



PROGRAM BOOK

**22. ANNUAL CONFERENCE
OF THE INTERNATIONAL
FUNCTIONAL ELECTRICAL
STIMULATION SOCIETY**

28-31 AUGUST 2018

NOTTWIL

SWITZERLAND



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WELCOME MESSAGE



Dear Colleagues,

It is a pleasure for us to welcome the International Functional Electrical Stimulation Society (IFESS) Conference 2018.

“Enhancing quality of life through electrical stimulation technology”

Structural and functional impairment can reduce the participation of social life. Having technologies based on electrical stimulation enables people with impairment to enlarge their possibility of participation and thus their quality of life.

The conference will focus on motor- learning with FES for the upper and lower extremities, spinal cord stimulation, breathing-coughing and airway management, stimulation of denervated muscles, pain, urology, fitness and cardio-vascular system, implantable systems, technologies and Quality of life with FES.

At the same time the Tetrahand World Congress take place - „adding quality to life“ (www.tetrahand2018.com)

With warm welcome at Swiss Paraplegic Centre in Nottwil,

Ines Bersch
Conference chair

SCIENTIFIC COMMITTEE / BOD MEMBERS

IFESS OFFICERS:

Thierry Keller	<i>president</i>
Simona Ferrante	<i>vice president</i>
Erika Geraldine Spaich	<i>secretary</i>
Michael Russold	<i>treasurer</i>

BOARD OF DIRECTORS:

Ines Dora Bersch-Porada
Milos R. Popovic
Glen Davis
Gad Alon
Dingguo Zhang
Philip Troyk
Christine Azevedo Coste
Ken Yoshida
Winfried Mayr

GENERAL INFORMATION

DATE

28 August Pre-conference workshop
29-31 August IFESS Conference

VENUE

Schweizer Paraplegiker-Zentrum
Guido A. Zäch Str. 1
6207 Nottwil
Switzerland

CONTACT

Organizing Secretariat
ASSZISZTENCIA Congress Bureau
H-1055 Szent István krt. 7.
Budapest, Hungary
Phone: +36 1 350 1854
Email: info@ifess2018.com
Website: www.ifess2018.com

ON-SITE REGISTRATION OPENING HOURS

28 August, Tuesday	07:30 – 18:30
29 August, Wednesday	07:30 – 17:30
30 August, Thursday	08:00 – 17:30
31 August, Friday	08:00 – 16:00

OFFICIAL LANGUAGE

Official language of the conference is English. No simultaneous translation will be available.

REGISTRATION FEE

Congress fee include: attendance to all scientific sessions and exhibition, program book, welcome reception, coffee breaks, lunches

BADGE

A name badge is provided with your registration documents upon your arrival at the conference registration.

Your personal badge is your entrance ticket to all scientific sessions, meeting areas, get together and lunches. For security and regulation purposes, the wearing of the badge is compulsory at all times inside the venue.

SPEAKERS ROOM - MERKUR ON 5TH FLOOR

We kindly ask you to please upload your presentation in the Speakers room on the day before you have the presentation (for example if your presentation scheduled on Thursday, please upload till Wednesday). The only exception if you are arrive on Tuesday after 18:00 and have presentation on Wednesday, then please make the uploading on Wednesday morning as soon as possible. Please bring your presentation on USB stick.

The opening time of Speakers room:

Tuesday	15:00 – 18:00
Wednesday	07:00 – 10:30
Thursday	08:00 – 10:30

INVITATION

The IFESS Board of Directors and the IFESS Officers cordially invites you to the **IFESS Association founding meeting** that will take place at the **2018 IFESS conference** in the **Swiss Paraplegic Center in Nottwil**,

Address: Guido A. Zäch Str. 1, 6207 Nottwil, Switzerland on Friday, August 31, 2018, 8:15-10:00 CEST

This will be the agenda:

1. Constitution
2. Foundation
3. Adoption of the Statutes
4. Elections:
of the members of the Board, and out of the Board members:
the President, the Vice-President, the Secretary and the Treasurer
5. Accept life members
6. Accept current regular members
7. Appoint Internal Auditors
8. Determination of the membership fee for the first financial year

We are looking forward to see you at the founding meeting in person!

With kind regards

Thierry Keller
President IFESS



KEYNOTE SPEAKERS



Dr. med. Anthony F. Di Marco

*MetroHealth Research Institute; MetroHealth Medical Center
Cleveland, USA*

Session 1: Breathing, coughing, airway management

08:30 - 09:00 | Wednesday, 29 August



Dr. med. Tim Reck

*Swiss Paraplegic Center, Center for Pain Medicine
Nottwil, Switzerland*

Session 2: Pain

09:00 - 09:30 | Wednesday, 29 August



Dr. Milos Popovic

*University of Toronto, Institute of Biomaterials and Biomedical Engineering
Toronto, Canada*

Session 3: Motor learning

10:30 - 11:00 | Wednesday, 29 August



Prof. Dr. Grégoire Courtine

*EPFL, Campus biotech, SV BMI
Geneva, Switzerland*

Session 4: Epidural and transcutaneous spinal cord stimulation

13:30 - 14:00 | Wednesday, 29 August



Prof. Dr. Jonathan Jarvis

*Liverpool John Moores University, Sport and Exercise Science
Liverpool, UK*

Session 6: Stimulation of denervated muscles

08:30 - 09:00 | Thursday, 30 August

Prof. Dr. Phil Troyk

*Illinois Institute of Technology, Biomedical Engineering
Chicago, USA*

Session 7: Implantable systems

10:30 - 11:00 | Thursday, 30 August



Prof. Dr. Kenneth Hunt

*Bern University of Applied Sciences
Burgdorf, Switzerland*

Session 8: Technologies

13:30 - 14:00 | Thursday, 30 August



Prof. Dr. med. Jürgen Pannek

*Schweizer Paraplegiker-Zentrum, Neuro-Urologie
Nottwil, Switzerland*

Session 9: Neuro-Urology

15:30 - 16:00 | Thursday, 30 August



Prof. Gernot Müller-Putz

*Graz University of Technology, Institute of Neural Engineering
Graz, Austria*

Session 10: Brain interfaces

10:30 - 11:00 | Friday, 31 August



Prof. Dr. Glen Davis

*The University of Sydney, Faculty of Health Sciences
Sydney, Australia*

Session 11: Fitness and cardio-vascular system

11:00 - 11:30 | Friday, 31 August



PROGRAM OVERVIEW

	28 AUGUST TUESDAY	29 AUGUST WEDNESDAY	30 AUGUST THURSDAY	31 AUGUST FRIDAY
08:15 - 08:30	Welcome			
08:30 - 09:00	Workshop FES in Paediatrics FES of the pelvic organs	Session 1 Breathing, coughing, airway management	Session 6 Stimulation of denervated muscles	General Assembly and Founders meeting
09:00 - 09:30		Session 2 Pain		
09:30 - 10:00		Poster session 1	Poster session 2	
10:00 - 10:30	Coffee break			
10:30 - 11:00	Workshop Stimulation of denervated muscles FES to improve hand function	Session 3 Motor learning	Session 7 Implantable systems	Session 10 Brain Interfaces
11:00 - 12:00				Session 11 Fitness and cardio-vascular system
12:00 - 12:30			Special Session FES Rowing	
12:30 - 13:30	Lunch			
13:30 - 14:45	Workshop Hands on	Session 4 Epidural and transcutaneous spinal cord stimulation	Session 8 Technologies (students' award)	Poster session 3
14:45 - 15:00				Session 12 Quality of life with FES
15:00 - 15:30	Coffee break			
15:30 - 16:00	Workshop Hands on	Session 5 Joined Ifess and Tetrahand session	Session 9 Neuro-Urology	Closing remarks
16:00 - 17:00				
17:00 - 17:30				
18:00 - 18:30	Get together	Schweizer Paraplegik- er-Zentrum guided tours	BOD Meeting	
18:30 - 19:00				
19:00 - 19:30			Banquet dinner	
19:30 - 21:00				

29 AUGUST | WEDNESDAY

AUDITORIUM 1

08:30 – 09:00	SESSION 1 - BREATHING, COUGHING, AIRWAY MANAGEMENT <i>Chairs: Michael Baumberger, Ken Yoshida</i>
A-0056	KEYNOTE: Dr. med. Anthony F. Di Marco <i>Louis Stokes Cleveland VA Medical Center, Cleveland, OH USA</i> 25 + 5 minutes
09:00 – 09:30	SESSION 2 - PAIN <i>Chairs: Michael Baumberger, Ken Yoshida</i>
A-0064	KEYNOTE: Dr. med. Tim Reck <i>Swiss Paraplegic Center, Nottwil, Switzerland</i> 25 + 5 minutes
09:30 – 10:00	POSTER SESSION 1 <i>Chairs: Erika Spaich, Phil Troyk</i>
A-0013	GAIT REHABILITATION WITH EXERCISE ASSIST ROBOT AND FUNCTIONAL ELECTRICAL STIMULATION (FES) FOR INCOMPLETE PARAPLEGIA: A CASE REPORT Junichi Inoue¹, Naohisa Miyakoshi¹, Michio Hongo¹, Ryota Kimura¹, Kimio Saito², Daisuke Kudo¹, Kazutoshi Hatakeyama², Motoyuki Watanabe², Yusuke Takahashi², Tomohiro Suda², Toshiki Matsunaga², Yoichi Shimada¹ <i>¹Department of Orthopedic Surgery, Akita University Graduate School of Medicine, Akita, Japan;</i> <i>²Department of Rehabilitation Medicine, Akita University Hospital, Akita, Japan</i> 3 minutes
A-0018	IMPROVED UPPER LIMB FUNCTION WITH COMBINED ROBOTIC THERAPY AND THERAPEUTIC ELECTRICAL STIMULATION IN A CASE OF CENTRAL CERVICAL SPINAL CORD INJURY Kagami K¹, Matsunaga T¹, Chida S¹, Hatakeyama K¹, Watanabe M¹, Takahashi Y¹, Suda T¹, Saito K¹, Shimada Y² <i>¹Department of Rehabilitation Medicine, Akita University Hospital, Japan;</i> <i>²Department of Orthopedic Surgery, Akita University Graduate school of Medicine, Japan</i> 3 minutes
A-0028	DEVELOPMENT OF AN ANATOMY-BASED FOREARM MODEL TO SIMULATE SELECTIVE MUSCLE ACTIVATION Johanna Baier¹, Jana Jedowski¹, Jan Loitz², Marc Neumann¹, Beate Bender¹ <i>¹Chair for Product Development, Ruhr-University Bochum, Germany;</i> <i>²MEDEL Medicine Electronics, Hamburg, Germany</i>
A-0053	DESIGN OF A FLEXIBLE PLATFORM FOR PROTOTYPING OF FES-BASED MOTOR REHABILITATION SYSTEMS Jorge Mercado¹, Janeth Fuentes², Cinthya Toledo¹, Enrique Velez², Norma Castellanos², Josefina Gutiérrez¹ <i>¹Instituto Nacional de Rehabilitación, Cd. de México, México;</i> <i>²Universidad Autónoma Metropolitana-Iztapalapa, Cd. de México, México</i> 3 minutes

A-0008	<p>MINIMALLY INVASIVE TECHNIQUES TO RESTORE COUGH IN TETRAPLEGICS Anthony F DiMarco^{1,5}, Robert T Geertman², Kutaiba Tabbaa³, Gregory A Nemunaitis¹, Krzysztof E Kowalski^{4,5,6} ¹<i>Department of Physical Medicine and Rehabilitation;</i> ²<i>Department of Neurosurgery;</i> ³<i>Department of Anesthesiology;</i> ⁴<i>Department of Medicine;</i> ⁵<i>Department of Research, Case Western Reserve University, MetroHealth Medical Center;</i> ⁶<i>Research Service, Louis Stokes Cleveland VA Medical Center, Cleveland, OH USA</i> 3 minutes</p>
A-0007	<p>HIGH FREQUENCY SPINAL CORD STIMULATION OF EXPIRATORY MUSCLE ACTIVATION: POTENTIAL NEW METHOD TO RESTORE COUGH Krzysztof E Kowalski^{1,3,5}, J Richard Romaniuk¹, Gary Pawlowski⁵, Anthony F DiMarco^{4,5} ¹<i>Research Service, Louis Stokes Cleveland VA Medical Center;</i> ³<i>Department of Medicine;</i> ⁴<i>Department of Physical Medicine and Rehabilitation; Case Western Reserve University;</i> ⁵<i>MetroHealth Research Institute; MetroHealth Medical Center, Cleveland, OH, USA</i> 3 minutes</p>
A-0010	<p>LONG-TERM PAIRED ASSOCIATIVE STIMULATION FOR INCOMPLETE CHRONIC SPINAL CORD INJURY: PHYSIOTHERAPIST PERSPECTIVE Savolainen S¹, Tolmacheva A², Rodionov A¹, Lioumis P¹, Kirveskari E¹, Ylinen A², Mäkelä J.P¹, Shulga A¹ ¹<i>Validia Rehabilitation Center;</i> ²<i>Helsinki University Hospital</i> 3 minutes</p>
10:00 - 10:30	Coffee break
10:30 - 12:30	SESSION 3 - MOTOR LEARNING <i>Chairs: Jonathan Jarvis, Christine Azevedo</i>
A-0055	<p>KEYNOTE: Dr. Milos Popovic <i>University of Toronto, Institute of Biomaterials and Biomedical Engineering, Toronto, Canada</i> 25 + 5 minutes</p>
A-0001	<p>DUAL CHANNEL VOLITIONAL ELECTROMYOGRAPHY(VEMG) SIGNAL ESTIMATION ALGORITHM DURING FUNCTIONAL ELECTRICAL STIMULATION(FES) Joonyoung Jung, Dong-woo Lee, Yongki Son, Baeseon Kim, Jabeom Gu, Hyung Cheol Shin <i>Electronics and Telecommunications Research Institute, Korea</i> 10 + 2 minutes</p>
A-0014	<p>THE FEASIBILITY OF USING FES TO IMPROVE THE MOBILITY OF PEOPLE WITH PARKINSON'S DISEASE. PRELIMINARY RESULTS FROM THE STEPS STUDY Paul Taylor^{1,2,3}, Trish Sampson¹, Ben Beare⁴, Val Stevenson⁴, Coralie Seary⁴, Diran Padiachy¹, James Lee¹, Paul Strike¹, Maggie Donavon-Hall⁵, Elsa Marques⁶, Peter Thomas², Sheila Nell ¹<i>Salisbury NHS Foundation Trust, Salisbury;</i> ²<i>Bournemouth University, Bournemouth;</i> ³<i>Odstock Medical Ltd, Salisbury;</i> ⁴<i>National Hospital for Neurology and Neurosurgery, London;</i> ⁵<i>Southampton University;</i> ⁶<i>Bristol University, UK</i> 10 + 2 minutes</p>

A-0041	<p>FES SYSTEM FOR HAND OPENING AND GRASPING WITH AUTOMATIC CONTROL BASED ON THE MICROSOFT KINECT SENSOR.</p> <p>Erika G. Spaich¹, Daniel Simonsen¹, John Hansen², Ole K. Andersen¹ ¹<i>SMI[®], Department of Health Science and Technology, Aalborg University, Denmark;</i> ²<i>Medical Informatics Group, Department of Health Science and Technology, Aalborg University, Denmark</i> 10 + 2 minutes</p>
A-0044	<p>POSTURAL PERTURBATIONS INDUCED BY PERONEAL AND TIBIAL NERVE ELECTRICAL STIMULATION</p> <p>Pierre Barralon, Eukene Imatz-Ojanguren, Milos Kostic, Iraitz Manterola, Thierry Keller <i>TECNALIA. Health Division. San Sebastián, Spain</i> 10 + 2 minutes</p>
A-0046	<p>A NOVEL THERAPEUTIC TOOL FOR STANDING BALANCE: A CASE STUDY</p> <p>Emerson P Grabke¹, Jae W Lee¹, David J Houston^{2,4}, Christopher Apostoli¹, Jaeun Yoo¹, Janelle Unger^{2,4}, Kristin E Musselman^{3,4}, Kei Masani^{1,4} ¹<i>Institute of Biomaterials and Biomedical Engineering, University of Toronto, Toronto, Canada;</i> ²<i>Rehabilitation Sciences Institute, Faculty of Medicine, University of Toronto, Toronto, Canada;</i> ³<i>Department of Physical Therapy, University of Toronto, Toronto, Canada;</i> ⁴<i>Toronto Rehabilitation Institute - University Health Network, Toronto, Canada</i> 10 + 2 minutes</p>
A-0047	<p>CLOSED-LOOP PROPRIOCEPTION TRAINING SYSTEM BASED ON WIRELESS HAND KINEMATICS SENSOR AND ELECTROTACTILE STIMULATION</p> <p>Milica Isakovic^{1,2}, Matija Strbac¹, Jovana Malesevic^{1,3}, Thierry Keller⁴ ¹<i>Tecnalia Serbia Ltd., Belgrade, Serbia;</i> ²<i>University of Belgrade – School of Electrical Engineering, Belgrade, Serbia;</i> ³<i>University of Belgrade – Biomedical Engineering and Technology, Belgrade, Serbia;</i> ⁴<i>Tecnalia Research & Innovation, San Sebastian, Spain</i> 10 + 2 minutes</p>
A-0051	<p>MEASURES OF EXCITABILITY IN CORTICOSPINAL AND SPINAL PATHWAYS BEFORE AND AFTER FES SUPPORTED WALKING</p> <p>Erika G. Spaich, Petr Šipka, Marjolein Thijssen, Natalie Mrachacz-Kersting <i>SMI[®], Department of Health Science and Technology, Aalborg University; Denmark</i> 10 + 2 minutes</p>
A-0052	<p>ELECTRICAL STIMULATION THERAPY BRINGS NEUROLOGICAL AND FUNCTIONAL CHANGES IN TOE-WALKING GAIT OF CHILDREN WITH SPASTIC CEREBRAL PALSY</p> <p>Rupsha Mukhopadhyay¹, Prasanna Kumar Lenka², Abhishek Biswas², Manjunatha Mahadevappa¹ ¹<i>School of Medical Science and Technology, Indian Institute of Technology, Kharagpur, Kharagpur, India;</i> ²<i>National Institute for Locomotor Disabilities (Divyangjan), Kolkata, India</i> 10 + 2 minutes</p>
12:30 - 13:30	Lunch Schweizer Paraplegiker-Zentrum Aula
13:30 - 15:00	SESSION 4 - EPIDURAL AND TRANSCUTAENOUS SPINAL CORD STIMULATION <i>Chairs: Winfried Mayr, Jürgen Pannek</i>
A-0057	<p>KEYNOTE: Prof. Dr. Grégoire Courtine <i>EPFL, Campus biotech, SV BMI, Geneva, Switzerland</i> 25 + 5 minutes</p>

A-0004	<p>LONG-TERM PAIRED ASSOCIATIVE STIMULATION – A NOVEL TREATMENT FOR INCOMPLETE SPINAL CORD INJURY PATIENTS</p> <p>Anastasia Shulga¹, Aleksandra Tolmacheva¹, Pantelis Lioumis¹, Sarianna Savolainen², Erika Kirveskari¹, Aarne Ylinen², Jyrki P. Mäkelä¹</p> <p>¹<i>Helsinki University Hospital, Finland;</i> ²<i>Validia Rehabilitation Centre, Helsinki, Finland</i></p> <p>10 + 2 minutes</p>
A-0025	<p>LONG-TERM PAIRED ASSOCIATIVE STIMULATION WITH NOVEL SETTINGS IMPROVES HAND FUNCTION IN PATIENTS WITH NON-TRAUMATIC SPINAL CORD INJURY</p> <p>Aleksandra Tolmacheva, Sarianna Savolainen, Erika Kirveskari, Jyrki P. Mäkelä, Anastasia Shulga</p> <p>¹<i>University Helsinki Hospital, Finland;</i> ²<i>Validia Rehabilitation Centre</i></p> <p>10 + 2 minutes</p>
A-0019	<p>LONG-TERM PAIRED ASSOCIATIVE STIMULATION: IMPROVEMENTS IN UPPER AND LOWER EXTREMITY FUNCTION</p> <p>Andrey Rodionov¹, Alexandra Tolmacheva¹, Sarianna Savolainen², Erika Haaksiluoto³, Jyrki P. Mäkelä¹, Anastasia Shulga^{1,4}</p> <p>¹<i>BioMag Laboratory, Helsinki University Hospital, Helsinki, Finland;</i> ²<i>Validia Rehabilitation Center, Helsinki, Finland;</i> ³<i>Clinical Neurosciences, Clinical Neurophysiology; Helsinki University Hospital, Helsinki, Finland;</i> ⁴<i>Clinical Neurosciences, Neurology, Helsinki University Hospital, Helsinki, Finland</i></p> <p>10 + 2 minutes</p>
A-0024	<p>FREQUENCY DEPENDANT FACILITATION OF MOTOR EVOKED POTENTIALS WITH TRANSCUTANEOUS SPINAL STIMULATION</p> <p>Al'joboori Y.D^{1,2}, Massey S.J², Donaldson N¹, Duffell L.D^{1,2}</p> <p>¹<i>Department of Medical Physics & Biomedical Engineering, University College London, Malet Place Engineering Building, London, UK;</i> ²<i>Aspire Centre for Rehabilitation Engineering and Assistive Technology, UCL Institute of Orthopaedics and Musculoskeletal Sciences, Royal National Orthopaedic Hospital (RNOH), London, UK</i></p> <p>10 + 2 minutes</p>
A-0040	<p>DIFFERENCE BETWEEN TONIC AND PHASIC PINCH CONTRACTIONS IN FACILITATION OF RESPONSES ELICITED BY CERVICAL TRANSCUTANEOUS SPINAL CORD STIMULATION</p> <p>Matija Milosevic^{1,2}, Yohei Masugi³, Atsushi Sasaki¹, Kimitaka Nakazawa¹</p> <p>¹<i>Graduate School of Arts and Sciences, University of Tokyo, Tokyo, Japan;</i> ²<i>Japan Society for the Promotion of Science, Tokyo, Japan;</i> ³<i>Institute of Sports Medicine and Science, Tokyo International University, Saitama, Japan</i></p> <p>10 + 2 minutes</p>
A-0049	<p>CLOSE-LOOP SYSTEM TO RESTORE MOVEMENT IN UPPER-LIMB AFTER PARALYSIS</p> <p>Ambroise Matthieu, Jackson Andrew</p> <p><i>Institute of Neuroscience, Newcastle University, Newcastle NE2 4HH, UK</i></p> <p>10 + 2 minutes</p>
15:00 - 15:30	Coffee break
15:30 - 17:30	SESSION 5 - JOINED IFESS AND TETRAHAND SESSION
18:00 - 19:00	Schweizer Paraplegiker-Zentrum guided tours Meeting point: Registration desk
18:30 - 19:30	BOD Meeting room: Pluto

30 AUGUST | THURSDAY

AUDITORIUM 1

08:30 – 09:30	SESSION 6 - STIMULATION OF DENERVATED MUSCLES <i>Chairs: Winfried Mayr, Michael Russold</i>
A-0058	KEYNOTE: Prof. Dr. Jonathan Jarvis <i>Liverpool John Moores University, Sport and Exercise Science, Liverpool, UK</i> 25 + 5 minutes
A-0036	STIMULATION OF DENERVATED MUSCLES IN PATIENTS WITH A LOWER MOTOR NEURON LESION (LMN) IMPLEMENTATION IN CLINICAL SETTING Ines Bersch, Ramona Moser <i>Swiss Paraplegic Centre Nottwil, Switzerland</i> 10 + 2 minutes
09:30 - 10:00	POSTER SESSION 2 <i>Chairs: Erika Spaich, Phil Troyk</i>
A-0021	THE EFFECTS OF NEUROMODULATION ON CENTRAL EXCITABILITY OF THE UPPER LIMB IN HEALTHY, ABLE-BODIED ADULTS Sarah Massey¹, Yazid Al'joboori^{1,2}, Anne Vanhoostenberghe^{1,2}, Lynsey Duffell^{1,2} <i>¹Aspire Centre for Rehabilitation Engineering and Assistive Technology, Royal National Orthopaedic Hospital, University College London, London, UK;</i> <i>²Department of Medical Physics and Biomedical Engineering, University College London, London, UK</i> 3 minutes
A-0003	EFFECT OF FREQUENCY MODULATED MAGNETIC STIMULATION ON MUSCLE ATROPHY IN RAT Yosuke Iwamoto¹, Toshiki Matsunaga², Daisuke Kudo¹, Ryota Kimura¹, Jumpei Iida¹, Yasuhiro Takahashi¹, Yasuaki Tsukamoto¹, Junichi Inoue¹, Yoichi Shimada¹ <i>¹Department of Orthopedic Surgery, Akita University Graduate School of Medicine, Akita, Japan;</i> <i>²Department of Rehabilitation Medicine, Akita University Hospital, Akita, Japan</i> 3 minutes
A-0016	WEARABLE ELECTRONIC SLEEVE FOR MUSCLE STIMULATION Kai Yang¹, Katie Meadmore², Chris Freeman¹, Neil Grabham¹, Ann-Marie Hughes², Yang Wei¹, Russel Torah¹, Monika Glanc-Gostkiewicz¹, Steve Beeby¹, John Tudor¹ <i>¹Electronics and Computer Sciences, University of Southampton, UK;</i> <i>²Faculty of Health Sciences, University of Southampton, UK</i> 3 minutes
A-0037	EFFECT OF NEUROMUSCULAR ELECTRICAL STIMULATION ON MASSETER MUSCLE IN ORAL PHASE DYSPHAGIA AFTER STROKE Sook Joung Lee¹, Min Kyu Park² <i>¹Catholic University of Korea, Daejeon St. Mary Hospita, Daejeon, Republic of Korea;</i> <i>²Chungbuk National University Hostpial, Cheongju, Republic of Korea</i> 3 minutes
A-0045	FES DRIVEN CYCLING BY DENERVATED MUSCLES Mariann Mravcsik^{1,2}, Christoph Kast³, Vargas Luna Jose Luis³, Aramphianlert Weerayot³, Hofer Christian⁴, Szabolcs Malik¹, Miklos Putz⁵, Mayr³, Jozsef Laczko^{1,2} <i>¹Wigner Research Centre for Physics, Budapest, Hungary;</i> <i>²University of Pecs, Pecs, Hungary;</i> <i>³Medical University of Vienna, Wien, Austria;</i> <i>⁴Ludwig Boltzman Institute for Electrical Stimulation and Physical Rehabilitation, Vienna;</i> <i>⁵National Institute for Medical Rehabilitation, Budapest, Hungary</i> 3 minutes

10:00 - 10:30	Coffee break
10:30 - 12:00	SESSION 7 - IMPLANTABLE SYSTEMS <i>Chairs: Manfred Bijak, Ken Yoshida</i>
A-0059	KEYNOTE: Prof. Dr. Phil Troyk <i>Illinois Institute of Technology, Biomedical Engineering, Chicago, USA</i> 25 + 5 minutes
A-0011	TOWARD A MULTI-CHANNEL WIRELESS SYSTEM FOR ELECTRICAL STIMULATION OF PERIPHERAL NERVES: MODELLING AND SIMULATION OF SIGNAL TRANSMISSION Cristian Pasluosta¹, Patrick Kiele¹, Thomas Stieglitz^{1,2,3} <i>¹Laboratory for Biomedical Microtechnology, Department of Microsystems Engineering (IMTEK), University of Freiburg, Freiburg, Germany;</i> <i>²Bernstein Center Freiburg, University of Freiburg, Freiburg, Germany;</i> <i>³BrainLinks-BrainTools, University of Freiburg, Freiburg, Germany</i> 10 + 2 minutes
A-0033	TRANSITIONING IMPLANTABLE NEURAL INTERFACES TO THE CLINIC: NAVIGATING REGULATORY TESTING Philip R Troyk^{1,3}, Stuart Cogan², Diana Easton², Solomon David³ <i>¹Illinois Institute of Technology, Chicago, Illinois, USA;</i> <i>²University of Texas, Dallas, Dallas, Texas, USA;</i> <i>³Sigenics, Inc., Chicago, Illinois, USA</i> 10 + 2 minutes
A-0039	IN-SILICO BIOPHYSICAL MYELINATED AND UNMYELINATED AUTONOMIC NERVE FIBER MODELS Michael Ryne Horn¹, Bradley Holinsky¹, Johannes Jan Struijk², Karen D. Alfrey³, John H. Schild³, Ken Yoshida³ <i>¹Galvani Bioelectronics, King of Prussia, PA, USA;</i> <i>²Dept of Health Science and Technology, Aalborg University, Denmark;</i> <i>³Dept of Biomedical Engineering, Indiana University-Purdue University Indianapolis, Indianapolis, IN, USA</i> 10 + 2 minutes
12:00 - 12:30	SPECIAL SESSION - FES ROWING
	KEYNOTE: Prof. Andrew J. Taylor <i>Harvard Medical School, Physical Medicine & Rehabilitation, Cambridge, USA</i> 25 + 5 minutes
12:30 - 13:30	Lunch <i>Schweizer Paraplegiker-Zentrum Aula</i>
13:30 - 15:00	SESSION 8 - TECHNOLOGIES (STUDENTS' AWARD) <i>Chairs: Thierry Keller, Glen Davis</i>
A-0060	KEYNOTE: Prof. Dr. Kenneth Hunt <i>Bern University of Applied Sciences, Burgdorf, Switzerland</i> 25 + 5 minutes
A-0009	FUNCTIONAL ELECTRICAL STIMULATION+HIGH PROTEIN SUPPLEMENTATION MINIMIZE ICU-ASSOCIATED SARCOPENIA A C Verceles¹, D Davis², G Alon³ <i>¹University of Maryland School of Medicine, Division of Pulmonary, Critical Care, and Sleep Medicine;</i> <i>²University of Maryland School of Medicine Department of Diagnostic Radiology & Nuclear Medicine;</i> <i>³University of Maryland School of Medicine Department of Physical Therapy & Rehabilitation Science</i> 10 + 2 minutes

A-0015	<p>FUNCTIONAL ELECTRICAL STIMULATION ASSISTED SWIMMING FOR PARAPLEGICS</p> <p>Constantin Wiesener¹, Jens Axelgaard², Rachel Horton², Andreas Niedeggen³, Thomas Schauer¹</p> <p>¹<i>Control Systems Group, Technische Universität Berlin, Germany;</i> ²<i>Axelgaard Manufacturing Co., Ltd., USA;</i> ³<i>Treatment Centre for Spinal Cord Injuries, UKB Unfallklinik Berlin, Germany</i></p> <p>10 + 2 minutes</p>
A-0031	<p>QUADRICEPS ELECTRICAL STIMULATION TO ASSIST SITTING PIVOT TRANSFERS BY PERSON WITH PARAPLEGIA</p> <p>Ana Claudia Garcia Lopes^{1,2}, Karine Pereira da Rocha², Lucas Oliveira da Fonseca², Claudia Ochoa-Diaz², Roberto de Souza Baptista², Antônio Padilha Lanari Bó², Charles Fattal³, Christine Azevedo-Coste⁴, Emerson Fachin-Martins²</p> <p>¹<i>Rede SARAH de Hospitais de Reabilitação, Brasília, Brazil;</i> ²<i>NTAAI-UnB, Universidade de Brasília, Brasília, Brazil;</i> ³<i>CRRF La Châtaigneraie, Menucourt, France;</i> ⁴<i>INRIA-LIRMM, Montpellier, France</i></p> <p>10 + 2 minutes</p>
A-0038	<p>REINFORCEMENT LEARNING CONTROL OF FUNCTIONAL ELECTRICAL STIMULATION OF THE UPPER LIMB: A FEASIBILITY STUDY</p> <p>Davide Di Febbo¹, Emilia Ambrosini¹, Matteo Pirotta², Eric Rojas¹, Marcello Restelli¹, Alessandra Laura Giulia Pedrocchi¹, Simona Ferrante¹</p> <p>¹<i>Politecnico di Milano, Milano, Italy;</i> ²<i>Inria, Lille, Nord Europe France</i></p> <p>10 + 2 minutes</p>
A-0042	<p>3D PRINTED HINGED MULTI-CONTACT CUFF ELECTRODES FOR RAPID PROTOTYPING AND TESTING</p> <p>Lindsay Richardson, Chandrama Ahmed, Macallister Smolik, Ken Yoshida</p> <p><i>Indiana University - Purdue University Indianapolis</i></p> <p>10 + 2 minutes</p>
A-0054	<p>COMPARISON OF PARAVERTEBRAL MUSCLE THICKNESS IN VOLUNTARY CONTRACTION AND CONTRACTION INDUCED BY SURFACE ELECTRICAL STIMULATION</p> <p>Minja Belić¹, Andrej M. Savić¹, Olivera Đorđević², Vladimir Kojić¹, Ljubica Konstantinović², Thierry Keller³</p> <p>¹<i>Tecnalia Serbia, Serbia;</i> ²<i>Rehabilitation Clinic "Miroslav Zotović", Serbia;</i> ³<i>Tecnalia, Spain</i></p> <p>10 + 2 minutes</p>
15:00 - 15:30	Coffee break
15:30 - 17:00	<p>SESSION 9 - NEURO-UROLOGY</p> <p><i>Chairs: Ulf Bersch, Jürgen Pannek</i></p>
A-0061	<p>KEYNOTE: Prof. Dr. med. Jürgen Pannek</p> <p><i>Schweizer Paraplegiker-Zentrum, Neuro-Urologie, Nottwil, Switzerland</i></p> <p>25 + 5 minutes</p>
A-0002	<p>HOME USE OF A WIRELESSLY CONTROLLED STIMULATOR TO DELIVER DORSAL GENITAL NERVE STIMULATION FOR SUPPRESSING BLADDER OVERACTIVITY FOLLOWING SCI</p> <p>Sean Doherty^{1,2}, Anne Vanhoostenberghe¹, Rizwan Hamid², Sarah Knight²</p> <p>¹<i>Aspire CREATE, University College London, UK;</i> ²<i>London Spinal Cord Injury Centre, Royal National Orthopaedic Hospital, UK</i></p> <p>10 + 2 minutes</p>

A-0012

IMPROVEMENT IN OVER ACTIVE BLADDER SYMPTOMS IN PATIENTS USING FUNCTIONAL ELECTRICAL STIMULATION OF THE COMMON PERONEAL NERVE FOR WALKING.

Nicola Hare¹, Petros Georgopoulos¹, Kate Philips¹, Joanne Johnson¹, Coralie Seary¹, Jalesh N Panicker^{1,2}, Valerie L Stevenson^{1,2}

¹The National Hospital for Neurology and Neurosurgery, UCLH NHS Foundation Trust, London, UK;

²University College London Institute of Neurology, London, UK

10 + 2 minutes

31 AUGUST | FRIDAY

AUDITORIUM 1

08:30 - 10:00	GENERAL ASSEMBLY AND FOUNDERS MEETING
10:00 - 10:30	Coffee break
10:30 - 11:00	SESSION 10 - BRAIN INTERFACES <i>Chairs: Milos Popovic, Ines Bersch</i>
A-0062	KEYNOTE: Prof. Gernot Müller-Putz <i>Graz University of Technology, Institute of Neural Engineering, Graz, Austria</i> 25 + 5 minutes
11:00 - 12:00	SESSION 11 - FITNESS AND CARDIO-VASCULAR SYSTEM <i>Chairs: Milos Popovic, Ines Bersch</i>
A-0063	KEYNOTE: Prof. Dr. Glen Davis <i>The University of Sydney, Faculty of Health Sciences, Sydney, Australia</i> 25 + 5 minutes
A-0032	TRUNK MUSCLE ACTIVATION TO IMPROVE TRUNK STABILITY, ARM POWER, AND PERFORMANCE IN WHEELCHAIR RUGBY PLAYERS Thomas Janssen^{1,2,3}, Ingrid Kouwijzer¹, Mathijs van der Meer¹ <i>¹Vrije Universiteit Amsterdam, Faculty of Behavioural and Movement Sciences, Amsterdam;</i> <i>²Amsterdam Rehabilitation Research Center, Reade, Amsterdam;</i> <i>³Amsterdam Institute of Sport Sciences, Amsterdam, the Netherlands</i> 10 + 2 minutes
12:00 - 13:30	Lunch <i>Schweizer Paraplegiker-Zentrum Aula</i>
13:30 - 14:45	POSTER SESSION 3 <i>Chairs: Erika Spaich, Phil Troyk</i>
A-0005	MINIATURIZED IMPLANTABLE ELECTRICAL STIMULATOR FOR SMALL ANIMALS, PRELIMINARY RESULTS Manfred Bijak¹, Martin Schmoll M^{1,2}, Ewald Unger¹, Jonathan Jarvis², Hermann Lanmüller³ <i>¹Medical University of Vienna, Austria;</i> <i>²Liverpool John Moores University, Liverpool, UK</i> 3 minutes
A-0006	DESIGN RULES FOR A TRANSCUTANEOUS CAPACITIVE ELECTRODE ARRAY FOR FUNCTIONAL ELECTRICAL STIMULATION OF PERIPHERAL NERVES Patrick Kiele¹, Cristian Pasluosta¹, Thomas Stieglitz^{1,2,3} <i>¹Laboratory for Biomedical Microtechnology, Department of Microsystems Engineering (IMTEK), University of Freiburg, Germany;</i> <i>²Bernstein Center Freiburg, University of Freiburg, Germany;</i> <i>³BrainLinks-BrainTools, University of Freiburg, Germany</i> 3 minutes
A-0029	AUTOMATIC CONFIGURATION OF AN EEG-TRIGGERED NEUROPROSTHESIS FOR GRASPING: PROOF-OF-CONCEPT STUDY Ryan G L Koh^{1,2*}, Jirapat Likitlersuang^{1,2*}, Xinyi Gong^{1,3}, Lazar Jovanovic^{1,2}, Isabel Bolivar Telleria^{1,2}, Matthew Myers^{1,2}, Milos R Popovic^{1,2}, José Zariffa^{1,2}, Cesar Marquez-Chin¹ *First and second authors contributed equally <i>¹Toronto Rehabilitation Institute – University Health Network, Toronto, Canada;</i> <i>²Institute of Biomaterials and Biomedical Engineering, University of Toronto, Toronto, Canada;</i> <i>³Division of Engineering Science, University of Toronto, Toronto, Canada</i> 3 minutes

<p>A-0034</p>	<p>FES-THERAPY DELIVERED WITH A STIMULATION GARMENT: A FIRST CASE-STUDY TRAINING GRASP FUNCTIONS AFTER SPINAL-CORD INJURY Bastien Moineau¹, Milad Alizadeh-Meghrazi^{1,2}, Cesar Marquez-Chin¹, Milos Popovic^{1,3} ¹<i>Rehabilitation Engineering Laboratory, Toronto Rehabilitation Institute-University Health Network, Canada;</i> ²<i>Myant Inc., Toronto, Canada;</i> ³<i>Institute of Biomaterials and Biomedical Engineering, University of Toronto, Canada</i> 3 minutes</p>
<p>A-0048</p>	<p>PRACTICAL EFFECTS OF USING ELECTRODES WITH DIFFERENT HYDROGELS AND GRID PATTERNS IN SURFACE ELECTRICAL STIMULATION Jovana Malešević^{1,2}, Minja Belić^{1,2}, Matija Štrbac¹, Vladimir Kojić¹, Goran Bijelić³, Thierry Keller³ ¹<i>Tecnalía Serbia, Belgrade, Serbia;</i> ²<i>Univesity of Belgrade, Serbia;</i> ³<i>Tecnalía, Donostia - San Sebastián, Spain</i> 3 minutes</p>
<p>A-0020</p>	<p>MOTOR REHABILITATION USING FUNCTIONAL ELECTRICAL STIMULATION AND AVATAR USING BRAIN-COMPUTER INTERFACES: A CASE REPORT Woosang Cho¹, Alexander Heilinger¹, Rupert Ortner¹, Ren Xu², Nensi Murovec¹, Manuela Zehetner¹, Stefan Schobesberger¹, Katrin Mayr², Christoph Guger^{1,2} ¹<i>G.tec medical engineering GmbH, Schiedlberg, Austria;</i> ²<i>Guger Technologies OG, Graz, Austria</i> 3 minutes</p>
<p>A-0017</p>	<p>RESPIRATORY RESPONSE DURING FUNCTIONAL ELECTRICAL STIMULATION CYCLING Takahashi Y¹, Muraoka T², Hatakeyama K¹, Watanabe M¹, Suda T¹, Chida S¹, Kagami K¹, Saito K¹, Matsunaga T¹, Iwami T², Shimada Y³ ¹<i>Department of Rehabilitation Medicine, Akita University hospital, Japan;</i> ²<i>Department of System Design Engineering, Faculty of Engineering Science, Japan;</i> ³<i>Department of Orthopaedic Surgery, Akita University Graduate School of Medicine, Japan</i> 3 minutes</p>
<p>A-0026</p>	<p>ULTRASOUND IMAGING ANALYSIS FOR THE OPTIMISATION OF FUNCTIONAL ELECTRICAL STIMULATION Jennifer Miller, Henrik Gollee <i>University of Glasgow, United Kingdom</i> 3 minutes</p>
<p>A-0022</p>	<p>LOGGING THERAPY SESSION DATA VIA AN UPPER LIMB FES REHABILITATION SYSTEM Mingxu Sun¹, Laurence Kenney¹, David Howard^{1,2}, Christine Smith³, Karen Waring¹, Helen Luckie¹ ¹<i>Centre for Health Sciences Research, University of Salford, UK;</i> ²<i>School of Computing, Science and Engineering, University of Salford, UK;</i> ³<i>Department of Allied Health Professions, Sheffield Hallam University, UK</i> 3 minutes</p>

A-0027	<p>POTENTIAL BENEFITS OF A FES-CYCLING PREPARATION FOR A COMPETITION OF AN INDIVIDUAL WITH A HIGH-LEVEL PARAPLEGIA</p> <p>Charles Fattal^{1,2}, Benoit Sijobert², Anne Daubigney³, Christine Azevedo-Coste²</p> <p>¹<i>Centre de Rééducation/Réadaptation Fonctionnelle La Châtaigneraie, Menucourt, France;</i></p> <p>²<i>Institut National de Recherche en Informatique et Automatique, CAMIN Université de Montpellier, France;</i></p> <p>³<i>Centre de Rééducation/Réadaptation Fonctionnelle COS-Divio, Dijon, France</i></p> <p>3 minutes</p>
A-0030	<p>COOPERATIVE CONTROL FOR A HYBRID REHABILITATION SYSTEM COMBINING ROBOTIC EXOSKELETON WITH FUNCTIONAL ELECTRICAL STIMULATION</p> <p>Dingguo Zhang, Yong Ren, Kai Gui</p> <p><i>Shanghai Jiao Tong University, Shanghai, China</i></p> <p>3 minutes</p>
A-0023	<p>IMPROVED HAND FUNCTION AFTER THERAPEUTIC ELECTRICAL STIMULATION AND REHA-BILITATION IN PERSONS WITH CERVICAL SPINE DISORDERS</p> <p>Matsunga T¹, Saito K¹, Kudo D², Iwamoto Y², Inoue J², Chida S¹, Hatakeyama K¹, Watanabe N¹, Takahashi Y¹, Kagami K¹, Suda T¹, Shimada Y²</p> <p>¹<i>Department of Orthopedic Surgery, Akita University Graduate School of Medicine, Akita, Japan;</i></p> <p>²<i>Department of Rehabilitation Medicine, Akita University Hospital, Akita, Japan</i></p> <p>3 minutes</p>
14:45 - 15:30	<p>SESSION 12 - QUALITY OF LIFE WITH FES</p> <p><i>Chairs: Gad Alon, Ines Bersch</i></p>
	<p>KEYNOTE: Tamara Roth</p> <p>25 + 5 minutes</p>
A-0043	<p>ABDOMINAL FUNCTIONAL ELECTRICAL STIMULATION (ABFES) FOR THE TREATMENT OF FUNCTIONAL CONSTIPATION IN MULTIPLE SCLEROSIS: A CASE SERIES</p> <p>Tamsyn Street¹, Emily Padfield¹, Carla Peace², Paul Taylor^{1,3}, Ian Swain⁴, Christine Singleton²</p> <p>¹<i>Salisbury NHS Foundation Trust, Salisbury, United Kingdom;</i></p> <p>²<i>Birmingham Community NHS Healthcare Foundation Trust, Birmingham, United Kingdom;</i></p> <p>³<i>Odstock Medical, Salisbury, United Kingdom;</i></p> <p>⁴<i>Bournemouth University, Bournemouth</i></p> <p><i>Salisbury NHS Foundation Trust, Salisbury, UK</i></p>
15:30 - 16:00	Closing remarks

POSTER AREA

The paper posters will be available on the 5th level Foyer of the Guido A. Zäch-Institut during the whole congress.

