to a maximal local vasodilation. TcPO₂ is useful in determining the severity of the ischemia and in studying microcirculatory function, mainly nutritive skin perfusion.

RESULTS

The potential effectiveness of SCS on microcirculatory blood flow was studied in different centers.

Two centers studied the effects of SCS on the capillary blood flow: *Jacobs M. et al.* (4) assessed capillary density, capillary diameter and red blood cell velocity before and after arterial occlusion in 35 patients treated with SCS. After SCS, 28 patients claimed relief of ischemic pain which could be confirmed by vital capillaroscopy. Capillary density and red blood cell velocity increased significantly. Patients with no pain relief did not show improvement of microcirculatory perfusion and amputation was necessary. In patients with continued pain relief and in whom ischemic ulcers healed, capillaroscopy showed maintenance of the microcirculatory blood flow. *Claeys L. et al.* (5) studied capillary morphology and red blood cell velocity in 47 patients with significant pain relief under stimulation. This study revealed an increase in the number of perfused capillaries, however, this increase was not significant. Mean capillary red blood cell velocity before stimulation was 0.11 mm/s and increased significantly to a mean value of 0.29 ($p < 0.021$).

Sciacca V. et al. (6) studied the effects of SCS by laser-Doppler fluxmetry and assessed the TcPO₂ vasodilation index. He demonstrated that laser-Doppler flux measurement is an accurate non-invasive method of evaluating changes in microcirculatory flow in patients with severe ischemic pain treated with SCS. The data demonstrated a statistically significant increase ($p < 0.005$) of flux and volume parameters under stimulation. *Horsch and Claeys* studied also the effects of SCS on microcirculatory blood flow using TcPO₂. (7,8) Clinical status was classified as Fontaine Stage III, chronic ischemic rest pain, in 144 patients and as Fontaine Stage IV, ischemic pain with ulcers or dry gangrene, in 63 patients. After a mean follow-up period of 35,6 months, major pain relief (>75%) was noticed in patients who retained their limbs. Sixty-four patients underwent major amputation despite SCS. Clinical improvement was confirmed by the increase in TcPO₂ ($p < 0.02$) from 24.2 to 48.1 mmHg in the stage III patients with limb survival, and from 16.4 to 37.2 mmHg in the stage IV patients with limb survival ($p < 0.03$). This centre performed a randomized-controlled study with one year follow-up in 86 Fontaine stage IV patients with endstage vascular disease undergoing 21 day intravenous prostaglandin E₁ (PGE₁) therapy for nonhealing ulcers.(9) Only patients with non-reconstructable vascular disease as proven by angiography were included. Inclusion criteria were an ankle systolic pressure <50mmHg, severe rest pain despite analgetic medication, and presence of nonhealing foot ulcers or dry gangrene. One week after the start of PGE₁ therapy, patients were randomized into receiving SCS plus PGE₁ (n=45 patients), or just PGE₁ (n=41 patients). At 12 months total healing of foot ulcers in the SCS-group was significantly better (69 vs.17%; $p < .0001$) and more SCS-patients achieved an outcome of Fontaine stage II (claudication pain, no rest pain or lesions) (40 vs. 10%; $p = .0014$). Despite this clinical improvement, differences in amputation rates were not observed (minor/ major amputations; respectively 13 vs.15% and 16 vs.20%). Foot TcPO₂ increased significantly for the SCS-group (+ 213 vs.-2%; $p < .0001$). Patients in either group whose TcPO₂ rose to 26.0 $\pm$ 8.6 mmHg on average were able to heal ulcers or toe amputation wounds. PGE₁-patients had temporary TcPO₂ elevations of about 33% on average but this

was gone by six months. SCS-patients had steady increases in TcPO₂, and maintained them at 12 months. Among the SCS-patients, those with baseline TcPO₂ ≤ 10mmHg had significantly less success at 12 months, this was not observed for the OMT-patients. The regional perfusion index increased significantly, 187 vs. 0%; p<.001).

DISCUSSION

Since 1967, SCS has become an accepted technique for the management of chronic intractable pain. The interest in neurostimulation for the treatment of pain was based upon the Gate Control Theory. Recently, SCS has also successfully been used for patients with ischemic rest pain. Indeed, the most important symptom in patients with critical limb ischemia is ischemic pain making a normal life impossible, and amputation is often the only alternative for pain relief when vascular reconstruction is impossible. Not only significant pain relief could be achieved but also healing of ischemic ulcers, suggesting that stimulation improves the microcirculatory blood flow. However, in spite of the spread of SCS for this indication, the precise mechanisms to explain the effects of stimulation on ischemic pain still remain uncertain. The Gate Control Theory of Pain (= theory of segmental pain inhibition) postulates that stimulation of large afferent nerve fibers (A-beta) in the dorsal columns of the spinal cord prevents the transmission of pain information from smaller diameter pain fibers (A-delta and C).(10)

Different hypotheses about the effector mechanisms for relief of ischemic pain under stimulation are actually discussed.(11) The first hypothesis is that the relief of ischemic pain is due to an inhibitory effect of spinal cord stimulation on the transmission of nociceptive pain impulses from the dorsal horn to the brain via the spinothalamic tracts. There is also evidence that stimulation reduces sympathetic vasoconstriction activity. It seems from animal experiments that surgical or chemical sympathectomy abolishes the vasodilatory effects of stimulation.

But, the relief of ischemic pain might be assisted by improvement of the microcirculatory blood flow, probably due to a release of the reflex sympathetically mediated vasoconstriction that is known to occur in response to pain and the inhibition of normal sympathetic activity. There is also the possibility that SCS may act by releasing neurotransmitters involved in pain modulation.

The theory that antidromic activation of the dorsal roots leads to a vasodilation is no longer accepted. Indeed, transection of the dorsal roots did not abolish the vasodilation under stimulation, but transection of the ventral roots or the peripheral nerve depleted this effect, as did a complete bilateral lumbar sympathectomy, indicating that spinal mechanisms are essential and that antidromic activation of primary afferents is unlikely to account for peripheral vasodilation.

CONCLUSION

Pain relief is definitely assisted by improvement of the microcirculation as shown in different experimental and clinical studies. TcPO₂ and capillary red blood cell velocity showed a significant overall increase in the patients with limb survival following the stimulation. This increase in cutaneous blood circulation explains the clinical improvement. It is unlikely that the improvement of microcirculatory skin perfusion is caused by an

improved arterial inflow since the ankle brachial pressure index or systolic toe pressure did not show significant alteration.

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MEASUREMENT OF THE FORCES IN THE CABLE OF A RECIPROCATING GAIT ORTHOSIS (RGO) DURING PARAPLEGIC WALKING

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SUMMARY

The force in both cables of an RGO was measured during walking for six paraplegic subjects. The force measured was related to the phase of walking as determined by foot switches. The force in the 'front' cable driving hip flexion in swing phase was non-existent in four subjects. In the other two subjects a maximum contribution of 5 Nm to hip flexion moment was recorded. The latter, when compared to hip flexion moments during normal gait, shows a one eighth maximum contribution to swing from the 'front' cable. The hip moment resisted by the 'back' cable, which supports the hips against bilateral hip flexion, ranged from a maximum of 12 Nm to 35 Nm. It is suggested that a reciprocal orthosis with only a 'back' cable fitted, and with the 'front' cable omitted, would provide the same function as the current LSU-RGO.

STATE OF THE ART

Recent developments in orthoses have included the reassessment of standard orthotic design features. Use of brakes and clutches at the orthotic hip joints, often in conjunction with electrical stimulation, can enhance some of the functions of the cable linkage in an RGO /1,2/. There is little direct evidence in the literature for the precise function of the reciprocal cable link. Indirectly the function of the reciprocal linkage has been assessed by measurement of oxygen consumption of patients walking in orthoses with and without such a link /3,4/. Patients with lesion levels below T4 walk using less energy in orthoses with a reciprocal link at speeds less than 0.2 m/s, and with less energy in orthoses without reciprocal linkage at higher speeds.

This research aims to quantify the force and resultant hip moment produced by the cables of a dual cable LSU-RGO with respect to phases of the gait cycle.

Subject	Sex	Injury level	Complete/Incomplete	Age	Walking Speed
A	M	T5	Complete	37	0.18 m/s
B	M	T12	Complete	44	0.17 m/s
C	M	C5/6	Complete	54	0.16 m/s
D	M	T4/5	Complete	28	0.18 m/s
E	F	T11/12	Complete	28	0.17 m/s
F	F	T7	Incomplete	40	0.42 m/s

Table 1 Injury level, sex, age and average walking speed during the trials of patients participating in the study

MATERIAL AND METHODS

The six paraplegic subjects who participated in the study (table 1), walked in an LSU-RGO as part of a upright mobility programme at the Regional Spinal Injuries Centre, Southport. The LSU-RGO is an HKAFO where the knee and ankle joints are immobilised and the hip joints are linked for flexion and

extension by two Bowden cables, which transmit motion when in tension. Standing in the orthosis with both feet on the ground the 'back' cable is in tension when resisting bilateral hip flexion, and the 'front' cable is in tension when resisting bilateral hip extension. When one foot is off the ground (i.e. during swing phase), the cables act in a reciprocal fashion limiting hip motion so that when one hip is flexed the other is extended by the same angle. If swing hip flexion is driven by stance hip extension, then the 'front' cable will be in tension.

Each patients' orthosis was customised by attaching a strain gauge transducer between the end of the cable and the hip joint of both the 'front' and 'back' cables. Force sensitive resistors (FSR's) were placed on the sole of the shoe under the heel and toe of each foot and used as switches to aid the division of the gait cycle into swing and stance phases. Patients walked 10 m along a straight track at a self-selected speed. At the end of the track the subject turned and rested for a few minutes before walking back along the track. A minimum of four trials were conducted for each patient and between 20 and 40 steps were available for analysis.

The FSR signals were used to divide force data into double support right leg back (RLB), double support left leg back (LLB) and right (RS) and left (LS) swing phases using the following criteria. Firstly the toe switch signal falling to the baseline value was used to indicate the start of swing phase. Secondly the heel switch signal starting to rise to a maximum was considered to be the end of swing phase and the start of the next double support phase. Cable force data was then transformed so that the time scale was represented as a percentage of the length of each gait phase. Mean cable force throughout the gait cycle was calculated for each subject. The maximum force in each cable and each gait phase was calculated and the mean and 95% confidence interval of the mean were calculated for each subject. A threshold of 10 N (0.3 Nm) was set to eliminate the effects of noise from calculations, if the force in the cable did not ever rise above this threshold, then the maximum force was considered to be 0 N. The distance between the cable attachment and hip joint centre was measured and used to calculate the moment induced at the hip by cable action.

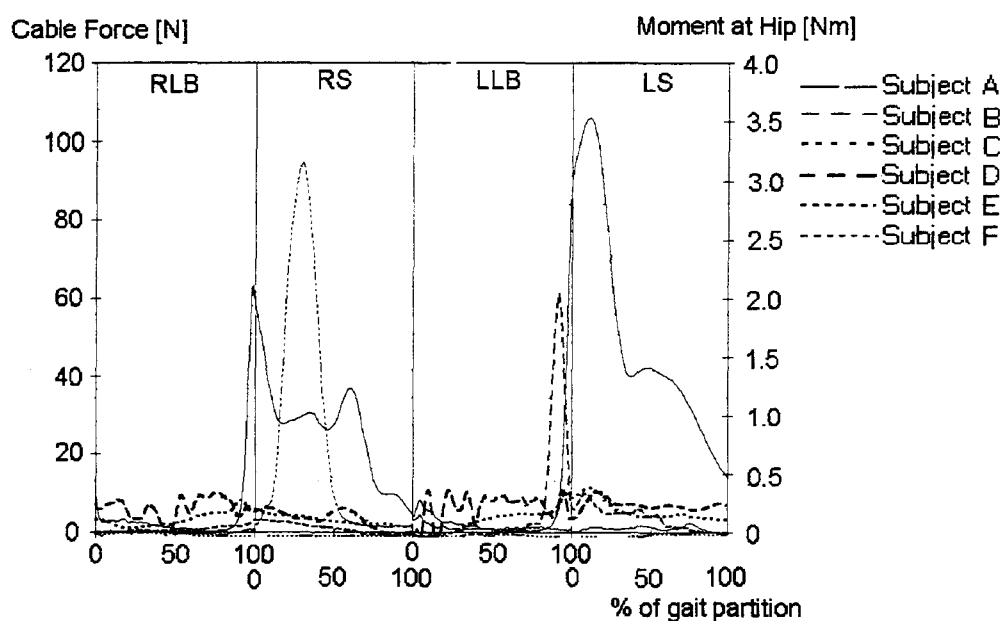


Figure 1 Mean force in the 'front' cable during the whole gait cycle for all subjects.