SOCIAL EVENTS

GET TOGETHER

We invite you for a welcome reception on the roof top of Hotel Sempachersee. Network with participants and enjoy the local cuisine and drinks.

Welcome reception is included in the registration fee.



BANQUET DINNER

The organizing committee is delighted to welcome all participants and their accompanying persons to the Banquet Dinner at beautiful Hotel Seeburg Luzern with a unique view of the lake and mountains. The ticket costs 90 EUR / person and includes return bus transfer (between Nottwil and Luzern), welcome drink, buffet dinner and wine. After 22.00 there will be a dancing party and drinks on your own expense.

Transfer from Nottwil to Luzern

We would like to meet you at the main entrance of the Hotel Sempachersee at 18.45.

Transfer from Luzern to Nottwil

If you wish to come with us to Nottwil, please note that the bus will start at 23.00 and 00.30.



ABSTRACTS

Dual Channel Volitional Electromyography(vEMG) Signal Estimation Algorithm During Functional Electrical Stimulation(FES)

Joonyoung Jung, Dong-Woo Lee, Yongki Son, Baeseon Kim, Jabeom Gu, and Hyung Cheol Shin

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(Joonyoung, hermes, handcourage, bskim72, gjb, shin)@etri.re.kr

Abstract: *The volitional electromyography(vEMG) detection algorithm is a key element for developing functional electrical stimulation(FES) technology that reflects the intention of motion. However, the conventional approaches have not been feasibly utilized in practice due to the nonlinearity and changeability of FES-induced EMG signals. Therefore, in this paper, an algorithm that can detect vEMG robust to the nonlinearity of FES-induced EMG signals using dual channel EMG has been studied. The proposed method can be implemented only with EMG and FES without additional equipment such as blanking circuit, and has been applied to the experiment to verify its effectiveness.*

Keywords: *Surface electromyography(sEMG), functional electrical stimulation(FES), stimulus artefact, M-wave*

Introduction

Functional electrical stimulation(FES) has been considered as one of the most effective ways to restore the declined muscle function of spinal cord injury patients and stroke patients[1]. Especially, recent studies have shown that the FES algorithm combined with motion intention of user can maximize the effect of the muscle restoration[2]. Therefore, many researchers have studied various methodologies in order to extract the intention of the motion such as joint motion and muscle contraction by using motion sensors(e.g., accelerometer[3], IMU sensor[4], etc.) and muscle activity measuring sensor(e.g., electromyography(EMG)[5]) during FES.

By utilizing the abovementioned sensors, the motion intention can be reflected to FES algorithm in two ways; i.e., motion intention triggered FES(MITFES) algorithm and motion intention controlled FES(MICFES) algorithm. In the MITFES algorithm, the motion intention of user is exploited as an indicator of whether or not to initiate the stimulation. Therefore, the stimulation in this system is initiated only when the quantified amount of motion intention exceeds a corresponding threshold level. In this system, however, because the motion intention cannot be reflected during the stimulation, the stimulation pattern is limited to a predetermined value. On the other hand, the MICFES algorithm is the method that the motion intention of user is exploited for determining the intensity of the stimulation in real time while the muscle is stimulated. Therefore, the MICFES received more attention because it can more effectively utilize the motion intention.

In order for MICFES algorithm, the most problematic challenge is improving motion intention detection accuracy while the muscle is stimulated. Few researchers have studied the methods for detecting the motion intention

while electrically stimulating the muscle. At the same time, skin surface adherable sensor such as surface EMG sensor has been utilized frequently as a means of detecting the motion intention due to its advantages of usefulness. Nevertheless, a major problem with EMG sensor is that the EMG signal can be easily contaminated by stimulus artefact and stimulation induced muscle contraction signal(i.e., M-wave). Therefore, conventional researches have focused on removing such stimulation induced signals in order to detect the EMG signal of volitional motion intention while stimulation, which is called volitional EMG(vEMG) signal.

The extraction of vEMG signal can be theoretically realized in several means. First, the stimulus artefact, the EMG signal which is indirectly measured stimulation current, can be easily removed by the hardware blanking circuit which turns-off the voltage amplifier of EMG sensor for a very short time synchronized with the stimulation frequency[6]. Second, well-established digital filters(e.g., comb-filter[7], adaptive linear prediction filter[6], and Gram-Schmidt prediction error filter[5]) can be utilized to remove the M-wave, which is induced muscle contraction EMG signal by FES, from stimulus artefact rejected EMG signal. Since the filtering algorithms are based on the inherent frequency characteristics of M-wave, it is essential to remove the stimulus artefact through a blanking circuit before applying the digital filter. However, the filtering methods are not yet feasibly established in practice because of the complexity and nonlinearity of the M-wave varying due to various physiological factors such as muscle fatigue and unpredictable individual differences. Furthermore, the aforementioned obstacles become more problematic because the complexity and nonlinearity can be maximized when the stimulation intensity changes rapidly that frequently occurs in practice.

For these reasons, a novel method for extracting vEMG signal regardless of nonlinearity and changeability of FES-induced signals is proposed in this paper. The proposed method can remove stimulus artefact and M-wave from contaminated EMG signal based on physiological characteristics of the human muscle. Moreover, the proposed method does not require precise prediction of M-wave unlike the conventional methods, and thus does not require additional equipment such as blanking circuit. For verification, it is applied to an experiments, which are reasonable to show the effectiveness of the proposed method.

Methods

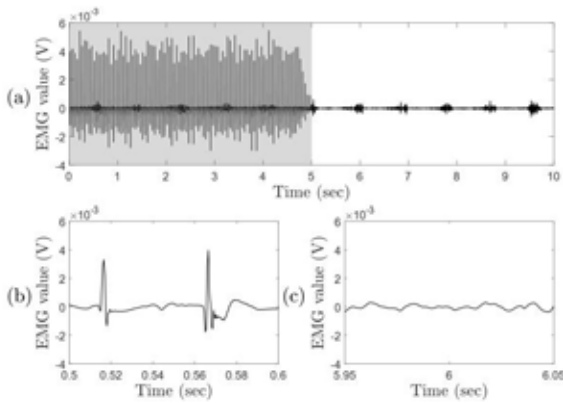


Figure 1: Comparison of EMG signals; (a) measured EMG raw signal where the muscle is periodically contracted voluntarily (with FES: grey region, without FES: white region), enlarged scale of EMG raw signals while the muscle is voluntarily contracted (b) when FES is activation, and (c) is not activating.

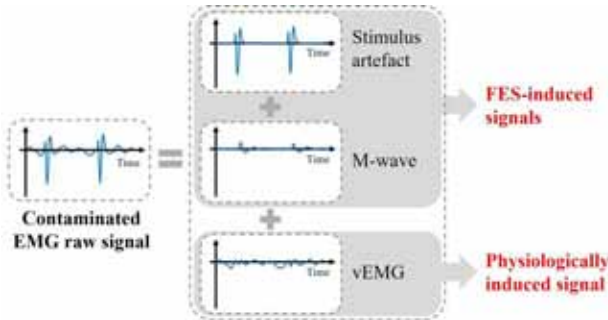


Figure 2: The components of contaminated EMG signal

Figure 1 shows the comparison of EMG raw signals of with and without FES. It should be noticed that the EMG signals were sampled at a rate of 2000Hz using a commercially available EMG sensor. As shown in the white region of Figure 1(a) and Figure 1(c), the EMG sensor is sensitive to contraction of the muscle and robust against external noise when the FES is not applied. However when the FES is applied, which can be shown in the grey region of Figure 1(a) and Figure 1(b), it is clearly shown that the EMG signal is contaminated by stimulation current. The components of contaminated EMG signal was studied by the previous researches as shown in Figure 2. When the stimulation current is delivered to the muscle, the stimulation current induces the stimulus artefact and M-wave. The amplitude and envelop of stimulus artefact differ according to the EMG sensors, because they depend directly on the performances of the voltage amplifier or built-in filters such as high pass filter and notch filter of each EMG sensors. Furthermore, since the amplitude of stimulation current is much larger than the M-wave and vEMG signal, the stimulus artefact saturates the amplifier of EMG circuit and thus the M-wave and vEMG are engulfed. The M-wave is an EMG signal that represents the stimulation current induced muscle contraction EMG signal. Lastly, the vEMG signal is the EMG signal which is physiologically induced by brain.

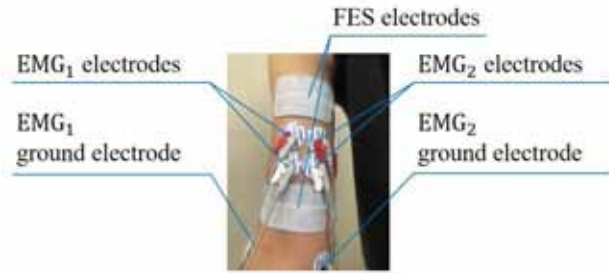


Figure 3: Dual channel EMG system for extracting vEMG.

As illustrated in Figure 2, the contaminated EMG signal is the result of linear summation of stimulus artefact, M-wave, and vEMG on the time axis. Therefore, former researchers assumed that the vEMG signal can be extracted by linear calculation between periodic stimulation iterations. This method is utilized by Muraoka et al. by taking subtraction between stimulation iterations and by not receiving the EMG signal during 20~25ms due to the instability of M-wave[7]. Muraoka suggested that by assuming the stimulus artefact and the M-wave are the same between repeated stimulation currents at the same frequency, it is possible to eliminate the FES-induced signals by taking subtraction of EMG signals between the iterations. Even if the stimulation current is maintained at the same value, however, the M-wave can be changed by various influences[8]. It is problematic because it can degrade the performance of the digital filtering method, because they are using the frequency characteristics of the M-wave or the optimization algorithm method for estimating the M-wave by the nonlinear programming. In addition, this method significantly decreases the sampling rate of vEMG and the controllability of FES, because it always has to stimulate the same stimulation repeatedly.

Therefore, we focused on developing vEMG extraction method robust to complexity and nonlinearity of FES-induced signals. As represented in Figure 2, the stimulus artefact and M-wave are the EMG signals which are induced by FES, whereas the vEMG signal is the EMG signal which is physiologically induced by brain. Note that the FES electrically induces a synchronous muscle recruitment, whereas the brain physiologically induces an asynchronous muscle recruitment as proven by previous researches[9]. For these reasons, when the FES is applied to the muscle, the FES-induced EMG signal is synchronously generated throughout the stimulated muscle. On the other hand, since the physiologically induced EMG signal is the result from asynchronous recruitment of muscle fibre, the vEMG signal is the signal that randomly generated throughout the muscle. Therefore, we assumed that the FES-induced EMG signal has the same tendency throughout the stimulated muscle, and that the vEMG signal is band-limited Gaussian random signal generated in the entire muscle region.

Based on the aforementioned assumptions, we proposed a dual channel EMG signal processing algorithm for extracting vEMG signal. Figure 3 shows the electrode placement position of the proposed method. Suppose that

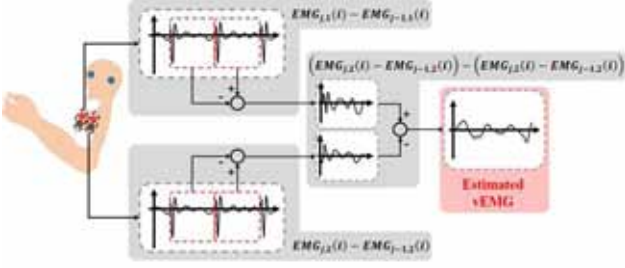


Figure 4: Procedure of vEMG estimation process.

the one channel of FES and two channels of EMG are attached to the one same muscle. Note that the amplitudes of each EMG channel in j -th iteration were defined as

$$EMG_{j,1}(i) = V_{FES,j,1}(i) + V_{V,j,1}(i) \text{ for } i = 0 \dots N-1 \quad (1)$$

and

$$EMG_{j,2}(i) = V_{FES,j,2}(i) + V_{V,j,2}(i) \text{ for } i = 0 \dots N-1 \quad (2)$$

where $V_{FES,j,1}(i)$ refers the EMG signals of FES-induced signals, $V_{V,j,1}(i)$ refers the vEMG signal, j is stimulation index, i is sampling index, and N is the total number of samples between stimulation iterations, respectively. From the above equations, we assumed that the amplitudes of stimulus artefact and M-wave are changed by the stimulation intensity and the position at which the EMG electrode is attached, but the shapes of them are assumed to be constant. It is reasonable assumption because the shapes of FES-induced EMG signals vary dominantly by the effect of muscle fatigue of which difference between adjacent stimulation iterations can be ignored[8]. Therefore, when each of EMG amplitudes is subtracted between adjacent iterations, i.e., $EMG_{j,\bullet}(i) - EMG_{j-1,\bullet}(i)$, differences between adjacent stimulation iterations of FES-induced EMG signals except for the differences caused by the stimulation intensity and electrode attachment position can be eliminated. It should be noticed that the vEMG signals can be maintained because the band-limited Gaussian signal can be maintained even if it is subtracted between adjacent iterations.

In order to eliminate the remaining differences, recall that the FES induces synchronous muscle recruitment through the entire region of stimulated muscle. By this reason, each channel of EMGs are equally and synchronously affected by the FES, and thus the difference between EMG channels can be considered to be the same at every stimulation iterations. Therefore, when the amplitudes of EMG are subtracted between each channels, i.e., $EMG_{\bullet,1}(i) - EMG_{\bullet,2}(i)$, differences caused by the stimulation intensity and electrode attachment position can be eliminated.

Consequently, the amplitude of vEMG can be easily estimated by

$$V_{V,j}(i) = (EMG_{j,1}(i) - EMG_{j-1,1}(i)) - (EMG_{j,2}(i) - EMG_{j-1,2}(i)). \quad (9)$$

By the Eq. (9), FES-induced signals which are almost impossible to be modelled or estimated can be eliminated, and thus the vEMG can be easily and successfully calculated.

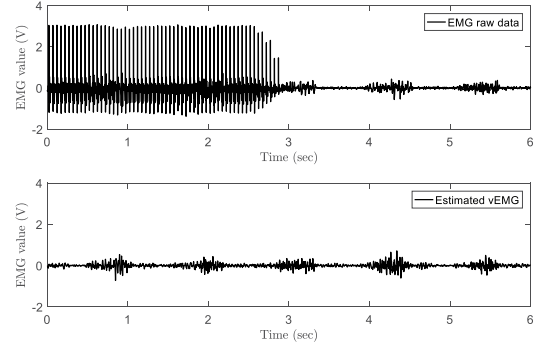


Figure 5: Experimental results of estimating vEMG under static FES current.

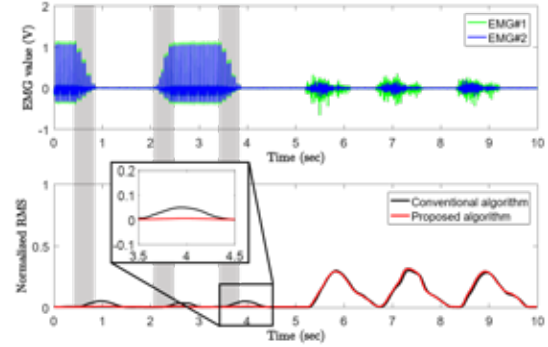


Figure 6: Experimental results of estimating vEMG under dynamic FES current. (The regions where the FES changes dynamically were highlighted with grey color.)

Figure 4 shows the procedure of the proposed vEMG estimation method. It should be noticed that Eq. (9) is derived from the assumptions based on the physiological muscle recruitment mechanism that FES-induced muscle changes are equally applied to the entire area of the stimulated muscle, thus it is important to place the EMG electrodes as close as possible in order to avoid unexpected effects. In addition, the proposed method is advantageous in that it can be applied more easily because the vEMG can be extracted only by EMGs without additional equipment such as blanking circuit.

Results

The performance of the proposed method is verified by experiments. It should be noticed that the proposed method is applied to a healthy male subject, and the experiments are conducted to determine whether the vEMG was detected under static and dynamic FES. Moreover, the performance of the proposed method was compared with that of the conventional method using blanking windowing combined comb filter for objective comparison. The FES and EMG devices utilized were Rehasim1 of Hasomed and iEMG of Physioblab, respectively.

Figure 5 shows the experimental results of estimating vEMG under static FES. Note that the FES was set to stimulate the muscle with a static stimulation current of 3mA for 2.5s, and ramp-down for 0.5s. In addition, the stimulation frequency and pulse width were set to 20Hz and 350us, respectively. As shown in the figure, the stim-

ulation artefact and M-wave were significantly eliminated, and thus the vEMG can be successfully extracted.

In order to further verify the performance, an additional experiment was carried out in a dynamically changing FES current situation. Figure 6 shows the experimental results. As shown in the figure, the experiments were proceeded in a dynamically changing situation such as ramp-up in 0.5s, maintaining for 1s, and ramp-down in 0.5s, and the other stimulation parameters were the same as in the former experiment. In this experiment, the performance of the proposed method was compared with that of conventional method of applying the comb filter after 20ms of blanking windowing. As shown in the below experimental results in the Figure 6, the proposed method can eliminate the stimulus artefact and M-wave even when the FES current is changing, whereas the conventional method cannot fully eliminate the FES-induced signals especially when the FES is drastically modulating. Moreover, the proposed method can effectively extract the vEMG regardless of the FES since the vEMG value estimated by the proposed method is almost equal to that estimated by the conventional method where the FES is not applied.

Discussion

In this paper, a novel algorithm that can effectively detect the vEMG with dual channel EMG during FES was proposed. While the EMG electrodes are closely attached in the range of stimulated muscle, the proposed method can extract the vEMG from the contaminated EMG signal based on the physiological characteristics of muscle contraction mechanism. In order to verify the vEMG estimation performance of the proposed method in the presence of nonlinearity of FES-induced signals, it was applied to the experiments with statically and dynamically controlled FES. In the experiments, the proposed method can successfully eliminate the stimulus artefact and M-wave which are the FES-induced EMG signals in each case.

References

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Home use of a wirelessly controlled stimulator to deliver dorsal genital nerve stimulation for suppressing bladder overactivity following SCI

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Abstract: *Incontinence is prominent in neurological patient populations such as Spinal Cord Injury. Electrical stimulation of pudendal afferents can increase bladder capacity and suppress reflex contractions. Presented is a single case study of an SCI subject using surface genital nerve stimulation at home over one week, using a wirelessly controlled stimulator and Android app based diary logger. An increase in voided volumes and time between voids was recorded, though incontinence, characterised by leak event rate and ICIQ score, remained unchanged.*

Keywords: *Bladder, Spinal Cord Injury, Incontinence, Dorsal Genital Nerve Stimulation, Neuromodulation*

Introduction

Following spinal cord injury (SCI), neural control of the Lower Urinary Tract (LUT) becomes aberrant. This leads to the development of Neurogenic Detrusor Activity (NDO) and Detrusor-Sphincter-Dyssynergia (DSD) affecting the LUT's ability to store and void urine. During storage, high intra-detrusor pressures and urinary incontinence become common, therefore urological management goals for storage of urine are to enable low pressures and maintain continence [1].

Electrical stimulation of sacral afferents can acutely inhibit NDO, reducing pressures and maintaining continence. This may be achieved superficially by stimulating the Dorsal Genital Nerve (DGNS), a purely afferent and superficial branch of the pudendal nerve, by applying electrodes to the dorsum of the penis or over the clitoris. DGNS is thought to both stimulate the striated sphincter and project onto autonomic pathways at a spinal level to inhibit detrusor activity [2]. It has been shown in standard cystometry studies to increase bladder capacity by 131 ± 101 ml, from 212 ± 131 ml without DGNS to 343 ± 159 ml with DGNS [3].

DGNS may be applied continuously or conditionally, having been shown to be equivalent in acute urodynamic study [4]. Continuous stimulation raises potential issues with habituation and device battery life, therefore a robust conditional stimulation paradigm is viewed as the gold standard option. Conditional stimulation requires knowledge of bladder activity to be fed back to appropriately trigger stimulation. This feedback may be provided automatically in a closed loop system utilising a means of physiological monitoring, or through a user's preserved sensation.

Numerous efforts have been made to enable physiological detection of NDO in a manner suitable for chronic implementation, recent options include implantable vesical pressure measurement combined with context aware thresholding of bladder events [5], use of external anal sphincter EMG [6] and implantable devices capable of measuring sacral afferent ENG [7]. However, none have yet been implemented as a viable option for chronic treatment and there are questions regarding chronic use of DGNS, such as the appropriateness of using sensation as a trigger or of electrode configurations and whether reflex inhibition is habituated with long term use, that may already be investigated using available techniques.

To date, the majority of chronic studies using DGNS have recruited sensate patients, able to trigger their own stimulation conditionally [8-10]. This has predominantly been shown to be a valid approach [8-10], however issues with easy access to stimulation trigger in some patients may be a limiting factor [11]. Further to this, whilst there is a large proportion of persons with SCI who possess some degree of pelvic sensation, there is a portion of these for whom the ability to detect unwanted bladder contractions may be too late to trigger conditional neuromodulation and further proportion who have no sensation at all [11, 12].

We hypothesised that by implementing stimulator control on an easily accessible User Interface (UI) we may increase acceptability of the technique and reduce problems associated with access to stimulation triggers. The design of this system has been outlined previously [13].

We present a case study of DGNS use in the home environment over one week using the described device, with a participant who had some preserved sensation.

Methods

Ethical approval was obtained from our local ethics board and the study was conducted in accordance with the Declaration of Helsinki.

System used

The stimulation system used consists of four components. Commercially available 2.5cm round electrodes (PALS[®], Axelgaard Manufacturing Co., Ltd.) were used along with commercially available Odstock Medical Pace stimulator (Odstock Medical Ltd.) modified to deliver 15 Hz stimulation. The traditional foot switch has been replaced with

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a Bluetooth low energy (BLE) connected switch, consisting of a MOSFET switch controlled by a BLE microcontroller with power source. This switch receives a stimulation profile and switching updates from a custom Android application. To stimulate the DGN electrodes were placed on the dorsum of the penile shaft. Electrodes were placed approximately 2cm apart, the cathode was placed proximally. Stimulation was set to 200 μ S pulse width and biphasic.



Figure 1: Wireless version of Odstock Pace stimulator with custom Android app

Experimental protocol

The experiment was carried out in 3 phases: a screening assessment where the participant underwent cystometry (CMG) to test for NDO and test the suppressive effect of DGNS, a control week completing a bladder diary whilst continuing usual care and an experimental week completing a bladder diary whilst using DGNS on top of usual care.

To assess the effectiveness of DGNS the participant first underwent CMG [14] to record baseline and “with stimulation” bladder pressures and capacity. During these tests the participant was supine. A 10.5 Ch catheter was placed urethrally and used to fill the bladder with room temperature saline at 60ml/min. Pressure was measured using Medex (Smiths Medical) pressure transducers placed at the level of the pubic synthesis, through 4.5Ch water filled catheters placed urethrally to measure vesical pressure (P_{ves}) and rectally to measure abdominal pressure (P_{abd}). Detrusor pressure was calculated as Eq. 1.

$$P_{det} = P_{ves} - P_{abd} \quad (1)$$

Infused volume was measured using a weight transducer. Signals were amplified using a CED 1902 isolated amplifier, digitised through a CED 1401 and recorded on Spike 2 software (Version 4, Cambridge Electronic Devices, UK) used to display data and trigger stimulation. To threshold stimulation amplitude, 15Hz bursts of one second were given in increasing amplitudes until 2x the

threshold for contraction of the external anal sphincter (EAS_{thresh}), detected visually, was reached. Stimulation was monophasic and delivered by a constant current stimulator (DS7, Digitimer, UK).

CMG was performed without stimulation, with DGNS applied at a rise of 10 cm H_2O and again without stimulation. First Detrusor Contraction Volume (FDCV), Maximum Cystometric Capacity (MCC) and Maximum Detrusor Pressure (MDP) were used for analysis.

A baseline bladder diary was then completed using the smartphone app. Leakage events, volume voided, urgency sensations and fluid intake was recorded over 6 days in the participant home. From this diary, the time between Clean Self Intermittent Catheterisation (CSIC) was calculated, excluding overnight periods.

Following the control week, the participant was set up with the Pace stimulator and wireless controller. The amplitude was set to as close to 2 x EAS_{thresh} as was tolerable. Stimulation was biphasic, 15Hz and set to 200 μ S pulse width. The stimulation mode was then set to User Controlled only, based on the participant having sensation of bladder activity. The participant then used DGNS at their discretion, to suppress bladder overactivity, over the following week at home whilst recording the same diary.

The International Consultation on Incontinence Urinary Incontinence Short Form (ICIQ UI-SF) was used as an additional measure, completed at the end of the control week and the end of the DGNS week. The ICIQ-UI Short Form is a brief patient-completed questionnaire for evaluating the frequency, severity and impact on quality of life of urinary incontinence in men and women.

Results

Participant characteristics

One 69-year-old male with a C5, ASIA D, SCI was recruited. Current bladder management was CSIC on urge, with chronic incontinence managed using pads and 10mg Oxybutinin od. Previous intra-detrusor botulinum type-A injections had been administered, though none in the preceding 12 months.

Baseline cystometry

Stimulation amplitude was set to 45mA, the maximum tolerable level, at 1.5 x EAS_{thresh} . Baseline CMG without stimulation had a mean volume from onset of NDO to MCC of 18ml, this increased to 125ml when DGNS was applied at onset of NDO. Results are shown in Tab. 1 and raw CMG traces in Fig. 2 below. No decrease in MDP was found, although two detrusor contractions were suppressed with increasing P_{det} .

Table 1: Standard CMG results. Including volume infused at first detrusor contraction (FDCV), Maximum Cystometric Capacity (MCC) and Maximum Detrusor Pressure (MDP)

Fill	FDCV/ml	MCC/ml	MDP/cmH ₂ O
Control 1	92	109	67
DGNS 45mA	71	196	60
Control 2	95	114	45

Table 2: Diary results including: volume voided expressed as mean ± standard deviation; incontinence events recorded per day expressed as mean; time between CSIC expressed as mean ± standard deviation, calculated excluding overnight periods; ICIQ UI-SF score

	Vol (ml)	Leak/day	Time between CSIC	ICIQ
Control	298 ± 128	3	2hr04 ± 1hr14	14
DGNS	371 ± 112	3	5hr33 ± 2hr20	14

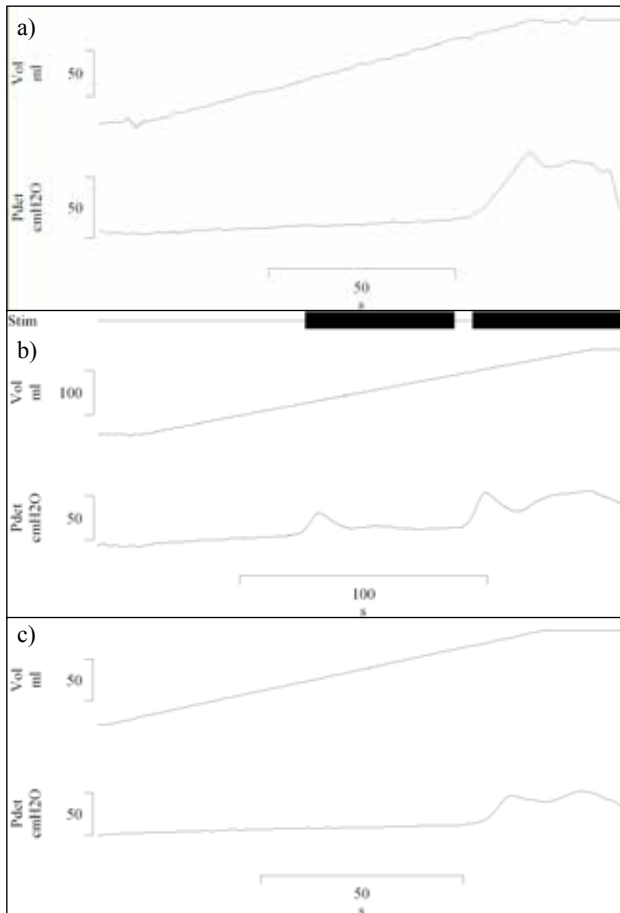


Figure 2. a) Control CMG performed prior to use of stimulation b) DGNS CMG, where stimulation was triggered at a rise in P_{det} for 60 seconds c) Control CMG performed following the with stimulation CMG.

Control week

Recordings were made on 6 days, volume output ranged from 150 to 660ml, mean 298ml. Fluid intake was not recorded. There was a range of 2-5, mean 3, reported episodes of incontinence a day and the ICIQ UI-SF score following this week was 14.

DGNS week

Stimulation amplitude was set to 50mA on the Pace, only 1.25x EAS_{thresh} recorded on the day. DGNS was used on 4 days, with a voiding volume range over this period of 250-600ml, mean 371ml. Fluid intake was not recorded. Reported incontinence events and the ICIQ UI-SF score remained at 3/day (range 2-4) and 14 respectively.

Discussion

The increase in void volume reported here of 73ml, or 25%, is a modest improvement. Acute studies have seen a mean increase of 131 ± 101 ml (62%) [3], whilst previous studies of DGNS use at home have reported increased void volumes of 145ml (72%) [8], and of 12% [10]. There was a large increase in time between voids whilst using DGNS of 3 hours 29 minutes, compared with 42 minutes reported in another case study [8].

Despite the increased volume and time between CSICs the leak event rate and ICIQ score remained unchanged. We know stimulating the pudendal nerve has a limited capacity to suppress ongoing NDO, average number of detrusor contractions suppressed has been 3 [15] and 4 [6]. One contributing factor may be an insufficient amplitude of stimulation, which was set to 1.25 x EAS_{thresh}, below what we consider to be optimal. It may be that the incontinence episodes were offset but not avoided or the case that the participant delayed time between voids for as long as possible, to test the DGNS. As reported by Martens et al. [11], better assessment of the reliability of individual’s sensation as a trigger would be valuable.

Stimulation was tolerated well by the participant and no side effects were reported. Autonomic Dysreflexia (AD) remains a risk for SCI patients, generally it has not been reported [8-10] and sharp rises in blood pressure found during NDO have been decreased previously using DGNS [16]. Symptoms of AD were not reported in the presented case.

The application of surface electrodes to the skin of the penis/clitoris has been problematic in previous reports, understandably. This was not reported as a problem by the participant.

Sensation of bladder activity may be present in a majority of SCI patients, one study reporting partial or totally preserved sensation in 77% of the population tested, including in 67% of the 52 complete SCI patients included [12]. To use non-continuous stimulation in SCI persons with no sensation, it may be possible to delay the onset of NDO, triggering DGNS following a set interval based on a preceding bladder diary so as to cover periods of time where incontinence events occur. This functionality is in the developed system [13].

The system was found to trigger stimulation reliably and to provide an accessible UI for a tetraplegic to trigger stimula-

tion. It is necessary to test the system further and as such further case studies of DGNS are planned. The reported results are, of course, limited as this is a single case study and all measures were self-reported. Patient controlled, transcutaneous DGNS remains an intriguing possibility for treatment.

Acknowledgement

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Effect of Frequency Modulated Magnetic Stimulation on Muscle Atrophy in Rat.

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Abstract: We evaluated the effects of frequency modulated magnetic stimulation on muscle atrophy in animal study. Atrophied hindlimbs were stimulated under constant (20Hz) or modulated (20Hz/5Hz) frequency for two weeks. The weight of tibialis anterior (TA) and the calf isometric muscle strength were measured and compared with non-stimulated and non-atrophy control group. There was no significant difference of the weight of TA between the modulated frequency stimulation and non-atrophy control group. In this study, animal experiments revealed for the first time the effect on the waste atrophic muscle by frequency modulation continuous magnetic stimulation.

Keywords: Frequency Modulated Magnetic Stimulation, Muscle Atrophy, animal study

Introduction

In many patients with upper motor neuron disease, the weak and atrophied muscles cause a difficulty of making useful motion of the limbs and doing activities of daily living. Therapeutic magnetic stimulation has a potential to recover the atrophied muscles, and constant stimulation frequency is usually applied during the stimulation. There is a hypotheses that frequency modulated magnetic stimulation is more effective to atrophied muscles. The purpose of this study is to evaluate the effects of frequency modulated magnetic stimulation on muscle atrophy in animal study.

Methods

Six-weeks-old Male SD rats were suspended by their tail for 3 weeks and their both hindlimbs were unweighted to make their muscles atrophied (Fig.1). They were randomly divided into three groups; 1) 20 Hz stimulation group, 2) 20 Hz/5 Hz modulation stimulation group, and 3) non-stimulation group. In the stimulation group, magnetic stimulation was performed with an external magnetic stimulation device (MagPro R 100 manufactured by MagVenture) for 30 min/day(Fig.2). The stimulation cycle was 5sec ON/5sec OFF. After the 2 weeks of stimulation periods, the tibialis anterior (TA) were surgically removed, and weight and calf isometric muscle strength were measured in each of 4 groups including control group (non-atrophy). Training effect of hindlimb muscle by frequency modulation type continuous magnetic stimulation was verified.

Results

The weight of TA was significantly larger in the non-wasted group than in the 20 Hz group, non-stimulated group, but was not significantly different from the 20 Hz/5 Hz modulated stimulation group (Fig.3). The Calf isometric muscle strength in the non-wasted group was significantly higher than that of the non-stimulated group, and there was no significant difference between

the 20 Hz group and the 20 Hz/5 Hz modulated stimulation group (Fig.4).



Figure 1: Rats were suspended by their tail



Figure 1: External Magnetic Stimulation Device (MagProR 100 manufactured by MagVenture)

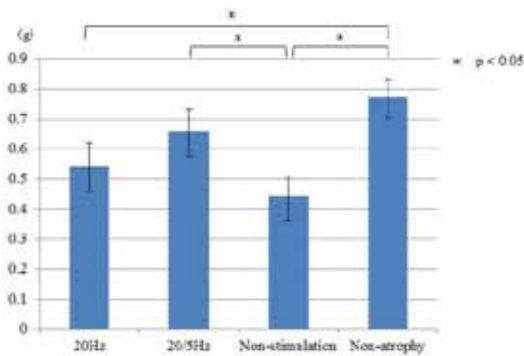


Figure 3: Weight of Tibialis Anterior

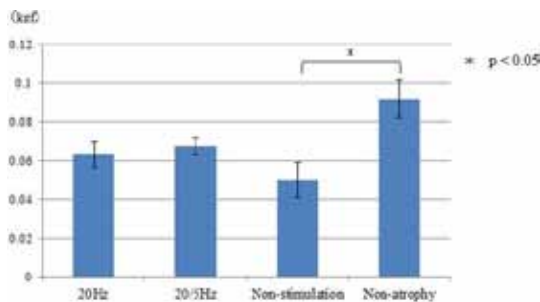


Figure 4: Calf isometric muscle strength

Discussion

Previous reports of magnetic stimulation effect on atrophied or paralyzed muscle were only in the field of constant frequency[1][2]. In this study, animal experiments revealed for the first time the effect on the waste atrophic muscle by frequency modulation continuous magnetic stimulation. For the further study, it is needed to evaluate the possibility of clinical application by additional muscle tissue evaluation.

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LONG-TERM PAIRED ASSOCIATIVE STIMULATION – A NOVEL TREATMENT FOR INCOMPLETE SPINAL CORD INJURY PATIENTS

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Abstract: *Our team has developed and applied to incomplete spinal cord injury patients a novel stimulation protocol called long-term paired associative stimulation (long-term PAS). Consisting of transcranial magnetic stimulation (TMS) and peripheral electrical stimulation (PNS), the protocol is non-invasive and safe (Fig.1). First clinical experiences are promising; we are currently working on further enhancing the effectiveness of the protocol as well as defining patient groups that will benefit the most.*

Keywords: *transcranial magnetic stimulation, paired associative stimulation*

A large proportion of spinal cord injuries (SCI) are incomplete. Even in clinically complete injuries, non-functional connections can still be preserved. Strengthening these residual pathways in incomplete SCI patients through a wide range of non-invasive methods has gained considerable attention in human SCI research.

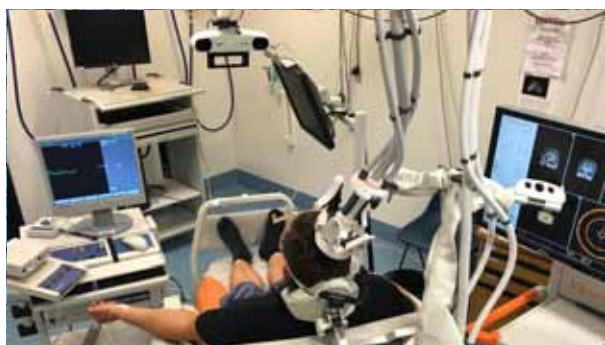


Figure1: PAS setup. TMS (right, eXimia magnetic stimulator, Nexstim Ltd, Helsinki, Finland), electrical stimulation (left, Dantec Keypoint® electroneuromyography device, Natus Medical Incorporated, Pleasanton, CA, USA), as well as the computer with the Presentation® (Neurobehavioral

Systems Inc., Albany, NY, USA) software (in the background).

Long-term potentiation (LTP), depending on the cooperativity and associativity of neuronal activation, is one of the central targets in counteracting the connectivity weakness after neuronal trauma and disease. Indeed, evidence from animal studies indicates that stimulation protocols inducing spike-time-dependent-like plasticity between upper and lower motor neurons are promising tools for strengthening the residual connectivity and promoting motor recovery.

Paired associative stimulation (PAS) is a combination of transcranial magnetic stimulation (TMS) - a safe, non-invasive procedure enabling the activation of a few cm² part of the cortex - with peripheral nerve stimulation (PNS). TMS and PNS activate upper and lower motor neurons in a synchronous manner, strengthening the connections between these neural pools presumably employing the principles of spike-time-dependent plasticity [1].

In healthy individuals, PAS can induce long-term potentiation (LTP)-like plasticity of the corticospinal tract (CST), as indicated by the facilitation of motor-evoked potentials (MEPs; responses to TMS recorded from muscles) in both motor and sensory tracts. PAS-induced MEP potentiation is physiologically relevant, correlating to increase in muscle voluntary force [1].

Although PAS has been extensively studied in healthy humans, until 2016 there have been only two works on PAS in SCI patients from other laboratories, none of them showing the effect of more than one session. Our group has developed novel settings for PAS protocol. Conventional PAS protocols require exact adjustment of TMS and PNS timing, which reduces the clinical feasibility of the protocol: neurophysiological measurements in SCI patients can be challenging. We have developed a robust stimulation protocol which

does not require exact adjustment of the timing and is effective (as indicated by the robust growth of motor-evoked potential amplitudes in healthy subjects after the stimulation [3]) even if performing some neurophysiological measurements is not possible [2,3]. TMS pulses are given at maximum intensity to ensure multiple collisions of pre- and postsynaptic pulses at the spinal cord level. For PNS, we use high-frequency peripheral pulses at minimal intensity required to elicit F-responses to ensure the activation of the motor neurons. Spike-time dependent plasticity (STDP) is dependent on numerous factors: the firing rate, the number of coactive synaptic inputs, the postsynaptic voltage and the timing of the inputs, among others. Importantly for this protocol, it has been shown *in vitro* that spike-timing relationships causing LTP can “win” out over those favoring LTD when multiple interactions occur at the same time [6]; multiple collisions occurring in our protocol most probably explain its robustness.

We were the first ones to successfully apply the novel protocol to incomplete SCI patients as a long-term treatment given over many weeks [4]. We showed the strengthening of lower limb muscles and even the return of some voluntary movement to previously paralyzed ankle muscles in an incomplete chronic paraplegic patient, and the improvement of hand function in an incomplete chronic tetraplegic patient. Since publishing our first report from these patients, the goal of our group has been to further develop the method and increase its efficiency and tolerability.

We are currently testing the method in various SCI patient subgroups (para- and tetraplegic, traumatic [5] and neurological) and both in upper and lower limbs in order to identify the patients that would benefit the most, as well as to elucidate optimal timing and duration of the stimulation. We have delivered PAS at variable treatment times ranging from 4 weeks to over one year to incomplete SCI patients. Stimulation parameters (cortical stimulation site as well as timing TMS and PNS) are individually tailored for each patient [2-5]. The results obtained are presented in the following IFESS 2018 abstracts: Tolmacheva et al, Rodionov et al and Savolainen et al. We have also launched a related translational project in order to study the mechanism of the treatment.

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MINIATURIZED IMPLANTABLE ELECTRICAL STIMULATOR FOR SMALL ANIMALS, PRELIMINARY RESULTS

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Abstract: According to PubMed roughly 10% of the annually added publications are describing findings from the animal model. Half of these studies are done in mice and rats. It can be assumed that there is a need for implantable electrical stimulators which are flexible, reliable and small enough ($\sim 1\text{cm}^3$) that even mice can tolerate it and move freely. The MiniVStim 12A is a battery powered implant with an outer diameter of 15mm and a volume of 1.2cm^3 . It can be preprogrammed according to the experimental protocol and controlled by resetting it with a magnet. It can deliver constant current monophasic pulses up to 2mA and 1ms pulse width. **Keywords:** Implantable stimulators, IPG, in vivo experiments, small animals

Introduction

In vivo basic research is strongly supported by the animal model. In 2016 roughly 1.4 Mio publications were added to Pubmed [1]. Out of this 670000 publications are related to humans (Search term : 2016[dp] AND "humans"[MeSH Terms]) and 210000 are related to animals (search term: 2016[dp] AND "animals"[MeSH Terms:noexp]). Half of the animal related publications deal with mice and rats, making 7.2% of all added publications.

Investigations in the field of muscle physiology, muscle conditioning and related require electrical activation of the target tissue [2], [3], resulting in the need of a reliable electrical stimulation system. Moreover, the availability of genetically engineered mice to study specific diseases might lead to an increased interest in reliable and fault proof stimulators, well tolerated by these small animals.

Two major approaches for implantable stimulators for small animals are found [4]. Battery powered implants on the one hand and externally radio frequency (RF) powered implants on the other. More or less the advantages of one system are the disadvantages of the other. Both systems require implantable electronic components which must be encapsulated in a biocompatible and bio resistive material. Also, both systems require electronic circuitry but RF implants can be typically built with fewer components. So, battery powered implants require, also related to the chosen battery higher volume. Battery size is crucial. In combination with the stimulation protocol it determines the implants lifetime. A battery powered implant does not require external components; the animal can move freely throughout the entire investigation timespan and must not be separated from the other animals during stimulation time. Vice versa, externally powered implants have "infinite lifetime" since there is no battery which drains but require, when

active, a transmission coil close to the implant [5]. This might limit the animal's freedom to move. Alternatively, the coil could be integrated in a special cage [6] but this requires separation of the animal from the others while stimulation is active, and only one animal at the time can be stimulated in such a cage. There are also hygienic issues with the coils attached to the cage and with the other required external components like transmitter electronics, power supply and cables.

With these thoughts in mind, a battery powered stimulation implant, if it is small enough that even mice can tolerate it ($V \sim 1\text{cm}^3$) seems to be a good choice in terms of easy handling and reliability.

To fulfil the different requirements of studies the stimulation protocol must be as flexible as possible in terms of programmable stimulation parameters like pulse width, pulse frequency and stimulation intensity. The flexible deliverance of the stimulation dose over the investigation time, like length of activity periods and rest periods or even continuous stimulation are of importance too.

Methods

The MiniVStim12A implantable stimulator is built around the Microchip (Chandler, AZ, USA) PIC16F1783 microcontroller. This microcontroller has an integrated 8bit Digital-to-Analog converter (DAC), an integrated operational amplifier (OPA), an uncalibrated 31kHz RC Oscillator for low power operation and a calibrated 500kHz RC Oscillator for higher computational performance. Different sleep modes, quick wake up time, the possibility to switch between the oscillator frequencies programmatically and to turn on and off the peripheral components (DAC, OPA) allow the implementation of energy saving strategies within the firmware.

A transistor output stage takes care of generating monophasic constant current stimulation pulses. A decoupling capacitor in series with the electrodes keeps the electrodes DC free.

The duties of an implemented reed switch are twofold. A magnet attached to the implant interrupts power supply and minimizes draining of the battery while the implant is not in use. Bringing the magnet for a short time in proximity of the implant resets the microprocessor. This feature is used to advance in a circular manner through preprogrammed stimulation patterns like Sleep \rightarrow Testing pattern

→ Study protocol pattern → sleep → ... This kind of implant control is not suitable for advancing through a high number of different protocols mainly because there has to be some sort of feedback to confirm the currently active pattern.

The first batch of manufactured implants revealed that from device to device the integrated low power oscillator (31kHz) scatters in a $\pm 10\%$ range from its nominal value. Since all timing parameters are derived from the oscillator they deviate from their nominal value in the same percentage range. When thinking of the pulse width and stimulation frequency in a physiological manner this deviation might not be very crucial. But when looking at the overall stimulation protocol, for instance 23h rest and 1h stimulation the stimulation might occur in a time window of $\pm 2h$ away from the expected onset. This might be impractical when animal monitoring during stimulation is desired. Furthermore, the stimulation time might shift from day to day.

So, we decided to individually calibrate the stimulators during the firmware flashing procedure. (Fig. 1)

The circuit board is connected to the Microchip programming device ICD3 and the Salea (San Francisco, CA, USA) Logic 8 Logic Analyzer. Both manufactures provide dynamic linked libraries (dll) that can be accessed from within Microsoft Visual Studio .net development environment. A custom-built C# application first flashes a very simple firmware into the microprocessor, just producing a rectangular signal on the ICSPDat pin. The logic analyzer evaluates the frequency of the signal. Out of this the actual RC oscillator frequency can be calculated and further, the related microprocessor register values to achieve the desired stimulation parameters are calculated with a parameter variation and optimization algorithm. The calculated values are inserted in the source code of the firmware; the final individual firmware is compiled and finally flashed via ICD3. All data linked to the serial number of the implant are stored in a MySQL database.

Results

The fully encapsulated MiniVStim12A (Fig. 2 right) has a diameter of 15mm, is 7mm thick and has a volume of 1.2cm^3 . Achievable stimulation parameters are: Monophasic, charge balanced constant current rectangular pulses with amplitudes of 0-2mA (8-bit resolution), pulse width from $32\mu\text{s}$ to $820\mu\text{s}$ in steps of $32\mu\text{s}$ and stimulation frequency 0.1-200Hz.

Lifetime strongly depends on the chosen stimulation paradigm. With a CR1220 (35mAh) battery (Fig. 2 left) the lifetime is 200days if every hour a 1s lasting stimulation train



Fig. 1: Setup for calibrating the implantable stimulator
Components: PC with program for semi-automated testing,
Microchip ICD3 flashing device, Salea Logic 8 Logic analyzer

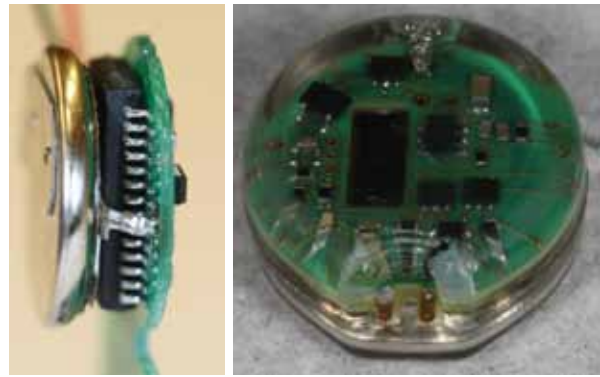


Fig. 2: Circuit board with mounted battery (left)
Encapsulated battery and electronics (right)

is delivered and goes down to 10 days if continuous 20Hz stimulation is applied.

The calibration procedure improved significantly the overall accuracy of the stimulation parameters. All implants from the initial batch with a $\pm 10\%$ deviation from the 31kHz oscillator frequency stayed finally in a $\pm 1\%$ range. The only exception is the pulse width. It is directly derived from the oscillator frequency and cannot be optimized for small pulse width.

Discussion

A small battery powered implantable stimulator that even mice can tolerate was developed. The stimulator receives during the manufacturing process an individually tailored firmware according to the study protocol. Oscillator calibration during the manufacturing process brings stimulation parameter accuracy to a $\pm 1\%$ range. Basic pattern control by magnet kept the handling simple and was well accepted by the users.

Acknowledgement

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Design Rules for a Transcutaneous Capacitive Electrode Array for Functional Electrical Stimulation of Peripheral Nerves

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Keywords: *Wireless transcutaneous capacitive coupling, targeted muscle reinnervation, sensory feedback, implant.*

Introduction

Sensory feedback of artificial limbs helps patients to execute complex motor tasks [1, 2], while increasing the sense of agency and embodiment simultaneously [2]. Herein, the sensory feedback system has to fulfil several requirements, e.g., intuitiveness, robustness, long-term stability and compatibility with the control scheme of the prosthesis. One approach for improving motor control is a procedure called targeted muscle reinnervation (TMR) [3], where remaining nerves from the arm are surgically placed in the chest area. The increased accessibility of the nerves after TMR, provides room for integration of a sensory feedback system. We propose to implant an electrode array for functional electrical stimulation (FES) of afferent nerves in the reinnervation area. To avoid percutaneous cabling, a coupling array is placed under the patient's skin to establish a capacitive-coupled energy and data transfer with the prosthesis. This approach avoids complex implanted electronics, which increases the long-term stability of the system and prevents pressure sores under the prosthesis socket. However, to provide a robust and selective system, it becomes important to evaluate design rules for the coupling arrays such as electrode size, influence of misalignment and minimum pitch of adjacent stimulation channels.

Methods

Various electrodes were used to evaluate the coupling performance through explanted skin in an *in-vitro* setup. The electrodes were made of MP35N embedded in a polymer stack made of 160 μm thick silicone, as substrate layer and Parylene-C as upper layer with a thickness of 10 μm . The electrodes differed in electrode size (3-21 mm) and composition: 1) uncoated, meaning the top Parylene-C layer was removed and 2) coated, where the top layer was intact. The skin under investigation was explanted from healthy patients during a tissue reduction surgery under ethical approval by of the University of Freiburg Medical Centre. Herein, electrodes were placed underneath the skin, representing the inner electrodes, and on top of the skin representing the outer array. Inner, outer electrodes and the skin were fixed in a custom made setup, which allowed alignment as well as a defined mis-

alignment of the outer and inner electrode arrays. Additionally, a second electrode pair (inner and outer electrodes) were placed with a defined pitch to the first electrode pair.

The electrical behaviour of the transmission line through the skin was evaluated using a periodic signal with a frequency sweep, while measuring the electrical response at the inner electrode. Electrodes were exchanged to investigate the influence of different sizes and compositions. The influence of misalignment and the electrical response at an adjacent electrode pair was also investigated.

Results

A model of the frequency dependent energy transmission through human skin was established, reflecting the influence of different electrode pairs varying in electrode size and composition. Furthermore, the electrical response of adjacent electrode pairs as a function of the pitch was evaluated.

Discussion

The present study sets fundamental design rules for a wireless transcutaneous multichannel communication system for FES applications. These preliminary results present as the first steps toward a new implantable device to elicit sensory percept after TMR.

Acknowledgement

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High frequency spinal cord stimulation of expiratory muscle activation: potential new method to restore cough

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Abstract: Lower thoracic spinal cord stimulation (LF-SCS) via disc electrodes has been shown to restore an effective cough in subjects with spinal cord injury (SCI). High stimulus amplitudes and potential activation of pain fibers however, significantly limits this application to high spinal cord injured individuals. The purpose of the present study was to evaluate in animal studies, a novel method of the expiratory muscle activation utilizing high frequency spinal cord stimulation (HF-SCS; 500 Hz). We found that HF-SCS results in the generation of large positive airway pressures (>40 cmH₂O) and peak airflows (>3 l/s) with very low stimulus amplitudes (1 mA). Our findings suggest that HF-SCS may be a useful technique to restore an effective cough in patients with various neuromuscular disorders with intact sensation such as stroke.

Keywords: Cough, respiratory muscles, spinal cord stimulation, rehabilitation

Introduction

Cough is a normal defensive reflex which functions to protect the airway. Cough is automatically triggered by the body's need to expel irritants and mucus from the airway passages. Lack of an effective cough may result in frequent aspiration of material, which could lead to recurrent respiratory tract infections. In patients with a weak or ineffective cough secondary to expiratory weakness or paralysis, such as SCI, stroke, and amyotrophic lateral sclerosis, aspiration often results in the recurrent development of atelectasis and pneumonia, which are major causes of morbidity and mortality. Low-frequency spinal cord stimulation with high stimulus amplitude (LF-SCS; 50 Hz, 15 mA) has been shown to restore an effective cough in patients with SCI resulting in a significant reduction in the incidence of respiratory tract infections [4-9]. However, the high stimulus amplitude requirement cannot be applied in other patient populations due to the stimulation of sensory fibers and development of pain.

Methods

Studies were performed on 9 dogs, anesthetized with pentobarbital sodium (25 mg/kg IV, initially and supplemented with additional doses of 1-2 mg/kg IV as required) and intubated. In all animals, a laminectomy was performed at the T8 level through which the eight-plate

stimulation lead with 4-mm electrode contacts was inserted onto the dorsal epidural surface of the spinal cord and advanced to the T9 level [2-3]. Airway pressure was monitored with a pressure transducer to assess the force of expiratory muscle contraction. HF-SCS was applied after tracheal occlusion, at functional residual capacity (FRC) and also over a wide range of lung volumes (0.3L below to 1.3L above FRC) expressed as the corresponding changes in pre-contractile airway pressure. In a separate maneuver, peak expiratory airflow rate was monitored by use of a heated pneumotachograph after release of airway occlusion once peak airway pressure was achieved during HF-SCS.

Given our previous success the responses to LF-SCS (50Hz, 15mA) with this system were used as our gold standard to which all comparisons were made. Further characterization of neural output from the expiratory motoneuron pools in response to HF-SCS was undertaken by recording single motor unit (SMU) activity from the internal intercostal (12th interspace) and transversus abdominis muscles (middle portion). The effects of single train (0.8s) stimulation (which would result in a single cough effort) and repetitive train (18 trains/min) of HF-SCS (repetitive cough) on SMU firing frequencies were evaluated in the same single animal over an extended period (70s).

Results

The mean peak airflow rates at precontractile airway pressures of -10, 0, and +30 cm H₂O were 0.9 ± 0.3 and 2.1 ± 0.2 and 5.2 ± 0.3 l/s (NS if compared to LF-SCS). Mean airway pressure generation at precontractile airway pressures of -10, 0, and +30 cm H₂O were 49 ± 3 and 62 ± 6 and 96 ± 10 cmH₂O (NS if compared to LF-SCS). Peak firing frequencies of SMU activity of the internal intercostal and transversus abdominis muscles during single train HF-SCS range between 6.8 and 17.6Hz. Peak firing frequencies of SMU during repetitive HF-SCS evaluated in the same single animal over 70s remained unchanged in the same physiologic range.

Discussion

We conclude that: 1) Large airway pressures equivalent to those achieved with LF-SCS (50Hz, 15mA) can be achieved with HF-SCS (500Hz) but with low stimulus amplitude of 1mA requirements over a wide range of lung

volumes, 2) expiratory motoneuron activation via HF-SCS allows processing of the stimulus within the motoneuron pools, resulting in a physiologic pattern of activation, 3) repetitive HF-SCS do not affect a peak firing frequencies of SMU activity. This technique has the potential to be applied in patient populations with intact sensation and who would benefit from restoration of an effective cough.

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Non-Financial Disclosure Statement

Dr. Anthony DiMarco owns patent rights for technology utilized in this research study.

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Minimally Invasive Techniques to Restore Cough in Tetraplegics

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Abstract: Lower thoracic spinal cord stimulation (SCS) via disc electrodes surgically placed via laminotomy incisions has been shown to restore an effective cough in subjects with spinal cord injury (SCI). The purpose of the present study was to evaluate a novel method of the expiratory muscle activation utilizing spinal cord wire leads, which can be implanted with minimally invasive techniques [1]. In 7 subjects supramaximal bipolar SCS at total lung capacity resulted in mean maximum peak airflow rates and airway pressure generation of 7.5 ± 2.0 l/s and 88 ± 11 cmH₂O, respectively. The degree of difficulty in raising secretions improved markedly. All subjects no longer required suctioning nor use any other means of secretion management. Subjects life quality related to respiratory care improved significantly.

Keywords: Cough, respiratory muscles, spinal cord stimulation, rehabilitation

Introduction

Respiratory complications account for significant morbidity and mortality in persons with SCI due to their inability to cough and clear secretions. Consequently, they are dependent upon caregiver assistance for the application of manual suctioning, assisted coughing maneuvers or other methods of airway management. We have recently shown that SCS via disc electrodes surgically placed via laminotomy incisions, is successful method in achieving an effective means of expiratory muscle activation and may restore an effective cough mechanism in subjects with SCI [2-6].

Methods

In 7 SCI subjects (2-37 years post injury), two parallel wire leads, each with two electrode contacts were inserted percutaneously under fluoroscopic guidance into the epidural space and advanced to the T9 and T11 spinal levels. Leads were connected to an implanted radiofrequency receiver (8×5×0.7cm; 20g) positioned subcutaneously over the upper rib cage. Post-implantation, each subject was instructed to apply stimulation every 30s for 5-10min, 2-3times/day and to use the Cough System device as needed for secretion management. Stimulus parameters were set at values resulting in near maximal pressure generation (30-40V, 50Hz, 0.2ms, 0.6s duration). Stimulation was applied by activating a small portable external

transmitter (10×6.5×2.5cm) connected to a rubberized antenna, which was secured to the skin with tape directly over the implanted receiver. The transmitter, powered by a rechargeable battery, delivers a radiofrequency signal to the implanted receiver, which is converted to an electrical signal that is transmitted to the electrodes. Maximum airway pressure generation and peak flow rate were monitored at functional residual capacity (FRC) and total lung capacity (TLC) as an index of expiratory muscle strength. Questionnaires were completed related to the current use of the device (average 1.6±0.3 yrs.), need for other methods of airway clearance, incidence of respiratory tract infections and benefits and complications with use of the Cough System.

Results

Each subject continued to use the device on a regular, daily basis. Mean maximum airway pressure generation and mean peak flow rates during spontaneous efforts were 27 ± 7 cmH₂O and 2.0 ± 0.6 l/s, respectively. Bipolar SCS at FRC resulted in mean airway pressure generation of 70 ± 11 , and peak flow rate of 4.4 ± 0.9 l/s, respectively ($p < 0.05$ compared to spontaneous efforts). Bipolar SCS at TLC resulted in mean airway pressure generation of 88 ± 11 cmH₂O, and peak flow rate of 7.5 ± 2.0 l/s, respectively ($p < 0.05$ compared to spontaneous efforts). Monopolar (T9 only) SCS at FRC resulted in mean airway pressure generation of 56 ± 7 cmH₂O, and peak flow rate of 3.5 ± 1.1 l/s, respectively ($p < 0.05$ compared to spontaneous efforts). Monopolar (T9 only) SCS at TLC resulted in mean airway pressure generation of 68 ± 14 cmH₂O, and peak flow of 4.8 ± 1.7 l/s, respectively ($p < 0.05$ compared to spontaneous efforts). Difficulty in raising sputum improved markedly ($p < 0.01$). The frequency during which cough interfered with daily activities decreased significantly. The incidence of acute respiratory tract infections fell from 3.1 ± 1.1 to 0.2 ± 0.1 events/subject year ($p < 0.02$).

Each subject stated that they were less dyspneic during spontaneous breathing, and that they experienced much greater comfort in raising secretions with use of SCS Cough System. All subjects no longer required suctioning nor use any other means of secretion management. Importantly, all participants also experienced less fear associated with eating and the potential risk of aspiration. Subject life quality related to respiratory care improved

significantly $p < 0.01$). There were no reports of bowel or bladder leakage during SCS.

Discussion

SCS via wire leads, which can be implanted using minimally invasive techniques, may provide a new useful alternative method to restore an effective cough mechanism with 1) lower surgical risk, 2) lower cost, 3) greater patient and physician acceptance compared to previous methods and also, may: 4) facilitate secretion removal, 5) reduces the need for caregiver support, 6) reduces the incidence of respiratory tract infections and 7) improves life quality.

Acknowledgement

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Non-Financial Disclosure Statement

Dr. Anthony DiMarco owns patent rights for technology utilized in this research study.

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FUNCTIONAL ELECTRICAL STIMULATION+HIGH PROTEIN SUPPLEMENTATION MINIMIZE ICU- ASSOCIATED SARCOPENIA

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Abstract: *This is an interim report from an ongoing study testing the hypothesis that adding high protein supplement and NMES can minimize muscle loss of mechanically ventilated patients admitted to ICU. The results confirm that compare to a group provided with ICU standard care, the experimental group lost significantly less muscle volume and CSA in both lower extremities at the end of 14 day stay in the ICU.*

Keywords: *ICU, Sarcopenia, Protein, NMES, Physical Therapy*

Introduction

Older, critically ill patients receiving mechanical ventilation (MV) are more susceptible to ICU-related sarcopenia due to undernutrition, pre-existing comorbidities, and physical deconditioning.[1] This sarcopenia leads to long-term functional impairment and immobility, also known as post-ICU syndrome (PICS). Standard physical therapy (PT) include passive mobility to non-responding patients and active mobility and strengthening exercises once patients respond to commands. Unfortunately, such standard PT fail to slowdown the sarcopenia in MV bed-bound group of patients.[2] Neuromuscular electrical stimulation (NMES) elicits involuntary contraction of targeted muscle groups and can attenuate loss of muscle mass in immobile hospitalized patients.[3] Enhancing nutritional intake with protein supplementation, can improve clinical and functional outcomes in critically ill patients.[4] We report the preliminary results of a study in progress testing the hypothesis that NMES, mobility-based physical therapy (PT) and supplemental nutrition/protein (NMES+PT+HPRO) constituting an experimental group can mitigate lower extremity muscle loss in critically ill mechanically ventilated patients.

Methods

Subjects were randomly assigned to a group that received standardized PT + standard recommended nutrition (control) or to a group receiving standardized PT combined NMES and High Protein supplementation (experimental). The outcome measures in this report were the volume and cross-sectional area (CSA) of the both thighs and legs. These data were assessed by CT on days 0, 7, and 14 and quantified using Medical Image Processing, Analysis & Visualization (MIPAV) software. Right and left lower extremities volume and CSA measurements for each subject were combined to determine total thigh and total leg volumes and CSAs, and the means of the control and experimental groups were compared. PT sessions were conducted 5 x week in both groups. Patients in the experimental group received Whey protein shakes twice daily dosed at 1.75 g/kg. NMES was applied to the quadriceps and dorsiflexor muscles of both lower extremities twice daily (30-minute sessions, 10 session/week) for 14 days or until discharge from the ICU.

Figure 1: Patient receiving NMES



Results

For this report, 15 patients in the control and 16 patients in the experimental groups had CT data at day 7. As a

result of earlier discharge, CT data on day 14 were obtained from control (n=7) and experimental (n=9). The groups percent loss of thigh volume at day 14 was -8.6 ± 8.6 (experimental) and -23.4 ± 13.2 (control) statistically favouring the experimental group ($p=0.028$). Thigh CSA data were -10.8 ± 12.7 (experimental) and -22.9 ± 11.1 (control) nearly reaching significance at $p=0.06$. Loss of leg volume was likewise significantly less ($p=0.047$) in the experimental group (-2.5 ± 14.0) compared to the control (-18.2 ± 12.9). There was no loss of leg CSA in the experimental group (0.4 ± 17.9) compared with significant loss of the control group (-17.5 ± 11.1 , $p=???$).

Older Americans Independence Center NIH Grant
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Discussion

Loss of muscle mass as a result of immobility experienced by patients admitted to ICU is a well-known phenomenon. Without adequate carbohydrate and enhanced protein intake, the recovery of the sarcopenic muscles is likely to be delayed. The reported findings herein support the hypothesis that combining mobility-based physical therapy with high protein (Whey) and NMES is likely to minimize the sarcopenia. However, the results are tentative due to a very small N at day 14, and considerable inter-subject variability reflected in the very large SD. We anticipate enrolling more subjects during 2018 and increase the statistical power of the current findings.

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Long-term paired associative stimulation for incomplete chronic spinal cord injury: physiotherapist perspective

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Long-term paired associative stimulation (PAS) [1] is a novel treatment under investigation for patients with chronic incomplete spinal cord injury (SCI). PAS comprises transcranial magnetic stimulation (TMS) and peripheral electrical nerve stimulation (PNS) given in a synchronous manner in order to induce beneficial plastic changes in human corticospinal tract. I have evaluated all patients participating in PAS-SCI project conducted at Helsinki University Hospital and Validia Rehabilitation Centre before, during and after the treatment. I will present a summary of all patient data obtained by manual muscle testing in this project so far. My presentation complements and summarizes three short talks (Shulga et al, Tolmacheva et al, Rodionov et al) to be presented at IFESS meeting 2018.

I will present the clinical results of the following completed and ongoing projects:

- 1) Pilot work on PAS in SCI [2], n = 2 patients, treatment duration = 12 weeks. Two patients participated in this study. Motor scores of upper limbs of the tetraplegic patient increased and the patient gained ability to grasp. Paraplegic patient regained dorsiflexion and plantarflexion of both lower limbs; these movements were completely absent before stimulation period.
- 2) The effect of PAS on hand motor score of patients with tetraplegia of traumatic origin [3], n = 5 patients, treatment duration = 4 weeks. In all patients, motor scores of the upper limbs increased, and kept increasing also without stimulation during follow-up period. PAS was found to be more effective than PNS alone.

- 3) The effect of PAS on hand motor score of patients with tetraplegia of neurological origin (ongoing work, estimated n = 5-7 patients, treatment duration = 6 weeks, registered at clinicaltrials.gov). Hand motor scores of all patients increased, and kept increasing during the follow-up period.
- 4) The possibilities of PAS to improve motor scores and hand function when applied for as long as improvement is observed (ongoing work, n = 1 patient, treatment duration = 1 year 2 months, registered at clinicaltrials.gov). Hand motor scores and SCIM scores of the patients kept increasing throughout the stimulation period.
- 5) The effect of PAS on leg motor score in tetraplegic patients (ongoing work, estimated n = 5 patients, treatment duration = 8 weeks, registered at clinicaltrials.gov). Leg motor scores and walking improved in the first patients involved in this study.

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Toward a Multi-Channel Wireless System for Electrical Stimulation of Peripheral Nerves: Modelling and Simulation of Signal Transmission

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Keywords: *Simulation, wireless transmission, targeted muscle reinnervation, sensory feedback, implants.*

Introduction

The lack of sensory feedback after limb amputation presents as a critical issue in current prosthesis, limiting the controllability and acceptance of prosthetic devices. Restoring natural sensory feedback via electrical stimulation of the remaining peripheral nerve fibers has been recently demonstrated [1]. Here, we propose an implantable device to be coupled with targeted muscle reinnervation (TMR) [2]. The implant delivers electrical pulses to the reinnervated afferent nerve fibers to elicit sensory percept. Stimulation signals are delivered from the prosthetic limb to the stimulation site without transcutaneous cabling. This is achieved by capacitive coupling through the skin between an outer and an inner electrode array. As the signals travel through the skin, the stimulation pulse shape is deformed by the skin impedance. Thus, understanding the impedance characteristics of human skin under electrical stimulation is crucial for the success of such device. We performed experiments with explanted human skin to model its electrical properties in time and frequency domains. From these models, filters are designed to predict and modify the shape of the external stimulation pulse before sending the signals to the stimulation site.

Methods

An *in-vitro* set up consisted of two electrode arrays placed on each sides of explanted human skin samples from healthy patients in a sandwich configuration was used for this study. The patients signed an informed consent approved by the ethical committee of the University of Freiburg Medical Centre. The skin samples were electrical stimulated using periodic pulses with different frequency ranges, while recording current and voltage during stimulation. These data were used to create an equivalent electrical circuit of the skin samples. From this equivalent circuit, control strategies were used to estimate the pulse shape deformations after traveling through the skin. These estimates were implemented in an inverse model of the skin to find the optimal shape for the external stimulation pulses.

Results

Models of the electrical behaviour of human skin were developed and electrical equivalent circuits were obtained. Using these impedance models of the skin, we derived the deformation imposed on the stimulation pulse shape after transitioning the skin. This allowed the design of filters to pre-shape the external pulses such that the optimum stimulation pattern is achieved at the stimulation site (i.e., afferent nerve fibers).

Discussion

We present efforts toward a wireless multi-channel stimulation framework to elicit sensory percept after TMR. Here, we model and simulate the effects of skin impedance on the shape of the stimulation pulse after being transferred to the stimulation site. We developed strategies to compensate for these alterations such that afferent fibers are stimulated with an optimum pulse shape. Future work include translating and verifying these results during *in-vivo* experiments.

Acknowledgement

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IMPROVEMENT IN OVER ACTIVE BLADDER SYMPTOMS IN PATIENTS USING FUNCTIONAL ELECTRICAL STIMULATION OF THE COMMON PERONEAL NERVE FOR WALKING

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Introduction

Functional Electrical Stimulation (FES) is used to improve walking speed and reduce falls in people with upper motor neurone foot drop. Percutaneous Tibial Nerve Stimulation (PTNS) has been shown to be a safe, clinically and cost-effective treatment for the management of drug refractory overactive bladder (OAB) symptoms in people with neurological disorders.³⁻⁶. The mechanism by which PTNS works to improve OAB remains uncertain.

In our experience some patients report improvement in lower urinary tract (LUT) symptoms after the commencement of FES. The Tibial and CPN's are the terminal branches of the sciatic nerve, both are derived from L4-S3 sharing a common innervation, we therefore hypothesise that stimulation of the CPN may have effects on lower urinary tract (LUT) functions similar to PTNS treatment. We therefore performed this scoping exercise to explore any possible relationship between FES use and changes in OAB symptoms, to inform the design of a future study.

Method

47 consecutive patients attending for set up with FES during a six month period were asked to complete a questionnaire assessing OAB symptoms (the ICIQ-OAB) at baseline and 3 months during their routine appointments. Walking speeds and a Visual Analogue Scale (VAS) of satisfaction with walking were also collected.

Results

Analysis revealed a significant improvement in walking speed at 3 months in the whole cohort ($p < 0.001$) and in MS patients ($p = 0.001$).

Additionally, satisfaction of gait improved significantly in all groups ($p < 0.001$).

There was a significant improvement of the ICIQ-OAB score (a reduction in score indicates an improvement in bladder symptoms) in the MS population over the 3 month period ($p = 0.043$). When individual LUT symptoms were separately analysed, significant improvements were seen in urinary urgency and urge incontinence.

There was a significant negative correlation of moderate strength within the MS cohort between baseline walking speed and the subsequent change in ICIQ-OAB score (correlation coefficient of $r = -0.40$, $p = 0.046$).

With respect to bladder impairment, a significant negative correlation of moderate strength was shown between baseline ICIQ-OAB score and change in score in the whole cohort and within MS patients; (Whole group $r = -0.466$, $p = 0.001$, MS group $r = -0.442$, $p = 0.008$).

Discussion

These results demonstrate a statistically significant improvement in OAB symptoms after 3 months of FES use within the MS patient cohort. The one unit reduction (17%) observed reflects a recognized clinically important difference.¹¹

When individual symptoms of bladder dysfunction were considered, the main areas demonstrating improvement were urinary urgency and urge incontinence. The impact of LUT dysfunction may of course be influenced by improvements in mobility and speed of accessing toileting facilities particularly with regard to incontinence. However it is unlikely that participants would report changes in urgency simply as a result of an orthotic effect on their walking. It would however be invaluable to correlate these findings with urodynamic studies.

A-0012

This is an observational study and has limitations, it does not suggest that FES be used to treat OAB symptoms but it does however for the first time

raise the possibility of FES impacting on OAB symptoms and warrants further investigation.

Gait Rehabilitation with Exercise Assist Robot and functional electrical stimulation (FES) for incomplete paraplegia : a case report

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Abstract:

A 51-year-old female with incomplete paraparesis due to cervical tumor (schwannoma) received combination therapy of gait rehabilitation with exercise assist robot and functional electrical stimulation (FES). During the rehabilitation period, the muscle weakness and gait function gradually improved, and finally the patient could walk alone. The combined use of robot and FES may be useful for the gait rehabilitation of incomplete paraparesis.

Keywords: paraplegia, gait rehabilitation, robot, functional electrical stimulation

Introduction

Both of rehabilitation robot and functional electrical stimulation are useful for neurorehabilitation [1, 2]. The Gait Exercise Rehabilitation Robot (GEAR, TOYOTA, Aichi, Japan; Fig. 1) is cutting edge robotics for gait rehabilitation of patients with hemiplegia mainly due to stroke. It can facilitate early improvement in gait independence [3]. The NESS L300[®] Foot Drop System (L300, Bioness Inc., Valencia, CA; Fig. 2) is worldwide functional electrical stimulation (FES) device for the treatment of foot drop gait. In this report, a case of incomplete paraplegia due to cervical tumor (schwannoma) showed improved muscle weakness and gait function after the combination therapy of robot and FES in gait rehabilitation.

Report of the case

A 51-year-old female with a history of cervical tumor (schwannoma) resection 9 years prior presented with numbness of both upper limbs. Follow up magnetic resonance imaging revealed recurrence of the cervical tumor (Figure 3.); no improvement of her symptoms was observed, thus tumor resection was performed. Histopathological examination indicated a diagnosis of benign schwannoma. After the surgery, cerebrospinal fluid leak from the postoperative wound was occurred, so that duraplasty was performed. Twenty days after the surgery, gait rehabilitation using GEAR and NESS L300 was started 5 days per week. (Fig. 4). GEAR was used on the left side and L300 was used on the right side, because activity of the left proximal muscle was poor compared with the right (Table 1). Conventional physical and occupational therapy were also performed. The total period of

rehabilitation programs was 4 weeks, and the patient wearing a short leg orthosis became to walk with a walker independently. At the final observation of 7 months after surgery, the patient was able to walk alone with mild bilateral lower extremity spasticity.