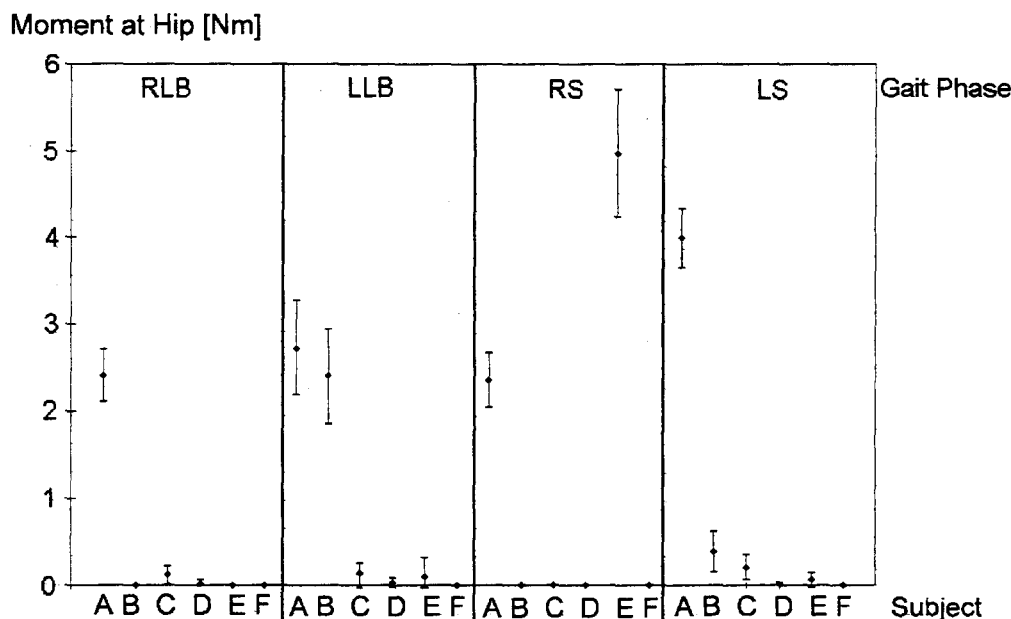


Figure 2 Mean maximum moment and 95% confidence interval of that mean grouped by gait phase for all patients.

RESULTS

The mean force for the 'front' cable is shown in figure 1. The maximum moments in the 'front' cable grouped by gait phase for each subject are shown in figure 2. For three subjects the force in the 'front' cable remains less than 10 N for the entire gait cycle and the resultant moment at the hip joint was considered to be 0 Nm. Tension in the 'front' cable for subject A was built up during the last 5% of the double support phase to 3 Nm and dissipated during the swing phase for both legs. A hip flexion moment of 5 Nm was built up and dissipated in the 'front' cable during the right swing phase of subject E. During left leg swing for subject E there was no significant tension in the 'front' cable. Subject B had a 2.5 Nm peak of tension in the 'front' cable during the last 10% of the double support phase with the left leg back.

The pattern of use of the 'back' cable was more consistent between subjects. There was tension in the 'back' cable throughout the double support phases, with maximum values ranging from 12 Nm to 35 Nm. During the first half of swing phase the tension in the 'back' cable dissipated, and then began to build up to a maximum value of 12 Nm.

DISCUSSION

It has been assumed that the reciprocal cable linkage in the LSU-RGO is used during the swing phase. The stance hip is said to undergo a tucking action which creates stance hip extension and thus drives hip flexion through tension in the 'front' cable [5]. The generation and dissipation of tension in the 'front' cable is expected during the swing phase of gait. This only occurred in one swing phase for one subject. Three subjects had no 'tension' built up in this cable at any point in the gait cycle. Subjects A and C generated tension in the 'front' cable at the end of double support through the action of bilateral hip extension. In subject C this tension had been dissipated by the time the toe left the ground and thus did not contribute to hip flexion during swing phase. The tension generated in the 'front' cable during double support for subject A was dissipated during the swing phase and thus contributed to hip flexion.

In the two subjects where tension in the 'front' cable was present during swing phase, the maximum moments produced were 3 Nm and 5 Nm. The flexion moment generated at the hip joint during the swing

phase of normal walking is 0.7 Nm per Kg body mass which would be approximately 40 Nm for the subjects in this study /6/. Thus the contribution to hip flexion by tension in the 'front' cable is at best one eighth.

The 'back' cable was used during double support to resist a hip flexion moment of between 12 Nm and 35 Nm and was present for all subjects during double support. Towards the end of swing phase a tension of 6 Nm to 12 Nm was built up in the 'back' cable, as the cable system was in a reciprocal mode at this time, it may have been retarding the swing of the leg, thus causing a shortening of the step length.

In conclusion, the 'front' cable contribution to hip flexion was at best only one eighth of normal and in most cases was non-existent. The 'back' cable was used as was expected and provided support during double stance. The 'back' cable may also be retarding hip flexion during the latter part of the swing phase. These findings suggest that a reciprocal orthosis with only a 'back' cable fitted, and with the 'front' cable omitted, would provide the same function as the current LSU-RGO.

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Gait improvement by peroneal nerve stimulation with surface electrodes; a case study

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SUMMARY

The peroneal nerve, which is found in the lower leg, consists of motor- and sensor fibers. The motor fibers innervate the extensor muscles in the lower leg. The sensor fibers transmit sensory information from a variety of receptors, including cutaneous receptors in the dorsal portion of the foot to the spinal cord. If peripheral nerves and the reflex arch through the spinal cord are intact the electrical stimulation of the peroneal nerve can be used to improve gait of spastic hemiplegic patients with foot-drop. For this purpose a special test-stimulator with surface electrodes and a force-sensitive sensor that could be placed under either the healthy or affected leg for heel strike detection was developed. In this case study stimulation- and control parameters were found for an optimized gait pattern.

STATE OF THE ART

Injuries in certain areas of the body can cause permanent loss of sensations and voluntary motor functions. Currently, regeneration of damaged neurons and restoration of functionally appropriate synaptic connections can not be achieved in human subjects. However, even when central nerve fibers are damaged, peripheral nerve fibers and muscles can remain viable indefinitely. Intact peripheral nerve fibers offer the possibility of the partial restoration of voluntary motor functions by using functional electrical stimulation (FES). This approach has been under development for the past 3 decades.

Many systems for gait improvement for hemiplegic- and paraplegic patients have been developed so far. Most of them are equipped with surface electrodes and a stimulation device. Heel switches, a variety of inclination and angle sensors and force-sensitive sensors are often used to detect heel strike. /1/ Current FES - systems use control signals which involve very limited feedback signals. Therefore, such „open loop FES - systems“ tend to overstimulate in order to ensure that muscles are sufficiently activated. This can lead to premature muscle fatigue. Other groups of FES systems are implantable. In contrast to surface systems, their electrodes are fixed directly to the surface of an peripheral nerve. Control signals and energy are provided from an external device with a RF link. With the advent of methods for electrical interfacing with nerves the various natural receptors (pressure, vibration, pain etc.) having the potential to provide feedback- and command signals are a realistic further alternative. /2/, /3/, /4/ In order to make a fully implantable FNS-system acceptable for every day use, it will be necessary to eliminate percutaneous wires, reduce the size and power consumption of the stimulator and the control unit.

MATERIAL AND METHODS

If an intact peripheral nerve is stimulated by a suitable electrical signal, action potentials are evoked, which propagate along the axon. By means of a simple bipolar electrode, the propagation occurs in both directions: on the one hand distal to effectors and on the other hand proximal to the spinal cord. In case of the peroneal nerve the orthodromically propagating action potentials in the motor fibers cause an extension in the ankle joint (raising of the drop foot). The sensor fibers of the nerve are innervated with both,

proprio- and exteroceptive receptors of parts of the lower leg. The antidromically propagating action potentials in these sensor fibers propagate through intra- and intersegmental neurons of the spinal cord to elicit the flexor reflex (withdrawal reflex) of the whole leg (flexion in the ankle-, knee,- and hip joint). Therefore, the peroneal nerve stimulation can be used to support gait of hemiplegic patients with drop foot. Fig.1 shows the propagating action potentials of the stimulated peroneal nerve.

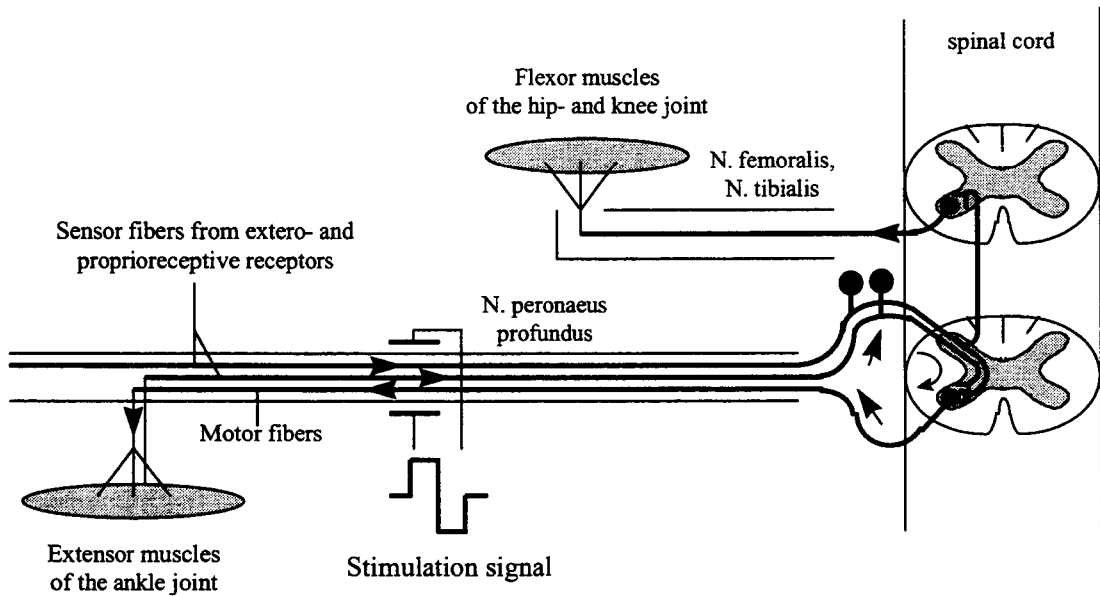


Fig.1: Scheme of propagating action potentials of the stimulated peroneal nerve. The distal propagating action potentials produce a contraction in extensor muscles of the ankle joint. The proximal propagating action potentials produce the flexor reflex (withdrawal reflex) in the whole leg (flexion in the ankle-, knee,- and hip joint).

For the purpose of gait improvement a test-stimulator was developed. The device allows the manual adjustment of stimulation parameters (amplitude, pulse- and stimulation duration and stimulation frequency). The stimulation signal is introduced to the n. peroneus profundus by surface electrodes placed just below the capitulum fibulae of the lower leg. A control unit is equipped with a force-sensitive sensor under the heel of the healthy leg which provides a delayed trigger signal for stimulation after the adjusted value of body weight is reached. Due to clonic spasm of the affected leg which would lead to a worse reproducibility of correct triggering signals, the force- sensitive sensor was placed at the healthy leg. An adjustable trigger delay is needed for trigger thresholds below 100 % of body weight (the swing phase of the affected leg is only possible when the healthy leg is in the stance phase).