Figure 1: Gait Exercise Assist Robot (GEAR)



Figure 2: L300[™] foot drop system



Figure 3: MR imaging of the recurrent cervical tumor



Figure4:Gait training with GEAR and L300

Discussion

In this case, combined therapy of gait rehabilitation using GEAR and L300 led to recovery of lower limb muscle strength and recovery of gait function in a patient with incomplete paraparesis due to cervical tumor. Though the patient showed paraparesis with left lower limb dominance, she was able to perform gait rehabilitation by wearing GEAR on the left lower limb and L300 on the right lower limb.

Hirano et al. reported that GEAR was effective for patients with hemiplegia after stroke [3]. The components of the GEAR system include a knee-ankle-foot robot, a low floor treadmill, a safety suspending device (can be used for body weight support), a robot weight support device, a monitor for patient use, and a control panel. The system determines the gait cycle from the pressure sensor and assists the movement of the hip and knee. FES has also been reported to be effective for hemiplegia after stroke [2]. NESS L300™ can assist the contraction of the tibialis anterior muscle during the walking swing phase against the cusp or falling feet, stabilize walking, and prevent falling. In this case, we showed its effectiveness by carrying out rehabilitation using GEAR on the side with more pronounced proximal muscle weakness and L300™ on the other side for a patient with paraparesis. The combined use of GEAR and L300 can be applied for the rehabilitation of patients with hemiplegia and paraparesis.

To verify the effectiveness of this rehabilitation method, it is needed to increase the number of cases treated with this combined therapy and compare it with conventional rehabilitation. Based on this case, we consider that rehabilitation with the combination of GEAR and FES for patients with incomplete paraplegia have a potential for muscle recovery and gait function improvement. For patients with paraplegia with more severe lower limb muscle weakness, further study is necessary.

In conclusion, we report a patient with cervical schwannoma who was rehabilitated using GEAR and the NESS L300™ Foot Drop System. The combined use of GEAR and NESS L300™ may be useful for rehabilitation of incomplete paraparesis.

Table 1. Patient’s clinical progress

	20 days after the surgery	6 weeks after the surgery	Final observation
MMT Iliop	G/G	N/N	N/N
Quad	G/F	N/N	N/N
TA	F/F	N/N	N/N
EHL	F/F	G/G	N/N
Ham	G/G	N/N	N/N
FIM gait	2	6	7
MAS	2	1+	1

MMT, manual muscle test; Iliop, iliopsoas; TA, tibia anterior; EHL, extensor hallucis longus; Ham, hamstrings; FIM, functional independence measure; MAS, modified Ashworth scale

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THE FEASIBILITY OF USING FES TO IMPROVE THE MOBILITY OF PEOPLE WITH PARKINSON'S DISEASE. PRELIMINARY RESULTS FROM THE STEPS STUDY

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Abstract: *The STEPS study (The Effectiveness of Peroneal Nerve Functional Electrical Stimulation (FES) for the Reduction of Bradykinesia in Parkinson's Disease (PD): A Pragmatic Feasibility Study for a Single Blinded Randomised Control Trial (STEPS)) aims gather information to inform the design of a future multi-centre trial to demonstrate the clinical effectiveness of the common peroneal stimulation to improve mobility for people with PD. Feasibility aims include the determination of recruitment and retention rates, acceptability of the protocol and intervention. 64 people with idiopathic PD were recruited over an 18 month period in a 2 centre study giving a recruitment rate of 1.8 per month per centre. 52 participants completed the protocol indicating a retention rate of 81%. Preliminary analysis indicates that 15 out of 23 participants who used FES for 18 weeks experienced a clinically meaningful increase in walking speed that was maintained 4 weeks after the intervention was withdrawn.*

Keywords: FES, Parkinson's disease, Bradikinesia,

Introduction

Functional Electrical Stimulation (FES) is commonly used to correct dropped foot following stroke and multiple sclerosis. The common peroneal nerve is stimulated to cause dorsiflexion in the swing phase of gait, increasing ground clearance and improving gait speed, efficiency and safety. The technique has received less use for people with Parkinson's disease (pwPD). While weakness of the distal muscles of the leg is a common presentation¹, the predominant gait deficits are characterized by bradykinesia (slowness of movement), hypokinesia (reduced movement size), festination (rapid but very short strides) and akinesia (difficulty in initiation of movement leading to freezing in gait). Three small and short term observational studies have investigated the use of FES in people who have walking difficulty due to PD and have shown clinically meaningful improvements in walking speed, freezing and step length^{2,3,4}. In two of these studies the improvements were maintained after the device was subsequently turned off, indicating that FES had had a training effect on gait. These changes were associated

with improved functional walking and reduction in the symptoms of PD. Participants in these studies have reported that the intervention had a useful impact on their daily lives and it was an intervention that they may choose to use as a long term mobility aid.

To fully demonstrate the benefits of FES in PD a well-designed randomised control trial is required. However, before such a study can be designed, additional information is needed. This feasibility study aimed to determine recruitment, willingness to be randomised and loss-to-follow-up rates in order to power a future study. Additionally we aimed to determine the appropriate outcome measures and methods of data collection, to evaluate the effectiveness and cost-effectiveness of FES in a standard clinical setting. In order to obtain a realistic estimate of probable loss-to-follow-up rate, the feasibility study follows the design we envisage for the subsequent full RCT.

Method

The study aimed to recruit 68 people with gait deficit due to idiopathic PD. A gait deficit was defined as a self-selected brisk walking speed of less than 1.25 ms⁻¹, reduced dorsiflexion or eversion in the swing phase of gait, festination (short rapid steps) or akinesia (freezing). The other selection criteria were; over 18 years of age, a Hoehn and Yahr score of between I and IV, able to walk more than 10m, able to stand from sitting without assistance, able to understand and comply with the study procedures and to be medically stable. Exclusion criteria were; epilepsy, pacemaker, pregnancy, significant comorbidity, injury to the common peroneal nerve, malignancy or dermatological conditions in the area of the electrodes and other treatment other than standard drug therapy (deep brain stimulation, duodopa, apomorphine).

Participants were recruited at 2 centres; Salisbury District Hospital and the National Hospital for Neurology and Neurosurgery (London). Potential participants were identified by medical consultants or PD nurses and offered a study information sheet. If they expressed an interest in the study they were assessed at a screening clinic either at the same appointment (London) or at a separate appoint-

ment (Salisbury). Additional information sheets were sent to pwPD who contacted the study following publicity in the local media and Parkinson’s UK website.

Recruited participants were invited to attend a baseline (week 0) appointment. After all assessments had been completed the participants were randomly allocated to one of two groups.

- Group 1 (control group) received usual care.
- Group 2 (FES) received FES in addition to their usual care.

The standard clinical application protocol⁵ established for the provision of FES in stroke and MS was followed for Group 2. They were taught to use the device over two 1 hour clinic appointments in the same week and followed up at 6 and 18 weeks, at which point the stimulator was returned to the clinic. Both groups were assessed at weeks 0, 6, 18 and 22, by an assessor blinded to the group allocation. All outcome measures were taken in the ‘on state’ of PD and without FES.

While it was not the aim of this feasibility study to assess the efficacy of FES, it was necessary to evaluate the proposed outcome measures for the subsequent study. The following outcomes were assessed:

- Bradykinesia (walking speed over 10m walk test (10mwt) with an additional 1m before and after. Participants were instructed to walk “briskly but safely”).
- Hypokinesia (step length in the 10mwt)
- Akinesia (new freezing of gait (N-FOG) questionnaire)
- PD motor symptoms and activities of daily living (Unified Parkinson’s Disease Rating Scale)
- PD relate quality of life (PDQ39 quality of life scale)
- Non disease specific Quality of life (EuroQol 5 dimension 5 level (EQ-5D-5L) quality of life scale)
- Falls (Falls diary)
- Fear of falling (Falls Efficacy Scale- international (FES-I))

- Balance (Mini-BESTest (Mini Balance Evaluation Systems Test))
- Resource use (Custom questionnaire of health related resource use for an economic evaluation)
- Opinions of study participants regarding the study design, FES and most important outcome measures (semi-structured interviews)

Results

158 pwPD expressed interest in participating in the study after receiving and information sheet. Following screening, 64 participants were recruited over a period of 18 months from the two centres, giving a recruitment rate of 1.8 participants per month, per centre. The principle reasons for exclusion were walking too fast ($>1.25\text{ms}^{-1}$) (40), did not meet other selection criteria (19), did not want to be randomised (2), personal reasons (5), did not want to travel (4), concern over commitment to the study protocol (3), not interested in the study (7), non-confirmed diagnosis of idiopathic PD (4) and did not want FES (1).

The mean age of those recruited was 70.4 sd 8.3 years and the mean time since diagnosis was 9.1 sd 5.1 years. There were 44 male and 20 female participants, which is line with the gender prevalence of PD. Seven participants had a Hoehn and Yahr score of I, 33 a score of II, 20 a score of III and 4 a score of IV. Twelve participants, 7 from group 1 and 5 from group 2 withdrew from the study giving a completion rate of 81%. The reasons for withdrawal were for Group 1; medication induced psychosis (1), non-adherence to assessment schedule (2), non-related medical complications (2), personal reasons (1), and for Group 2; medication induced psychosis (1), FES device to fiddly to use (1), Increased PD symptoms (1), did not tolerate sensation of FES (1), personal reasons (1).

Stimulation was applied using an ODFS[®] Pace. The median stimulation parameters were; rising ramp 150ms, extension 150ms, falling ramp 50ms, frequency 40Hz and

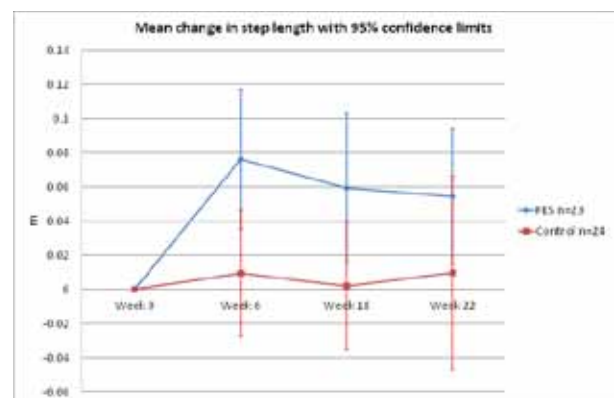


Figure 1. Mean change in walking speed relative to baseline (week 0) with 95% confidence limits.

Figure 2. Mean change in step length relative to baseline (week 0) with 95% confidence limits. FES was withdrawn at week 18. All measurements taken without FES.

a symmetrical waveform. The intensity was set to produce a comfortable level of dorsiflexion and eversion (median 40mA, range 24 to 86mA). In most cases the electrodes were placed on the head fibula and motor point of the tibialis anterior except for 2 participants who used a popliteal fossa position for the common peroneal nerve. In the later cases the position was chosen because of oedema.

At the time of writing not all the results of the study are available so it is not possible to present a full analysis of the outcome measures. However initial analysis of 47 (Group 1 n=24, Group 2 n=23) participants who completed the 10mWT indicates that 15 group 2 participants achieved a substantial clinically meaningful increase⁶ in walking speed of 0.1ms⁻¹ while 5 achieved this in Group 1. Additionally Group 2 demonstrated an increase in step length that was not seen in Group 1. These results are summarised in figures 1 and 2. (Full results from STEPS will be available for IFESS conference)

Discussion

Preliminary results from the STEPS study indicate the feasibility of recruiting and retaining sufficient participants to complete a larger study and provides information that will determine the number of study sites for that study. Nevertheless the extensive list of assessment and the time that is required (90 to 150 min) for each assessment session may have had some impact of study recruitment and retention, suggesting that a reduced number of assessments may be advisable for any future study. There was some evidence of reluctance to be randomised and disappointment at group allocation may be a factor leading to the withdrawal of three of the Group 1 non-completers. Overall the device was well tolerated by the majority of participants although two participants withdrew from the study due to device related issues.

It is encouraging that initial analysis of walking speed and step length indicate a clinically meaningful training effect from FES and that this effect is maintained for 4 week after the intervention is removed. In conclusion, preliminary analysis of the STEPS study supports the design and execution of a fully powered efficacy study for the use of common peroneal stimulation to assist the mobility of people with Parkinson's disease.

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The ODFS[®] Pace was supplied by Odstock Medical Limited (UK). Electrodes were Uni-Patch 51x51mm from Covidien (USA).

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FUNCTIONAL ELECTRICAL STIMULATION ASSISTED SWIMMING FOR PARAPLEGICS

22. Annual IFESS Conference

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Abstract: A new method for functional electrical stimulation (FES) assisted swimming has been developed. This includes the development of waterproof electrodes, cables, and a stimulator. In preliminary experiments, an extension and flexion movement of the knee could be induced for a complete paralyzed subject. Furthermore, the developed setting stayed safe and dry during several sessions. To investigate the overall benefit of FES assisted swimming a pilot study was designed which started in 2018. During this study, up to ten complete paraplegic subjects shall be trained to swim with FES assisted leg movement while swimming speed and heart rate are compared to swimming without FES-support. Additionally, the effects of the training on spasticity, the well-being, and the usability of the technology shall be assessed.

Keywords: FES, Swimming, paraplegic

Introduction

A spinal cord injury (SCI) is often associated with paralysis of the lower extremities which means a severe restriction of physical activity and health for the affected subjects. Depending on the level and severity of the injury, this involves a functional limitation of various body sensory and motor functions below the level of lesion. In case of a traumatic SCI, the physical inactivity is in stark contrast to the condition prior to the injury, especially for young patients.

Participation in physical and therapeutic activities following a paraplegia is often limited due to the loss of voluntary motor function and inefficient temperature regulation of the affected extremities, autonomic dysfunction, and early muscle fatigue. In addition, often specially adapted equipment and assistants are needed. Despite all these obstacles, sportive and therapeutic activity after paraplegia can contribute to a reduction in concomitant diseases and to an increase in the emotional well-being of those affected [1, 2].

In the majority of cases, paraplegia results in complete or incomplete paralysis of the lower extremities. Therefore, effective and safe lower extremity training is limited and training exercises of the upper extremities are recommended such as arm-crank ergometer, wheelchair ergometer

or swimming. All these exercises can improve physical fitness by up to 25 % with regular exercises [3]. Mobility in the water is often the only experience of unaided body movement (except for the transfer in and from the pool) within the environment that most paralyzed patients enjoy. In addition, there is a plurality of therapeutic effects described in the literature as an increase of muscle strength, improved coordination, reduction of spasticity and a reduction of contractures [4].

Functional electrical stimulation (FES) is used successfully in FES cycling or rowing [5, 6]. The corresponding muscles for knee extension and flexion or hip extension and flexion are stimulated depending on the crank or joint angle during cycling or triggered by a pull switch while rowing. Due to the combination of arm and leg training, a significantly higher training effect can be achieved. In addition, an improvement in perfusion and lower limb bone density has been observed in some studies [5]. In this paper, we want to present our recent work on the combination of FES assisted swimming in paraplegic patients.

Methods

During the relearn phase of swimming for paraplegics, the independence in the water is first achieved on the back since the prone position is more difficult to maintain without muscle power at the hip joints. Furthermore, symmetrical strokes are taught initially by the swimming instructor during the relearn phase, because asymmetrical swimming techniques cause the paralyzed limbs to roll and the patient finds it difficult in maintaining a straight course [4].

Afterward, there are several possible swimming techniques for paraplegics with slight modifications compared to non-paralyzed subjects. For patients with thoracic or lumbar lesion height [4] recommends backstroke, breaststroke, crawl stroke and butterfly stroke in which the butterfly stroke is the most difficult to learn.

For normal breaststroke in unimpaired subjects, the so-called frog kick is used as leg technique, which includes knee flexors and extensors, thigh adductors and abductors, gluteus and the plantar-flexors. In preliminary tests, we found out that a complex movement like the frog kick is

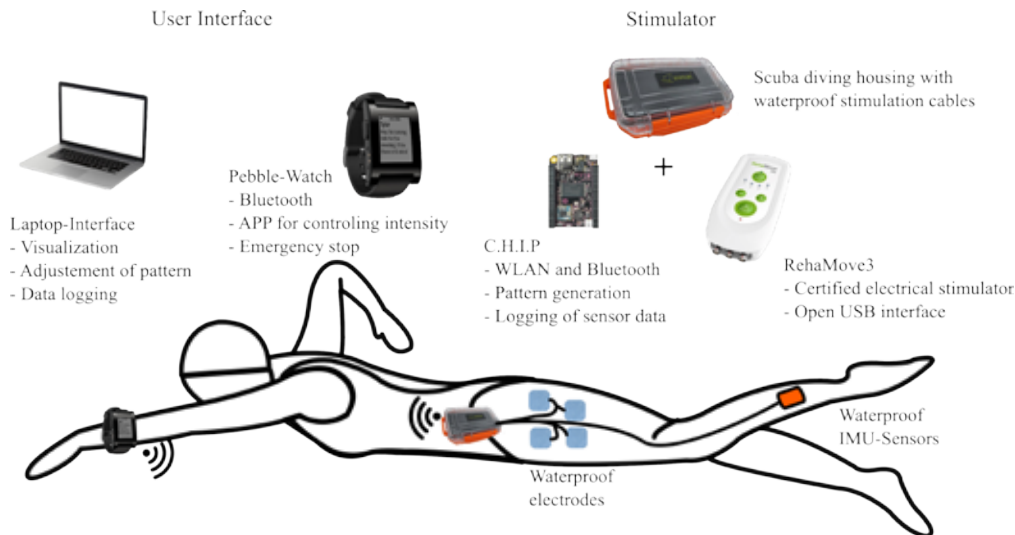


Figure 1: Experimental FES swimming setting including the waterproof stimulator (Hasomed RehaMove3, CHIP embedded PC, scuba diving housing) the user interface (Pebble I smartwatch, Laptop), waterproof IMU sensors and waterproof electrodes.

not realizable with FES. For backstroke and crawl, the so-called flutter kick can be used for the lower legs with FES support. For this technique, the knee extensors and flexors and the gluteus are mostly involved. In [7, 8] the knee angle course for healthy non-expert swimmers for crawl is analyzed. Here, after a short and strong extension phase, a plateau phase can be observed where the knee joint is fully extended. During the plateau phase, the other knee is flexed until 40-50 degrees and then directly extended until the plateau phase. To reproduce this movement for paraplegic patients a periodic stimulation pattern is used which is shown in Fig 3. The pulse width is kept constant at a level of 300-400 μs while the current amplitude of the biphasic pulses is ramped on and off.

To our best knowledge, there is no study or work on FES in water to produce a functional movement. There are several works on Iontophoresis for the transdermal delivery of pharmaceuticals using low DC currents. Furthermore, in [9] waterproof surface EMG electrodes are used to compare EMG signals on land and in water. Here, standard EMG electrodes are fixed and waterproofed using 3M Tegaderm as a waterproof oversize backing. Due to the fact that chlorinated water in swimming pools has a conductance of 2.5-3 mS/cm which results in resistance of 333-400 Ohm a direct stimulation with non-waterproof electrodes would produce a parasitic short circuit between electrodes during stimulation.

Therefore, Axelgaard Manufacturing developed a waterproof electrode with a snap connector which stays waterproof over at least 30 minutes (see Fig. 4). To fix the snap connector a 3M Tegaderm adhesive has been used. In tests with healthy subjects, it has been shown that the connection between cable and electrode must be waterproof as well. Therefore, a tight silicone tube is used as a cover for the connection between electrode and cable.

During preliminary tests for the STIMSWIM pilot study, an experimental FES swimming setting was developed (Fig.1). For the stimulator, the RehaMove3 (Hasomed GmbH, Ger-

many) is used in combination with a wireless embedded PC which executes the stimulation pattern and collects sensor measurements. The stimulation is controlled via a Kivy App running on a standard laptop. In the water, the subject can control the stimulation via a customized smartwatch App.

Preliminary experimental results

To find the best swimming technique and stimulation setting several preliminary tests have been executed with one paraplegic subject under medical supervision of the Unfallkrankenhaus Berlin¹. The participant gave written informed consent.

The stimulation of the gluteus was excluded due to the fact that it is not possible to place the electrodes on a paraplegic without help. Furthermore, the hip position of a paraplegic in backstroke swimming technique depends on the level of control over the waist and hip. In preliminary tests, we found out that the lower the hip the less propulsion which can be achieved by stimulating the knee flexors and extensors. As a result crawl stroke was decided to be used in combination with FES for the planned study. Furthermore, during tests with floats at the ankle a default upward movement of the ankle could be observed for crawl stroke which results in a more streamlined position in the water. In Fig. 4 three photos in the sagittal plane are displayed which show the different states of the stimulation. During this test, the subject was asked not to swim with his arms to get a stable position. During the trial underwater video data has been captured using a waterproof GoPro action camera. Using the video data the left knee angle was tracked as shown in Fig. 3 using the video processing software Kinovea. Compared to [7, 8] the plateau phase of the knee

¹Ethical approval of Berlin Chamber of Physicians Eth-28/17

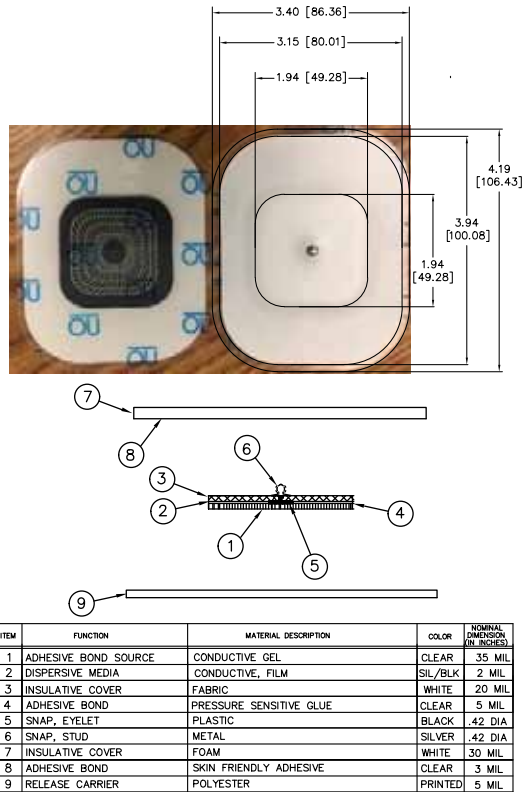


Figure 2: Photo and construction plan of Axelgaard Ultrastim® snap electrode with oversize water fast backing with an electrode area of 22.9 cm² [10, 11]

angle after the full extension is reduced. Due to the missing arm movement, the knee moves automatically to the rest angle of 90 degree. During swimming with arms knee angle tracking was not possible due to the swimming speed and role movement of the trunk. Furthermore, the reached minimum flexion angles are 20 degrees higher compared to non-paralyzed swimmers. The stimulation setting including the stimulator, cables, and electrodes stayed dry over the full trial duration of 30 minutes. We found out that the synchronization of the knee extension with the contralateral elbow extension in the case of crawl stroke is needed to increase the swimming speed and effectiveness. Furthermore, if the arm movement is synchronized to the leg movement then the rolling of the body around the longitudinal axis is minimized. Therefore, we plan for the next trials to sense the arm motion by an inertial sensor to control the stimulation of the leg, or to provide a sensory stimulation to the swimmer to inform him/her about the movement of the stimulated leg as biofeedback. In addition, the influence of the Hamstring stimulation was rated quite low compared to the propulsion produced by the Quadriceps only. Therefore, for the planned study either quadriceps only or the combination of quadriceps and hamstrings shall be stimulated.

The STIMSWIM pilot study

The STIMSWIM pilot study shall investigate the technical feasibility of FES to support swimming motions by the legs

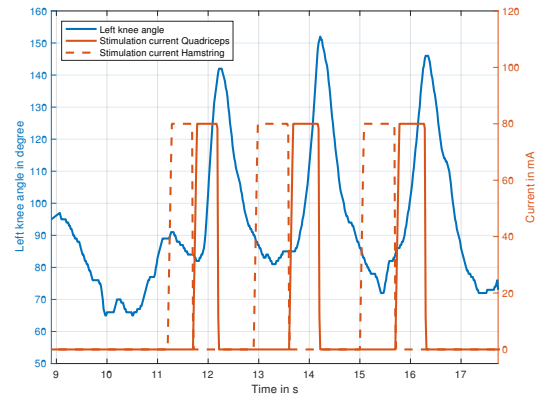


Figure 3: Left knee angle for three consecutive strokes during stimulation of the Quadriceps and Hamstring muscle group.

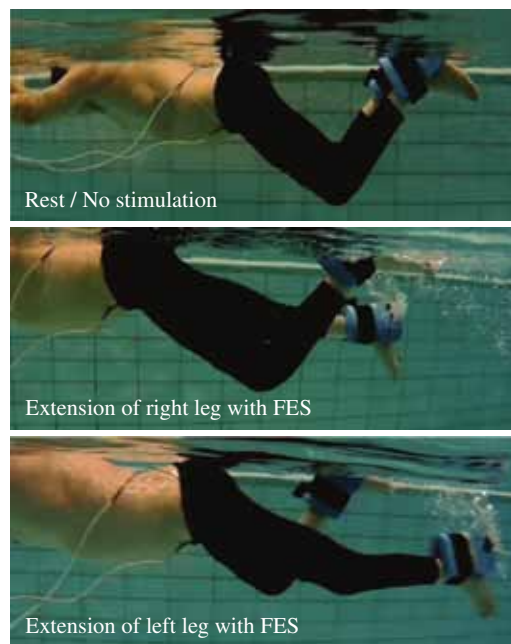


Figure 4: Experiment with a paraplegic subject (Th5, ASIA scale A) with floats at the feet with asynchronous stimulation of the left and right quadriceps and hamstrings.

in up to 10 subjects with complete paralysis of the lower extremities after spinal trauma. The subjects have to be over 18 years and must give written informed consent. There are three main questions which shall be answered within this trial. Does the swimming speed increase compared to non-assisted swimming? 2. Does the general well-being of the subject improve during the trial? 3. How is the acceptance of the technology by the user? The trial comprises of a land and a swimming phase. After the recruitment and initial assessment, the subject is asked to carry out a four-week FES cycling training. During the land training, he/she is asked to train at least three times a week for 30 minutes with a standard RehaMove FES cycling ergometer. At the beginning and end of this training phase, the thigh diameter and maximum cycling power are assessed. This preliminary FES cycling training is needed to build up a defined baseline for the swimming trial. During the swimming phase, the

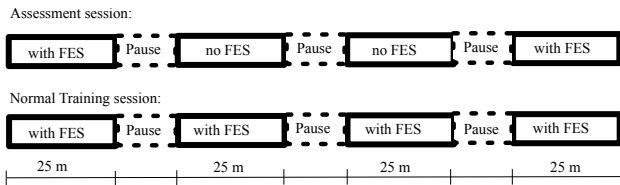


Figure 5: Comparison of assessment and training session. For each assessment session, the subject shall swim the same distance while the time needed is measured. The distance of each swimming trial will be fixed to 25 m.

FES cycling shall be reduced to two times a week.

Table 1: Trial plan for the swim training during the STIMSWIM study. A means training with FES and B without.

ID	Time after assessment	Assessment
T0	Four weeks after recruitment/assessment and FES cycling training (3 times a week)	Execution of Modified Ashworth Scale Test, Measurement of swim distance and speed with and without FES (ABBA)
T1	After 4-6 training sessions (maximum 30 days after last assessment)	Execution of Modified Ashworth Scale Test, Measurement of swim distance and speed with and without FES (ABBA)
T2	After 8-12 training sessions (maximum 30 days after last assessment)	Execution of Modified Ashworth Scale Test, Measurement of swim distance and speed with and without FES (ABBA)
T3	After 12-18 training sessions (maximum 30 days after last assessment)	Execution of Modified Ashworth Scale Test, Measurement of swim distance and speed with and without FES (ABBA)

Afterward, the swimming training starts which follows the trial protocol shown in Tab.1. The swimming assessment consist of a strict ABBA pattern to eliminate the effect of fatigue. Furthermore, the swimming trials of an assessment session either with FES or without are separated by a five-minute pause. In between the assessment, the subjects shall train with FES only in four separate training blocks as shown in Fig. 5. The training is supervised by a pool attendant to eliminate the risk of severe events. At the beginning and end of each assessment, the spasticity shall be specified using the Modified Ashworth Scale test. Furthermore, the subject is asked to fill in a questionnaire about his/her well-being and the usability of the FES swimming training. At the moment 3 subjects could be recruited and we started the FES cycling training. The study shall be finalized by the end of this year.

Discussion

A new concept for FES assisted swimming for paraplegics was proposed which uses a waterproof stimulator and electrodes to produce a swimming movement of the paralyzed legs. During experiments, a periodic FES induced extension and flexion of the knee could be shown which produced a

propulsion movement in the water. To assess the improvement in speed, swimming distance and well-being a pilot trial was set up. If it is possible to show that an effective swimming training including the paralyzed legs can be realized a completely new aqua therapy for paraplegics can be built up. In addition, the stimulation could also be used recreationally by paraplegics for diving. Furthermore, it is conceivable that not only complete paraplegic patients but also incomplete paraplegic patients or stroke patients could benefit from an FES-assisted gait therapy in water. An improvement in physical functions and walking ability in manual underwater training has been shown in several studies [12, 13].

Acknowledgment

We would like to acknowledge Axelgaard Manufacturing Co., Ltd., USA for developing, producing and donating the stimulation electrodes. Furthermore, we would like to thank all participants and partners in the STIMSWIM clinical trial for their support and commitment.

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Wearable Electronic Sleeve for Muscle Stimulation

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Abstract: Functional electrical stimulation (FES) is increasingly being used in upper limb rehabilitation post stroke, however comfort and ease of donning/doffing can limit uptake. This paper presents research into a user-friendly electronic sleeve (e-sleeve) for wearable FES application developed through co-design with end users. The properties, fabrication, and the designed structure of the e-sleeve, were assessed and refined through iterative interaction with end users. Different electrode array layouts were fabricated to optimise the user experience. The e-sleeve uses dry electrodes to facilitate ease of application and the electrodes can survive bending a sufficient number of times to ensure an acceptable usage lifetime. A cleaning method has been identified to enable reuse of the e-textile after contamination. The application of the e-sleeve has been demonstrated via muscle stimulation on the upper limb to achieve functional tasks (e.g. hand opening, pointing).

Keywords: FES, wearable, electrode, e-sleeve, stroke rehabilitation

Introduction

Stroke and other neurological disorders (e.g. Parkinson's, Multiple Sclerosis) can result in significant difficulty in using the arm and hand. Many stroke survivors need assistance with everyday arm-related tasks, which impacts on their quality of life [1,2]. Intensive, repetitive, task-oriented training has been shown to be beneficial for arm rehabilitation [1] and this can be delivered through functional electrical stimulation (FES).

FES is applied via electrodes on the skin which electrically stimulate the underlying nerves. This contracts the muscle allowing the person to practice specific movements that can be altered by an appropriate selection of the stimulation pattern.

However, there are a number of barriers to using FES, which limit stroke survivors' use of this technology. For example, current commercial FES devices use large electrodes resulting in simple and imprecise movements and fast fatigue. The wet gel electrodes are difficult to use as they are very sticky. They are not suitable for long term use due to the ease of contamination, deterioration and drying out [3].

Aiming to improve the user experience, this research has developed an easy to use e-sleeve with integrated dry electrode array that is printed directly onto the fabric, allowing

the selection of the optimised muscle groups for muscle exercises. The e-sleeve development forms part of the UK Medical Research Council (MRC) funded SMARTmove project (www.smartmove.soton.ac.uk). The ultimate goal is to develop an efficacious training system that can be used both at home and in clinic centres for stroke rehabilitation.

Methods

Fabric electrode array fabrication: Screen printing is a well-established and cost-effective fabrication method in both the textile and printed electronics industries. It enables the versatile layout of designs. The electrode array was fabricated by printing bespoke functional pastes using the DEK248 semi-automatic screen printer shown in Figure 1.

The electrode array consists of four printed functional layers printed in sequence:

- 1) An interface layer to provide a smooth surface on the fabric for subsequent printing;
- 2) A silver layer to form conductive pads and interconnects;
- 3) An encapsulation layer over the interconnects to provide protection and electrical insulation;
- 4) A carbon loaded silicone rubber layer over the conductive pads to form a good electrical and mechanical connection to the skin.

A more detailed description of the fabrication process is available in a previous publication [4].



Figure 1. DEK 248 screen printer used in this work

Electrode durability test: Clothing experiences rigorous bending during everyday usage especially during donning and doffing so it is important that any wearable electronics should survive these processes. To simulate this, bending durability was assessed by flexing the electrode array on a

10 mm radius for 600 cycles using the bespoke equipment shown in Figure 2.



Figure 2. Bending test equipment

In addition to bending, an appropriate cleaning method for the e-sleeve is also required to remove any contamination and bacteria built up during wearing. To evaluate contamination, the electrode arrays were worn for 45 minutes, twice a day, for 5 days. The bacterial level without and with cleaning was assessed using the following process:

- 1) Electrodes were placed in a sterile tube containing PBS (Oxoid) and autoclaved glass beads.
- 2) The tubes were vortex mixed for 2 minutes to remove any attached bacteria.
- 3) Aliquots of 50 μ l were spread over tryptone soya agar (TSA, Oxoid) plates.
- 4) Agar plates were incubated at 37°C, overnight, before colonies were counted.

Three types of wipe were compared: 5% SQ53 [5], Huggies Baby Wipes and Wet Ones Wipes.

E-sleeve design: It is important that the final design of the e-sleeve meets the needs of the users. For example, for stroke survivors, the garment must be easy to don and doff using a single hand to enable independent use. Therefore, different garment designs including a short and long cylindrical sleeve and a T-shirt configuration were assessed by the end user group (EUG) consisting of a total of 10 stroke survivors and carers. A ready-made cylindrical sleeve may simply be pulled on by the user. However, Velcro and zip approaches may also be used to assemble the sleeve on the arm. These alternative approaches were evaluated by the EUG group. Therefore, an optimised design was achieved through interaction with the EUG.

Muscle stimulation test: The FES training system includes an electronic control system, the fabric electrode array sleeve and a movement sensor. Figure 3 shows the targeted usage scenario for the stroke survivors. The movement produced by 24 individual electrode array elements (see Fig 4) was recorded at the beginning of each training session. The movement sensor then records the initial and final position for each target gesture (e.g. hand opening, pointing). The control system calculates the optimised

combination of the electrode array elements to achieve the targeted movement.



Figure 3. FES training system

Results and Discussion

Fabric electrode array fabrication: The printed samples, after printing each of the functional layer(s), are shown in Figure 4. The fabric electrode array maintains good breathability and flexibility as the materials are only printed on the areas where necessary, rather than all over the fabric. In addition to the electrode layer shown in Figure 4, three different layouts of the electrode layer (Figure 5) were also printed for evaluation of user comfort during stimulation.

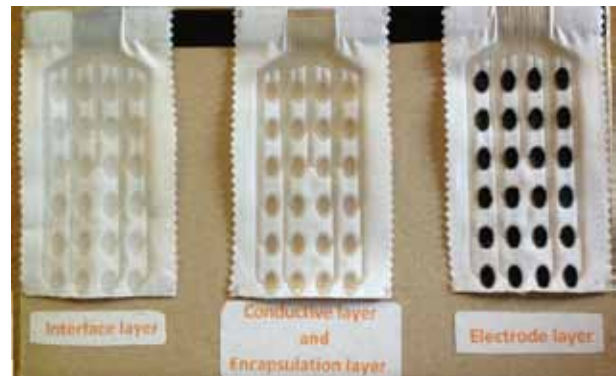


Figure 4. Fabric electrode array printing stages

The user can become uncomfortable as the electrical stimulation increases in intensity. In this study, the users comfort increases going from the electrode arrays in Figure 4 (right) to Figure 5 (left); and increases further from Figure 5 (left) to Figure 5 (right). Figure 4 (right) is the least comfortable during stimulation and Figure 5 (right) the most comfortable. However, there was no discernible difference between Figure 5 (left) and Figure 5 (middle). Although Figure 5 (right) offers the highest comfort during stimulation, the breathability is poorer because the fabric has increased coverage by the non-breathable electrode material. Therefore, this design may cause the user discomfort in terms of breathability of the skin. The range of electrode array designs may be used to accommodate the needs of the different end users who may exhibit individual pain thresholds.

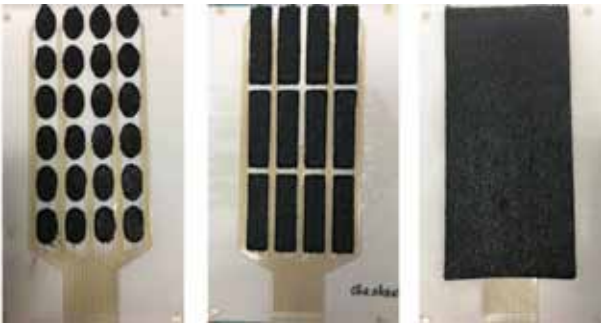


Figure 5. Alternative top electrode layouts

Electrode durability test: The electrode array shows good durability to bending as there was no visible damage after 600 bending cycles and the resistance between the bottom conductive silver track and the carbon electrode did not change.

This work also evaluated the bacteria of the electrode array with and without wiping after wearing for 5 days. The results show that low numbers of bacteria colonies were visible and the bacteria were cleaned by wiping (Figure 6). All three types of wipe worked very well, showing similar results.



Figure 6. Bacteria with and without wiping (5% SQ53 wipe).

E-sleeve design: The EUG preferred a sleeve to a T-shirt as they did not want the FES integrated into their everyday clothing. The sleeve can be worn under a long-sleeve garment or even with a T-Shirt. When they were asked their preference between two short sleeves (one for the forearm and one for the upper arm) and one single long sleeve covering the whole arm: 4 people chose the short sleeves, 5 people chose the long sleeve and 1 person had no preference.

Three types of sleeve assembly methods (zip, Velcro, pull-on) were also assessed by the stroke survivors and carers. All the participants preferred the pull on design. The zip design is difficult to put on using a single hand and the Velcro design is difficult to align consistently. The pull-on design with integrated electrode array e-sleeve is shown in Figure 7.



Figure 7. E-sleeve with left end peeled back to reveal the electrodes

Muscle stimulation test: Initial functional tests of the e-sleeve were performed on eight unimpaired participants who were instructed to provide no voluntary movement. The electrode array on the e-sleeve was positioned to cover the muscles shown in Figure 8.

Table 1 shows the joint tracking error achieved with each test subject in each of the two selected poses. Examples of the electrode usage to achieve hand opening and pointing are shown in Figure 9. The 24 electrode array elements are shaded according to the level of stimulation applied to each, with darker colours indicating greater levels of stimulation. Black indicates the maximum specified pulse width has been reached; it was 35 μ s in this study.