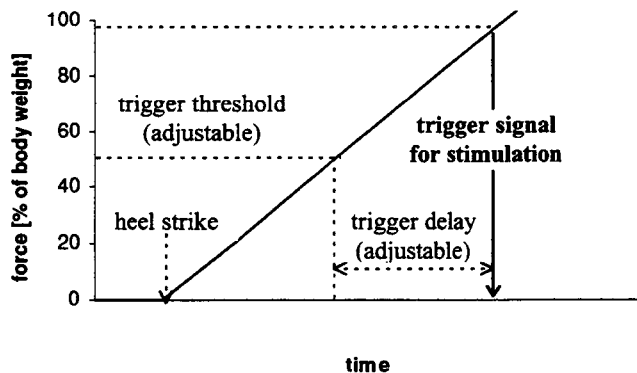


Fig.2: Schematic diagram of the sensory unit. A force- sensitive sensor under the heel of the healthy leg provides a delayed trigger signal for stimulation after the adjusted value of body weight is reached. An adjustable trigger delay is needed for trigger thresholds below 100 % of body weight.

This case study was conducted with a 50-year old man suffering from spastic hemiplegia and foot-drop. Stimulation- and control parameters (trigger threshold, trigger delay) were adjusted for different gait conditions by a physiotherapist in order to achieve an optimized gait pattern. Fig.3 shows flexion in the ankle-, knee-, and hip joint during walking when stimulation is applied. The stimulation signal is a train of rectangular biphasic pulses which have a duration of 0,5 ms + 0,5 ms at 40 Hz. Various gait experiments were conducted on a treadmill.

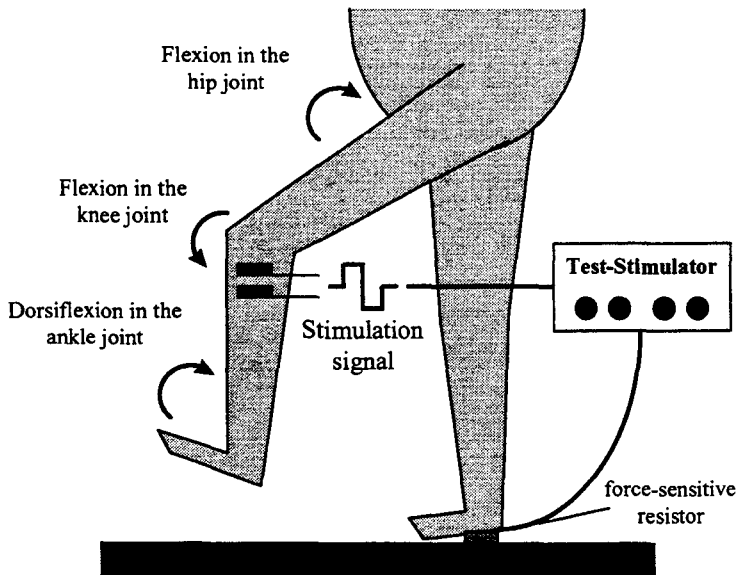


Fig.3 Flexion in the ankle-, knee-, and hip joint during walking when stimulation is applied with the test-stimulator. A force-sensitive sensor under the heel of the healthy leg provides a trigger signal after the adjusted value of body weight is reached. The stimulation- and control parameters have to be adjusted for different gait conditions in order to achieve an optimized gait pattern. The stimulation signal is introduced to the n. peroneus profundus by surface electrodes placed just below the capitulum fibulae of the lower leg.

RESULTS

In order to achieve an optimized gait pattern it was necessary to adjust on line stimulation- and control parameters. The amplitude of the rectangular biphasic stimulation signal was in the range of 50 Vp - 65Vp / 38 mAp - 49 mAp. It was dependent from both the electrical electrode-skin resistance and the special area of electrode placement. Therefore, optimal placement of the electrodes had to be found empirically before each experiment. The duration of the stimulation signal was 350 ms for all walking speeds. Fig.4a and Fig. 4b show the relation of control parameters at different walking speeds and trigger thresholds.

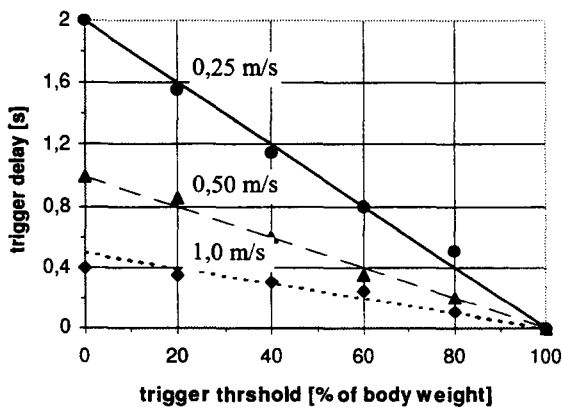


Fig.4a: Trigger delay vs. trigger threshold at various walking speeds

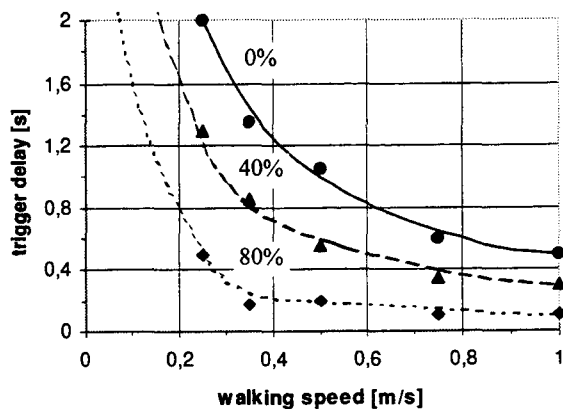


Fig.4b: Trigger delay vs. walking speed at various trigger thresholds

Furthermore, within the framework of another experiment the patient should achieve the maximum walk distance within a time interval of 15 min. He was allowed to select various walking speeds and to make interruptions. Fig.5 shows the measured walk distance of each experiment vs. time after start of training.

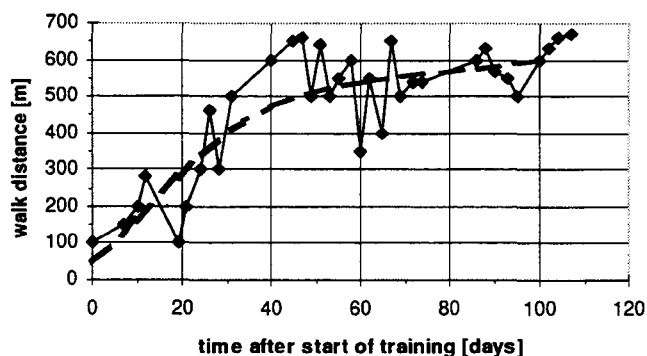


Fig.5: Achieved walk distance within a constant time interval of 15 min vs. time after start of training. Each point represents the result of one experiment. The dashed curve (averaging of the received measurements) shows increase of the walk distance over time.

DISCUSSION

In this case study a significant improvement of the subject's gait could be demonstrated. As Fig. 4a and Fig. 4b show trigger delay becomes 0 independently from walking speeds when trigger threshold is adjusted near 100 % of body weight. However, in order to achieve reproducible trigger signals, trigger threshold has to be less than 100% and trigger delay has to be greater than 0. As Fig. 5 shows soon after the beginning of the experiments the walk distance was increased (see dashed curve). This is a consequence of the muscle- and gait training by the stimulation.

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THE EFFECT OF ELECTRIC STIMULATION ON THE BLOOD FLOW DYNAMICS IN THE VICINITY OF A PRESSURE SORE

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SUMMARY

Spinal cord injured (SCI) subjects suffer of secondary complications, such as pressure sores. It has been shown that the electric stimulation increases the rate of pressure sore healing /1/. However, the mechanisms involved in the observed enhancement are still not known.

We tested the hypothesis that the electric stimulation changes the blood flow dynamics and improves the metabolic supply to the adjacent tissue. Signals, measured by laser Doppler flowmeter in 10 pressure sores before, during and after the application of biphasic currents for 40 minutes were compared. The amplitude of stimuli was adjusted to produce only a visible contraction of the tissue. Self-adhesive electrodes were used.

Signals were analysed in the time-frequency domain by the wavelet transform with Morlet wavelet /2/. The relative contributions of the rhythmic activity in the frequency interval between 0.009 Hz and 0.02 Hz, which is supposed to reflect the metabolic activity, and in the frequency interval between 0.02 Hz and 0.055 Hz, which is supposed to reflect the neurogenic activity of the adjacent vessels, are increased during electric stimulation. The differences become greater after electric stimulation, although not statistically significant, with $p=0.09$ and $p=0.06$ respectively. None of the other rhythmic activities changed during, or after electric stimulation.

STATE OF THE ART

The application of electric currents to restore neuromuscular function (FES) of disabled subjects was shown to produce also therapeutic side effects /3/,/4/. One of the side-effects is decreased incidence of pressure sores in long-term FES-treated spinal-cord-injured subjects. On animal experiments it was also demonstrated that the blood flow and metabolic activity increase after long-term muscle stimulation /5/,/6/,/7/. Those observations initialised an extensive clinical study of long-term effects of electric currents, applied across the pressure sore. It was shown that the rate of pressure sore healing is greater when the sore is stimulated with low-frequency pulsed currents compared to conventional treatment /1/.

The basic physiological mechanisms through which electric currents/fields accelerate wound healing is however still not known. Analyses of endogenous growth factors, multifunctional regulatory molecules found in the wound fluid, enabled insight into the healing process and contributed to the explanation of observed beneficial effects of electrical stimulation /8/. In this study we tested the hypothesis that electric currents improve the metabolic activity in the skin at the wound edge which then contribute to increased healing rate.

MATERIAL AND METHODS

The data for the present study were obtained from three volunteer spinal cord injured subjects. Ten sessions were performed in total. The subjects were asked to remain relaxed during the measurements, laying on the back, and trying to breath evenly. Three measurements were done for each subject per session: 20 minutes of data acquisition before applying the electric stimulation, 40 minutes during the stimulation, and finally 20 more minutes after the stimulation.

For acquiring the blood flow signals, a four channel laser Doppler flowmeter (Moor FloLAB system) was used. Four channels were acquired for each subject: right hand, left hand, right leg and at the edge of the pressure sore, on the intact part of the skin. The sampling frequency was set to 40 Hz with a time constant of the instrument of 0.2 s. The gain on the instrument was set independently on each channel.

The signals were first downsampled and detrended. Once detrended, they were analysed in the time-frequency domain using a Morlet wavelet transform algorithm /2/. Absolute and relative energies were calculated for each one of the five main frequency components present in the blood flow: cardiac, ranging from 0.7 to 2.2 Hz; respiratory, ranging from 0.15 to 0.7 Hz; myogenic, ranging from 0.55 to 0.15; neurogenic, ranging from 0.02 to 0.055 Hz; and metabolic, ranging from 0.009 to 0.02 Hz /2/. The relative and absolute energies were also calculated. The resulting energies before, during, and after the stimulation were finally statistically compared using a Wilcoxon rank sum test.

RESULTS

The relative energy contribution of each of the five frequency intervals of our interest, calculated from the blood flow signal measured in the vicinity of a pressure sore are presented in figure 1. No significant changes of the cardiac, respiratory, and myogenic rhythms are observed both during and after application of electric currents. The obtained values for those three spectral components are similar with high probability.

The neurogenic component is slightly increased during the electrical stimulation, having similar mean, but lower variation after its application, which results in higher probability that the mean values differ, but not statistically ($p=0.06$).

When comparing the relative energies during and after the stimulation for the metabolic component we found a slight increase. This increase continued after the stimulation, however the probability that two mean values, before and after stimulation, differ is below the value set as statistical significance, which is at $p < 0.05$.