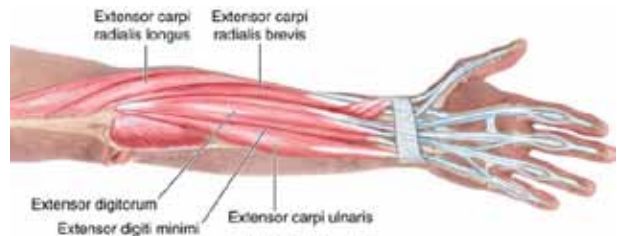


Figure 8. Muscles covered by the electrode array

Table 1. Joint tracking error for targeted movements

Subject	Hand opening	Pointing
1	2.6%	7.9%
2	2.7%	4.4%
3	5.4%	7.2%
4	1.03%	14.7%
5	8.1%	12.5%
6	8.9%	9.6%
7	8.3%	9.3%
8	10.2%	12.7%

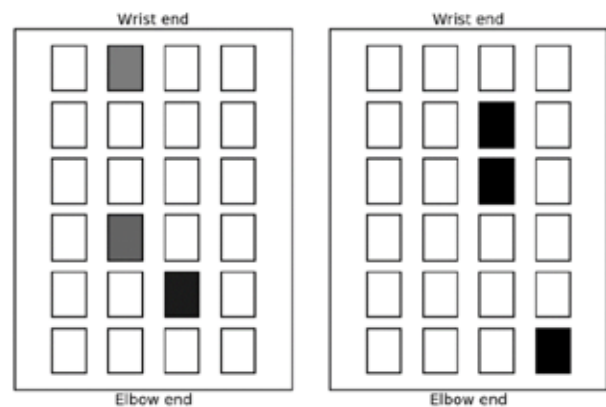


Figure 9. Optimised stimulation for hand opening (left) and pointing (right) – shading corresponds to intensity

Conclusions

A fabric electrode array with four functional layers has been manufactured using screen printing. Four electrode layouts with different electrode shapes and sizes were achieved and evaluated. The electrode array showed good bending durability and can be cleaned by wiping the electrode surface with a range of cleaning wipes. Microbiology tests confirmed that bacterial contamination had been removed successfully. The electrode array must be integrated into an elastic fabric to form a clothing item for use. The pull-on sleeve was ranked as the preferred choice of design over the alternatives. Muscle stimulation to achieve targeted movements (e.g. pointing, hand opening) has been achieved by stimulating the optimised combination of electrode array elements.

Future work

The future work will test the e-sleeve using an advanced iterative learning control to achieve more precise movement. The size of the electronics will be minimised. We will further test the system on the stroke survivors in the EUG group.

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RESPIRATORY RESPONSE DURING FUNCTIONAL ELECTRICAL STIMULATION CYCLING

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Abstract: The aim of this study was to compare the respiratory response during functional electrical stimulation (FES) with different stimulation frequencies in a single case and to discuss the relationship between the differences in respiratory response and metabolic efficiency. The subject, a 21-year-old healthy man, performed cycling protocols at 20- and 50-Hz stimulation frequencies on a stationary recumbent tricycle. We calculated the rate of change in oxygen uptake ($\dot{V}O_2$), respiration rate (RR), and tidal volume (TV) as well as the metabolic efficiency. Metabolic efficiency and the rate of change in $\dot{V}O_2$, RR, and TV were higher at 50 Hz than at 20 Hz. The change in the RR was not significant. Therefore, respiratory response during FES cycling was independent of the stimulation frequency, although the RR was increased.

Keywords: FES cycling, metabolic efficiency, respiratory response

Introduction

Functional electrical stimulation (FES) cycling improves muscle strength [1] and cardiopulmonary fitness [2] in individuals with lower-limb paralysis. Low metabolic efficiency compared to that on voluntary movement [3] has been known to be a problem for FES cycling. Additionally, changes in the respiratory response (e.g. : respiratory rate, tidal volume) due to exercise may be different at different stimulation frequencies. However, the relationship between metabolic efficiency and these differences have not been sufficiently considered. The aim of this study was to compare the respiratory responses during FES cycling at different stimulation frequencies (20 Hz and 50 Hz) in a single case and to discuss the relationship between the differences in respiratory response and metabolic efficiency.

Methods

The subject was a 21-year-old healthy man (height 174 cm, weight 63 kg). Cycling was performed on a stationary recumbent tricycle (Fig 1). Dyna-mid DM2500 (Minato medical science, Japan) was used as the stimulation device, and the stimulation waveform was a burst wave. The subject performed cycling protocols at 20- and 50-Hz stimulation frequencies. The quadriceps femoris and ham-

string muscles were stimulated for 10 minutes after 5 minutes of passive cycling using a motor. An encoder and peripheral interface control microcomputer switched the timing to stimulate each muscle according to the angle of the crank-shaft.

Kinematic data measurement

Kinematic data were acquired using two three-dimensional motion analysis systems (V120: Trio, OptiTrack), located on both the right and left sides of the subject, operating at 50 Hz. Reflection markers were applied on the greater trochanter, knee joint, malleolus, crankshaft, and pedal shaft, bilaterally. A floor reaction force vector was measured by a three-axis forces sensor (USL06-H5-500N-C, Tech) included in binding pedaling.

Respiratory response and gas exchange

Tidal volume (TV), respiration rate (RR), oxygen uptake ($\dot{V}O_2$), and carbon dioxide output ($\dot{V}CO_2$) were measured while cycling using a breath-by-breath gas analyser (Minato medical science, Japan). All data were obtained both at rest and in the exercise phase as the average of 1 minute as the stable interval.

Data analysis

We calculated the rate of change of $\dot{V}O_2$, RR and TV, and calculated metabolic efficiency (η) using the following equation [3]:

$$\eta = \frac{\text{useful work done}}{\text{metabolic energy cost}} \times 100 [\%]$$

$$= \frac{\text{useful power output}}{\text{metabolic power input}} \times 100 [\%]$$

The variables were calculated from kinematic data using a rigid body link model [4] and Hill's equation [5]. Metabolic energy cost was calculated from $\dot{V}O_2$ and $\dot{V}CO_2$ by the Weir's equation.



Fig 1: FES cycling

Table 1 Values of VO₂, RR, and TV at rest

	20 Hz	50 Hz
VO ₂ (ml/min)	235.1 ± 12.5	246.8 ± 28.2
RR (/min)	17.7 ± 1.4	15.9 ± 2.1
TV (ml)	549.8 ± 48.0	545.6 ± 80.0

Mean ± standard deviation

Table. 2 Metabolic efficiency and rate of change of VO₂, RR and TV.

	20 Hz	50 Hz
VO ₂ (%)	23.8	47.6
RR (%)	25.2	39.2
TV (%)	-5.2	7.1
Metabolic efficiency (%)	14.7	24.5

Results

Table 1 shows the values of VO₂, RR, and TV at rest and at each stimulation frequency. VO₂, RR, and TV at rest showed almost same values at 20 Hz and 50 Hz.

Table 2 shows the rate of change and metabolic efficiency of VO₂, RR, and TV. VO₂ and RR increased during cycling. Metabolic efficiency and the rate of change of VO₂, RR, and TV were high at 50 Hz compared to that at 20 Hz.

Discussion

The metabolic efficiency in this study was similar to that in previous studies [3]. As the rate of change of TV was very low compared with other data, we considered that TV does not change by FES cycling, as observed our case. It seemed that rate of change of RR at 50 Hz was greater than that at 20 Hz. However, this difference (14%) considers only two rates, which may not be significant. Therefore, respiratory response during FES cycling was independent of stimulation frequency in this case.

The rate of change of VO₂ at 50 Hz was high compared to that at 20 Hz. These changes may reflect the difference in skeletal muscle activity. As TV did not change, VO₂ increased with an increase in RR. As both stimulation frequencies, 20 Hz and 50 Hz, were low, minimum respiratory changes could meet the oxygen requirement of the skeletal muscles. Low metabolic efficiency at 20 Hz might mean lesser oxygen requirement than that at 50 Hz. Future studies using a stimulation frequency higher than 50 Hz are necessary.

Acknowledgements

We would like to thank Yasuaki Nemoto and Kosei Himori for their practical assistance.

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IMPROVED UPPER LIMB FUNCTION WITH COMBINED ROBOTIC THERAPY AND THERAPEUTIC ELECTRICAL STIMULATION IN A CASE OF CENTRAL CERVICAL SPINAL CORD INJURY

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Abstract: This study used combined robotic therapy and Therapeutic Electrical Stimulation (TES) in a patient with a central cervical spinal cord injury. The patient had significant upper limb motor dysfunction and required assistance for all activities of daily living (ADL) before treatment. Upper limb function was much improved following 15 treatments and the patient eventually achieved independence for ADL in the hospital. Both robotic therapy and TES can be used according to need. This approach helped promote recovery of upper limb function.

Keywords: Robotic therapy, TES, Cervical spinal cord injury, Upper limb function.

Introduction

In recent years, opportunities to use robots for rehabilitation have increased [1]. In addition, reports on Therapeutic Electrical Stimulation (TES) have increased, with demonstrated effectiveness. In this study, report a patient with central cervical spinal cord injury who had improved upper limb function using a combination of two rehabilitation methods.

Case presentation

A 38 years old male was injured his neck in a motorcycle accident. He had no cervical fractures but complained of paralysis and numbness in both upper limbs. The final diagnosis was central cervical spinal cord injury of C5/C6 level.

Evaluation: Strength before treatment based on Manual Muscle Testing showed the following on the right: deltoid, Poor; biceps, Good; triceps, Poor; hand flexion, Trace; hand extension, Normal. On the left: deltoid, Poor; biceps, Good; triceps, Poor, finger flexion/extension, Trace. Grip strength was unmeasurable. Although numbness in both upper limbs was relieved and no perceptual abnormality was apparent, the patient had difficulty using the upper limbs, and required assistance for all ADL.

Treatment: Rehabilitation began 5 days after the injury. Robot therapy and TES were performed for 20 minutes each after 40 minutes of occupational therapy, 5 times a week, for a total of 15 sessions. The ReoGo[®]-J (Teijin Pharma Co., Ltd., Japan) (Fig. 1) was used for Robotic rehabilitation. The NESS H200[®] Wireless Hand Rehabilitation System (Bioness Inc., USA) (Fig. 2) was used for TES.

Result: The treatment was continued for 4 weeks. At the end of treatment, strength recovered to Normal in all proximal muscles. Grip strength was 16 kg in the right hand and 21 kg in the left. Finger dexterity remained poor on both sides. However, he became independent for ADL in the hospital.



Figure 1: ReoGo[®]-J



Figure 2: NESS H200[®] Wireless Hand Rehabilitation System

Discussion

The ReoGo[®]-J enables multi-directional reaching movements, and can be used to select 5 motion-assist mode

levels. The NESS H200® Wireless Hand Rehabilitation System is an orthotic type electrical stimulation system. It can be used to adjust the intensity of stimulation in extensor, flexor, and thumb muscles.

Both robotic therapy and TES were able to flexibly adjust the treatment program according to recovery status. As a result, functional recovery was enhanced. In addition, robot rehabilitation was effective because it provided visual feedback for the results of treatment. Central cervical spinal cord injuries without bone involvement have a good prognosis in many cases [2]. Therefore, the results in this case were not clearly due to combined robotic therapy and TES. This was a case study and was not designed to demonstrate efficacy. Therefore, a large-scale study is needed.

Conclusion

Upper limb function improved in a patient with central cervical spinal cord injury using combined robotic therapy and TES.

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LONG-TERM PAIRED ASSOCIATIVE STIMULATION: IMPROVEMENTS IN UPPER AND LOWER EXTREMITY FUNCTION

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Abstract: Paired associative stimulation (PAS) is a safe noninvasive method that employs combination of navigated transcranial magnetic stimulation (nTMS) and peripheral electrical nerve stimulation (PNS). This association of stimuli repeated over a period of several months leads to clinically significant plastic changes, strengthening synaptic connections in the corticospinal tract. This project aims at exploring the long-term therapeutic effects of PAS, the potential for returning movement to chronic patients, and the underlying neural mechanisms. We report first evidence of the potential of long-term PAS for returning normal hand motor scores in chronic tetraplegic patient (6 years after injury). We also report first experiences in walking/standing improvement in tetraplegic patients.

Keywords: paired associative stimulation, transcranial magnetic stimulation, movement, chronic SCI

Introduction

Paired associative stimulation is a non-invasive neuromodulation method that can produce stable neuroplastic changes in the corticospinal tract, which are significant for motor recovery after SCI. The treatment is based on the studies recently performed at BioMag Laboratory (Helsinki University Hospital), which successfully employed an MRI-guided neuronavigated transcranial magnetic stimulation and novel settings [1] that allowed to enhance corticospinal transmission in healthy subjects [2] and SCI patients [3,4]. Our previous applications of the long-term PAS with the novel protocol enabled chronic incomplete para- and tetraplegic SCI patients to regain some voluntary movements in fully paralyzed muscles and enhance movement capability in weak muscles. The effects sustained for at least 1 month after the last stimulation session.

Here we report the results from two different projects. Based on the previous studies we aimed at exploring to what extent SCI patients can recover if the stimulation is provided for as long as clinically significant improvement is observed (project 1). In addition, we probed effectiveness of PAS therapy for improving walking capability in chronic SCI patients (project 2).

Methods

Project 1: A patient with traumatic chronic incomplete SCI was provided with PAS treatment for as long as improvement in upper extremity performance was observed (1 year 2 months). Conventional SCI rehabilitation procedures were not interrupted or changed.

Project 2: We are enrolling patients with incomplete tetraplegia and some preserved lower extremity function and provide 8-week PAS therapy for both legs. Lower extremity motor scores and walking function are evaluated. All patients were selected using following inclusion criteria: incomplete tetraplegia, chronic stage of disease (at least 1,5 years since injury) and some preserved motor function in at least half of the lower limb muscles defined by manual muscle test (MMT). Exclusion criteria were any contraindications for MRI or TMS [5]. The study was approved by the Ethics Committee of the Hospital District of Helsinki and Uusimaa.

One PAS session consisted of stimulation of 3-6 nerves and corresponding cortical areas and lasted about 1,5-3 hours (20 minutes per nerve). In the first project PAS was given for as long as clinical improvement was observed. In the project 2, 8-week PAS therapy (28 sessions) is employed for all patients. Stimulation sites in the motor cortex and stimulation parameters were individually adjusted for each patient [1]. In the project 1 several hand nerves and corresponding cortical sites were stimulated. In the project 2, peroneal, tibial, femoral and gluteal nerves and corresponding motor areas in the brain were stimulated. Accuracy of stimulation was ensured by utilizing NBS navigation system (Nexstim, Finland). The system allows accurate reproducible targeting of TMS between session as well as controlling stimulation location within one session [6].

Results

Project 1: All evaluated parameters (e.g., muscle strength and grip force) grew in a stable manner throughout the stimulation period; this correlated with the number of given stimulation sessions. Importantly, spinal cord independence measure (SCIM) indicated a stable improvement of patient's independence and quality of life. No serious adverse effects were reported by the patient.

Project 2: At the time of abstract submission, first patient has completed the study and benefited from the treatment (leg motor score and walking function improved). Second patient has received 7-week stimulation treatment thus far. Interim evaluation performed after 4 weeks of PAS-therapy by physiotherapist blinded to the treatment revealed that the total MMT score has increased in right leg by 11 points and by 6 points in left leg (see Fig.2) and his walking function improved. We will enroll additional 3 patients.



Figure 1: Stimulation setup.

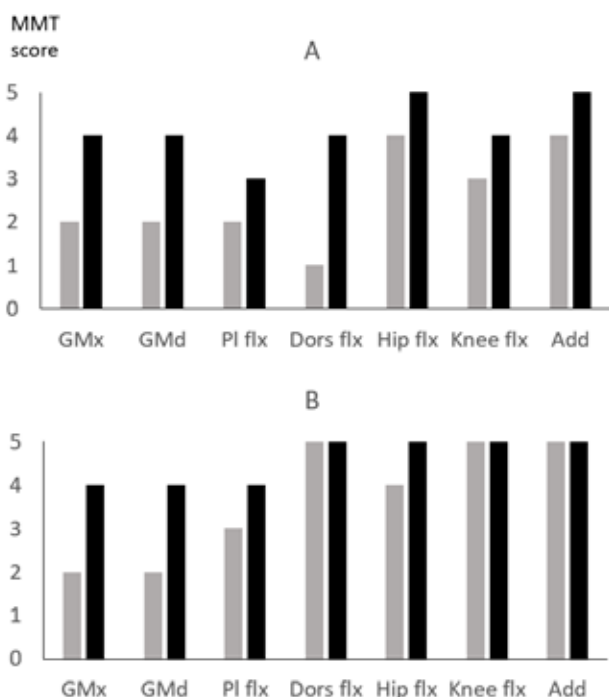


Figure 2. Total MMT motor scores showing PAS-induced recovery of neurological function in different muscle groups in right leg (A) and in left leg (B) in a representative chronic tetraplegic patient. Grey bars – MMT scores before stimulation, black bars – after 4 weeks of stimulation. GMx - Gluteus maximus, GMd - Gluteus medius, Pl flx - ankle plantar flexors, Dors flx - ankle dorsiflexors, Hip flx - hip flexors, Knee flx - knee flexors, Add – adductors.

Discussion

These results are the first direct clinical evidence of the long-term effectiveness and safety of long-term PAS in functional improvement of limbs in chronic SCI patients. The neural mechanism that underlies PAS therapeutic action probably is related to synaptic plasticity. When the presynaptic membranes of the upper motor neurons (MN) are depolarized in synchrony with the postsynaptic membranes of the lower MNs, the synapses between them become strengthened, resulting in increase of signal transmission. Evidence from animal studies indicates that

stimulation protocols inducing spike timing –dependent plasticity between upper and lower motor neurons are promising tools for strengthening the residual corticospinal connectivity and promoting motor recovery [e.g. 5]. The facilitative effect after one PAS session was shown to persist up to 90 minutes [6]. However, only long-term PAS application enabled uncovering its longer lasting effects and therapeutic significance for SCI rehabilitation.

Acknowledgement

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MOTOR REHABILITATION USING FUNCTIONAL ELECTRICAL STIMULATION AND AVATAR USING BRAIN-COMPUTER INTERFACES

A Case Report

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Abstract: Brain computer interfaces (BCIs) have been employed in rehabilitation training for post-stroke patients. In this study we report the results of one patient who extremely improved after 28 sessions of BCI training. Five assessments were conducted to observe any behavioral changes after the intervention such as upper extremity Fugl-Meyer assessment (UE-FMA) and 9 hole-peg test (9HPT). The UE-FMA increased from 25 to 46 points after the intervention. He could not perform the 9HPT in the first session. After the 18th session he was able to perform the 9HPT and reduced the time from 10'22" to 2'53". These results provide the insights of the parameters which are important for motor improvement. A randomized controlled clinical study with large scale of the sample size is required to show the efficacy of the system.

Keywords—*brain Machine interfaces, motor imagery, stroke rehabilitation, functional electrical stimulation, avatar*

Introduction

Stroke is one of the main causes of mortality and long-term disability worldwide. Stroke survivors suffer from movement restrictions of their affected limb and have the tendency of less frequent use of them. Therapies such as constraint induced movement therapy encouraged to use the paretic limbs more often and showed the therapeutic evidence [1], but it is limited to the patients with residual movement in their paretic side. Several therapies based on passive movement therapy are available for the patients with severe paralysis. Passive therapies such as continuous passive motion therapy have been employed for the patients and showed the functional improvements. However, they do not include or cannot monitor the patients' active engagement of the therapy which is one of ingredients in motor learning.

Motor imagery based brain-computer interfaces (BCI) have been employed in rehabilitation training for stroke patients to fill the gap between patients' expectation and the therapy outcomes. Its efficacy has been shown in multiple studies

implementing exoskeletal devices, robots, or functional electrical stimulation (FES) which induce passive movement of their affected limbs [2]–[5]. During repetitive BCI training

sessions, patients even with severe impairments can complete the sensorimotor loop in his/her brain linking coherent sensory feedback with motor intention.

A ready-to-use BCI system, called recoveriX[®] (g.tec medical engineering GmbH, Austria) was recently introduced to bring the current BCI technology to stroke society. recoveriX provides visual feedback with animated upper extremities in virtual reality (avatar) and proprioceptive feedback producing passive FES movement. In this paper, we report the motor improvement from three patients after recoveriX training and investigate the assessment scores as well as the demographics and characteristics of patients.

Patients and methods

Study Design

Each patient received 25 sessions of BCI feedback training over three months. A pre-measurement was conducted two days before intervention and a post-measurement was done two days after the intervention. Informed consent was obtained from all the patients.

Patients

The patient had affected hands in their right limb and fulfilled the following inclusion criteria: (1) ability to understand written and spoken instructions; (2) hemiparesis; (3) time since stroke of at least 4 days; (4) stable neurological status other than stroke; (5) ability to participate in the study for 3 month; (6) no pregnancy; (7) no implanted medical devices such as pacemakers; (8) no implanted metallic fragments in the upper extremities; (9) no cerebellar lesion; (10) no severe hemi-neglect; (11) no epilepsy; (12) no fractures or lesions in the upper extremities; (13) no severe lung diseases or liver disease; (14) no severe pusher syndrome; (15) ability to maintain a seated position for one hour; (16) no sensory disorder feeling pain or unsuitably reacting to sensory stimuli. Table 1 summarizes the information about the participants.

Table 1. Patient information

Age [years]	Gender	Paretic side	Time since stroke [months]	Lesion location
53	male	right	11	Cortical, Subcortical

recoveriX training

One run of training was composed of 60 trials and one session contained three or four runs, depending on the patient's condition and level of fatigue. The total time of one session was about 60 minutes including preparation and cleaning time. Patients wore EEG caps with active 16 electrodes (g.LADYbird, g.tec medical engineering GmbH). The electrode positions were according to international 10/10 system (extended 10/20 system): FC5, FC1, FCz, FC2, FC6, C5, C3, C1, Cz, C2, C4, C6, Cp5, Cp1, Cp2, Cp6. A reference electrode was placed on the right earlobe and a ground electrode at position of FPz.

Two FES electrodes were placed on the skin over wrist extensors of the left and right forearms. The parameters of FES (g.Estim, g.tec medical engineering GmbH, Austria) were adjusted to find the optimal passive movement for each individually, without pain for patients with mild or moderate muscle spasm, or until muscle contraction was observed in the target muscle of their paretic side for patients with severe muscle spasm.

They were set to a frequency of 50 Hz and a pulse width of 300 μ s. The therapist increased the amplitude of stimulation current until smooth dorsiflexion of the wrist was produced. The sequence of motor tasks was specified by the recoveriX software in pseudo random order with randomized inter-trial intervals. The patients first heard an attention beep sound.



Figure 1. Time sequence of one trial. Two seconds after the attention beep sound, the side of each trial is presented. Then, the feedback phase begins after 1.5 seconds later for 4.5 seconds

Two seconds later, an animated arrow with spotlight to the expected hand for motor imagery indicated the task of each trial with an auditory instruction saying either "left" or "right". When the recoveriX detected the appearance of the correct hand side, FES and avatar feedback are activated during the feedback phase. Feedback is otherwise deactivated. Updating the feedback was carried out five times per second. The animated forearm movement in avatar simultaneously performed the similar wrist dorsiflexion produced by FES.

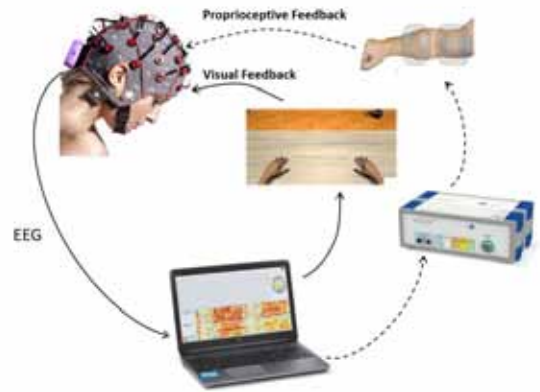


Figure 2. A ready-to-use BCI system, recoveriX

Assessment

- Primary behavioral outcome measures**
 FMA is a stroke-specific measuring method of evaluating sensorimotor functions, balance, joint mobility, and joint pain. The score provides the impairment of patients assessed by therapists or medical staffs with high reliability. We used the FMA of upper extremity (maximal score = 66 points) as a primary behavioral outcome measure because the upper extremities are the task-related body parts during the training. It is a quantitative measurement method that measures recovery after stroke. FMA is used for clinical purposes and in research. It supports the assessment of the degree of damage and describes the recovery after a stroke.
- Secondary behavioral outcome measures**
 The secondary outcome variables are also measured. 9HPT measures the time to complete the test for finger dexterity and Barthel Index (BI) is a questionnaire to test the ability to care for him/herself. Modified Ashworth Scales is to exam the spasticity of the patient, a lower score means less spasm in his/her paretic limb. The wrist (MASWrist) and hand (MASHand) was tested for this assessment. Fahn's tremor rating scale (FTRS) scores the tremor degree by counting the number of crossing the border of spiral image on paper with a pen. A lower score in FTRS means less tremor.

Results

FMA_{Total} remarkably increased from 25 to 46 points. Both FMA_{Wrist} and FMA_{Hand} had a jump from 0 to 6 point and from 3 to 11 points respectively as well as FMA_{UE} from 22 to 27 points. Increment was also observed in BI from 90 to 95 points and MAS showed that less spasm was measured in the paretic wrist (from 2 to 1) and hand (from 1.5 to 1). FTRS also reduced from 4 to 3 points. It was not possible to conduct 9HPT due to the level of impairment when the therapy started. After the 18th session, he was able to participate in 9HPT. The elapsed time for completing the test

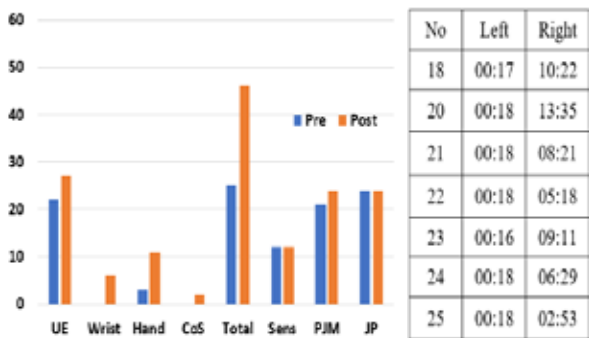


Figure 3. FMA scores and 9HPT. The FMA_{total} is the sum of subscales from FMA_{UE} , FMA_{Wrist} , FMA_{Hand} , and FMA_{CoS} . The tables shows 9HPT results of both healthy (left) and paretic (right) side.

was gradually reduced from 10'22" to 2'53" in the paretic side while no obvious change happened in the healthy side. He also quickly learned the BCI use and reached 100% of accuracy level multiple times and maintained high accuracy until the last session (see Figure 4).

IV. Discussion

Five assessments were performed to evaluate the sensorimotor recovery after the intervention with various perspectives of measuring any behavioral changes. FMA_{Total} showed motor improvements including the UE, wrist, hand, and coordination and speed, so it reflects the overall motor improvement in upper extremities. The instruction to the patient was motor imagery of only wrist dorsiflexion while sensory feedback was provides for wrist and hand with correct movement intention. The higher points in UE can be explained by implicit motor learning during the training. Patients learned how to control their paretic wrist and hand as well as upper extremity during the BCI training.

9HPT was the most sensitive among these five assessments in this particular patient. Questions can rise up about the number and it may come from learning mental strategies instead of motor recovery. When we compare the overall time of healthy side, it does not support that the shortened time is from mental strategies. Our primary measure, FMA indicated that he improved in motor recovery. However he could not perform the 9HPT until the 18th session, because of his impairment. It has high sensitivity in functional improvement in upper limbs and is more applicable for the patients with moderate and mild impairment. The patients showed lower score in either MAS_{Wrist} or MAS_{Hand} meaning that the spasticity reduced after the training. It is reported that less spasm is one of the prerequisites to regain the motor control from the paralysis. The FTRS also decreased implying that they were able to move their hand with less tremor.

The classification accuracy may be another important measure. The patient learned how to use BCI and reached even an accuracy of 100% multiple times. Previous study showed that it is not required to have high accuracy for motor

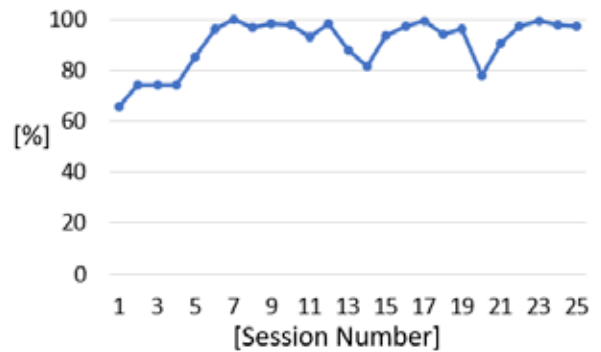


Figure 4. BCI classification accuracy over 25 sessions

recovery and the correlation between the BCI performance and motor recovery should be investigated further.

The location of the lesion caused by stroke are diverse from patient to patient. This heterogeneous characteristics of patient challenges in predicting the potential beneficiary of the BCI rehabilitation treatment. We observed the age and FMA score may be important to determine the forecasting the motor improvement after this recoveriX training. Another important factor which can influence the effect of the training is the impairment level of patients. This has been reported from other therapy as well that the moderate patients can have more therapy effect than the patient with mild or sever impairment.

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The Effects of Neuromodulation on Central Excitability of the Upper Limb in Healthy, Able-bodied Adults

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Abstract: *Transcutaneous electrical nerve stimulation (TENS) has been shown to inhibit corticospinal mechanisms for the management of upper limb spasticity at frequencies > 90 Hz. Delivering transcutaneous spinal cord stimulation (tSCS) in kHz frequency bursts (HF-tSCS) has been proposed as an alternative therapy. This study compares the effects of TENS and HF-tSCS on upper limb motor-evoked potential (MEP) and H-reflex amplitude in 2 participants. Wrist extensor MEP amplitude decreased for 60-mins following TENS. However, this increased following HF-tSCS. The effects of both therapies on wrist flexor MEP amplitude were inconclusive, however H-reflex amplitude decreased immediately after both in one subject. Preliminary results suggest that HF-tSCS may not be as effective as TENS for spasticity management.*

Keywords: *Spasticity management, upper limb, neuromodulation, high-frequency stimulation*

Introduction

Neurological components of spasticity occur due to a lack of descending control over interneuronal circuits in the spinal cord [1]. Forms of neuromodulation effective in the management of upper limb spasticity range from neuromuscular electrical stimulation [2], to central stimulation of the spinal cord [3] or brain [4]. However, synergies between agonist-antagonist pairs following stimulation via alternative routes and using varying frequencies is lacking in the upper limb. Spasticity has been characterised by evaluations of motor-evoked potentials (MEPs) [5] and H-reflex amplitude [6]. These measures allow for the assessment of inhibitory and excitatory mechanisms at both cortical and spinal level.

Transcutaneous electrical nerve stimulation (TENS) has been shown to decrease MEPs after 30-minutes of intervention at 90 Hz [7]. At 200 Hz, TENS was also shown to have a positive effect on presynaptic inhibition [8]. These effects on cortico-spinal excitability help towards relieving symptoms of spasticity.

More recently, the use of transcutaneous spinal cord stimulation (tSCS) has been proposed as a therapy for the treatment of spasticity and neuropathic pain [3,9]. However, 49-71% of people who have experienced conventional tSCS for the treatment of neuropathic pain find the sensation unpleasant [9]. High-frequency tSCS (HF-tSCS) (up

to 10 kHz) has been shown to have effects on chronic back pain without this unpleasant sensation [10]. The use of HF-tSCS may increase uptake in the use of this type of therapy for spasticity management.

This study investigated the effects of HF-tSCS compared to TENS in the upper limb. This will help us to understand the extent of alteration to inhibitory and excitatory pathways that HF-tSCS is able to achieve.

Methods

Participants

In this abstract, we present two participants for whom the effects of both interventions were measured on MEP amplitude and one participant whose H-reflex amplitude was also assessed. For the larger study, we will recruit 20 participants over the age of 18, with no known neurological conditions. Ethical approval for this study has been granted by the University College London Research Ethics Committee and informed consent will be sought from all participants who take part.

Data Collection

Electromyography (EMG) electrodes were placed over the flexor carpi radialis (FCR) and extensor carpi radialis longus (ECRL) muscles (figure 1). The electrodes over the FCR were the same adhesive electrodes used for the TENS intervention, only the EMG recording cables were replaced with stimulating cables. EMG data were sampled at 10 kHz and recorded through LabChart 8 software via a Powerlab (ADInstruments). This was externally triggered using Signal software (Cambridge Electronics Design) and a Power1401 ADC (Cambridge Electronics Design). Low pass filtering, with a cut-off frequency at 50 Hz, was implemented in LabChart 8 software.

TENS intervention

The participant was sitting upright in a comfortable chair. TENS was delivered via adhesive electrodes (Covidien adhesive electrodes, 2.4 cm diameter) placed over the FCR (figure 1). Stimulation was delivered at 150 Hz and pulse width 100 μ s with 2 seconds of stimulation on and 2 seconds off for 30-minutes of intervention [11]. Threshold was defined as the intensity at which muscle twitch was first induced when stimulating. The stimulation amplitude was set at 80 % of threshold and kept constant for the duration of the intervention.

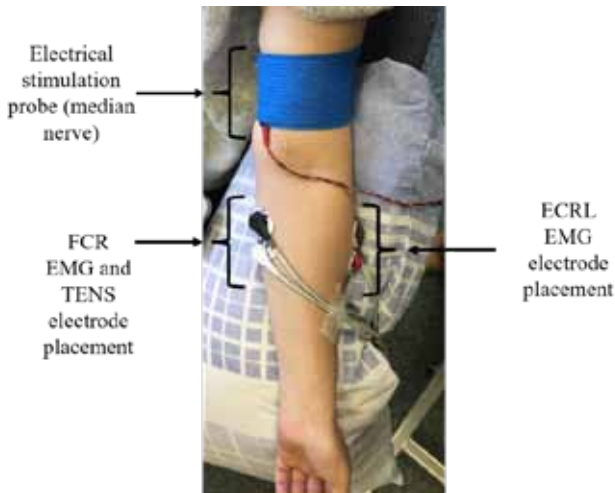


Figure 1: set-up showing EMG recording electrodes, TENS electrodes and the stimulating probe array used for H-reflex elicitation.

HF-tSCS intervention

In a separate session, HF-tSCS was supplied with a research stimulator (Digitimer DS8). Threshold was determined using conventional tSCS with a biphasic square wave at a frequency of 1 Hz and a 1 ms pulse width. This was the lowest intensity at which posterior root reflexes were elicited in the desired muscles. The high-frequency tSCS was then delivered at 30 Hz, with a 9090 Hz carrier frequency (biphasic square wave, pulse width 50 μ s), with each high frequency burst lasting 1ms. This was supplied via self-adhesive surface electrodes (PALS Neurostimulation adhesive electrodes, 5cm diameter) placed over C6 and T1 vertebral levels (figure 2), and delivered in 2 second bursts following 2 seconds of no stimulation for 30-minutes at 80 % of threshold intensity.

H-reflex protocol

The H-reflex was evoked in the FCR by stimulating the median nerve with a 1 ms monophasic pulse at 7 s intervals via a bar electrode array. Two stimulation sites were tested: the cubital fossa [12] and approximately one third of the distance from the elbow to the shoulder [13], to select one where the H-reflex could be evoked.

Before intervention, a recruitment curve was obtained for the H-reflex in the FCR. The stimulation intensity where the H-reflex was largest relative to the M-wave was used for the remainder of the experiment. This was used to elicit 20 baseline H-reflexes, 20 immediately following intervention and at 15-minute intervals thereafter for 60 minutes. This is illustrated in figure 3.

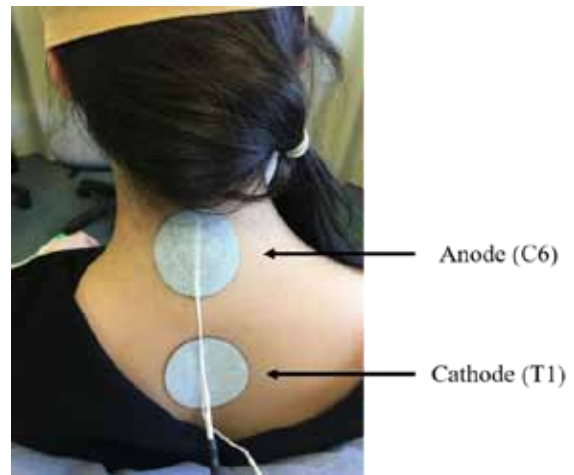


Figure 2: stimulating electrode placement over the vertebrae for HF-tSCS.

Measurements of the H-reflex amplitudes of each stage were averaged and peak-to-peak values were calculated for each of these points and represented as a percentage of the baseline measurement.

MEP protocol

MEPs were triggered in the FCR and ECRL using a circular transcranial magnetic stimulation TMS coil (13 cm external diameter) to stimulate the primary motor cortex via a Magstim 200.

Before intervention, the hotspot for eliciting MEPs in the FCR and ECRL was identified, and MEP recruitment curves were carried out to identify resting threshold. Stimulation intensity for the remainder of the experiment was 1.2x threshold. Twenty MEPs were elicited before, immediately following intervention, and at 15-minute intervals thereafter for 60 minutes (figure 3).

Results

The stimulation intensities used for outcome measures and interventions are displayed in table 1.

Table 1: Stimulation parameters for outcome measures and intervention.

Participant	H-reflex (mA)	MEP (%)	TENS (mA)	High-frequency tSCS (mA)
1	4.0	54	11.2	35
2	5.6	60	7.0	40.5

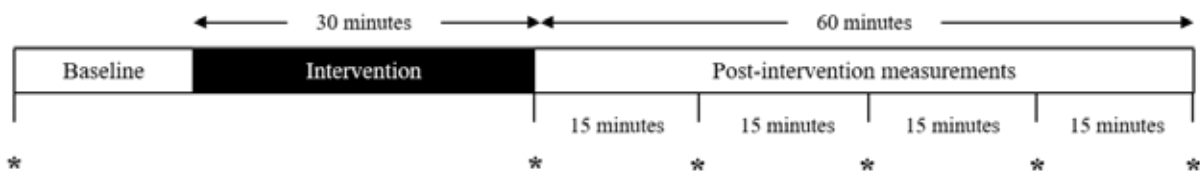


Figure 3: experimental timeline. * represents the times where measurements of MEP and H-reflex amplitude were taken.

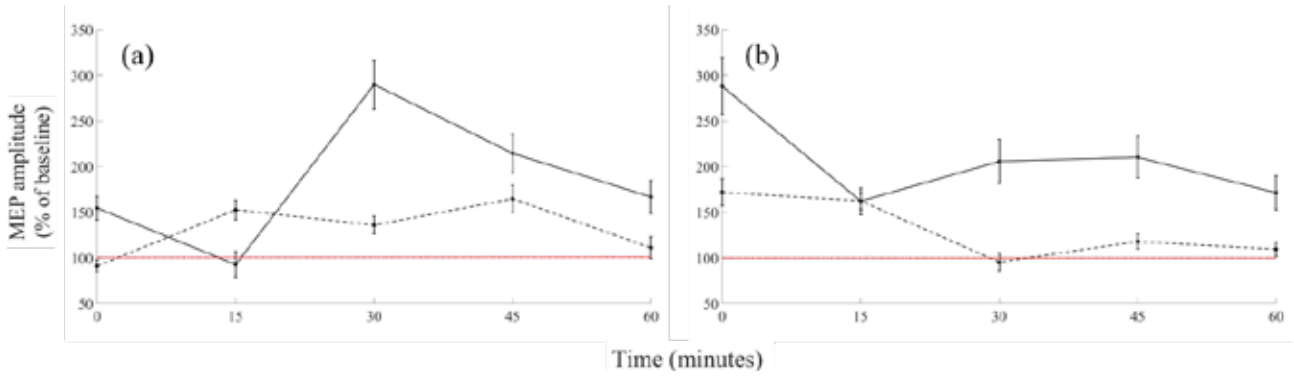


Figure 4: Mean (SEM) normalised FCR MEP amplitude (% of baseline) following HF-tSCS (dashed line) and TENS (solid line) intervention for Participant 1 (a) and Participant 2 (b).