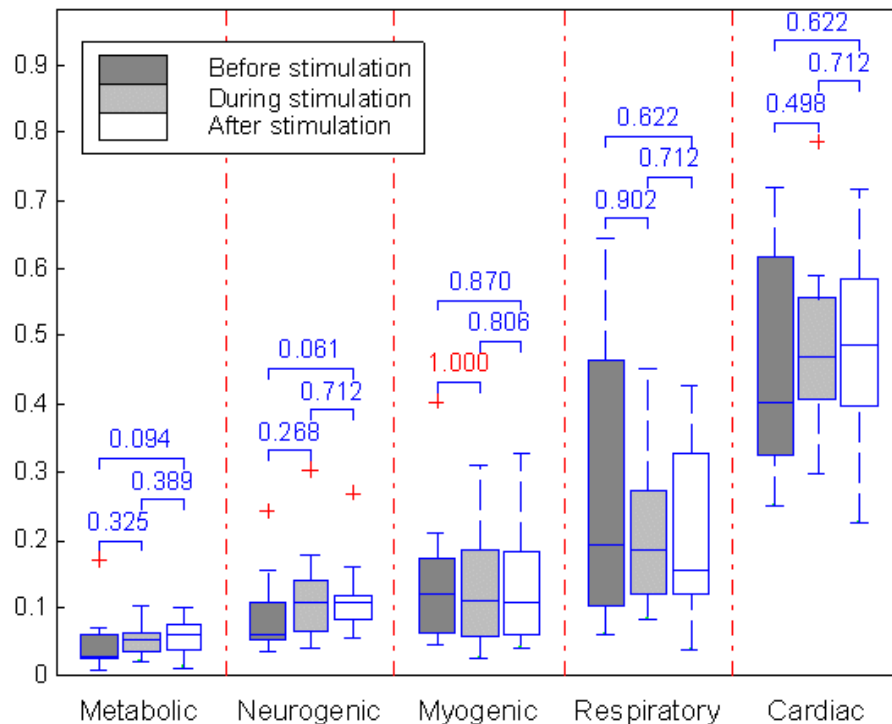


Fig 1.: Relative energy contribution of spectral components of blood flow measured at the edge of pressure sores, on the intact part of the skin

DISCUSSION

We show that a short-time application of low-frequency pulsed currents changes the metabolic and neurogenic activity in the skin at the edge of a pressure sore. The differences are observed when the mean values of the relative energy contribution of those two components of the spectrum, calculated from the blood flow signal, are compared before and after the application. However, both differences are slightly above the set threshold for significance. If a greater number of stimulated pressure sores and subjects would be included in the study, it might be expected that the variability of the data would decrease and improve the significance of the obtained results. We conclude that the short-term effects of electric stimulation evaluated in this study might cumulatively lead to significantly improved rate of healing already observed in long-term studies.

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CYCLING DEVICE FOR PARAPLEGICS USING FES

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SUMMARY

The following article describes a tricycle which can be used by paraplegics without assistance. Paraplegics can get on and off the tricycle independently using hydraulic adjustment of the saddle height. The two rear wheels can be swiveled with adjustable hydraulic damping, which avoids the stability problems of a standard tricycle when riding around bends. The principle driving power is assumed to be provided by Functional Electrical Stimulation of the femoral muscles. A hub motor is integrated in the front wheel to increase the radius of action and as additional drive for getting up gradients and in the case that muscle force is not sufficient. The desired drive power is adjusted by a throttle grip on the handlebar. Additionally the percentage of motor power can be adjusted. The force applied to the pedal, the absolute angular position of the crank, and the angular velocity of the front wheel are continuously measured by a force measurement pedal and a goniometer. Based on this data the motor and the Functional Electrical Stimulation of the legs are controlled.

STATE OF THE ART

The most common means for paraplegics whose upper-body muscles are healthy to move by themselves is the wheelchair. Disadvantages are the lack of accessibility to many environments and the fact that the total force is generated by the muscles of the upper part of the body only. The leg muscles, whose connection to the brain is cut by a spinal cord lesion, weaken over time.

Compared to other means of locomotion cycling has the advantage that the force applied to the pedal is converted into motion with very high efficiency. The use of three- and four-wheel cycling devices by paraplegics using FES has been described by various authors /1,2,3,4/. The novel features of the exercise tricycle described here distinguishing it from already-existing cycling devices are: paraplegics are able to get on and off and ride the tricycle without assistance; the two rear wheels and the main frame can be inclined in parallel, which avoids stability problems when riding around bends; an auxiliary motor is integrated in the front wheel to increase the radius of action.

MATERIAL AND METHODS

Getting on and off the tricycle

The rider's position on the tricycle (Fig. 1a) is erect as on a standard bicycle, which is preferable for psychological reasons. The saddle pipe consists of a double effective hydraulic cylinder which allows the saddle to move up and down. For a paraplegic subject getting on the exercise tricycle from the right side the wheelchair is placed close to the saddle (which is in the lowest position 0.65m above ground) and hooked onto the tricycle frame with a simple hook. Then the feet are fixed on the two force measurement pedals /5/ by easy-to-handle velcro fastenings (the main frame is very low in front of the crank bearings so that one foot can easily be lifted to the pedal on the other side of the frame), the left hand grasps the pipe behind the saddle while the right hand stays at the wheelchair, and the buttocks are lifted onto the saddle. Then the wheelchair is pushed away, both hands grasp the handlebar, and the saddle is pumped up

to the riding position by a double effective pump cylinder mounted in front of the handlebar. For getting off the tricycle the outlet which closes the circuit between the upper and lower chambers of the saddle pipe cylinder is opened and the saddle is automatically moved to the lowest position by the rider's weight.

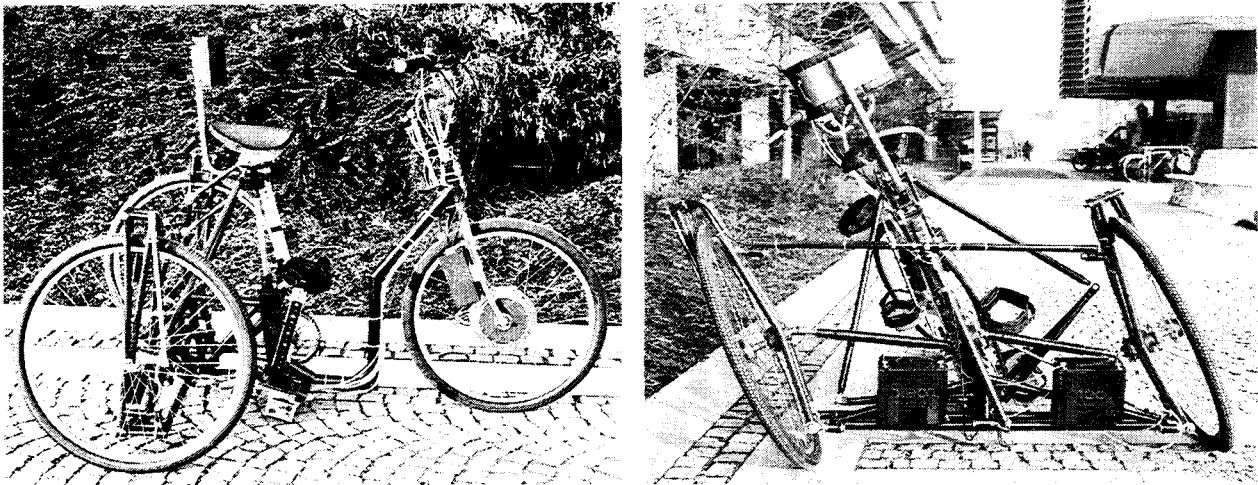


Fig. 1 a) Side view of the tricycle

b) Back view of the tricycle in inclined position

Behaviour in bends, inclination-function

A standard single-tracked bicycle is inclined during bending. Usually a tricycle cannot be inclined, which raises the danger of turning over in bends with increasing velocity of the tricycle and decreasing width of the wheel track (here only 1.09m). Moreover the horizontal component of the acceleration makes riding even more difficult for a paraplegic subject who cannot use his hip muscles as stabilizers. Here a special construction of the rear axle, consisting of an articulated parallelogram on which the rear wheels and the main frame of the tricycle are mounted, allows inclination of the rear wheels and the main frame of the tricycle in parallel (Fig. 1b). The damping of the inclination is adjusted or the inclination-function totally locked by a double effective hydraulic cylinder which is controlled by a throttle. This enables subjects with little training to ride the tricycle at low speeds without employing the inclination-function. The maximal inclination is limited by two articulated triangles (Fig. 2) to the side of the saddle. In the highest position of the saddle the maximal angle of inclination is $\phi=30^\circ$. At maximal inclination the endpoint of one triangle rests on the lower part of the inclination parallelogram. With the saddle in the lowest position the maximal inclination is already reached with a vertical position of the saddle pipe ($\phi=0^\circ$), which guarantees sufficient stability for getting on the tricycle. Also if the tricycle is in an inclined position and a dynamic erection of the tricycle is impossible the outlet can be opened, which automatically moves the saddle to the lowest position and brings the main frame back to the vertical position.

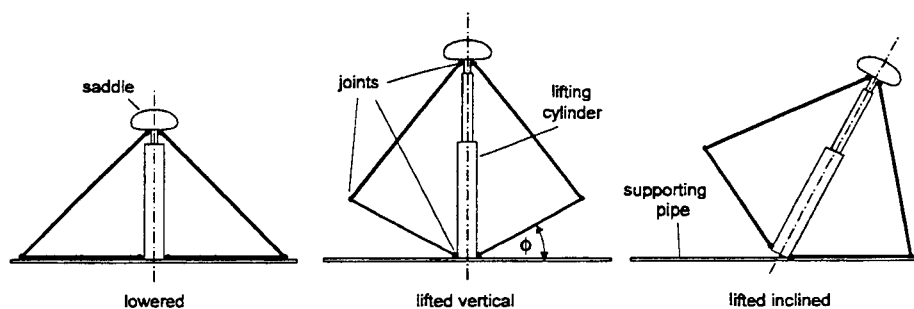


Fig. 2: Schematic diagram of the function of the articulated triangles limiting the inclination

Drive, brakes

In addition to the drive torque generated by the muscle forces, power can be generated by an auxiliary motor integrated in the front wheel. Especially for getting over gradients the auxiliary motor is essential, moreover it guarantees that the rider can get back to his starting point in case of problems with the generation of muscle force. The auxiliary motor also enables persons with very weak muscles at the beginning of their training period to use the exercise tricycle and it can be used for overcoming the initial inertia when the tricycle is started from rest. The auxiliary motor (hub motor with nominal power 500 W) is also used as a brake with electrical feedback into the accumulators. The power supply of the motor consists of two lead accumulators which are mounted on the lower part of the inclination parallelogram. In addition to the motor brake the tricycle has two mechanical drum brakes integrated in the rear wheel hubs.

Electronic control

Fig. 3 is a schematic diagram of the electronic control of the exercise tricycle. The angular velocity of the front wheel $\dot{\rho}$, the absolute angular position of the crank ε and the components F_{Px} and F_{Pz} of the pedal force in the plane of the crank rotation are measured continuously and read into the computer with a frequency of 50 Hz. The angular velocity of the crank $\dot{\varepsilon}$ is calculated from the measured data. The stimulation intervals of the single muscles Gluteus Maximus, Rectus Femoris and Hamstrings of each leg are determined using the numerical results of the optimization done by /6/. The total drive power (motor and stimulation) is adjusted by a throttle grip: in the positive direction the tricycle is powered by muscle force and motor torque in the ratio adjusted on the switchboard of the handlebar; in the negative direction the stimulation is switched off and the motor is in braking mode. The averaged power generated by the stimulation is varied by varying the amplitude of the stimulation signal, that is, the amount of throttle-turning in the positive direction. In accordance with the input data the computer sends a voltage signal to the motor and to the stimulator, which sends a signal to the surface electrodes. If the velocity of the front wheel is higher than the defined maximal velocity $\dot{\rho}_{max}$ or if one component of the pedal force goes beyond the allowed maximal forces F_{Pxmax} and F_{Pzmax} the stimulation is stopped, the motor is switched to braking mode, and the pedals are switched to idling to avoid injuries because of too-high stresses (e.g. in case of spasms). If the mechanical brakes are applied the stimulation is switched off and the motor, if not already in braking mode, is switched to idling.

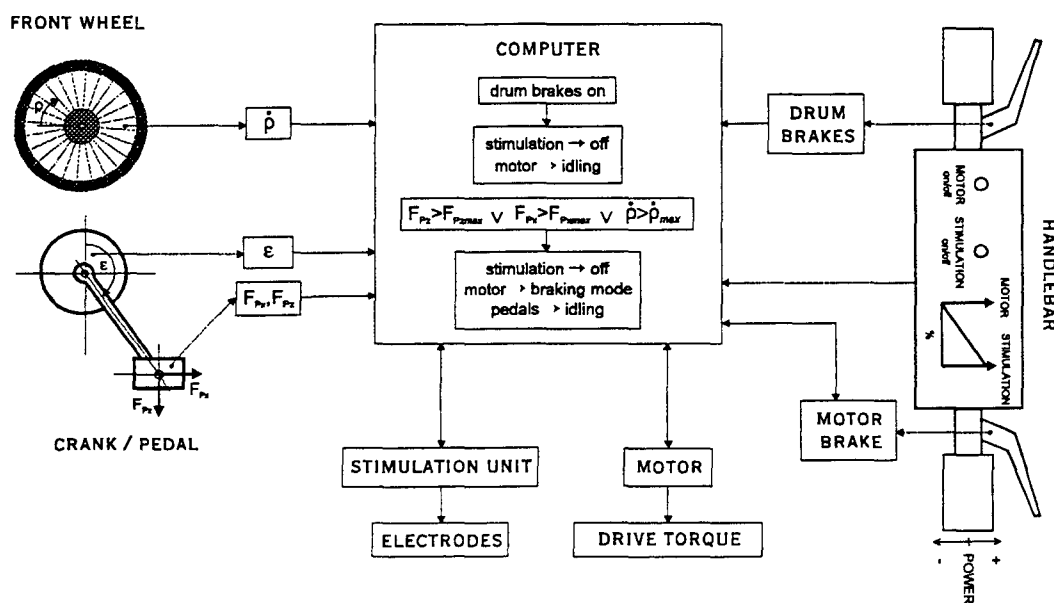


Fig. 3: Schematic diagram of the electronic control

RESULTS

The first driving tests were carried out with able-bodied subjects. The road behaviour of the exercise tricycle is identical to that of a standard bicycle. Paraplegics can get on and off and ride the tricycle without assistance, but the total mass of 28 kg of the tricycle with hydraulic components and auxiliary motor is difficult to accelerate for paraplegic subjects who only use a few stimulated muscles for generation of the drive torque; in most cases an additional torque of the auxiliary motor is necessary. Another difficulty is the number of cables necessary for the support of the surface electrodes and the force measurement pedals.

DISCUSSION

To make the tricycle easier for paraplegics to handle the total mass has to be reduced. Instead of the hydraulic circuit for lifting the saddle a lighter electronic solution based on an electromechanical lifting cylinder could be used. The standard computer has to be substituted by a miniaturized control unit (e.g. microcontroller combined with ASICs for the control of motor and stimulation). The currently-used lead accumulators (24V/15Ah) have a mass of 8kg, and replacing them with nickel-metal-hybrid accumulators would reduce the mass by half, with lithium-ion accumulators by two-thirds. The disadvantage is that these relatively new technologies are expensive. For riding shorter distances the weight could also be reduced by just using smaller accumulators. For data transmission from the force measurement pedal to the computer, telemetry should be used for future developments. The most effective way to avoid problems with cables and to get reproducible results would be to use a leg pacemaker for which the electrodes are implanted and the stimulation signals are transmitted to the implanted stimulation unit by telemetry.

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STANDING BALANCING WITH ARMS RELEASED AND LOADED

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SUMMARY

In this work we were trying to assess differences in balancing capabilities in intact person standing when the free arms movement is allowed, compared to arms crossed on the chest and while loaded. The experiments were performed in Mechanical Rotating Frame apparatus where are allowed rotations in artificial ankle joint, while the knee and hip joints are braced in a frame and upper body is free to act. The preliminary experiments on two subjects show no improved balancing capabilities with the arms allowed to move free.

STATE OF THE ART

The persons with complete spinal cord injury at thoracic level suffer from any movement ability in the lower limbs. The muscles passing across the ankle, knee and hip joints are cut from the brain commands and control. Shank and thigh are two major segments without control, while are the body segments above the hip joint still remaining under voluntary control. The above statements include some simplifications which are not crucial for the idea of the presentation. If shank and thigh are made rigid as a single segment, then the upper body rotation in sagittal plane is still possible in ankles, which are not under voluntary control. Limited forward/backward movements are also possible in spinal region, which is above the lesion level and thus still under voluntary control. The body system described acts as a double inverted pendulum, with only the second joint powered with voluntary muscle action. Therefore, the system is underactuated.

Matjačić et al. /1,2/ showed that the approach described may result in successful balancing in intact and paraplegic person if small passive stiffness is added in the ankle joint (approx. 10Nm/°). Their experiments, based on the description above, account for one segment consisting from shank and thigh and the second segment consisting from the whole upper body. The upper body included: trunk, head and neck and both arms being crossed at the chest. The mass and inertia properties for some segments and BW = 80 kg are (Table 1):

Segment	Mass	length [m]	rad. of gir.[m]	J _{proximal} [kgm ²]
Head-Arms-Trunk	67,8%BW=54,24kg	0,295	1,456	10,00
Arm (one side)	5.0%BW=4,0kg	0,560	0,645	1,45

Table 1 Mass and inertia data for HAT and arms /3/

Inertia of each segment calculated around proximal end is represented as J_{proximal}. The majority of the mass and inertia in the upper body is gathered in trunk and head, while both arms contribute approx. 20 % of the HAT segment. This is valid until the arms are close to the chest. The theoretical model changes considerably with the hands being released and allowed to move free during the standing trials as is the case in our everyday standing activities. The question arises, how much are the arms motions contributing to the standing

stability in normal standing and to balancing after disturbance events. Here we are presenting standing trials of intact person in Mechanical Rotating Frame (MRF) apparatus with the arms crossed at the chest and also while being released.

MATERIALS AND METHODS

The MRF was designed in order to allow convenient adjustment of (added) stiffness in ankle joint and to prevent rotations in the two other joints: knee and hip, by fixing shank and thigh in hiperextension. The rotation in ankle is allowed in sagittal plane only, with the rotation axis of apparatus aligned to the rotation axes of ankles. Details of apparatus are given in /1,2/. An important element in the system is rotary hydraulic valve, which together with accompanying control system represents an adjustable spring providing also moment bursts or constant moment offset. Pressure sensors in hydraulic system allow measurement of ankle moment with high accuracy. The position of body segments is acquired with Optotrak (Northern Digital Inc.) system, which uses infrared active markers and line CCD cameras for coordinate calculations. Five markers were attached: to the MRF in the axis of rotation centre, to the MRF above the locked hip joint, in the lumbosacral joint, on shoulder rotation axis and on the right hand. Position information allows calculations of angles in ankle, and lumbosacral joint and provides follow-up of arm movements. Angular values are required for verification of Newton-Euler model. The apparatus in addition to the standard standing trials allows also audio feedback. Angular information is processed into pitch and amplitude level on two: front and back loudspeaker. With this information the tested subject can, in addition to the proprioceptive position information, rely also on hearing.

Standing position and balancing were characterised with two variables:

- 'posture' expressed as a mean value of measured moment in the artificial ankle joint. Due to the MRF construction, the is moment is linearly increasing with increasing angle in ankle joint.
- 'activity' in desired time interval (20 s) is determined as standard deviation value of moment. Both variables are determined indirectly with pressure measurements in hydraulic system.

During preliminary tests two intact male subjects, age 23 years, weight 80 kg, height 180 cm, were measured in three consecutive days. Every person passed every day 60 trials, each lasting twenty seconds. Thirty of them were standard and same number with audio feedback. Further trial division is shown in table 2. The 50 Nm moment disturbances with 200 ms duration were injected in random order in anterior and anterior or posterior directions to access balancing capabilities.

Arms/disturbance	anterior only	anterior or posterior
Arms crossed	5	5
Free arms	5	5
With weights	5	5

Table 2 Number of measurement trials

RESULTS

For each trial were calculated 'posture' and 'activity' variables and then averaged for five trials to form a group as shown in table 2. These data are then represented in graphs 1a and 1b for person BP and graphs 2a and 2b for person MP. The nomenclature used for groups in Figures 1 and 2 is shown in table 3.

Event	group label
no cognitive feedback, anterior direction disturbances	B1
no cognitive feedback, anterior/posterior direction disturbances	B2
cognitive feedback, anterior direction disturbances	C1
cognitive feedback, anterior/posterior direction disturbances	C2

Table 3 Group labels used in figures 1 and 2

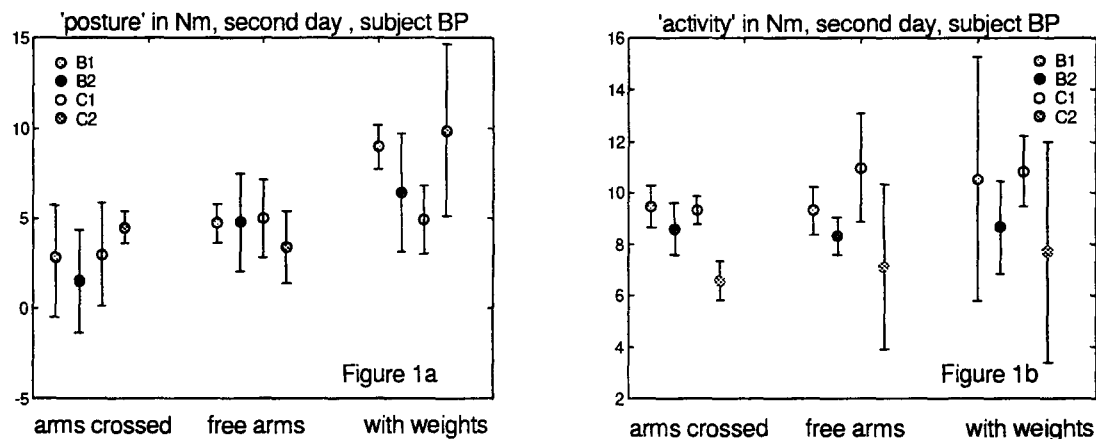


Figure 1 'posture' and 'activity' variables for trials B1 to K2 and with subject BP

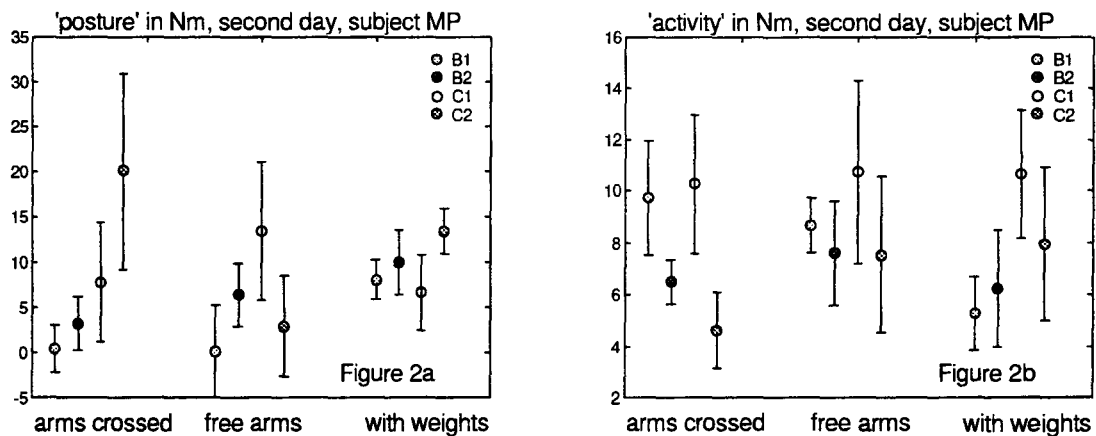


Figure 2 'posture' and 'activity' variables for trials B1 to K2 and with subject MP

DISCUSSION

The trials B1, B2 and C1, C2 were done for three protocols: arms crossed, free arms and with weights. We expected that would variables 'posture' and 'activity' for all three protocols group together in distinctive manner and form easily recognizable groups with superior 'posture' and 'activity' capabilities for e.g. free arms standing. Figure 1a could not confirm this hypothesis. As well it is impossible to attribute better 'posture' balancing capabilities to subject MP (figure 2a).

The 'activity' variables in figures 1b and 2b for two subjects with free arms also do not seem to differ significantly from the other two protocols (arms crossed and with weights). Also, when comparing B1 and B2 with no cognitive information, to the C1 and C2 with cognitive information given, no major differences appear. To further confirm and better justify these findings a larger subject group will be investigated.

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STRENGTH IMPROVEMENT OF KNEE EXTENSOR MUSCLES IN PATIENTS WITH CHRONIC HEART FAILURE BY NEUROMUSCULAR ELECTRICAL STIMULATION

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SUMMARY

Seven patients with chronic heart failure were subjected to a 2 month course of neuromuscular electrostimulation of bilateral knee extensor muscles. A significant increase in isokinetic peak torque and isometric muscle force could be demonstrated. This increase in muscle force could be maintained during a 20 minutes fatigue test.