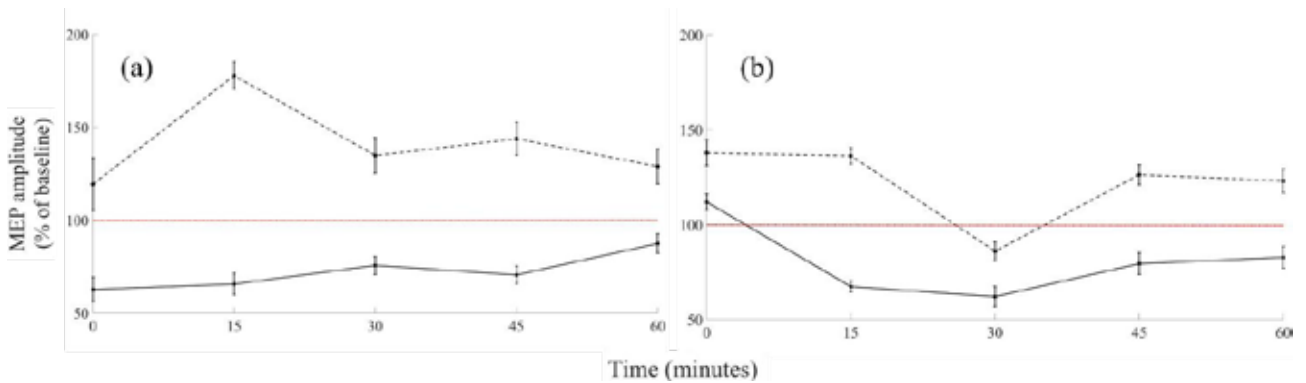


Figure 5: Mean (SEM) normalised ECRL MEP amplitude (% of baseline) following HF-tSCS (dashed line) and TENS (solid line) intervention for Participant 1 (a) and Participant 2 (b).

FCR MEP amplitude was not inhibited by either intervention (figure 4), remaining at or above baseline amplitude for 60-minutes following both interventions. This was true for both subjects tested. The data indicated that the interventions may have facilitated MEP amplitude in this muscle, particularly following TENS, but the data was rather variable between the two subjects tested.

For both subjects, ECRL MEP amplitude had decreased at 15-60 minutes following TENS intervention (figure 5). This effect was not seen following HF-tSCS, with MEP amplitude remaining close to or above baseline for 60minutes following the intervention. As with the wrist flexors, the data indicates that HF-tSCS may have facilitated MEP amplitude in the ECRL.

Following HF-tSCS and TENS intervention, H-reflex amplitude decreased to 42 % and 35 % of baseline respectively, immediately after the intervention (figure 6). H-reflex amplitude remained below baseline for 60 minutes after TENS intervention, but increased after HF-tSCS.

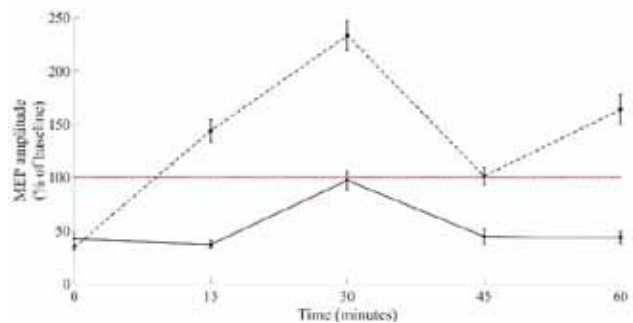


Figure 6: Mean (SEM) normalised H-reflex amplitude (% of baseline) following HF-tSCS (dashed line) and TENS (solid line) intervention for Participant 1 (a) and Participant 2 (b).

Discussion

Our results indicate that TENS therapy has inhibited H-reflex and ECRL MEP amplitudes, and has facilitated FCR MEP amplitude in both participants. This is contrary to previous findings of Tinazzi et al. [11] with the same stimulation parameters. With the exception of ECRL MEP amplitude measured immediately after intervention for participant 2, MEP amplitude has been inhibited following TENS. This indicates that this intervention has triggered

reciprocal inhibition in the ECRL and had an excitatory effect on the FCR.

The effects of HF-tSCS on both H-reflex and FCR MEP amplitude indicate a facilitation of ECRL MEP amplitude in both participants. In the study by Tinazzi et al. [11], an increase of 64 % from ECRL MEP baseline was observed after TENS. An increase of 19 % and 38 % were seen here following HF-tSCS in the two participants respectively. Further investigation will determine whether this type of therapy could cause a statistically significant reduction in ECRL MEP amplitude and therefore be effective in the management of upper limb spasticity with less discomfort.

Results for changes in H-reflex amplitude following both interventions are highly variable, and the H-reflex could only be elicited in one participant. The H-reflex is a notoriously difficult measure to obtain in the upper limb and many studies have investigated its reliability [12, 13]. However, this measure allows us to investigate spinal excitability, which is altered in those with spasticity [14]. Using both H-reflex and MEP amplitude as outcome measures gives further relevance when investigating the potential effects of electrical stimulation on spasticity.

Our further investigation will assess the impact of HF-tSCS on spinal and cortical excitation compared to TENS. Results presented here indicate that HF-tSCS may have facilitatory effects on antagonist muscles. For effective treatment of spasticity, it is important for us to gain a better understanding of the neurophysiological effects of different interventions.

Acknowledgement

We would like to give thanks to the Leslie Trust for funding this project. We would also like to thank Digitimer Ltd for the loan of the DS8 stimulator.

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LOGGING THERAPY SESSION DATA VIA AN UPPER LIMB FES REHABILITATION SYSTEM

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Abstract: *This paper reports on an approach to capturing real-time therapy session data using an upper limb functional electrical stimulation (FES) system to support our understanding of its usability in clinical environments and to record therapy delivered. The recently developed advanced FES system, FES-UPP, which is allowed clinicians to quickly and easily set up controllers to deliver FES-support for patient-specific upper limb functional task practice. One stroke patient participant carried out 7 therapy sessions in clinical environments. Some example information has been summarized from the logged data and shows a noticeable increase in the efficiency of therapy delivery with using FES-UPP system.*

Keywords: *Upper limb, Rehabilitation, Functional electrical stimulation, Therapy session data*

Introduction

FES technology is showing promise as a tool to promote upper limb recovery following a stroke [1, 2]. However, the small number of commercial FES systems are insufficiently flexible to support the varied, yet challenging functional task practice that the literature suggests may be needed to promote motor re-learning. For example, most systems provide a small number of stimulation channels, with some systems are restricted by design to stimulation of the particular body anatomy. To address this problem, the University of Salford and Odstock Medical have developed an advanced FES system, FES-UPP, which allows clinicians to quickly and easily set up controllers to deliver FES-support for patient-specific upper limb functional task practice.

Hochstenbach-Waelen and Seelen [3] report the low uptake of rehabilitation technologies for the upper limb in routine clinical practice and summarized in their paper the potential factors that may be behind this finding. Of particular note, any rehabilitation technology should be quick and easy to setup. Therefore, techniques to capture the usability of our new system were required. Further, the ability to capture data on the therapy delivered (as opposed to simple therapy contact time, which is often reported as a proxy measure of therapy input) would be of great value in future clinical studies of the new system.

Previously, we used direct observation of an earlier prototype of the FES-UPP system [4] but this approach is time consuming and always required input from the researchers and/or therapists. Here we describe the design and

implementation of a system to log data reflecting use of the FES-UPP system. We illustrate its application with data collected as part of a clinical evaluation of the system in three clinical settings.

Methods

Design of the FES-UPP system

The FES-UPP system has been reported in detail by Sun et al. [5, 6]. In summary, the FES-UPP system consists of a 5-channel stimulator running an FES finite state machine (FSM) controller, the FES-UPP software installed on a tablet PC, body-worn sensors and an instrumented object. The FSM controller represents a functional task as a sequence of movement phases. The output for each phase implements the stimulation to one or more muscles. Progression between movement phases is governed by the therapist-defined rules, which may be based on data from body-worn sensors, the instrumented object, button pressing signals, or clock time for timeout. The instrumented object detects when a patient grasps, releases, or replaces the object onto a surface.

The FES-UPP software guides clinicians through the setup of a FSM for a given patient and task. The software concept is to break the setup of a FSM for a particular upper limb functional task into five stages:

- 1) Create, modify and select tasks;
- 2) Don electrodes and sensors, and initial channel setup;
- 3) Set up stimulation parameters for each phase and capture manual transitions data;
- 4) Set up transition conditions; and
- 5) Set up task instructions and feedback.

Once the five stages have been completed for each of the selected tasks, the therapy session manager guides the patient in repeated attempts at the task(s). In addition, it also provides feedback on task performance to the patient and clinician.

Design of the therapy session data logging

The FES-UPP software on the tablet logs data in a set of automatically created patient-specific files for each therapy session. The data and directory structures are shown below.

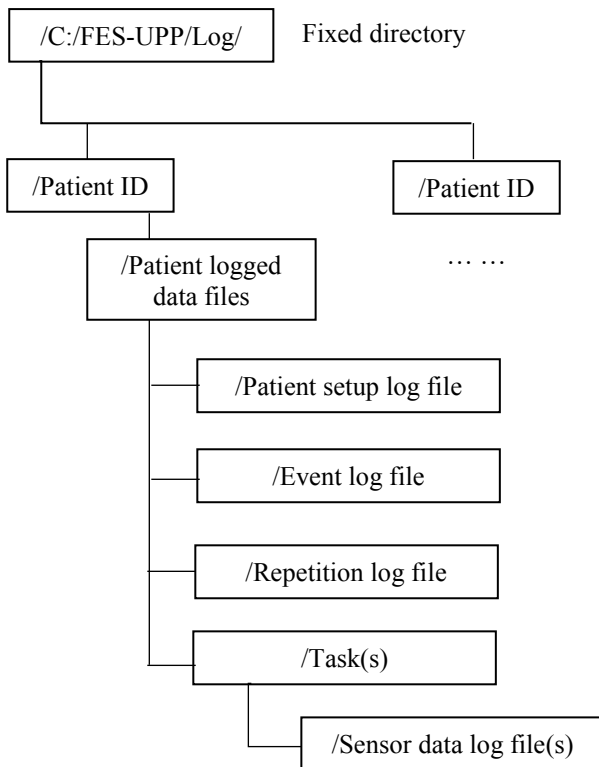


Figure 1: Directory design

The patient logged data files include patient setup file for each functional task, key interaction events between the therapist and software, information corresponding to each repetition of task and Quaternion angle data from sensor used for tracking body segment movement (see Fig. 1 and Tab. 1).

Table 1: Patient logged data files.

Item	Ext	Number of files	Example file name
Patient setup log file	.xml	1	Z04_03-02-2017_13.00.xml
Event log file	.txt	1	Event log.txt
Repetition log file	.txt	1	Repetition log.txt
Sensor data log file (s)	.txt	/	Rep 1.txt

Patient logged data files

The **Patient setup log file** contains the core setup information, including FSM parameters (e.g. number of movement phases, phase name(s), muscles to be stimulated during each phase), stimulation parameters that defined stimulation profiles (targets, ramp time, delay time and motor threshold), and transition rules etc. The **Patient setup log file** could be reloaded from the tablet hard drive for use in a new therapy session.

The **Event log file** contains the key software interaction events that occurred during the FES-UPP session. The timestamped and logged events include when the user

logged on/off the software, and entered different setup stages and session manager.

The **Repetition log file** contains information corresponding to each repetition of a task included the task name, repetition number, time spent in each movement phase, reason(s) for leaving each movement phase, and whether a repetition was successful. A successful repetition was deemed to have occurred when the FSM had progressed through each movement phase and returned to the neutral phase.

A **Sensor data log file** was automatically created for each repetition of a task while in therapy session manager. It logs the continuous quaternion data from those sensors assigned to a body segment and associates the data with a movement phase number and computer time.

The software uses “appointment date and time” to name a unique directory for each therapy session.

Experiment demonstration

To illustrate the application of the approach, below we report on case study data gathered as part of a clinical evaluation of the system. Following ethical approval (REC ref 16/YH/0258), the study aimed to evaluate the system in three different clinical settings. In each case, the system was used by trained therapists without on-site technical support. In this paper we report on use of the system in very early post-stroke rehabilitation (less than 1 week) with 1 participant who had severely impaired upper-limbs. The patient participant was treated by three therapists using the FES-UPP system during 7 therapy sessions, spread over approximately 4 weeks.

Table 2: Therapist participants

Therapist participants	PT ¹	OT ²	TA ³
Clinical experience on treating stroke patients (years)	6	15	1
FES experience	Yes, lower limb only	No	No
No of session completed	2	2	3

¹PT = physiotherapist;

²OT = occupational therapist;

³TA = rehabilitation therapy assistant;

One PT, an OT and a TA, none of whom had prior clinical experience of upper limb FES treated the patient participant reported here (see Tab. 2). All three therapists completed a two-day training session to learn how to use the FES-UPP system and to follow the study protocol. A clinical manual and on-line training materials for the system were available to the therapists during the study.

In each therapy session, the participant was asked to carry out one or two functional tasks assisted by electrical stimulation. The tasks were imported by the therapist from a standard hand-arm activity library in the FES-UPP setup software.

Table 3: The therapy session information for patient participant.

Therapy No	Performed task(s)	Total Reps No	Success rate ¹ (%)	Total practicing time (mins)	Total therapy time (mins)	Efficiency ² (%)
1	Reach to Target	8	100%	2.2	35.8	6.5
2	Sweeping coins	10	40%	3.8	50.2	8.2
3	Reach to Target	7	85.7%	2.8	48.7	6.1
4	Reach to Target	7	71.4%	9.9	76	17.8
	Sweeping coins	3	100%	1.6		
5	Sweeping coins	67	100%	23.8	50.3	89.5
6	Sweeping coins	56	98.2%	14.1	34.6	68.8
7	Sweeping coins	98	100%	19.4	25.8	305.5
Mean		36.6	96.1	11.1	45.9	24.2

¹Successful rate (for a task) = (number of successful repetitions of this task/ the total number of attempts at the task)×100%;

²Efficiency (for a session) = (total practicing time of this session/ total therapy time at the session)×100%

Results

Two different functional tasks, tailored to suit the impairment level of this particular stroke participant were set up across the 7 therapy sessions (see Tab. 3). The two tasks were “Reach to target” and “Sweep coins”. On one occasion, the participant managed to complete two functional tasks.

All 7 therapy session data were successfully logged. Some example outcomes were extracted from the patient logged data files, and summarized in Tab. 3 and Fig. 2. They include the performed tasks, total repetition number of each task, success rate, total practicing time, total therapy time, the efficiency in each therapy session and the therapist-defined rules. The total practice time was extracted from the *Repetition log file* and defined as the sum of time period when the FSM had progressed through each movement phase and returned to the neutral phase in the session manager. The total therapy time of a session was extracted from the *Event log file* and defined as follow:

Total therapy time = Software log off time –log on time

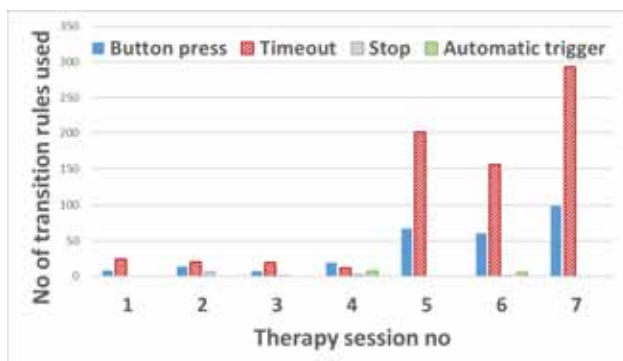


Figure 2: Transition rules used for the participant

Fig. 2 illustrates the type of therapist-defined rules used in movement phase transitions for each task within each session. In all cases, therapists used a single rule. The automatic trigger defines a transition between two succes-

sive phases, based on data from body-worn sensors or the instrumented object.

Discussion

In this paper, we have reported an approach to recording real-time therapy session data each time the FES-UPP system was used. Redundant information was logged for each therapy session. Useful outcomes have been extracted from the patient logged data files. On average, the participant achieved 36.6 repetitions within 11.1 minutes practice time per session across the study. The participant achieved a very high success rate (96.1%) Part of the reason for this was that all three therapists almost always chose to use simple transition rules, such as timeout or a button press (Fig. 2). It will be interesting to explore whether, as therapists gain confidence in the use of the FES-UPP they will exploit the opportunity to use motion sensor or object-based rules, which offer greater potential for patient engagement in the practiced activity. Tab. 3 illustrated a significant increase in the efficiency delivered in the last three therapy sessions. The number of repetitions and amount of practice time during the last three sessions increased, while the total therapy session time decreased. The outcomes extracted from the patient logged data files demonstrated the potential of FES-UPP system to be used in busy clinical environments.

Conclusions

In this paper, we reported the design and implementation of an approach to log real-time therapy session data reflecting use of the recently developed FES-UPP system. The FES-UPP system has potential to allow therapists to efficiently deliver high intensity, high repetition task orientated upper limb therapy in a clinical setting. Therapists with little or no FES experience and without any programming skills could use FES-UPP system to set up a range of functional activities on severe early-stage stroke patients. One stroke patient participant carried out 7 therapy sessions in clinical environments. Redundant infor-

mation was logged for each therapy session to support our understanding of its usability in clinical environments and to record therapy delivered. Some example information has been summarized from the logged data and shows a noticeable increase in the efficiency of therapy delivery with using FES-UPP system.

Nevertheless, future work to extract more information from the redundant logged data files is still required. The logged data files has potential to provide the feedback about the patient performance to the therapists during each therapy session.

Acknowledgement

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Improved Hand Function after Therapeutic Electrical Stimulation and Rehabilitation in Persons with Cervical Spine Disorders

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Abstract: Purpose: to evaluate the improvement of hand function in persons with cervical spine disorders by therapeutic electrical stimulation (TES) and rehabilitation.

Methods: The H200[®] Wireless Hand Rehabilitation System was used for TES therapy. Eight individuals who had hand dysfunction caused by cervical disorders were enrolled. TES program using the H200[®] Wireless System was started after the injury or surgery of the cervical spine. The Japanese Orthopaedic Association (JOA) score of hand-fingers function and grip strength were used for the assessments of hand function. **Results:** The mean JOA score improved significantly from 1.5 to 2.7 at the end of the study ($p < 0.05$). The mean grip strength improved significantly from 7.9kg to 16.0kg at the end of the study ($p < 0.05$). **Conclusion:** TES therapy using the H200[®] Wireless Hand Rehabilitation System is effective for the improvement of hand function in persons with cervical spine disorders.

Keywords: therapeutic electrical stimulation (TES), hand function, cervical spine disorder, rehabilitation

Introduction

The loss of hand function is one of the most devastating effects of cervical spine disorders. It sometimes severely limits the activities of daily living (ADL) and quality of life (QOL). After the surgery of the cervical spine, traditional rehabilitation therapy (e.g. occupational therapy) is the major treatment method.

Partially paralyzed muscles because of cervical spine disorders have a potential to be stimulated electrically through their surviving motor nerve supply. This provides an opportunity to improve hand function by therapeutic electrical stimulation (TES).

The H200[®] Wireless Hand Rehabilitation System (Bioness Inc. Valencia, USA) is a device that recovers the function of hand by stimulating the muscles with surface electrodes. We investigated the effectiveness using it to patients with hand dysfunction caused by cervical spine disorders.

Methods

Patients with hand dysfunction caused by cervical spine disorders who admitted to university hospital for rehabilitation during April 2017 to February 2018 were considered for the study. Patients with cardiac pacemakers,

uncontrolled seizure disorders, pre-existent functional limitations of the upper limb, serious contractures of shoulder, elbow, or wrist, severe dementia, severe skin problems in the arm, metal implants in upper limb, wrist circumference too large for appropriate fitting of the stimulation apparatus, no reaction to the test stimulus, or intensive electrical stimulating treatment before this trial, were excluded from the study.

The H200[®] Wireless Hand Rehabilitation System was used in this study. The System has two main parts that communicate wirelessly with each other: the functional stimulation support (orthosis) and the control unit (micro-processor) (Figure 1). The orthosis fits to patient's forearm and wrist, and communicates wirelessly with the control unit. Inside the orthosis, electrodes deliver mild stimulation that help hand move. The hand-held remote control unit lets the clinician adjust the level of stimulation and turn the unit on and off. In this trial, exercise mode (alternating extension and flexion) was selected. Stimulation amplitude was individually adjusted to obtain an optimal motor reaction without any side effects such as pain or skin irritation. The subjects were stimulated 10 to 20 minutes a day, 5 times a week.

Assessments were made at immediately after before the start of treatment, and at the end of the treatment. The Japanese Orthopaedic Association (JOA) score of hand-fingers function and grip strength were used for the outcome measures. The JOA score is an outcome measure to evaluate the neurological function of cervical disorders, and has been widely used in Japan (Table 1) [1]. Paired t-test was performed in order to find any significant difference in this treatment.



Figure 1: The H200[®] Wireless Hand Rehabilitation System

Table 1: The JOA score of hand-fingers function [1].

Grade	Hand-fingers function
0	Unable to feed oneself with any tableware including chopsticks, spoon, or fork, and/or unable to fasten buttons of any size
1	Can manage to feed oneself with a spoon and/or fork but not with chopsticks
2	Either chopstick-feeding or writing is possible but not practical, and/or large buttons can be fastened
3	Either chopstick-feeding or writing is clumsy but practical, and/or cuff buttons can be fastened
4	Normal

Results

A total of eight persons (five male and three female) who had hand dysfunction were enrolled. The average age was 67 years (range, from 45 to 72 years). Three were cervical myelopathy (after operation), two were post cervical cord injury, one was cervical disc herniation, and one was cervical spondylosis (after operation). All persons were less than ten days after injury or operation. The mean therapeutic period was 65 days.

The mean JOA score before the treatment was 1.5, and improved significantly to 2.7 at the end of the study ($p < 0.05$) (Figure 2). The mean grip strength before the treatment was 7.9kg, and improved significantly to 16.0 at the end of the study ($p < 0.05$) (Figure 3).

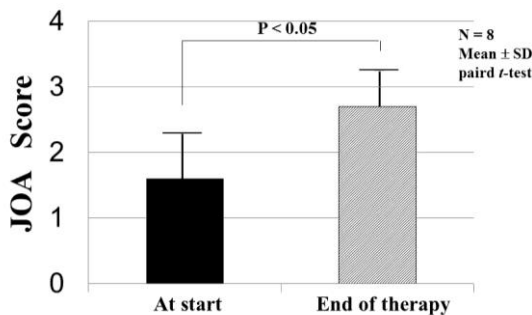


Figure 2: Improvement of JOA score of upper-extremity motor function

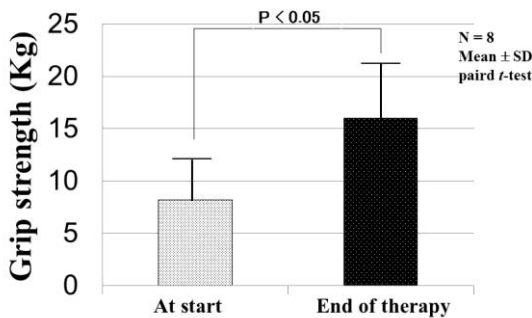


Figure 2: Improvement of grip strength

Discussion

The H200[®] Wireless Hand Rehabilitation System stimulates the appropriate nerves and muscles of the forearm and hand and helps to re-educate weak or paralyzed muscles. It is programmed by clinician to stimulate the appropriate nerves and muscles of patients forearm and hand. The effectiveness of the H200[®] (wired system) is reported about patients who had strokes. Alon and colleagues used it to stroke patients and reported that Fugl-Meyer score improved significantly compared to control group [2]. Berner and colleagues also reported by using the H200[®] (wired system) to post stroke patients and concluded that wrist dorsal flexion and Box and Blocks test were improved during the therapy [3]. In this study, we investigated about persons with hand dysfunction caused by cervical spine disorders using the H200[®] Wireless System. The mean JOA score of upper extremity and grip strength improved significantly at the end of the study. This system also has a potential to improve upper extremity function in persons with cervical spine disorders.

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Frequency Dependant Facilitation of Motor Evoked Potentials with Transcutaneous Spinal Stimulation

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Abstract: *Electrical spinal stimulation (SS) is currently used in the treatment of pain and spasticity in the spinal cord injured population (SCI). More recently SS has been shown to enable step-like movements and generate controlled motor responses upon verbal command. This is thought to be somehow due to activation of residually spared pathways; however, the underlying mechanism is unclear. We have previously shown that spinal stimulation by trains of current pulses enables facilitation of descending signals in healthy individuals. More recently, the use of "painless" high-frequency stimulation has become popular. In this study we compared the effects of high-frequency and conventional stimulation on corticospinal excitability.*

Keywords: *Spinal Stimulation, High-frequency stimulation, Transcutaneous, Posterior-root reflex, Motor Evoked Potentials.*

Introduction

Injury to the spinal cord results in chronic disability but the majority of clinically-complete lesions are actually incomplete, meaning that some neurons in the spinal cord remain intact even though descending control of spinal central pattern Generators (CPGs) has been lost [1]. Electrical stimulation of the spinal cord has been shown to encourage spinal circuits to produce (previously unavailable) leg movements [2-4] with similar effects from epidural or transcutaneous delivery [5]. However, transcutaneous spinal stimulation additionally stimulates the back muscles, causing pain at greater amplitudes.

It has been suggested that different stimulation patterns may reduce the level of discomfort encountered from transcutaneous delivery of spinal stimulation. Specifically, it has been proposed that the application of spinal stimulation (SS) in high-frequency bursts is associated with reduced discomfort and locomotor-like behaviour in the legs, compared to the application of conventional stimulation [6, 7].

In this study we will investigate the effects of different transcutaneous SS patterns/configurations on lower limb muscle activity and sensation in 20 non-spinally injured subjects.

Background

Electrical spinal stimulation (SS) can be applied to the spinal cord either by implanting electrodes [2, 8-11], or by placing electrodes on the skin surface at the lower back,

known as transcutaneous spinal stimulation (tSS) [12-16]. This form of SS has been shown to facilitate movement in the lower limbs of subjects with long-standing spinal cord injuries [17, 18]. Following SCI a proportion of connections in the spinal cord are inactive or dormant resulting in functional decline [19]. SS is thought to increase excitatory drive, encouraging these spared connections to transmit signals, and allowing some previously unavailable movements to take place [9, 20, 21]. So far, at least four people have been able to stand and have shown increased EMG activity during assisted stepping with implanted SS [10, 11], with similar effects on treadmill stepping with tSS [14, 17]. SS using surface electrodes is simple to use, affordable, and, if proven beneficial, can be used for training/daily tasks at home. This could hugely benefit the SCI community.

Conventional single pulses of tSS activate motoneurons through a monosynaptic pathway referred to as a posterior root-muscle reflex (PRR) [22-24]. As frequencies increase distinct patterns emerge, for example at frequencies of 20-50 Hz locomotor-like activity can be seen in the lower limbs in motor complete SCI individuals [4]. However, at the required amplitude of stimulation, the pulse current may be painful. So-called *Russian* stimulation currents are alternating, high-frequency (2.5-10 kHz) bursts [25] that have been shown to increase muscle force when combined with training in healthy subjects [26] and is considered to be 'less painful' [27] in its delivery in comparison to conventional stimulation. It has also been shown to be beneficial for pain management in individuals with chronic back and lower limb pain [28-30]. This has led to the belief that higher amplitudes of stimulation required to sufficiently activate spinal circuitry can be administered without concomitant pain [6]. However, it is unclear why: which pathways are activated by this high-frequency stimulation (monosynaptic, polysynaptic etc.).

In uninjured people, descending drive modulates spinal CPGs during walking. Following SCI if, some of these descending pathways remain intact, they may contribute to the excitability during motor tasks. Findings from a preliminary electrophysiological study in intact subjects (Duffell et al. *Unpublished; INRS 2017*) demonstrated instant facilitation of motor-evoked potentials (MEPs) with trains of conventional tSS. For lower limb, facilitation was maximal 50 ms after a train of SS was delivered. To investigate this further, in this study we are exploring the reflex responses in lower limb following transcutaneous SS with different stimulation waveforms.

Methods

Up-to twenty healthy volunteers (aged 18-60) with intact nervous systems will be examined. All protocols have been approved by the UCL Ethical committee. For the purpose of this abstract, we only show pilot data from the first 2 subjects.

A. Experimental Setup

Electromyography (EMG) activity in the lower limb was recorded using surface electrodes (2.4 cm Ø, Covidien) placed bilaterally over the bellies of the quadriceps, hamstrings, tibialis anterior and soleus muscles. Reflex responses in the lower limb were established using transcutaneous spinal stimulation (SS) at vertebral levels T11/12 in the supine position (Fig.1). EMG signals were amplified using the D360 8-Channel Patient Amplifier (Digitimer, UK) and digitised using CED 1401 (Cambridge Electronics Design Ltd, UK). Data was then assessed using Signal software (Sampling rate 1000 Hz) provided by Cambridge Electronics Design Ltd before further analysis in MATLAB.

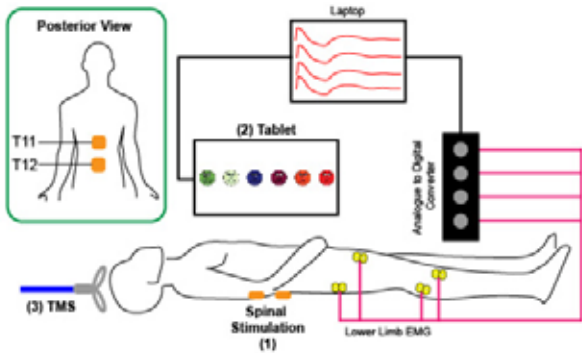


Figure 1: Experimental setup

B. Stimulation Parameters

Spinal stimulation was administered via self-adhesive surface electrodes positioned over vertebral levels T11-12 (Fig.1; 5 cm Ø electrodes, PALS). Reflex responses to three types of waveform were assessed (Fig.2): Single pulse Conventional-Monophasic (1 ms pulse width), 1ms burst of ~10kHz monophasic, and 1ms burst of ~10kHz biphasic.

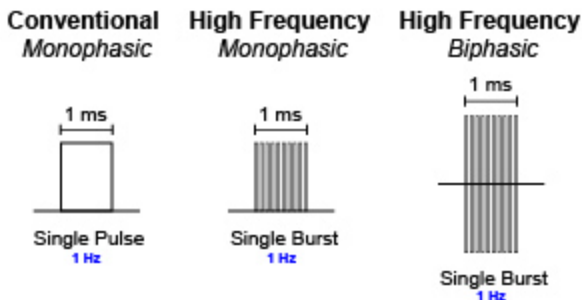


Figure 2: Single pulse/burst current waveforms: Conventional monophasic single pulse (Con-MSP), High-frequency monophasic single burst (HF-MSB) and High-frequency biphasic single burst (HF-BSB).

For the final part of this study, 10 trains of these single pulses/bursts were delivered transcutaneously followed by a TMS pulse at an interstimulus interval of 50 ms. (Double cone coil, Magstim 200).

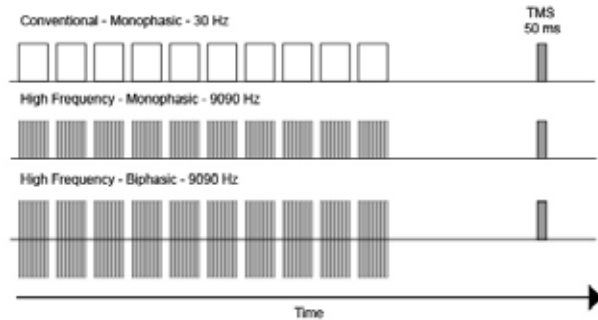


Figure 3: Stimulation trains followed by TMS pulse

In order to achieve this stimulation frequency a Modified-DS8R biphasic constant current stimulator was used (provided by Digitimer, UK).

C. Reflex Threshold and Sensation protocol

Single pulses/bursts (Fig.2) were used to detect motor threshold in lower limb muscles, but not exceeding 200 mA. Once the motor threshold was identified for all waveforms, pain sensation was assessed using a visual analogue scale (Fig. 4).

Here, participants graded the level of pain following individual single pulses/bursts and trains (Fig.2-3) delivered at the current required to elicit motor threshold (mA) for conventional stimulation (C_{thr} ; Table 1. orange). If participants elicited a reflex in response to high-frequency stimulation, this assessment was conducted at both C_{thr} (Table 1. orange) and the current required to elicit motor threshold (mA) for High-frequency stimulation (HF_{thr} ; Table 1. yellow).



Figure 4: Visual Analogue Scale (VAS, 0-10)

D. Cortical MEP Threshold and SS protocol

Motor evoked potentials (MEPs) in the lower limbs were elicited using focal transcranial magnetic stimulation (TMS) over the M1 area of the cortex and a recruitment curve produced to identify stimulation threshold. Once

TMS threshold was selected, adaptations in MEP amplitude was assessed following single pulses/bursts and trains of SS at C_{thr} (Fig.3).

the next stage of the study. Therefore, MEP analysis was conducted only at C_{thr} .

Results

Pilot data obtained thus far for this study are represented in Figures 5-7.

While establishing motor threshold in response to spinal stimulation, we identified a lack of PRR when using the biphasic form of the high-frequency stimulation at the 200 mA limit. Interestingly, we were able to produce PRRs with the monophasic high frequency waveform in one subject (Fig.5) which is about 3x the current required from conventional monophasic stimulation illustrated in Table 1.

Table 1: Average stimulation threshold (n=2, Mean ± SD); Conventional monophasic single pulse (Con-MSP), High-frequency monophasic single burst (HF-MSB) and High-frequency biphasic single burst (HF-BSB).

	Conv-MSP	HF-MSB	HF-BSB
Reflex Thr (mA)	49.9 ± 3.9	178.7	>200

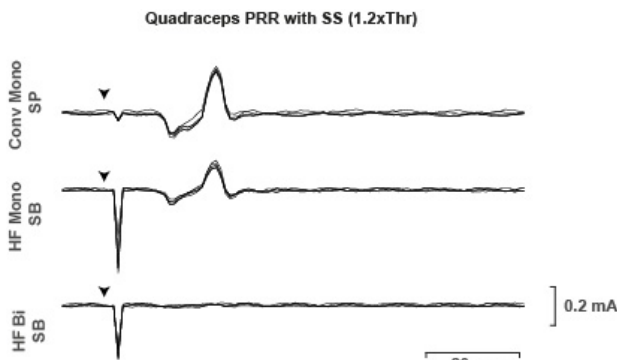


Figure 5: PRR Traces

Once motor thresholds were obtained, an assessment of pain severity was conducted. High-frequency stimulation is often delivered at the same current intensity required to elicit C_{thr} (mA); therefore, we aimed to identify the level of comfort when the intensity was: (1) delivered at C_{thr} (Table 1. orange) and (2) delivered at HF_{thr} (Table 1. yellow). As our maximal current for high frequency stimulation was 200 mA, identification of motor threshold with this waveform was only attainable in one subject (Fig. 5). Figure 6 illustrates a diminished pain score with high-frequency stimulation when delivered at C_{thr} . Interestingly, at HF_{thr} , the pain score for trains was similar to that seen in conventional stimulation.

Whilst HF_{thr} was used here to rate sensation, repeated delivery of these trains proved to be too uncomfortable for

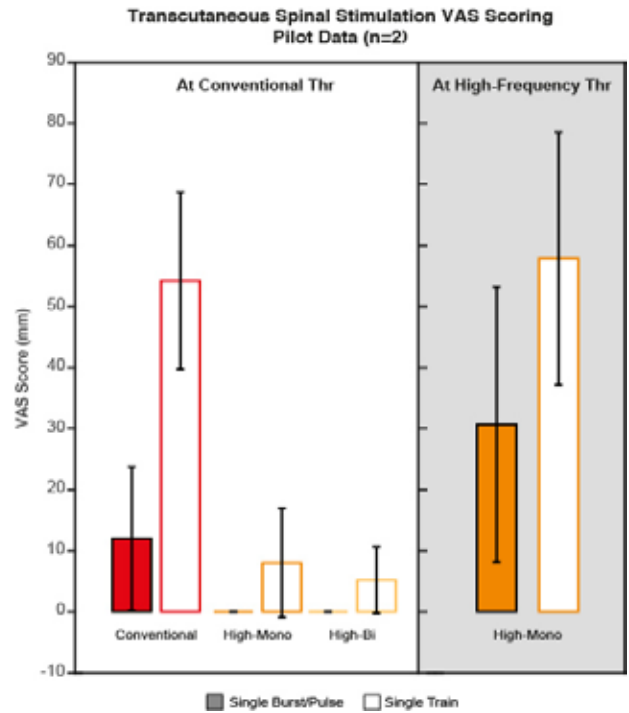


Figure 6: VAS response to waveforms

Data shown in Figure 7 indicates that with either single pulses or bursts, there is only a small but similar facilitation of the MEP, with trains, facilitation is much greater using conventional monophasic pulses. Note that unit amplitude (red line) is with TMS alone.

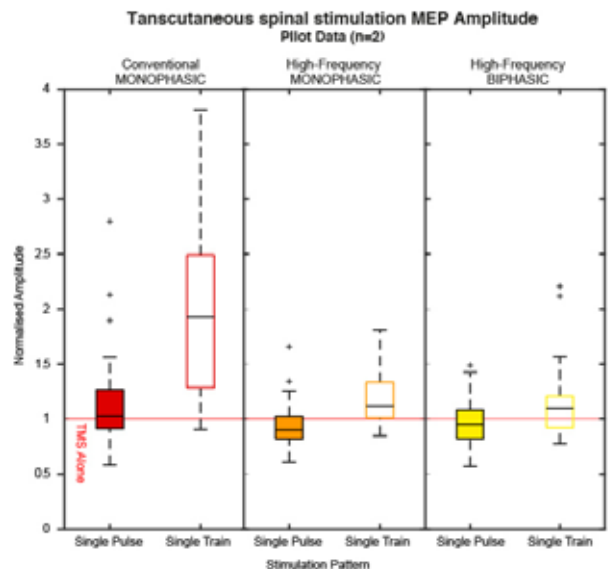


Figure 7: MEPs following SS delivered at C_{thr}

Discussion

The main novel findings of this investigation relate to the mechanism and clinical use of high-frequency stimulation.

Firstly, in order to elicit lower limb PRRs, high-frequency stimulation requires at least 3x greater current (mA) than conventional pulse stimulation. This is important because the pain from high-frequency stimulation must be compared to conventional stimulation when the motor responses are equivalent as this is reported as more comfortable [13, 27]. Secondly, examination of pain sensation revealed that although high-frequency stimulation is less painful at C_{thr} , when the current is at HF_{thr} this advantage is lost. This indicates that although the application of high-frequency stimulation is more comfortable, its ability to produce PRRs is lost.

Finally, here we have shown that the facilitation of MEPs is absent when high-frequency trains of SS are followed by TMS, unlike with conventional stimulation. These early findings suggest that the high-frequency stimulation used in this study is not facilitating descending drive when used at C_{thr} for PRR.

Further investigation of other high-frequencies is necessary. Although our results so far suggest a lack of facilitation of descending drive, high-frequency stimulation could potentially be altering intraspinal circuitry, afferent input, descending tracts (other than CST), ascending tracts and muscle interactions (due to the position of the transcutaneous electrodes).

Acknowledgement

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Long-term paired associative stimulation with novel settings improves hand function in patients with non-traumatic spinal cord injury

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Abstract: We have shown in a pilot study that long-term paired associative stimulation (PAS) with novel settings developed in our laboratory leads to clinically relevant motor improvement in incomplete spinal cord injury (SCI) patients [1]. We have successfully applied this PAS protocol to 5 incomplete traumatic SCI patients in a double-blinded randomised study and showed that the technique is safe and has long-lasting effect [2]. In an ongoing clinical study in patients with SCI of neurologic origin, we are extending the use of long-term PAS for a new type of SCI.