STATE OF THE ART

Patients with chronic heart failure (CHF) develop significant skeletal muscle atrophy and abnormalities in skeletal muscle metabolic function. These skeletal muscle alterations may contribute to exertional fatigue which is a major limiting symptom in patients with CHF./1/2/ The cause of the atrophy is related to disuse, repetitive ischaemia linked to reduced blood flow on exercise, or to neural and hormonal factors activated in heart failure./3/

The leg musculature seems to be affected the most, also displaying a higher percentage of type II fibres, lower activities of mitochondrial enzymes, and a decreased capillary density./4/5/ Isometric strength of the knee extensor muscles in patients with CHF is markedly lower due to a smaller muscle cross-sectional area./6/

Physical training can have a positive effect on the CHF patient primarily by maintenance of skeletal muscle structure and reversing the muscle metabolic abnormalities./7/ Small muscle group exercise will optimise the muscle perfusion during exercise and places a lower demand on the heart than whole body work./8/

Percutaneous neuro muscular electrical stimulation (NMES) is in widespread use to delay atrophy of skeletal muscles associated with disuse in both disused and healthy muscles with the same efficacy as voluntary contraction./9/. NMES allows training of skeletal muscles without active exertion. Thus patients with CHF using NMES could achieve positive training effects without facing the fear of over exertion or dyspnea probably appearing in voluntary exercise.

The aim of the present investigation is to show the effect of NMES on strength and endurance of knee extensor muscles in patients with CHF.

MATERIAL AND METHODS

1. Patients

Patients were selected from the outpatient department of cardiology when they met the following inclusion criteria: An established diagnosis of severe chronic heart failure making the patients eligible for heart transplantation (HTX). 2. Stable phase of the disease, 3. Established drug therapy including intravenous administration of prostaglandin E2 via a pump. Exclusion criteria were: Pacemakers, marked peripheral edemas, lack of motivation and compliance, unstable course of the disease or drug regime and any disorders which counteracted neuromuscular electrical stimulation of the thigh muscles.

2. Stimulation protocol

As stimulation protocol we used a modified regime as previously published./10/ A custom made device delivered biphasic symmetric, constant voltage impulses with 0.7 milliseconds pulse width and a frequency of 50 Hertz. The contraction period lasted 2 seconds with a relaxation interval of 6 seconds between the contractions. The daily amount of stimulation started with 30 minutes per day, 5 days per week and increased to 60 minutes per day after 2 weeks. Overall treatment time was 8 weeks. The stimulation was effected by way of self adhering surface electrodes measuring 130 cm² (Bentronics, Munich, Germany) placed bilaterally upon the distal and proximal aspect of the anterior thigh. Stimulation amplitude was set to achieve a strong tetanic contraction of the knee extensor muscles without sensible inconvenience. Repeated measurement of stimulation induced force production revealed values corresponding 25 to 30% of maximal voluntary contraction. After familiarization treatment was continued by the patients at home. The patients were reviewed once a week to encourage adherence to the stimulation program.

3. Strength Measurement

3.1. Evaluation of isokinetic peak torque and maximal isometric force at an knee angle of 60 degrees was carried out on a Cybex 6000. After instruction patients were seated on the device and the axis of the lever arm was aligned to the rotational knee axis. After warm up the patients performed 4 knee extensions and flexions with an angular speed of 60 degrees/second. The best value was regarded as peak torque (PT Isokin 60 deg/s). Values are related to body weight (PT Isokin 60 deg/s %BW). In the same position isometric strength of knee extensor muscles was measured at a knee angle of 60 degrees. The best trial out of 4 was regarded as maximal voluntary contraction (MVC 60)

3.2. Fatigue protocol

Fatigability of knee extensors muscles was assessed by a procedure which proved to be well suited for CHF patients./11/ Patients sat on a custom built chair with unsupported feet and knees flexed with an angle of 90 degrees. A force transducer (UA 20, Hottinger Baldwin) was fixed between the chair and the patients ankle by a velcro strap, allowing no knee extension beyond 90 degrees. The signal of the force transducer was sampled by a measurement system (BMC, Hottinger Baldwin) and stored on a personal computer. After familiarization the patients were asked to perform 3 maximal isometric knee extensions. Rest intervals between trials was 1 minute. The best value was regarded as maximal voluntary contraction (MVC 90₀). An individual submaximal level was calculated for each patient corresponding to 30 - 40 percent of this MVC 90. This force level had to be reached by submaximal isometric muscle contractions of 1 second duration 20 times per minute according to an acoustic signal given by a timer. The targeted force level was indicated by a visual colored feedback on the computer. Each 40 seconds of exercise (i.e. 20 contractions) were followed by a break of 20 seconds. Re-evaluation of MVC 90 was performed after every 5 minutes. The overall duration of the test was 20 minutes. The decline of the MVC 90 during these 20 minutes is expressed in absolute values and is calculated in percentage of initial values. The procedures were performed with both legs. Measurements were consistently carried out by the same person. During the entire tests heart rate and oxygen saturation were monitored via a finger sensor (Sensor Medics).

RESULTS

Nine patients were included in the NMES protocol so far. One patient died shortly after onset of the treatment because of his underlying disease and one patient disagreed to continue after the initial examinations. Therefore we report 7 patients who finished the NMES protocol. The characteristics of the patients are listed in table 1. Two patients reported muscle soreness after onset of the NEMS protocol forcing one of them to pause for 2 days. After resumption of NMES no adverse effects occurred. The patients reported no difficulties in handling the stimulation device and applying the electrodes. Isokinetic and isometric strength measurements improved significantly after the stimulation period. There was no significant difference in the values of both legs prior to the stimulation and the increase in strength was equivalent in both thighs. The mean values of both legs are presented in table 2.

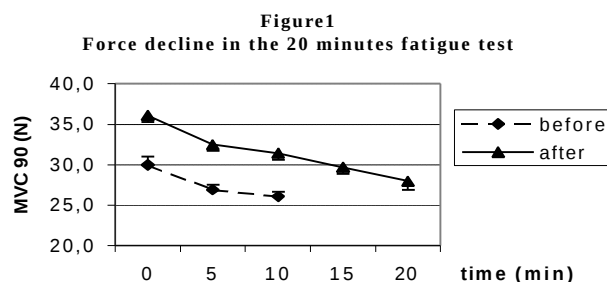
Male/female (n)	6/1
Age (years)	56.0 ± 5.0
Height (cm)	176.0 ± 9.2
Weight (kg)	68.0 ± 14.1
CHF since years	1.83 ± 0.41
Ejection fraction %	20.1 ± 10
NYHA class II/III	1/6

Table 1: Demographic data of the subjects. Values are expressed as mean ± SD

PT 60 deg/s (Nm)	101.0 ± 8.7	113.5 ± 7.2	p=0.04
PT Isokin. 60 deg/s %BW	143.0 ± 10.5	162.0 ± 8.0	p=0.02
MVC 60 (Nm)	145.0 ± 10.5	158.0 ± 11.05	p=0.02
MVC 90 (N)	30.05 ± 1.95	36.1 ± 1.7	p=0.04

Table 2: Strength measurements before and after the NMES period. Values are expressed as median ± SEM

The fatigue test of the knee extensor muscles showed a significant increase in strength values (MVC 90) initially and after 5 and 10 minutes fatigue protocol respectively. MVC 90 after 5 minutes rose from 30.0 ± 1.9 to 36.1 ± 1.7 N and after 10 minutes from 28.9 ± 1.2 to 32.5 ± 1.7 N (Median ± SEM, p=0.04). 3 patients stopped the first test after 10 minutes and 1 after 15 minutes due to marked localized muscle fatigue. After the NMES period all patients were able to finish the test without complications. A trends towards decreased fatigability was observed after the NMES period which did not reach statistical significance.(figure 1)



DISCUSSION

We were able to demonstrate a substantial increase of maximal muscle strength of knee extensor muscles of 18.2% in isometric MVC 90 and 13.3 % in isokinetic PT. This force increase could be maintained during the fatigue test suggesting an improved local fatigue resistance of the stimulated muscles. Whereas several studies confirm beneficial effects of endurance training on exercise capacity in CHF patients /12/ only limited data are available regarding strength training in this group of patients. Strength training in patients with CHF has been shown to enhance muscular efficiency and to increase muscle mass./8/ Active training of skeletal muscles in CHF patients is associated with marked rise of heart rate./8/ In our findings NMES seems to raise heart rate only little above resting values and therefore diminishes stress on the cardio-vascular system. Similar results have been demonstrated in elderly male subjects./13/ In our stimulation protocol monitoring of NMES induced force output ranged from 25 to 30% of MVC 90. This amount is well within the range reported by other studies to be necessary to achieve substantial increase in maximal muscle strength./9/ A stimulation protocol with an intensity producing a response of 25% MVC yielded strength improvements of about 20% of the initial MVC in patients with atrophied muscles./14/ Our patients trained between 8 and 12 weeks performing 40 to 50 training sessions. This exceeds the training time in most studies claiming positive effects of NMES on muscle strength. /15/ The patients tolerated the percutaneous stimulation and did not report painful sensations. 2 patients developed muscle soreness after the onset of the stimulation. The occurrence of muscle soreness has also been reported by other investigators at the beginning of NMES./16/ No additional physical exercise carried out by the patients which could be responsible for the increase in thigh muscle strength.

NMES in patients with severe heart failure proves to be a promising method for maintaining and increasing muscle strength without exerting marked stress on the cardio-vascular system.

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FUNCTIONAL RECOVERY DUE TO EMG-TRIGGERED FES IN CHRONIC BRACHIAL PLEXUS PALSY - A CASE REPORT

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INTRODUCTION

Chronic brachial plexus palsy can lead to major impairment in everyday life. Frequently young males are affected due to motor cycle accidents /1/. Even if partial reinnervation occurs, muscle strength is often too weak for functional use. The aim of this single case study was to examine, whether EMG-triggered FES can improve muscle strength in chronic partially denervated muscles.

MATERIALS AND METHODS

Patient

A 26 year old patient with left chronic brachial plexus palsy due to a motor cycle accident 26 months ago had reached a constant status of muscle strength in his left arm. Despite intensive conventional training muscle strength for shoulder abduction and elbow flexion had not further increased for 6 months. At that time, EMG-triggered electrical muscle stimulation was started.

Training sessions and stimulation parameters

The so called „feedback“-training program of the stimulator uses the preprocessed EMG-signal of remaining voluntary muscle activity to trigger electrical stimulation: The signal of a weak muscle is compared with a trigger threshold. If the threshold is exceeded, stimulation of the same muscle is activated for the duration of two seconds.

The electrical muscle training was performed for 25 weeks, comprising 89 training sessions for each muscle (deltoideus and biceps brachii muscle). Each training session lasted for 25 minutes. The actual stimulation time was 18,8 hours for m. biceps and 19,6 hours for m. deltoideus. For the study a pulse width of 500 μ s for each phase of the biphasic impulses and a frequency of 50 Hz were chosen. An average amplitude of 50 V_{pp} (m. biceps) respectively 65 V_{pp} (m. deltoideus) was used.

Measurements

At the beginning and the end of the treatment period clinical muscle testing (grade 0-5 according to the BMRC) was performed, isometric muscle strength was assessed by an CYBEX 6000 dynamometer and a functional questionnaire concerning activities of daily life was answered.

RESULTS

For shoulder abduction and elbow flexion an increase of muscle strength was observed both, clinically (Fig.1) and by dynamometry (Fig.2). Moreover, the patient reported a distinct improvement in activities of daily life.

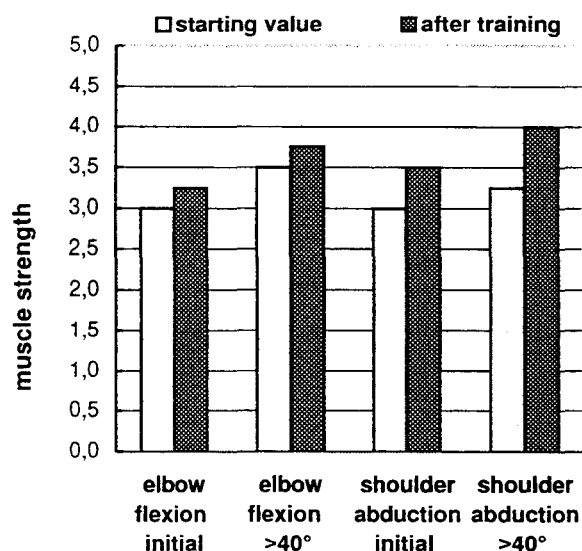


Fig.1: Clinical muscle testing (grade 0-5 according to the BMRC) at the beginning and after the training period

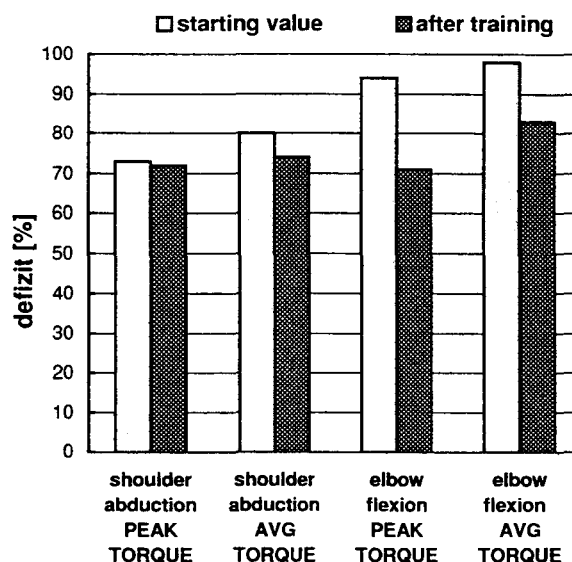


Fig.2: Isometric torque measurement of shoulder abduction and elbow flexion at the beginning and after the training period

DISCUSSION

In the present case, EMG-triggered FES was able to improve muscle strength and functional movements in chronic brachial plexus palsy with distinct subjective benefits.

ACKNOWLEDGEMENTS

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AN ADAPTATION STRATEGY FOR ON-LINE LEARNING IN ARTIFICIAL NEURAL CONTROL OF GAIT GENERATION BY MEANS OF NMES

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SUMMARY

Recently, Sepulveda *et al.* /1/2/ developed an artificial neural system for controlling swing phase stimulation pulse width. The latter system included novel *punishment* and *reward* strategies to improve on control performance. The present work is a discussion of these adaptation strategies as applied to locomotion restoration by means of NeuroMuscular Electrical Stimulation (NMES). In the original system, a human operator activated the on-line learning process whenever the resulting swing motion required *punishment* or *reward* of the neural controller. The latest version of the system included an automatic on-line scheme which compared angular data generated by means of NMES with data from a normal human being. Low correlation coefficients between NMES-generated and normal trajectories lead to *punishment* of the neural controller. High correlation coefficients resulted in neural controller *reward*. Both the original and the new system used the same strategies for *punishment* and *reward*. The strategies were found to work well as seen from control performance indexes and learning stability analysis. The best performance in most cases was obtained when *punishment* was applied.

STATE OF THE ART

Fruitful attempts have been made over the last twenty years to restore locomotion in spinal cord injured (SCI) subjects. Significant work has been done by exploring the withdrawal reflex /3/4/. Hybrid systems have been produced as well /5/6/7/. With regard to control issues, open loop /8/ and closed-loop systems /9/10/11/ have been designed - preference being currently given to the latter, closed-loop approach. However, in spite of all attempts to date, progress towards restoration of locomotion has been slow. Control difficulties arise from the neuro-musculo-skeletal system's high non-linearity and time-variance. In addition, suitable models of human locomotion have yet to be created /12/. To deal with this situation, control schemes should explore the use of fuzzy logic and/or artificial neural networks. In light of this, the present work demonstrates the use of simple artificial neural networks for control of reciprocal gait by means of NMES. The system consisted of a two-channel stimulation device controlled by a computer-based, three-layer neural network. The adaptive scheme included off-line and on-line learning. On-line learning consisted of positive (*reward*) and negative (*punishment*) reinforcement.

METHODS

A computer-based, three-layer artificial neural network was used for control of gait swing generated by neuromuscular electrical stimulation (NMES). The test subject was a 32 year old male with a Brown Sequard lesion at the C5/C6 level (Frankel grade D). Two stimulation channels were used: 1 - left femoral nerve; 2 - left common peroneal nerve. Penny&Giles flexible goniometers were used for monitoring left knee and ankle flexion/extension angles, respectively. The artificial neural controller was based on an Operator Model /2/. As such, the artificial network was trained to substitute an expert human operator who was previously responsible for making changes in stimulation parameters based on the observed motion. Network inputs (Figure 1) consisted of knee and ankle goniometer signals. Output values were proportional to changes in the NMES Pulse Width (PW) applied to the femoral and common peroneal nerves, respectively.

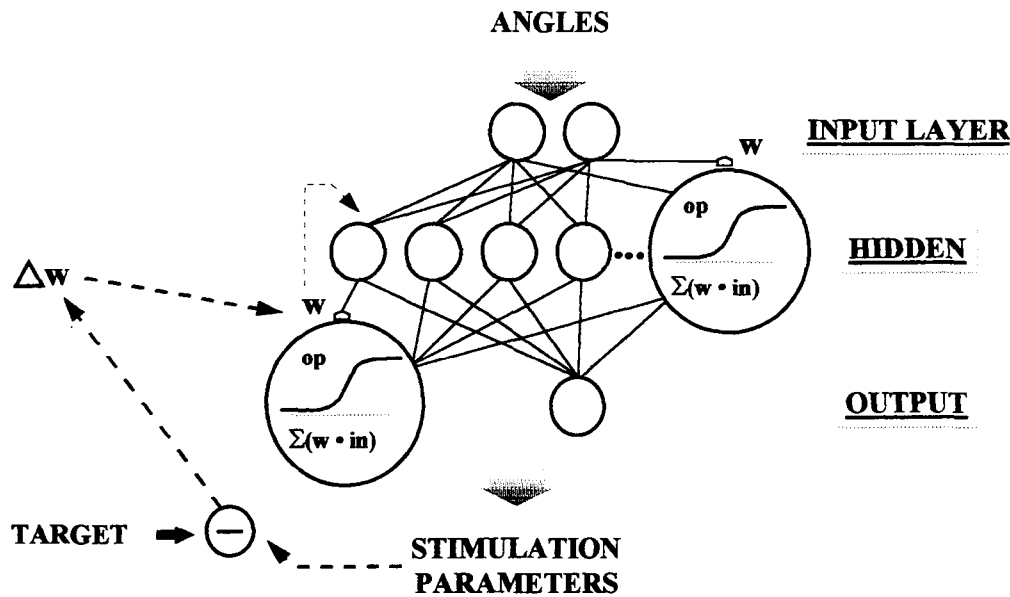


Figure 1 - Artificial neural network used for controlling stimulation parameters. Input angular data are integrated in the hidden layer and used for updating stimulation parameters (output layer). The broken lines in the left portions of the figure indicate the off-line learning process whereby predicted variations in stimulation parameters are compared to target ideal values (obtained from the recorded data). The difference between predicted and target values is then used to update connection strength (or weight: w) patterns in the network /13/. As seen in the enlarged neurons, activation functions were sigmoidal. *op*: neuronal output. *in*: unique input from previous layer.

For on-line learning, *punishment* was applied when the generated motion was found to be inappropriate. *Reward*, or positive reinforcement, was applied when the decisions made by the artificial network lead to improvement in the motion. *Punishment* consisted of 10% reductions in the magnitude of randomly selected synaptic weights (w) (10% of middle-to-output weights, and 10% of input-to-middle weights). This strategy is based on the knowledge that no particular connection or neuron is responsible for the network's behavior. Thus, the weights to be altered had to be chosen at random. Also, larger synaptic weight changes may compromise network learning stability, while smaller changes may not preclude the network from repeating mistakes. When *Reward*, was applied, the network was presented with the goniometer history from the latest, good cycle, while setting the target outputs to values equivalent to making no changes in the applied PW. A backpropagation algorithm /13/ was then applied during the interval between one swing cycle and another. *Reward* took place in as many inter-cycle intervals as necessary or until a new good cycle was observed.

Performance Evaluation

Step-tracking error coefficients were calculated as follows: 1 - Operator selected a good step to be used as reference (data from a session were discarded if no suitable step was obtained). 2 - Data from several steps were gathered for each test (different days). 3 - The difference between test steps and the reference step was estimated. For this purpose, the mean square error (MSE, mean of the square of the difference between joint angles from a test step and joint angles from the reference step) was calculated for each step. Then, the average MSE values for an entire test session was calculated. 4 - Global average MSE values were calculated for each test type. In this context, large average MSE values indicated poor performance, while small MSE values indicated the opposite. Initially, the average MSE values were calculated for the network trained off-line only (TWFL: Test Without Further Learning; on-line learning was inactivated). MSE values were also calculated for the cycles immediately following

punishment and *reward* in the on-line learning scheme. In addition, all networks previously submitted to *punishment* and/or *reward* underwent further TWFL testing.

RESULTS AND DISCUSSION

Average MSE values were calculated for the various situations listed in Table 1 (the magnitude of the errors reported in Table 1 is small because the angular data were normalized to between 0.0 and 1.0 for better handling by the neural network). From variations on the average MSE from test A to test B it appears that network control performance degrades towards the end of a test session. This may be attributed to fatigue and/or reflex habituation and suggests that the network training sets should include samples gathered after fatigue and/or habituation onset. For this reason, results from tests F, G, and H should be compared only to test B. These tests were applied at the end of a test session, after 40 to 60 cycles had been produced.

The low errors in tests C and D show how well the network adapts during on-line learning with *punishment* or *reward* (compared with test A). However, the system's immediate response to a combination of *reward* and *punishment* is not as good (test E). Tests F, G, and H indicate whether the applied learning scheme is stable. With regard to intelligent systems, stability refers to a scheme's ability to learn new information without forgetting what it learned in the past. When compared to average MSE values for test B, results for tests F, G, and H indicate that network learning is stable. In fact, there appears to be improvement in motion control as evidenced by the marked reduction in the error, especially for test F.

TEST	S1 Average MSE (var)
A	0.0436 (0.0013)
B	0.1939 (0.0004)
C	0.0104 (0.0001)
D	0.0152 (0.0005)
E	0.0515 (0.0034)
F	0.0518 (0.0002)
G	0.1499 (0.0009)
H	0.1284 (0.0005)
Global Average MSE	0.0542 (0.0032)**

TABLE 1 - Performance Coefficients for various tests. Test A: TWFL on Neural Network (N.N.) trained off-line, at beginning of session. Test B: TWFL on N.N. trained off-line, after 40 steps. Test C: every cycle after *punishment* (P) only. Test D: every cycle after *reward* (R) only. Test E: every cycle after R+P. Test F: TWFL on N.N. trained off-line followed by P only. Test G: TWFL on N.N. trained off-line followed by R only. Test H: TWFL on N.N. trained off-line followed by R+P. var: associated variance. **: variance associated with Global average MSE value.

CONCLUSION

Clinical tests indicated that the system's performance significantly improved following application of *reward* or *punishment*. Results were not as good after *reward* and *punishment* were applied in the same session. Performance coefficients for the system with a network trained off-line only were equal to about 0.75 (1.0 indicates an almost normal step). This value rose to 0.91 and 0.92 following *reward* and *punishment*, respectively. When both schemes were applied in sequence, the performance coefficient was 0.83, still higher than that for the network trained off-line only. Thus, the proposed on-line learning

scheme seems promising. Similar strategies may be considered in the future for control of devices aimed at restoring lost mobility in spinal cord injured subjects.

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Battery-powered miniature implant for nerve stimulation

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This paper describes of a battery-powered miniaturized implant. The single-channel stimulator can be used for the excitation of motor and sensory nerves with mono- or biphasic impulses. The development of this implant was started for a project with guineapigs, which should be stimulated at the cochlea with various stimulation parameters and a daily stimulation scheme for a defined training periode. The use of a battery powered implant avoids infection problem associated with permanent percutaneous cable connections and simplifies animal care.