Keywords: paired associative stimulation, transcranial magnetic stimulation, peripheral electrical stimulation.

Introduction

Many therapeutic strategies for SCI aim at enhancing the partial sparing or restoring of the corticospinal tract (CST) [3]. Transient plastic changes in the residual CST can be induced through PAS, the synchronization of transcranial magnetic stimulation (TMS) with electrical peripheral nerve stimulation (PNS) [4].

It was previously unknown whether PAS can have clinically relevant effects after SCI. We have recently shown that long-term PAS improves motor performance in patients with traumatic SCI [1, 2]. Based on these results, we designed a clinical study on patients with SCI of non-traumatic origin, assuming that these patients might have more preserved corticospinal connections and thus could respond to PAS even better than traumatic SCI patients. Additionally, in a study conducted in healthy volunteers, we further improved our PAS protocol and applied it in this clinical study.

Methods

In the study including 5 incomplete traumatic SCI patients [2], each patient received PAS to randomly selected hand as well as PNS combined with sham-TMS to contralateral hand for 4 weeks (16 sessions in total). In a healthy subject study (unpublished data), we tested PAS protocols with different frequencies of PNS component (higher and lower frequencies than previously used), the outcome being measured with motor-evoked potentials (MEP).

In an ongoing single-blind patient study (registered at clinicaltrials.gov), we are applying optimal PAS protocol

derived from the abovementioned work to one hand for 6 weeks. In contrast to the previous study [2], only one hand gets the stimulation; stimulation time is longer; setting for PNS are more optimal.

Results and conclusion

The study in incomplete traumatic SCI patients [2] demonstrated that long-term PAS leads to long-lasting improvement of motor score, is superior to PNS in its efficacy, and is safe (Fig.1).

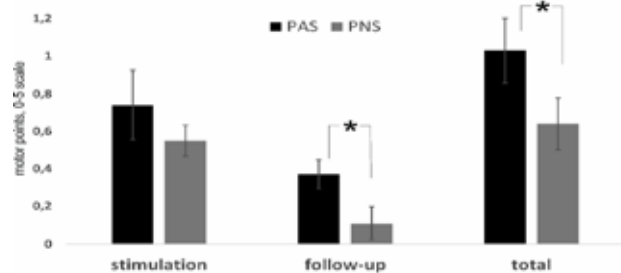


Figure 1: Improvement in the PAS-treated and PNS-treated hand during stimulation (immediately after the 4-week stimulation vs before the stimulation), follow-up period (1 month after vs. immediately after the 4-week stimulation), and in total (1 month after vs. before the stimulation). PAS, paired associative stimulation; PNS, peripheral nerve stimulation

In the healthy subject study, we defined PNS parameters which are more efficient than previously used settings (unpublished data) as estimated by the increase in MEPs up to one hour after stimulation.

The ongoing clinical study (estimated n=7 patients) is currently showing safety and long-lasting motor score improvement of the stimulated hand.

Efficacy of PAS and the availability of the required equipment in many hospitals would allow to easily incorporate the non-invasive technique into medical practice. Further studies with larger number of patients are justified.

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ULTRASOUND IMAGING ANALYSIS FOR THE OPTIMISATION OF FUNCTIONAL ELECTRICAL STIMULATION

22. Annual IFESS Conference

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Abstract: *Ultrasound imaging can be used to evaluate muscle contractions and could provide more information on the way in which electrical stimulation affects muscles. The purpose of this study was to investigate the differences in skeletal muscle behaviour 1) during voluntary and FES-induced contractions, and 2) with different stimulation parameters. Ultrasound videos and ankle torque were recorded during FES contractions with different combinations of current, pulsewidth and inter-pulse interval, and during voluntary contractions of the same intensity. Changes in torque and muscle deformation were evaluated and suggested that co-contraction between muscles could explain the differences between voluntary and FES-induced contractions. Furthermore, pulsewidth was found to have the greatest effect on muscle deformation, although a complimentary relationship exists between pulsewidth and current intensity.*

Keywords: *FES optimisation, stimulation parameters, ultrasound*

Introduction

Functional electrical stimulation (FES) involves the application of low intensity electric current to produce the artificial contraction of a muscle by exciting the nerves which innervate it. FES is widely used in the rehabilitation of muscles affected by stroke or spinal cord injury, and can allow basic functional movements to be performed by paralysed muscles [1].

Despite the wide range of applications, the use of FES is limited by the early onset of muscle fatigue. This has been attributed to muscle fibres being recruited differently during an FES-induced contraction compared to a voluntary contraction. During voluntary muscle contractions, the size principle dictates that smaller more fatigue resistant motor units are recruited first. In contrast, it is widely accepted that FES-induced contractions do not follow this principle. Furthermore, the same muscle fibres are repeatedly recruited, unlike during voluntary contractions where asynchronous activation of varied muscle fibres allows replacement of fatigued fibres [2]. The exact mechanism of motor unit recruitment during FES and how it differs from recruitment during voluntary contractions is still unclear.

Ultrasound imaging (USI) is a potential tool which could help to improve understanding of muscle behaviour during electrical stimulation. This non-invasive imaging technique uses the behaviour of sound waves travelling through tissue to

allow internal structures such as muscles to be visualised. B-mode ultrasound allows both static and dynamic parameters of the muscle to be measured in vivo. Static parameters describe the muscle morphology in terms of size, shape and structure (e.g. thickness, fibre length and pennation angle). Dynamic parameters are the changes in these measurements which occur when the muscle contracts and provide an indication of muscle activity. The use of ultrasound imaging is well established and several studies have demonstrated its use for obtaining size measurements and relating architectural parameters of the muscle with muscle activity [3].

The aim of this study to use USI to analyse the behaviour of skeletal muscle during both voluntary contractions and FES-induced contractions under different stimulation parameters. This could improve the understanding of the mechanisms of muscle activation by electrical stimulation. Furthermore, determining how different parameters affect the muscle can help improve the effectiveness of FES interventions.

Methods

Participants: Ten healthy able-bodied volunteers (2 male, 8 female, 33.4 ± 11.5 years) participated in this study. All participants gave written informed consent and the study was reviewed by the College of Science and Engineering Ethics Committee at the University of Glasgow.

Apparatus: Ankle torque was measured by a dynamometer (Biodex, USA) and was recorded by PC via a data acquisition board (DAQ-6024E, National Instruments, USA) at a sampling frequency of 50Hz. Ultrasound videos of the medial gastrocnemius muscle (GM) were recorded on an Echoblaster

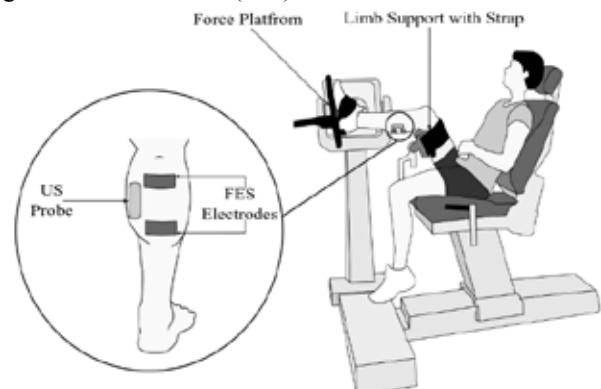


Figure 1. Experimental setup: participant is seated on dynamometer with foot strapped to the force platform. USI probe and FES electrodes are positioned over the GM.

128 ultrasound (Teleded, Italy) with a sampling rate of 40 frames per second, using a linear probe of 60mm length. A computer controlled FES stimulator (RehaStim v1, Hasomed, Germany) was used to deliver the electrical stimulation through 5x9cm PALS Platinum electrodes (Axelgaard, USA) placed over the gastrocnemius muscle. The FES stimulator was controlled through custom MATLAB & Simulink Models through a single-board computer (Raspberry Pi, UK). The experimental setup is shown in Fig. 1.

Procedures: The study had four main parts: determine the maximum voluntary contraction (MVC), setting the stimulation parameters, FES protocol and voluntary protocol.

1. Maximum Voluntary Contraction (MVC)

The MVC was determined using the burst superimposition technique. Participants performed an isometric MVC, during which a short burst of supramaximal stimulation was delivered. If the burst did not cause a change in ankle torque of more than 10%, it was considered a true MVC.

2. Stimulation Parameters

The maximum and minimum current (I_{max} and I_{min}) to be used for each participant were defined as follows:

- I_{min} : the lowest value of current required to produce a muscle contraction which registers a torque output on the dynamometer. This was found by applying a pattern of stimulation trains where for each value of current tested the pulsewidth consisted of a ramp up phase (2.5s), a constant phase (5s) and a ramp down phase (2.5s). The current during the first train of pulses was 2mA and increased in increments of 2mA until the minimum current was found.
- I_{max} : the lowest value of current required to produce an activation curve that gradually increases to a plateau and does not increase in torque from the previous value of current tested. A current activation curve tests one value of current at a time by slowly increasing the pulsewidth over 10 seconds before remaining constant for a further 5 seconds.

The pulsewidth and inter-pulse interval (IPI) values were the same for all subjects, yielding 12 different combinations of stimulation parameters as shown in Tab. 1.

Table 1. All combinations of stimulation parameters

I_{min}	I_{max}
PW1=300 μ s, IPI1=50ms	PW1=300 μ s, IPI1=50ms
PW2=350 μ s, IPI1=50ms	PW2=350 μ s, IPI1=50ms
PW3=400 μ s, IPI1=50ms	PW3=400 μ s, IPI1=50ms
PW1=300 μ s, IPI2=25ms	PW1=300 μ s, IPI2=25ms
PW2=350 μ s, IPI2=25ms	PW2=350 μ s, IPI2=25ms
PW3=400 μ s, IPI2=25ms	PW3=400 μ s, IPI2=25ms

3. FES Protocol

Stimulation trains were applied to produce one contraction with each combination of stimulation patterns (12 contractions in total) in a random order. Each

muscle contraction lasted 10 seconds (2.5s ramp up phase, 5s constant phase, 2.5s ramp down phase) and contractions were separated by a 5 second rest period. There were three variations of this FES protocol:

- Constant: all stimulation parameters remained constant for a single contraction.
- Variable Inter-pulse Interval: the inter-pulse interval was varied by ± 5 ms around a mean value (IPI1 or IPI2) for each contraction.
- Variable Pulsewidth: the pulsewidth was varied by ± 20 μ s around a mean value (PW1, PW2 or PW3) for each contraction.

Each variation of the protocol was carried out with 5 minute rest periods between them. The order was randomised.

4. Voluntary Protocol

The participant performed voluntary contractions to reach certain torque values by following a target on a computer screen. The target values were based on the torque produced during the FES protocols. There were 12 contractions in total, matching the 12 combinations of stimulation parameters in each FES protocol.

Outcome Measures: The two main outcome measures were the deformation of the muscle recorded from the ultrasound and the torque produced. The tracking software was based on Darby et al. [4] and uses automatic segmentation to define anatomically distinct regions of the muscle, i.e. it separates the upper and lower aponeuroses and the muscle tissue itself. By creating a point distribution model (PDM), an active shape model (ASM) can be fitted to new images by performing a probabilistic search for known shapes. The thickness of the muscle is obtained from the output of the tracking software and is defined as the average distance between the superficial and deep aponeuroses. Muscle deformation x , is defined as the change in muscle thickness (ΔT) as a percentage of the muscle thickness at rest (T_0) as shown in Eq. 1.

$$x = \frac{\Delta T}{T_0} \times 100\% \tag{1}$$

Results

An example of typical torque and muscle deformation for a single participant is shown in Fig. 2. The torque increased as the stimulation intensity increased and the value of torque produced was similar for each combination of stimulation parameters across all variations of FES (constant, variable inter-pulse interval, variable pulsewidth) and voluntary contractions. For all variations of FES, the muscle deformation increased by a similar amount for a particular combination, i.e. the thickness of the muscle increased. In contrast, during voluntary contractions the muscle deformation is negative, i.e. the muscle thickness decreased, and the amplitude of the change in thickness is also smaller.

Initial group results from four subjects, shown in Fig. 3, indicate that muscle deformation is significantly increased by increasing the pulsewidth at the minimum current value during both the ramp up and constant phases.

At the maximum current value, increasing the pulsewidth has no significant effect during the ramp up phase but causes a decrease in muscle deformation during the constant phase.

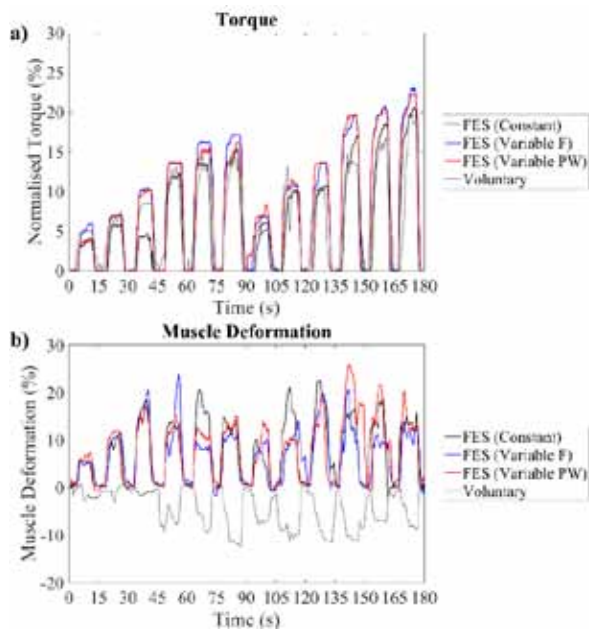


Figure 2. a) normalised torque and b) muscle deformation for a single subject in order of stimulation intensity (IPI of 50ms and 25ms for contractions 1-6 and 7-12 respectively).

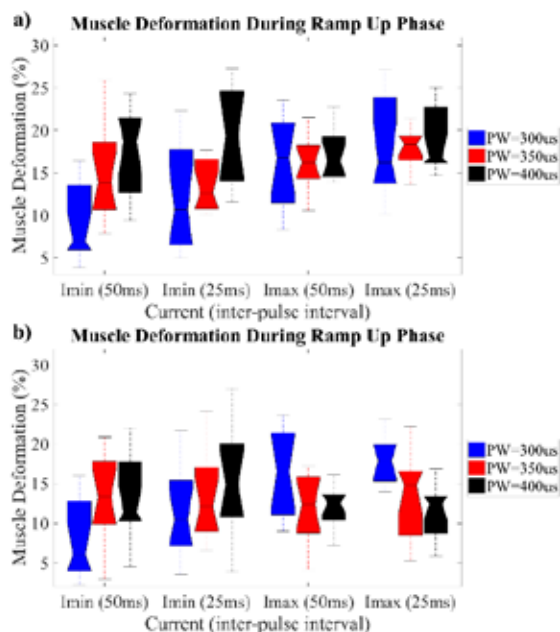


Figure 3. Muscle deformation for each combination of stimulation parameters, measured during a) the ramp up phase and b) the constant phase.

Discussion

The differences in muscle deformation between voluntary and FES-induced contractions are consistent with the behaviour of synergistic muscles. During voluntary

contractions both the gastrocnemius muscle and the deeper soleus muscle are activated, therefore a possible explanation for the decreased deformation is that the co-contraction of these muscles causes the soleus to restrict or compress the gastrocnemius muscle at these relatively low levels of torque. In contrast, during FES-induced contractions the soleus is not activated by electrical stimulation and the increased deformation, which is expected with increased fibre activation and pennation angle, can be seen. This illustrates the complex interactions between different muscles which cannot be achieved with FES.

The relationship between muscle deformation and pulsewidth is similar to that of previous studies which investigated the effect of different stimulation parameters on torque and agrees with the widely accepted concept that a higher pulsewidth recruits more muscle fibres [6-7]. These studies also showed a relationship between current intensity and torque which is not as significant to muscle deformation. At high current intensities muscle deformation is either relatively unchanged or decreases with increased pulsewidth, however the torque produced does continue to increase. This suggests that although the pennation angle is not changing, more muscle fibres are still being recruited, and therefore there is a complimentary relationship between pulsewidth and current intensity.

In conclusion, the changes in muscle deformation seen during voluntary and FES-induced contractions of different intensities provide further insight into the behaviour of muscles under these different conditions.

Acknowledgement

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POTENTIAL BENEFITS OF A FES-CYCLING PREPARATION FOR A COMPETITION OF AN INDIVIDUAL WITH A HIGH-LEVEL PARAPLEGIA

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The literature contains considerable data showing that physical training programs are crucial to reduce the consequences of inactivity. In recent years, several innovative techniques have been developed to train the “active” mobility of the lower limbs in SCI rehabilitation programs. The primary objective of functional electrical stimulation (FES) is to mobilize the motor participation of as many sublesional muscles as possible, thereby improving cardiovascular and respiratory physiology. Cycle ergometers are motorized and thus offer only passive mobilization. Another possibility is the recumbent bike with foot pedaling. It combines therapeutic training under FES with pleasure and offers the option of outdoor cycling. The great difference between the FES-driven recumbent bike and the cycle ergometer is the need to control the stimulation pattern of the bike with regard to the terrain - trajectories (e.g., turns), surfaces, topography - and the cycles of crank rotation. Equipped with pedal angle sensors, the technology embedded in these devices has continuously progressed, and the bikes have become far lighter. Over 360° of pedal rotation, each muscle is stimulated for a predetermined period corresponding to a portion of the pedaling cycle. Generally, this involves the glutei, quadriceps and hamstring muscles. The intensity of stimulation applied to these muscles determines the moments of force and the rate of rotation produced on the pedals. The stimulation pattern is pre adjusted over the course of training to determine the best muscle synergies to be implemented.

This case study presents the feasibility of a long period of training of a paraplegic subject on a FES-assisted recumbent bike – initially fixed on a stationary stand and then over open terrain. The other objectives were to assess the impact of this type of training on pain, cardiorespiratory function, muscle atrophy, body composition and bone metabolism and the medical-technical requirements in order to personalize the adaptations of the stimulation patterns and use of the recumbent bike in a standardized outdoor environment.

Training modalities

A home FES program consisting in 30-mn sessions 2 to 3 times per week was proposed to the

patient followed by a FES program on the recumbent bike, first stationary and then on open terrain in a standardized environment (Table 1). The stimulation at the start of training was a generic pattern provided by the stimulator and designed to be adjusted in order to optimize pedaling performance, provide smooth and regular pedaling, and reduce fatigability. The subject can directly adjust the stimulation intensity delivered to the muscles, via the FES stimulation box interface. We have modified the pattern to optimize the pedaling of our patient (Fig.1).

Profile of the subject

The subject was JP, 47 years old at the time of inclusion. He had been the victim of a vertebromedullary trauma in May, 1995, that left him with paraplegia T3, AIS A with no zone of partial preservation, and an ASIA motor score of 50 and an ASIA sensory score of 20.

Tolerance indicators. No osteoarticular, cutaneous, or cardiorespiratory morbidity was noted. The systolic and diastolic blood pressure and the pulse rate measured 1 minute after the end of electrostimulation in each of the weekly sessions never exceeded a mean 154 mmHg \pm 15 (R: 135-193), 95 mmHg \pm 8 (R: 78-109) and 76 bpm \pm 8 (R: 61-92), respectively. At 5-minute recovery, the values were as follows: 144 mmHg \pm 12 (R: 112-157), 92 mmHg \pm 10 (R: 70-106) and 69 bpm \pm 10 (R: 49-87), respectively. Spasticity never ended a session. The weekly perceived effort (Borg Score) rating fluctuated over the first 6 months between 9 to 15 but tended to decline in the second period of training to 7. The initial level of satisfaction was high, around 8/10, but fell at points to 6/10 before returning to 8/10, and peaked at 10/10 the day after the competition.

Training began on the stationary Berkelbike Pro® and, in week 19 when JP switched to the competition ICE Trike Adventure, his pedaling duration increased dramatically. In parallel, non-stationary trials on this same bicycle showed an increase in the pedaling time in week 17 coinciding with three technical changes: switching the bike to fixed-gear (with pedals permanently coupled to the rear wheel), stimulation distributed over the different quadriceps heads, and the determining effect of changing the rolling surface for better ground adhesion. After the Cyathlon competition –week 22-, JP interrupted his cycle training but continued with two FES sessions per week at

home between weeks 22 and 29. At the end of this interruption, he had maintained an optimal endurance level and pedaled for 13 minutes and 44 seconds.

Impact indicators. We evaluated four factors: thigh circumference, body mass, BMD and cardiorespiratory function. Thigh circumference did not significantly increase, although JP noted a change in the shape of his thighs and said that he felt more at ease wearing short pants or shorts. The body mass (DXA) at the beginning and the end of the cycle training suggested an overall decrease in body fat in the arms and trunk – that is, above the lesion level. BMD showed a positive trend, with the T-score changing from -1.6 to -1.5. The increase in BMD mainly concerned the pelvis and leg bones. Last, in terms of cardiorespiratory measures, the maximum load of 90 W was maintained for 1 minute at the beginning but also the day after training. The maximum heart rate (MHR) changed from 96 to 103% of the mean value. VO2max showed a small drop but the final measure may have been underestimated in the final phase.

The subject’s perceived quality of life was reflected by both the Physical and Mental Component scores on the SF36. All dimensions but physical and emotional functioning showed significant improvement of at least 10%. The score on the Rosenberg Self-Esteem Scale was 36/40 on inclusion but rapidly improved and remained at a level of 39 or 40/40 up to the competition. Finally, the functional impact was assessed in two situations:

- Speed during Cybathlon 2016 at week 22. The subject distinguished himself by reaching the objective of covering 750 m in under 8 minutes. He covered this distance in 467 s at an average speed of 5.80 km/hr and a maximal speed of 6.14 km/hr. The pedaling was smooth and regular as evidenced by the low variability in his speed.

- Endurance at week 29. Although JP interrupted his cycle training between weeks 22 and 29, he continued home FES and showed a significant improvement over his previous performances by covering in one go a 1,080-m run in 13 minutes and 44 seconds for a mean speed of 4.6 km/hr and a maximal speed of 9.4 km/hr.

Conclusion

FES-discipline at Cybathlon 2016 brought together paraplegic individuals, researchers, engineers, industrialists and clinicians around a medical-technological challenge. Our feasibility study required considerable effort and energy from the subject, JP, and great availability on the part of his team. Several important conclusions can be drawn: (1) a person who has been paraplegic for many years (more than 20) with a high lesion level (T3 AIS A) can undertake this type of challenge if the prerequisites are met; (2) not all the muscles are essential, although the quadriceps play a decisive role in driving the cranks and the hamstrings are important in stabilizing the knee; (c) this type of training is without danger if the safety precautions are respected; (4) the training itself, the challenge of participating in a competition, and the sheer pleasure of cycling outdoors without attracting stigmatizing attention all had a powerful impact on JP’s self-esteem and perceived quality of life; and (5) the degree of progress we observed justifies a multicenter, controlled and randomized study with the main objective being 75% improvement over a 4-month training period.

Acknowledgments

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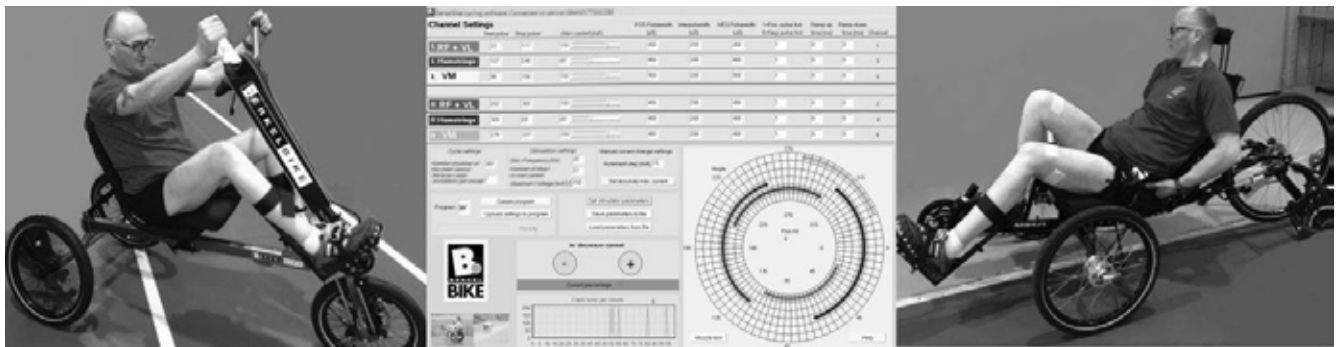
Table 1. Schedule for the muscle training program

Inclusion	Clinical examination / venous Doppler ultrasound of lower limbs /exercise test /mapping of sublesional muscles for electrical stimulation
1st to 6th month	Home electrostimulation (isometric mode): 2 to 3 30-minute sessions per week using the Cephar Physio 4® with 4 cables: Parameters: rectangular currents with rising ramp, frequency: 30 Hz, pulse duration: 300 µs, [redacted] stimulation trains: 10 s and rest time: 3 s Repartition of electrodes: [redacted] -month 1: right and left rectus femoris, right and left biceps femoris (surface electrodes: 5 x 5 cm) -months 2 to 6: right and left quadriceps (rectus femori, vastus lateralis and vastus medialis), right and left hamstrings (biceps femoris, semi-membranous, semi-tendinous) (larger surface

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	electrodes: 4.5 x 10 cm)
7th to 11th month	<p>FES on stationary recumbent bike Berkelbike Pro® then non-stationary: 2 to 3 30-minute sessions per week with the Berkelbike FES Box® with 6 cables</p> <p>Parameters: rectangular currents with rising ramp, frequency: 30 Hz, pulse duration: 300 µs, [REDACTED]</p> <p>stimulation trains: 10 s. Maximal intensity: 150 mA</p> <p>Repartition of electrodes: [REDACTED]</p> <p>-2 large electrodes for the right and left quadriceps (1 for rectus femori + vastus lateralis and 1 for vastus medialis)</p> <p>-1 large electrode for the right and left hamstrings</p>
12th month	Cyathlon competition

Fig. 1. a) Berkelbike b) Final stimulation pattern for sublesional muscles (RF: rectus femoris, VL: vastus lateralis, VM: vastus medialis) c) Ice Trike Adventure



DEVELOPMENT OF AN ANATOMICALLY-BASED FOREARM MODEL TO SIMULATE SELECTIVE MUSCLE ACTIVATION

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Abstract: Functional electrical stimulation (FES) is an established method in motor recovery, but the quality of the movements is still not satisfying especially for the hand. Current research focuses on the experimental determination of the best stimulation configurations. Electrode arrays are used in combination with sensors that enable automatic evaluation of the stimulated movements. Nevertheless, it is not possible to test all combinations in experiments. Modelling and simulation has been shown to be a good option to research FES more in detail, but lack in the analyses of selective muscle activation. This paper presents the development of a new forearm model, that includes additional Regions-of-Interest (ROI) to represent the individual muscles and enable the simulation of selective muscle activation.

Keywords: FES, grasping, selectivity, anatomically-based model, simulation

Introduction

Functional electrical stimulation (FES) has received much attention in recent years due its positive effects on motor recovery of patients after stroke or spinal cord injury. By attaching electrodes to the skin of the forearm, functional hand movements can be stimulated during physical training of grasping tasks. However, the induced movement depends on several influence factors and especially for the hand it is difficult to achieve defined and physiologic movements [1–3]. To achieve a functional grasp of the hand selective movements of the wrist and fingers need to be combined [3]. The stimulation of selective wrist and finger movements depends on where the motor innervation nerve is activated. To stimulate a muscle or muscle part individually, the terminal branch of the innervating motor nerve has to be excited. Otherwise, all muscles innervated by branches of this nerve with junctions, that are located distal with respect to the stimulated nerve section, will also be activated [1]. Thus, the ideal stimulation setting is the combination of electrode position and properties plus stimulation parameters that lead to an excitation of the individual terminal nerve branches; just before the nerve entry point (NEP) [5]. Due to the high number of muscles, in case of the forearm, it is particularly important to use the correct electrode positions, also referred to as motor points (MPs), for stimulation [1,4].

Current research focuses on the experimental determination of the MPs by evaluating the stimulated movement for many different electrode positions. To avoid time consuming replacement procedures, multichannel systems with electrode

arrays are used. The stimulated movement is then evaluated manually by an expert [6] or automatically by measuring the movement [2,4,7] or force [8] to select the best combination from the tested. Nevertheless, this procedure is still time consuming and not all stimulation settings can be tested. Therefore, another approach in research is to model and simulate FES. Simulations have been used before e.g. to analyse the influence of electrode size and position or current amplitude on the stimulation [5,9,10]. With regard to selectivity, different evaluation criteria have been used. Kuhn and Keller [9] used the depth/width ratio of an activation volume defined by a threshold value to generally evaluate the selectivity of a stimulation. Others defined for one muscle a so-called motor axon volume (MAV) to determine the activation level of that muscle depending on the stimulation settings [5,10]. However, to investigate the influencing factors on selective muscle activation using simulations, it is not sufficient to look at general effects or one single muscle. The adjacent muscles have to be considered as well.

In this paper we present the development of an anatomically-based model of the forearm, that includes several Regions-of-Interest (ROIs) to represent the individual muscles. A ROI was defined as a specific volume around the NEP of a muscle, which was assumed to cover the terminal nerve branches. Thus, the model can be used to analyse the influences on selective muscle activation having regard to the spatial distribution and interdependences of different muscles.

Methods

The presented development is completely based on MR image data of a healthy subject (male, 28y, right forearm, axial scan with slice thickness 1.4 mm), who also is available for future experiments. Thus, a good comparability should be given. At first, an anatomic 4-layer model was built. Then the positions of the ROIs were determined in the image data and the ROIs were integrated into the 4-layer model. To determine the required positions, experimentally values of the NEPs were taken from literature and transferred to the anatomy underlying this work.

The development of the model was realized using a CAD software (Solidworks, Dessault Systems). Figure 1 shows the anatomic 4-layer-model, that consists of the two bones, ulna and radius, which are surrounded by muscle tissue, a fat layer and a skin layer. Every 30th image of the data set was used to design these structures. Therefore, the contours of the bones, the muscle-fat limit and the most outer contour, the skin, were approximated by circles and ellipses. The model was extended since it did not

cover the most lateral extension of the lateral epicondyle of the humerus (LEH), but this was used for the reference system when defining the positions of the ROIs. In accordance with the visible proportion of the epicondyle an extension of one slice thickness (1.4 mm) seemed to be appropriate to approximate the real position of the most lateral extension of the epicondyle. The distal end of the model was defined by slice I_{195} , which showed the position of the radial styloid process (RSP). As the bones started more distal and ended more proximal, the corresponding slices were used additionally. Thus, for the design of the 4-layer model the following MR images were used: I_0 , I_{10} , I_{30} , I_{60} , I_{90} , I_{120} , I_{150} , I_{180} , I_{186} , I_{195} .

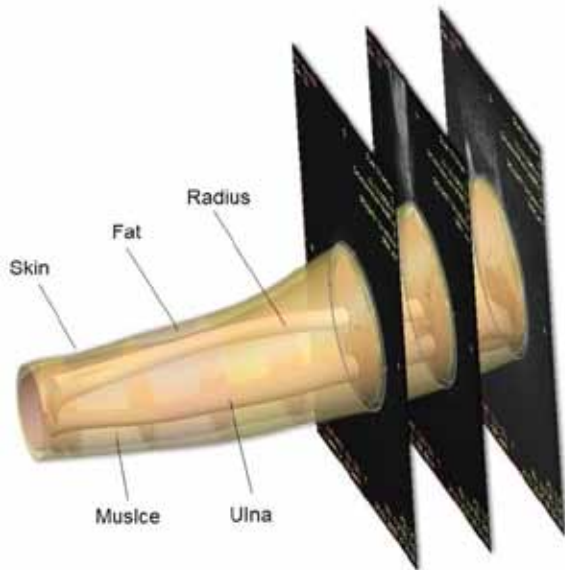


Figure 1: Anatomic 4-layer model with skin, fat, muscle and bone layer. The contours of the bones, the muscle-fat limit and the most outer contour, the skin, were traced on every 30th MR image to model the layers.

First, the images were correctly positioned and scaled. For this, they were aligned to coordinate systems of parallel planes, which were separated according to the image distances in the scan, e.g. $30 \times 1.4 \text{ mm} = 42 \text{ mm}$ for I_0 and I_1 . The required size of the images determined by measuring image height and width in ScanIP. Afterwards the mentioned contours were traced in all images and corresponding volume models were generated. The skin layer was modelled with a constant thickness of 1 mm similar to other layer models [9,10]. Therefore, it was not necessary to trace the skin-fat limit in the images.

To determine the positions of the ROI, it was necessary to match the required muscles correctly in all axial slices. To realize this, we took advantage of the 3D modality of the scan and performed a 3D-segmentation (Simpleware ScanIP). Due to the simultaneous use of the sagittal and coronal sections, the individual muscle courses could be tracked through neighbouring axial slices. This was essential for the correct matching. Figure 2 shows such a 3D-segmentation for seven muscles of the forearm with marking in all three sections (A-C) and corresponding volume models (D).

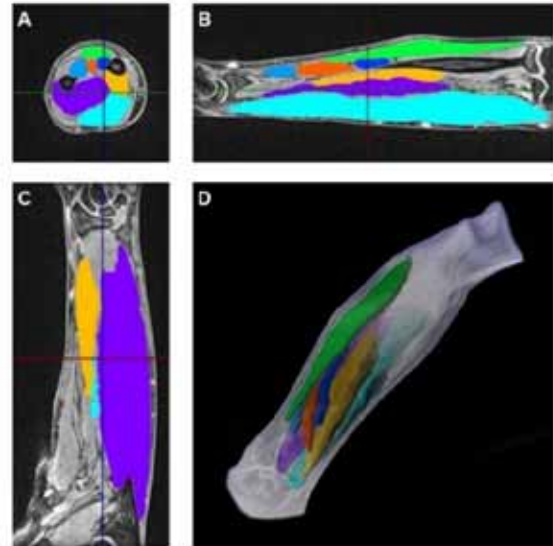


Figure 2: 3D-segmentation of the individual muscle: axial (A) Axial view; (B) Sagittal view; (C) Coronal view; (D) 3D view (same colours as in Figure 5).

Based on this matching the ROIs were designed and integrated to the layer-model. As the ROIs were defined in this work as specific volumes around the NEPs of muscles, first, these positions had to be determined. This was realized based on reference values from literature. Several studies were found and analysed, but only one fulfilled our requirements; good transferability and analysis of all 19 muscles of the forearm.

Liu et al. [11] analysed the positions of NEPs of the muscles in 10 cadaveric forearms. For each detected position the distance to the lateral epicondyle of the humerus was documented, as indicated by L_{NEP} in Figure 3. Then the distances were standardized in respect to a reference length, that was defined by the radial styloid process (Figure 3, L_{Ref}). Thus, all point positions were given in percent values in respect to L_{Ref} . For the setup of the model, the median as well as the minimum (most proximal) and maximum (most distal) were used. Figure 3 depicts the four steps needed to determine the position of one NEP. The first step was to measure the reference length of the anatomy used in this work. This was realized by identifying the two reference points in the images, which was already done when building the 4-layer model. The lateral epicondyle was found on I_0 and the radial styloid process on I_{195} . As the scan direction was approximately parallel to the radius, the reference length was calculated according to equation (1). In the second step the distances to the NEPs were calculated for the underlying anatomy according to equation (2). The corresponding slices I_{NEP} were determined according to equation (3) and loaded into the model with the position, they had in the scan. Finally, the corresponding muscle was outlined in the assigned slice.

$$L_{Ref} = (N_{RSP} - N_{LEH}) \times 1.4 \text{ mm} = 273 \text{ mm} \quad (1)$$

$$L_{NEP} = L_{Ref} \times X_{NEP} \quad (2)$$

$$I_{NEP} = \frac{L_{NEP}}{1,4 \text{ mm}} \quad , I_{NEP} \in \mathbb{N} \cap [0, 195] \quad (3)$$

The median slices were used as real positions of the NEPs and in consequence as centres of the ROIs. In contrast, the minimum and maximum slices were used to define the course of the muscle surface and in consequence the extrusion direction of the ROI. On each of the slices, the muscle surface, through which the nerve enters the muscle, was identified according to Safwat and Abdel-Meguid [12]. Figure 4 visualizes this approach for the flexor digitorum superficialis muscle.

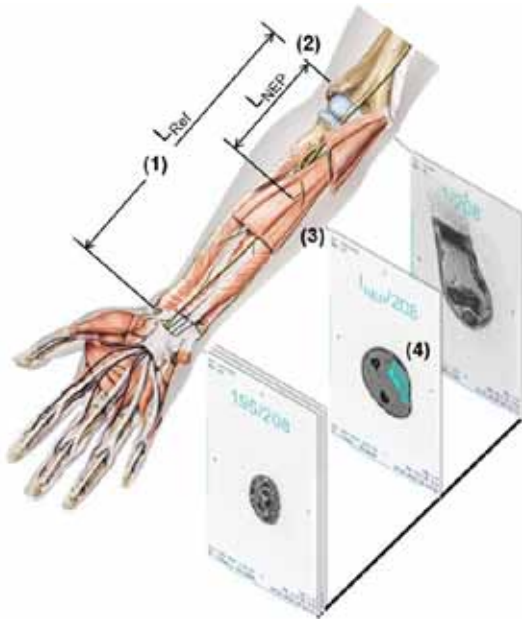


Figure 3: Approach to determine the NEP of a muscle in the image data: (1) Determination of the reference length; (2) Calculation of the distance to the NEP in the used anatomy; (3) Assignment of the corresponding slice; (4) Identification of the muscle.

Results

The aim of this work was to develop an anatomically-based model of the forearm, that can be used to analyse the influences on selective muscle activation having regard to the spatial distribution and interdependences of different muscles. Figure 5 shows the developed model. It includes four different tissue layers with anatomically-based shape and nine ROIs to represent seven individual muscles: Extensor digitorum ED (green), Extensor pollicis longus

EPL (light blue), Extensor pollicis brevis EPB (red), Abductor pollicis longus APL (dark blue), Flexor digitorum superficialis FDS (turquoise), Flexor pollicis longus FPL (orange), Flexor digitorum profundus FDP (purple). Table 1 shows the values that were used to model the corresponding ROIs. For the two flexor digitorum muscles the values reported by Liu et al. [11] covered nearly the whole muscle body. As this would lead to inaccurate representations of the muscles, additional literature was considered to reasonable split the regions. For the FDS a functional split was defined according to Bickerton et al. [13]. One NEP was defined for the muscle bodies moving the fingers II and V and another NEP for that part of the muscle moving finger III and IV. In contrast the FDP was split according to the anatomy, as the muscle generally is innervated by two nerves, the ulnar nerve and the anterior interosseous branch of the median nerve [14].

The developed 4 layer-model is basically the same as previous simplified layer models, that have a circular or rectangular base, which is extruded either parallel or tapered [5,9,10]. In contrast to the existing models in the presented model the single layers have an anatomic shape based on MRI data. All models have in common that the muscle layer is a continuous layer of homogeneous muscle tissue without differentiation of various individual muscles. The developed model was extended correspondingly. Inspired by the MAVs used by Gomez-Tames et al. [5] and Loitz et al. [10], the model includes ROIs to represent several muscles and enable their differentiation during simulation.