The implant consists of a microcontroller, a stimulation stage and a telemetry link. The stimulation parameters are stored in an internal EEPROM. Amplitude, impuls width and frequency of the impulses can be adjusted in 16 defined steps. The on/off stimulation scheme can be selected from a list of 16 stimulation on-intervals (5-80min.) and from a list of 16 off-intervals (0,5-8hours).

The implant is powered by a 3V-Lithium cell (CR927). The life span varies with the used parameters and can be increased by switching the system off during longer stimulation pauses, via the telemetry link.

All parameters and modes of the implant are set from a PC via the RS232 interface controlling the bidirectional 1MHz RF link. The wireless link to a PC supports automated standardised measurements. For easy identification a serial number is stored in the implant memory.

The implant electronics is manufactured in Fine-Pitch SMD. The die of the microcontroller was bonded in a special ceramic case to decrease the component size. For the packaging the implant is sealed in pacemaker epoxy, the overall dimensions are 23x13x7,5mm.

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AN IMPLANTABLE TELEMETER FOR E.N.G. SIGNALS

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SUMMARY

The use of naturally-occurring sensory nerve signals for the control of prostheses has been advocated for some years and, more recently, demonstrated in a few disabled subjects with percutaneous wires for connection to the electrodes. We describe the main features of an implantable device for amplifying and transmitting these neural signals from within the body. The noise performance is similar to some non-implanted ENG amplifiers (670nV r.m.s.) and we believe that the device is small enough to implant in the leg. The battery, in the external part, should last about 4 hours, before recharging, which we expect to be long enough for some applications. The external "transmitter" can power the implant through a substantial thickness of tissue. However the lateral position of the transmitter must be maintained to within 10mm (in the most critical direction): this is made easier by displaying to the user a measure of the power coil coupling and an indicator which shows when the ENG signal is being properly demodulated. These telemeters may allow more extensive clinical trials and experiments with new applications.

STATE OF THE ART

The work of Hoffer /1/ and Stein's group /2/ in the 1970s showed that it is possible to record the electroneurogram (ENG) from electrodes in cuffs around nerves over long periods. In 1986, Hoffer and Sinkjaer /3/ advocated the use of these naturally-occurring sensor signals as control inputs to neuroprostheses. Signals have been investigated from the cutaneous afferents /4/, muscle afferents /5/, and the bladder /6/. In Aalborg, the ENG from implanted cuffs has been used for two types of patient to control stimulation: to correct footdrop following stroke /7/ and to provide grasp in tetraplegia /8/.

However, in these clinical experiments, the cuffs were connected by percutaneous wires which is not a satisfactory method for larger trials. As part of the EU Biomed 2 SENSATIONS project, we have been working on an implantable telemeter which can amplify the ENG from one cuff and transmit this through the skin to a signal processor. The device is intended for use in many applications.

The ENG signal picked up by electrodes in a cuff is small, typically a few microvolts. If the noise is measured from platinum electrodes in saline, we find no more noise than that which is due to the access resistance, the resistance through the electrolyte, calculated using the formula for Johnson Noise ($v^2 = 4kTBR$). There is no significant additional noise from the electrode-saline interface. Nevertheless, the signal to noise ratio is poor since the total r.m.s. noise is usually about half a microvolt. The signal is also corrupted by interference from the EMG of nearby muscles. This interference can be reduced by design of the cuff and the amplifier /9,10/, also by making a judicious choice of the frequency response. For the telemeter, we aimed for a passband from 800-8000 Hz for this reason.

MATERIALS AND METHODS

We decided to avoid the use of implanted batteries, instead providing power to the implant by radio-frequency induction. Two goals were essential in the design of the telemeter.

- The ENG amplifier had to be chosen so as to add little noise without requiring much current from the supply.
- The amplifier and the telemetry have to operate and be stable in the radio-frequency magnetic field which provides the power.

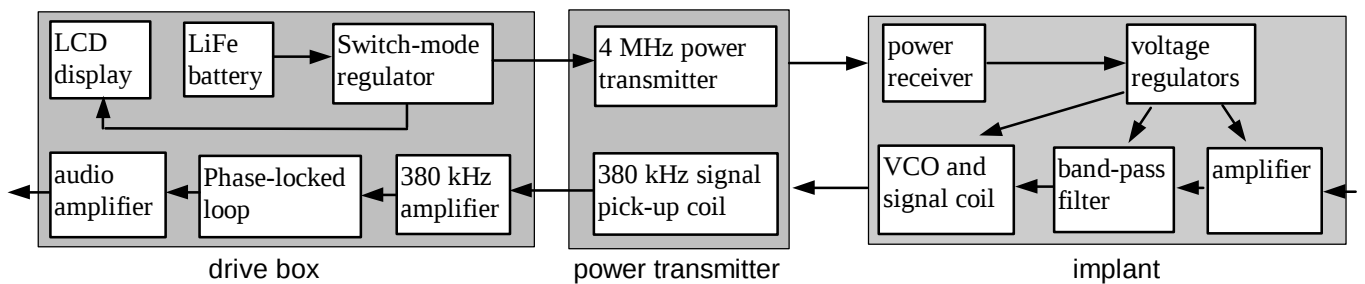


Figure 1. Block diagram of the telemetry system

The performance of many integrated amplifiers was assessed before deciding to use the AMP01 at the front end. This bipolar-transistor instrumentation amplifier has a low current noise ($0.15 \text{ pA}/\sqrt{\text{Hz}}$) so that its noise is not strongly dependent on the source resistance. Given the amplifier voltage noise of $5 \text{ nV}/\sqrt{\text{Hz}}$, with a 500Ω and $1 \text{ k}\Omega$ source resistances, the noise referred to the input should be 459 and 551 nV respectively, of which 175 and 351 nV are due to the source resistance (i.e. the electrode access resistance) itself. The amplifier draws 2.2 mA at 10 V .

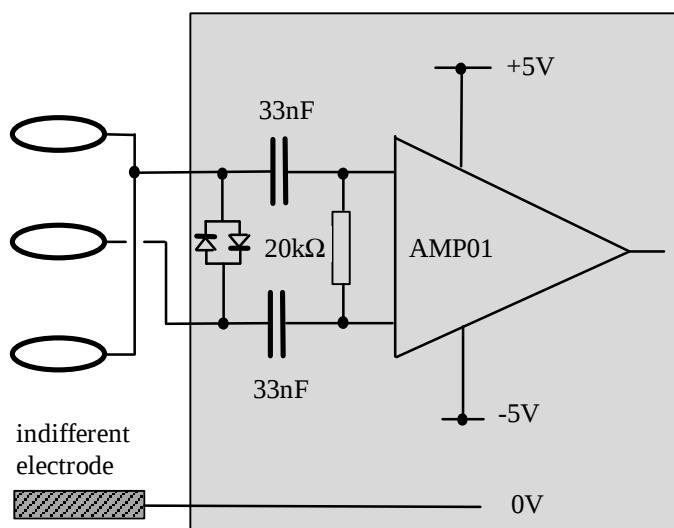


Figure 2

Figure 2 shows the front end of the amplifier connected to a quasi-tripolar cuff. The difference between the potential on the centre electrode and the connected outer electrodes is amplified. These potentials are referred to an indifferent electrode, shown outside the cuff. The 33 nF capacitors are in series with two of the three electrodes, thus ensuring that no direct current flows in normal or fault conditions (unless the fault is a leaky capacitor). The only exception occurs if the voltage between the cuff electrodes exceeds 0.6 V , when one of the diodes will conduct. These diodes provide some protection to the amplifier if the recording cuff is placed very close to stimulating electrodes. The telemeter is

intended for use in the presence of stimulation. No arrangements for input blanking are provided but the time constant for recovery of the input circuit is only $330 \mu\text{s}$ ($= 20 \text{ k}\Omega * 16.5 \text{ nF}$).

The telemetry uses a frequency-modulated (f.m.) carrier at 380 kHz , below the radio-frequency used for power so that harmonics of the power frequency do not interfere with the signal. Also, to reduce cross-talk between the power and signal channels, morphognostic coils are used

/11/. The power transmitter is Class D so that the harmonics in the magnetic field and the spurious radio-frequency emission are small. The f.m. carrier is demodulated by a phase-locked loop.

A 500 mA.hr lithium-iron battery is used because of its high energy density (50*30*20 mm). It is characteristic of these batteries that their e.m.f. varies almost linearly with the stored charge. This has the advantage that the amount of stored charge can be measured with a voltmeter, however, the change in voltage, from 5.0 to 8.4, means that a regulator is required before the transmitter. The switch-mode regulator allows step-up or step-down operation.

RESULTS

We built and tested the first versions of the system using packaged components and then the implant was designed as a thick-film hybrid by Graseby Microsystems Ltd. In this miniaturised version, the circuit must work properly within the 4 MHz field. We got satisfactory behaviour after making modifications to improve the decoupling and move a conductor which carries r.f. current further from the AMP01 chip. The *measured* performance is listed in the Table.

Critical coupling is that coupling between coils at which the secondary voltage is maximal: it is a satisfactory coupling in use. The LCD on the drive box displays the transmitter current which varies inversely with the coupling, thus allowing the position of the transmitter to be optimised. The contours in Figure 3 show the region over which the power supply in the implant is stabilised. The contours for the signal channel, where the phase-locked loop is actually locked, are shown in Figure 4. These figures show that at 20mm spacing, in the central operating region, the system operates with lateral displacements up to ± 10 mm in the x direction and ± 15 mm in the y direction. Phase lock is indicated by an LED on the drive box.

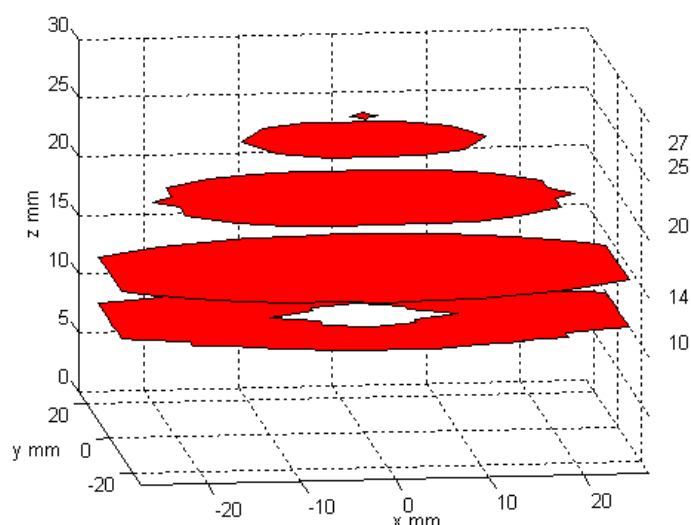


Figure 3. Region where implant power supply is regulated.

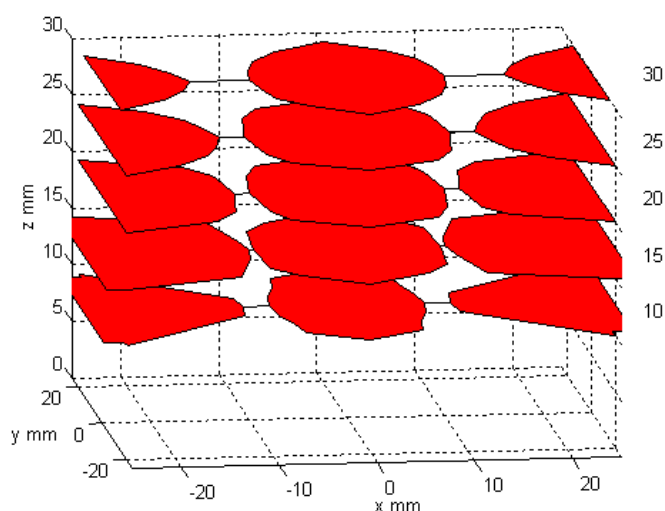


Figure 4. Region where the PLL is locked

Performance	
• Gain	76,000
• Pass-band	950-9000 Hz
• Input noise (1 k Ω source)	670 nV r.m.s.
• CMRR (across the pass-band)	>95 dB
• Size of implant (approximately)	54*28*7 mm
• Spacing for critical coupling (coil-coil, power channel)	20 mm
• Transmitter voltage used	6.6 V
• Transmitter current at critical coupling	100 mA
• Battery life (at critical coupling)	4.2 hours

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