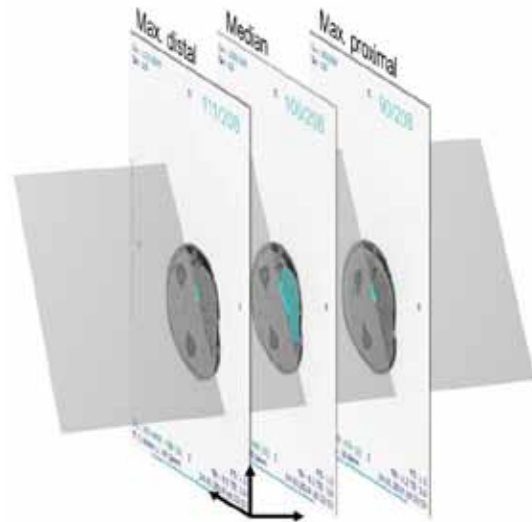


Figure 4: Design of the ROIs. To get the muscle course, a temporary plane was defined based on the muscle surfaces identified in the max. proximal and distal planes.

Table 1: Percent values taken for the modelling, most proximal (line 1), median (line 2) and most distal reported values.

ED	EPL	EPB	APL	FDS-1 Finger II +V	FDS-2 Finger III + IV	FPL	FDP-1 Median nerve	FDP-2 Ulnar nerve
18 %	40 %	41 %	34 %	(- 5.5 %)	(- 5.5 %)	25 %	(- 5.5 %)	(- 5.5 %)
33 %	53 %	60 %	39 %	74 %	52 %	35 %	37 %	27 %
50 %	68 %	70 %	45 %	(+ 5.5 %)	(+ 5.5 %)	60 %	(+ 5.5 %)	(+ 5.5 %)

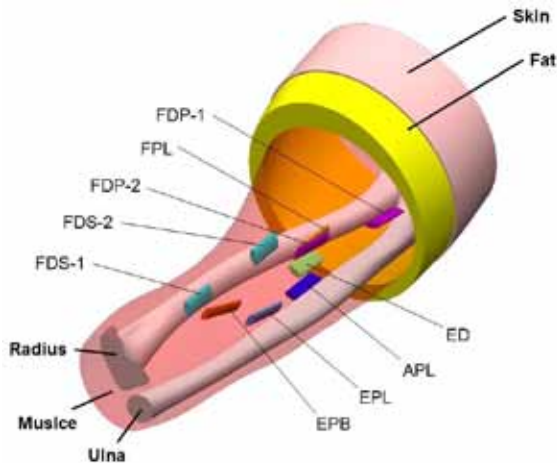


Figure 5: The resulting anatomically-based model with 9 ROI to differentiate 7 muscles. The skin and the fat layer were sectioned to visualize the ROIs in the muscle tissue.

Discussion

In this work a new anatomically-based forearm model was developed, that is supposed to enable simulation-based analyses of the influences on selective muscle activation during FES. The model bases on the common approach to use simplified layer-models for simulations but was extended appropriately to enable the differentiation of various individual muscles. Despite the abstractness of the muscle representations as a specific volume around the NEP, it is expected that individual muscle activation during FES can be simulated reliably using the presented model. For one individual muscle this has already been demonstrated [5,10]. Nevertheless, no evaluation of the presented model has been performed so far. Therefore, a systematic comparison of simulated muscle activities with real movements will be conducted. First this will be done for the scanned person, but to enable the generalization of future analysis further comparisons with random persons will also be conducted. After a successful evaluation, the new model can especially be used to analyse how muscles can be activated individually. Electrode position is probably one important influence factors, but other factors as current amplitude or fat thickness have an impact too. The presented model will enable detailed analyses of all these influencing factors to improve the stimulation of functional and physiological hand movements.

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Automatic Configuration of an EEG-Triggered Neuroprosthesis for Grasping: Proof-of-Concept Study

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Introduction

Functional electrical stimulation therapy (FEST) can restore voluntary motor function after spinal cord injury and stroke [1]-[4]. In each FEST session, patients are repeatedly asked to perform targeted functional movements with an impaired limb and, after a few seconds, a therapist triggers the electrical stimulation that facilitates the attempted movement. Central to the potential mechanisms that explain the efficacy of FEST is the massed practice of functional movements in which a motor command (i.e., attempted practiced movement) is met with the corresponding proprioceptive and somatosensory activity resulting from the artificially produced movement [5]. The objective of this study was to develop a novel FEST system to further emphasize these key factors in FEST, through the integration of 2 technological solutions. First, a brain-computer interface (BCI) was used to trigger the functional electrical stimulation (FES) by detecting the participants' intention to move using neurological indicators obtained through real-time analysis of their electroencephalographic (EEG) activity. Second, a computer vision (CV) system identified objects used in therapy and informed the electrical stimulation of the required grasp type.

Methods

The EEG-triggered FEST assisted by computer vision (CV+BCI+FEST), shown in Fig. 1, had three main components:

1) A neuroprosthesis for grasping, implemented with two four-channel programmable electrical stimulators, was designed to facilitate precision and lateral pinch (stimulator 1) as well as power and lumbrical grasps (stimulator 2). The specific grasping sequence of each stimulator could be triggered with an external digital signal.

2) A BCI was created using a single monopolar electroencephalographic (EEG) electrode. The specific electrode site was selected with an initial configuration process which also identified the participant-specific frequency components displaying a reduction of power indicative of attempted movements. The BCI acted as a 'brain switch' which was activated with decreases in alpha (8 Hz - 12 Hz) or beta (13 Hz - 13 Hz) components of EEG and it generated two independent digital signals (used to control each stimulator). Participants were not trained to operate the BCI and there was no time limit to activate it.

3) A computer vision system, created using a computer camera (webcam) to identify eight objects requiring the grasp types facilitated by the neuroprosthesis (two objects for each of the four grasps).

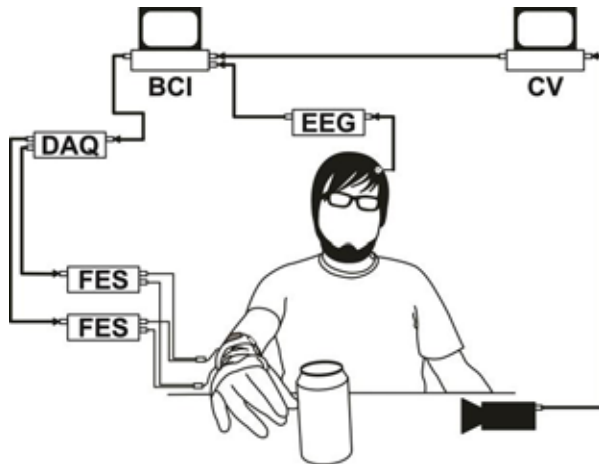


Figure 1. Experimental setup. An object was first placed on a table in front of the participant. A computer vision system (CV) then identified the object and determined the type of grasp required to hold it. The CV system then informed of the required grasp to a brain-computer interface (BCI) via TCP/IP (transmission control protocol/Internet protocol) which used this information to determine the specific stimulation sequence to trigger to produce the required movement. The participant was then asked to attempt to grasp the object. The BCI would then trigger the stimulation sequence to facilitate the intended movement upon detecting the participant's intention to move.

Results

Six participants (2 women and 4 men), one with a chronic spinal cord injury (C6 level, AIS B), tested the system by each grasping, lifting, and releasing objects placed in front of them 80 times (480 trials in total). All individuals provided written informed consent to take part in this study, which was approved by the Toronto Rehabilitation Institute Research Ethics Board. Participants required on average 5.9 +/- 1.5 seconds to activate the BCI. The CV system had a classification accuracy of 90.8%.

Discussion and Conclusions

The system presented here is a demonstration of different technologies that could be integrated to deliver a novel upper limb

therapy. The quick and automated configuration of the neuroprosthesis provided by the CV system could allow for an efficient use of each therapeutic session (e.g., an increased number of repetitions for multiple movements), while the BCI allows triggering of the stimulation using neurophysiological indicators of intended movement.

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COOPERATIVE CONTROL FOR A HYBRID REHABILITATION SYSTEM COMBINING ROBOTIC EXOSKELETON WITH FUNCTIONAL ELECTRICAL STIMULATION

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ABSTRACT

Functional electrical stimulation (FES) and robotic exoskeletons have been used for physical rehabilitation of paraplegic patients, respectively. Both of these two techniques still have their own intrinsic limitations that hinder the further application. In this paper, we present a hybrid rehabilitation system that combines FES with a compliant knee exoskeleton to overcome the defects of each approach. The study focuses on cooperative control strategy in controlling rhythmic movements, i.e., the swing of shank, to demonstrate the efficiency of hybrid rehabilitation. Two muscle groups (Vasti and Hamstrings) are stimulated to generate active torque in synchronize with passive torque compensation from exoskeleton for knee joint. The knee joint angle and the mutual torque between the exoskeleton and human leg are used as feedback signals for the control system. The

cooperative control aims to allow arbitrary and automatic distribution of assistive torque between FES and knee exoskeleton via regulating a tunable gain. The reference trajectories of the exoskeleton and FES are provided by central pattern generator that acts as a phase predictor to deal with unexpected phase confliction between the two compliant mechanisms, i.e., human shank and exoskeleton. Experimental evaluation of our hybrid FES-exoskeleton platform is conducted on both healthy subjects and paraplegic patients, which shows good performance of torque distribution and no significant phase confliction during the test.

Index Terms

Functional electrical stimulation, robotic exoskeleton, hybrid rehabilitation, cooperative control, central pattern generator

QUADRICEPS ELECTRICAL STIMULATION TO ASSIST SITTING PIVOT TRANSFERS BY PERSON WITH PARAPLEGIA

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Abstract: Although sitting pivot transfer (SPT) be useful for the main displacement that assure daily life activities performed by person with paraplegia, it leads to upper limb impairments caused by an overload through the shoulders. Then, we aimed to provide a proof-of-concept that paralyzed muscles electrically recruited might be applied as a strategy to assist people with paraplegia during transfer (FES-assisted transfer) avoiding risks. A setup was developed to host a non-conventional clinical trial in 5-case series composed by subjects with different injury levels of paraplegia. The kinematic/kinect analysis reveals that the FES-assisted transfer in a bilateral quadriceps strategy triggered during an appropriate instant of the SPT was able to redistribute the weight-bearing towards the feet avoiding shoulder overload.

Keywords: spinal cord injuries, paraplegia, electrical stimulation, biomechanics, assistive technology.

Introduction

Transfers supported by upper limbs from the wheelchair to other surfaces is a central ability to compensate the paralyzed lower limbs, allowing a crucial displacement to assure independence and autonomy for people with spinal cord injury (SCI). However, a high number of this type of transfer may lead to musculoskeletal overload, notably affecting shoulder joints [1]–[4]. Despite the identifiable risk to shoulder impairments, the SPT remains as the most performed transfer by people facing post-SCI paraplegia [5], [6]. Usually, people with paraplegia perform it, in an independent manner, more than 15 times a day, almost always resulting in an acute or chronic pain shoulder condition as outcome [5]–[8].

Neuromuscular Electrical Stimulation (NMES) to perform tasks, called as Functional Electrical Stimulation (FES), must be automated by systems to coordinate appropriately artificial (paralyzed muscles electrically triggered) and voluntary recruitment during the transfer. This kind of operation requires triggering at specific instants and during short phases in the sequence of movements impossible to be manually controlled [9]–[11].

With a view towards innovative assistive devices, we aimed to provide a proof-of-concept that paralyzed muscles electrically recruited during specific phase of the SPT might be applied as a technology to assist person with paraplegia (FES-assisted transfer) avoiding risks.

Methods

Subjects and the Sitting Pivot Transfer (SPT)

This study received ethical approval from the SARAH Network Rehabilitation Hospitals. After providing informed consent, 5 subjects (Table 1) volunteered to participate in a non-conventional clinical trial to test the effect of the FES-assisted transfer applied in a bilateral quadriceps strategy during the lift pivot phase of the SPT. The SPT was separated in time by linear periods called: (1) pre-lift, (2) lift pivot and (3) post-lift phases.

Table 1: Characterization of the 5-case series.

Variables	C1	C2	C3	C4	C5
Age (years old)	34	44	49	40	24
Gender	female	male	male	male	female
Chronicity (years' post-SCI)	14	5	9	22	2
Neurological level	T6	T10	T11	T2	T4
AIS	A	A	A	A	A
Cause of the SCI	firearm	firearm	accident	firearm	accident
BMI (kg/m ²)	21.8	28.7	21.8	15.7	20.0
Handedness	right	right	right	right	right
Transfer orientation preferred	to the right	both	to the left	both	to the right
Transfers done in the last 24 h	19	17	15	11	15
Had already done NMES?	yes	no	no	no	yes

Setup and experimental protocol

Participants used two seats without armrests (Figure 1) to transfer from the sitting seat to the target seat. For all transfers, the seats were positioned at a 15° angle over two independent force-platforms (Bertec Corporation; Columbus, Ohio). A third force-platform was placed in front of the others to accommodate the feet during the SPT. Eight three-dimensional cameras around the seats and platform ensemble (Qualisys®, Gothenberg, Sweden) were arranged and synchronized with a system to trigger the NMES on the femoral quadriceps (50 Hz, pulse width of 450 μ s, Hasomed, RehaStim) during the beginning of the lift pivot phase by mean of pressure sensors embedded in a glove wore by the participants during the trials [10]. The current intensity was previously chosen according to the quadriceps muscle response enable to evoke a sustained contraction for 1 second. Reflective markers were placed around the head, trunk, pelvis and upper limbs allowing to create a model to kinematic analysis.

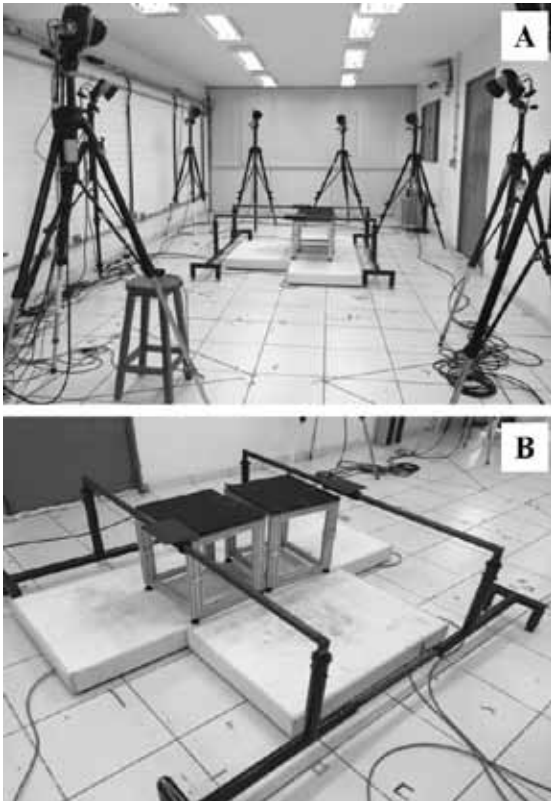


Figure 1: The experimental setup to prove the FES-assisted transfer concept. A widescreen (A) and an image zoomed (B) were presented.

The coordinates of the markers were recorded based on a global reference frame using the 8-cameras in our motion capture system. Each participant was submitted for series of trials (going and return SPT) alternated by trials with or without FES-assisted transfer. The type of trial to begin (non-FES or FES-assisted transfer) was randomly defined and a total of 6 trials were performed by subject.

Data analysis

Participants' anthropometric measures were used to estimate the segmental inertial properties. The vertical component of the force by platform was used to calculate the maximum force normalized by body mass: the key biomechanical variable used in this report. All analysis considered the lift pivot phase of the SPT.

Results

Three kinds of effect were found: (1) optimal FES-assisted transfer, (2) FES-assisted transfer, and (3) unclear FES-assisted transfer. The optimal FES-assisted transfer means trials in which a clear redistribution of the vertical component of the force was identified towards the feet platform (Figure 2). The FES-assisted transfer was used to qualify a light redistribution towards the feet (Figure 3), whereas unclear FES-assisted transfer means trials that is not possible to identify clearly the redistribution of the force towards the feet platform.

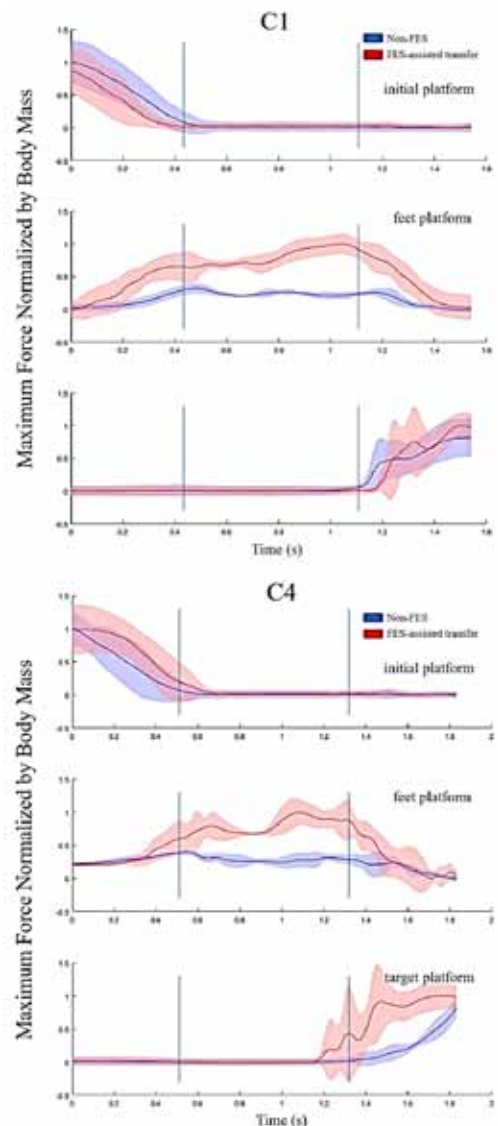


Figure 2: Graphs showing the redistribution of the weight borne for cases 1 and 4 (C1 and C4) by each platform force (vertical component of the force) during the lift pivot phase for trials without (no-FES, blue curve) and with FES-assisted transfer (red curve).

By visual analysis, each participant apparently performs the transfer with a greater or smaller trunk inclination, and it seems that participants C1 and C4 performed a greater amplitude of anterior trunk inclination (an apparently good strategy to be helped by FES), while participants C2, C3 and C5 performed the transfer with a lower amplitude of anterior trunk inclination.

Only in the C4, we perceived that the participant did a decreased amplitude of trunk inclination, perhaps induced by the electrostimulation in the phase that proceeded to elevation and pivot.

The case 5 (C5, figure 4) presented a greater variation inferred by the range defined by the standard deviation (area immediately above and below the curve line filled in blue or red).

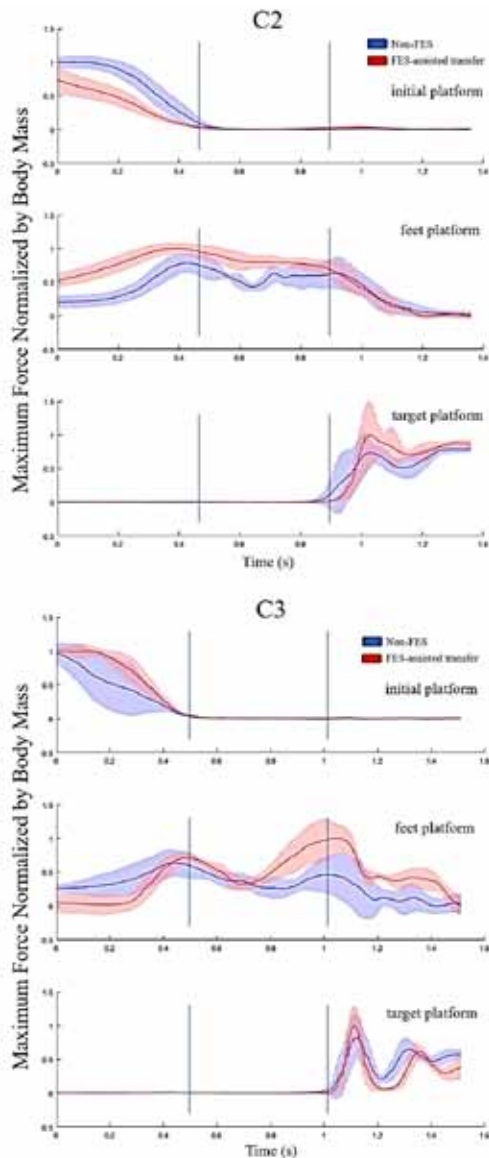


Figure 3: Graphs showing the redistribution of the weight borne for cases 2 and 3 (C2 and C3) by each platform force (vertical component of the force) during the lift pivot phase for trials without (no-FES, blue curve) and with FES-assisted transfer (red curve).

Discussion

It is interesting to correlate that the C1 was female, had high paraplegia, 24 years of age, and 14 years of injury; eutrophic (21.8 kg/m^2), athlete, and use NMES for four hours per week; while the C4 was male, also had high paraplegia, was almost twice the age of the participant C1 (40 years of age), lived longer with the spinal cord injury (22 years), was underweight according to references BMI, was sedentary, had no visible contraction of abdominal muscle and did not use NMES in daily life. The C5 was a female participant who also had high paraplegia, had the same age as C1 (24 years of age), only 2 years of injury, also eutrophic (20.0 kg/m^2), active, with no visible contraction of abdominal muscle that also used NMES in the daily. The other two participants (C2 and C3) were a man with medullar lesion that conferred paraplegia classified as low, were respectively 44 and 49 years old, lived at 5 and 9 years of injury, were identified by BMI as obese (but with a

lot of lean mass) and eutrophic, athlete and active, possessing strength levels 3 and 2 in abdominal muscle, both of which did not use NMES in daily life.

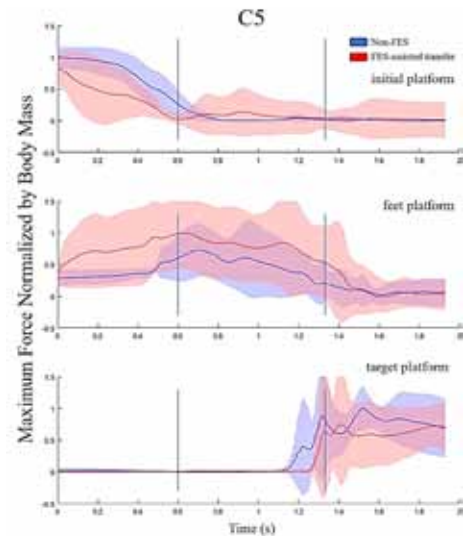


Figure 4: Graphs showing the redistribution of the weight borne for case 4 (C4) by each platform force (vertical component of the force) during the lift pivot phase for trials without (no-FES, blue curve) and with FES-assisted transfer (red curve).

Our series of cases reported people with different ages and length of stay in the condition of paraplegia, which on the one hand could be a limitation of the study, on the other hand, could provide us with a better delineation that different levels of paraplegia could benefit from the FES automated and controlled in the context of the transfer studied. In addition, such diversity also allowed to identify different SPT strategies, which were not explored in the scientific literature and mentioned in Koontz et al. (2011) and Kankipati et al. (2015) [4], [12] who report three main types of SPT strategies, characterized by different trunk and upper limb positions.

As previously reported, the population with SCI and functionally more active, performs innumerable transfers throughout the day and as quoted in Pentland and Twomey (1994), transfers are among the activities that most cause pain in upper limbs, in this way, resources assisted technology that favors SPT, reducing the incidence of lesions due to overuse, or even in those who already have pain injury [6], [13],[14]. Throughout the clinical trial we realized that individual adjustment of force would be important, since each subject has a specific characteristic. We noted that a very important factor was the safety of the individual that the NMES would work properly: the safer he was, the more he could transfer the weight to the lower limbs and the more he used the FES in the raising and pivot phase, which may have occurred with the C1, who already used NMES in their context and at the pre-test time opted for a lower degree of muscle contraction (decrease in the intensity of NMES).

In contrast, the higher the current intensity, the greater the muscle contraction triggered and the higher the hip lift on the seat. In this context, if the subject did not present a good trunk balance, it could destabilize and this may be a hypothesis of why C4 chose a lesser degree of muscle contraction, since he had not experienced sports and had no strength in the abdomen, your trunk balance. Another hypothesis would be

that the lower weight of the subject would already be sustained by a lower muscle contraction degree and for this reason the subject in the C4, who presents a low weight, may have chosen a lower degree of force when compared to the whole sample.

In the kinetic evaluation, the vertical component of the force progressed from the initial bank to the feet and then to the final seat, which was already expected if the SPT had passed correctly and taking advantage of the tension generated by quadriceps contraction, as reported by Lopes et al. [11] and Gagnon et al. [15].

When observing the mean vertical force component of each subject throughout the trials, it is noted that the high paraplegics (C1 and C4) have a greater tendency to discharge more weight in the feet with the use of FES, as observed with the normalized force on the platform underfoot. In the C5, despite being a high paraplegic, showed greater difficulty to perform the transfer, so it presented a greater variability of results with a large standard. This observation interested us because it appears that individuals with high paraplegia (fewer trunk muscles with preserved voluntary contraction and consequently some seated balance difficulty) could benefit more from FES in quadriceps during SPT.

Another interesting consideration is that C1 and C4 have more time in the paraplegic condition than the rest of the sample (14 years and 22 years respectively), raising the question: Do they feel more confident in SPT and have more injury time? Are they able to discharge more weight in the feet and that is also why they chose less strength for quadriceps? Another hypothesis could be that C1 and C4 chose the lowest degree of quadriceps muscle contraction for SPT. Would it be the choice for the lower degree of muscular contraction to allow greater trunk flexion with better accommodation of the weight loss in the lower limbs?

Lopes et al. (2016) had found evidence that FES in transfer with specific electrostimulation of the quadriceps could reduce the overload imposed on the UL. However, such evidence was a single case report with subject characterized as a low paraplegia condition [11]. With the current analysis it is possible to verify that paraplegics, especially those with high level of lesion, can benefit more from quadriceps FES and it is also possible to show that only the quadriceps NMES triggered the outcome that we expected, and it is not necessary to complement the NMES to other muscle groups.

It is worth noting that there are few studies that consider the influence of the lower limbs during SPT. The literature indicates that foot support usually makes up 25% of the individual's body weight during the raising and pivot phase [15], [18].

The one-second NMES activation time was chosen for all participants, but it is known that not all individuals perform the same SPT strategy and do not have the same duration as cited by Gagnon et al. (2009), Koontz et al. (2001) and Kankipati et al. (2015) [6][4][13]. This aspect may be better improved in future studies.

This study, by means of an unconventional clinical trial design, given its non-randomized and applied case series format, proved the concept that electrostimulation could aid

the seated pivot transfer of a sample of people with paraplegia that varied between high and low paraplegia and with different abdominal muscle contraction responses.

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TRUNK MUSCLE ACTIVATION TO IMPROVE TRUNK STABILITY, arm power, and performance in wheelchair rugby players

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Abstract: Trunk stability is impaired in wheelchair rugby players with tetraplegia reducing arm power and performance. The purpose of this study was to evaluate the effect of electrically activating the trunk muscles on trunk stability, arm force/power and wheelchair rugby performance in players with high SCI. In 10 wheelchair rugby players, electrical stimulation (ES) was simultaneously applied to the abdominal and lower back muscles during reaching, arm power, and wheelchair skills tasks. Results show that ES-induced trunk muscle activation positively affected trunk stability, blood pressure, and arm force/power. No effects were found in wheelchair rugby skills, probably due to abdominal strapping.

Keywords: Wheelchair rugby, electrical stimulation, trunk control, blood pressure, muscle performance

Introduction

Important aspects in wheelchair rugby (WR) are quick wheelchair turning, braking, acceleration from standstill, and ball handling. However, as these aspects largely depend on trunk stability and upper extremity power, they are impaired in most players with high spinal cord injury (SCI), due to the (partial) loss of innervation of upper extremity and trunk muscles. In addition, performance may be hampered by the generally low blood pressure in these individuals as a result of a disturbed sympathetic innervation. Abdominal strapping, commonly used to counteract these problems, may only solve some problems and can even have detrimental effects (e.g., lower reaching). Another solution may be by electrical stimulation (ES) induced co-contraction of paralyzed trunk muscles. The aim of this study was, therefore, to assess the effects of increased ES-induced co-contraction of trunk muscles on trunk stability, arm force/power, blood pressure, and wheelchair rugby performance in players with high SCI.

Methods

Ten wheelchair rugby athletes with a cervical SCI participated. ES was applied by using a portable electrical stimulator with 4 channels (Compex 3 Professional, Cefar-Compex, DJO Benelux) and 8 self-adhesive electrodes (Enraf Nonius, EN-Trode., 50x90 mm rect, Axelgaard Mfg. Co., Ltd.). ES was simultaneously applied to the rectus abdominus, obliquus externus abdominus and erector spinae muscles to create co-contraction (Fig.1). A

continuous protocol with biphasic pulses was used. Frequency (30Hz) and pulse duration (300 μ s) were fixed, and current amplitude (between 30 and 100 mA) was individually set at the highest level tolerable for each participant.

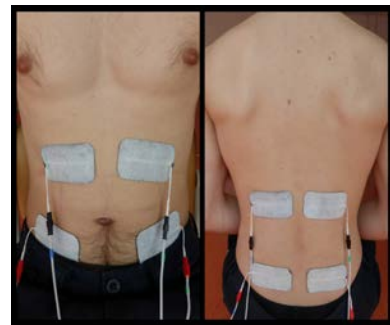


Figure 1: placement of ES electrodes

Trunk stability, arm force, arm power and blood pressure were measured on the same day. On a second day WR skills were measured. Each test was performed with and without ES on the same day. Not all participants could perform all tests due to the large number of tests. The order of testing (i.e. ES or non-ES) was randomized. Stability was assessed with reaching tasks in different directions (Fig. 2), arm force and power with an isokinetic test on a dynamometer (Fig. 3), blood pressure during an ES protocol and wheelchair rugby skills with the USA Wheelchair Rugby Skill Assessment. For every test, the ES condition was compared to the non-ES condition.



Figure 2: reaching task. This is reaching diagonally with dominant arm

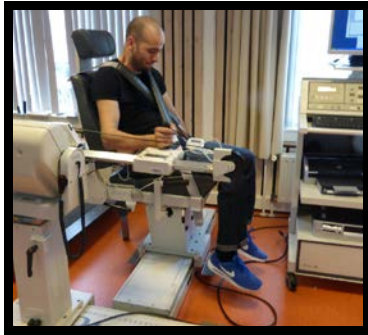


Figure 3: arm force and power measurements

Results

Trunk stability, defined as reaching performance improved in the ES situation (Fig.4), especially in the diagonal reaching task on the dominant side. Overall reaching distance (ES 14.54±9.26 cm, noES 13.61±9.75 cm) increased significantly.

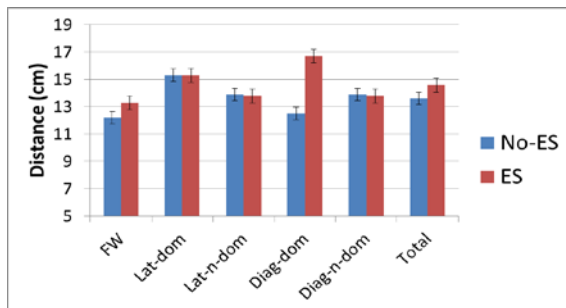


Figure 4: results from the 5 reaching tasks with and without ES.

Arm force (ES 154.29±102.62 Nm, noES 147.96±97.39Nm), and arm power (ES 37.14±25.34 W, noES 35.66±23.99 W) were significantly improved with ES (Fig. 5). Both systolic and diastolic blood pressure showed a significant increase after ES application. Wheelchair rugby skills were not significantly improved with the use of ES.

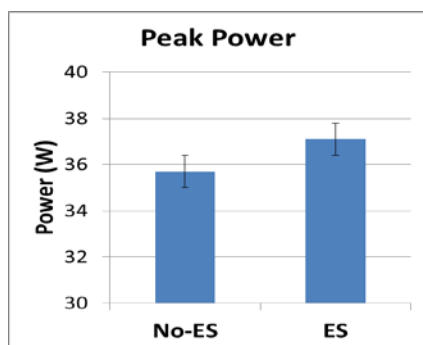


Figure 5: peak power with and without ES

Discussion

With ES it was possible to create co-contraction of the trunk muscles in WR athletes with high SCI, inducing more trunk stability, depicted by a higher measured reaching distance. The increased stability probably caused a

more stable base to deliver arm force on, as can be concluded from the higher measured arm force and arm power in the condition with ES. Moreover, because of stimulation of the trunk muscles, the systolic and diastolic blood pressure both significantly increased. However, WR skills were not significantly improved with the use of FES.

In conclusion, ES-induced trunk muscle activation positively affects trunk stability, blood pressure, and arm force/power. No effects were found in wheelchair rugby skills, probably due to abdominal strapping. More research is needed to assess different ES (training) protocols, and to compare the effects of abdominal strapping with ES application. This study shows that ES is a promising intervention in sport, rehabilitation and daily life.

Transitioning Implantable Neural Interfaces to the Clinic: Navigating Regulatory Testing

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Abstract: *Designs for neural interfaces are moving towards both extreme miniaturization and deployment to clinical testing. Clinical deployment requires approval from regulatory agencies, and while the requirements and procedures vary, depending upon the country, most applications for approval require preclinical testing based upon ISO standards for medical devices, which are difficult to apply to the miniature devices. Satisfying regulatory requirements often requires adaptation and judgment in the regulatory testing process.*

Keywords: *Neural Interfaces, ISO standards, regulatory testing*

Introduction

As developers implantable of neural interface stimulation and recording system plan for the translation of new technologies to the clinic, they face the hurdle of regulatory testing and ultimate approval. For traditional implantable devices, such as pacemakers, FES systems, spinal stimulators, and DBS stimulators, their physical size is most often defined by a titanium enclosure on the order of centimeters in diameter. Emerging implantable device designs for cortical, and peripheral, nerve interfaces benefit from extreme miniaturization in which the devices approach the size of the associated neural structures that they interface with. Examples are electrode arrays for brain-machine-interfaces, nerve cuff interfaces, and neural prostheses in the central and peripheral nervous system, which are all orders of magnitude smaller than the traditional-style devices and may include electronics not sealed within a hermetic enclosure. In making applications to regulatory agencies for clinical trial approvals, the expectation is that preclinical testing will be done using established ISO standards such as ISO 10993, 14708, and 60601. Yet these standards contain testing methods that are designed for significantly larger devices and are often incompatible with the new miniature implants. Here we report about some experiences with a cortical interface known as the Wireless Floating Microelectrode Array (WFMA).

Methods

The WFMA is the core element of the IntraCortical Visual Prosthesis (ICVP) system. It is an implantable 16-channel micro stimulator with integrated electrodes that penetrate the cortex – there are no leads. The WFMA

“floats” on top of the brain with its normal movements. By using a collection of WFMA, a pattern of stimulation can be delivered with the intention to create a visual perception for those with blindness. Owing to its small size, taking this device through regulatory testing requires adaptation of established testing methods.



Figure 1: (L)WFMA implantable stimulator. Device is 5mm diameter x 0.68mm thick. (R)Concept of ICVP system.

Results

As an example, ISO 10993 requires a minimum of 30-50cm² of device surface area for extractions. Since the WFMA has a surface area about 0.5cm², this would mean that up to 100 devices would be required per test, and multiple samples are needed for a multiplicity of tests. In our initial assessment, about 4000 WFMA devices would have been needed for performing all of the ISO 10993 testing. This would have been prohibitively costly and time consuming (for device fabrication). We resolved this dilemma by designing a WFMA surrogate of much larger size that was equivalent to 87 WFMA. Space precludes describing other examples in this abstract.

Discussion

Our experiences are not unique. Others within the FES and neural interface community are facing these same issues. By exchanging details of experiences, the regulatory testing process can be eased, and perhaps ISO standards can be changed to accommodate emerging systems.

FES-therapy delivered with a stimulation garment: a first case-study training grasp functions after spinal-cord injury

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Introduction

Functional electrical stimulation (FES) is used following spinal cord injury (SCI) to retrain motor function (therapeutic use) or to obtain compensatory contraction (assistive use). FES often requires assistance from a clinician to place and secure the self-adhesive gel electrodes used to deliver the stimulation. We aim to make FES use more independent and practical by producing stimulation garments with embedded electrodes and wires.

Material and Methods

An FES-shirt is being tested on a 45-year-old participant who had a complete (AIS A) SCI at the C6-C7 level 21 years ago. After an initial evaluation, a custom-made FES-shirt was produced to ensure a tight fit on the left hand and forearm. The stimulation electrodes were knitted together with the sleeve and pre-positioned over target grasping muscles. Twenty one-hour sessions (three sessions/week) have been conducted so far, with FES protocols aiming for diverse grasping motions and strengthening of the weaker muscles. Ad-hoc changes were made between sessions on the FES-shirt to improve usability. The participant has been instructed on how to set up the FES-shirt and to attempt to execute the movement voluntarily.

Results

During the initial evaluation, the participant had a Spinal Cord Independence Measure score of 56/100 and the manual muscle test rated flexor digitorum at one, and opponens pollicis, flexor pollicis brevis and lumbricals muscles at zero.

Several modifications were made to the FES-shirt, particularly to improve range-of-motion and electrode contact on the thumb. The participant was fully independent for the initial set-up by the 3rd session, with an average set-up time of 17 minutes (donning FES-shirt, applying water on electrodes, and tuning intensity) and for triggering stimulation. Water needed to be reapplied on electrodes one to three times per session to allow comfortable stimulations.

The participant gradually became more accustomed to the procedure and tolerated higher intensity of stimulation. FES yielded progressively greater finger movement from flexor digitorum, lumbricals, and pollicis brevis muscles. The main task, lifting and

turning (pronation then supination) a weighted 500ml water bottle with a cylindrical grip, showed improvement as well: in the first execution, the highest weight used was 300g, and in the latest sessions the highest weight used was 1100g. Firm two-point pad pinches on wooden blocks and pebbles were made possible without using tenodesis. While the thumb had the least responsive muscles (wasted thenar eminence), FES allowed a firmer lateral pinch on a credit-card in the last sessions.

Limitations of this study included variable time to find the FES-shirt position eliciting the best grasp, and variable comfort of stimulations and strength produced.

Discussion

Despite a long lasting and severe injury, the participant was able to use the FES-shirt to lift heavy objects and to help manipulate small objects (active pinches instead of tenodesis).

Conclusion

This first FES-shirt prototype showed satisfying usability in one participant with quadriplegia. Several practical issues had to be solved. A new prototype is being made for the next 20 sessions. This study will now include more participants with SCI or who have sustained a stroke.

Stimulation of denervated muscles in patients with a lower motor neuron lesion (LMN)

Implementation in clinical setting

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Abstract:

Introduction

Electrical Stimulation of denervated muscles of the lower limbs has been proved to increase muscle mass and to improve the trophic of the muscle tissue. Furthermore, already structural altered muscle can be re-changed from connective and fat tissue into contractile muscle tissue. Some evidence exists that in the acute phase after LMN, the stimulation of denervated muscles might support the process of re-innervation. The aim of the data analysis was to present the application area of denervated muscles during acute, subacute and chronic phase after a LMN.

Results

167 stimulation protocols were analyzed. The stimulation was mainly performed in the upper (30%) and lower limb (70%) muscles. 69% of the patients started to stimulate within the first two years after lesion and 31% after two years. The stimulation during primary rehabilitation started 3 (Median) ± 3.1 (SD) month after lesion. In 49.3% the stimulation was applied for prevention of pressure sore, 58.4 % for motor learning/reinnervation and 26.1% for preservation of contractile muscle tissue.

Conclusion

Stimulation of denervated muscles is mainly used for motor learning and support of reinnervation followed by prevention of pressure sore, both in the lower limbs.

Keywords: *Electrical Stimulation, Denervated Muscles, Clinical Application*

Introduction

Introduction

In the last decade the stimulation of denervated muscles got more attention. Not at least because of the promising results of the RISE project. In this EU project it was shown that electrical stimulation of denervated muscles in spinal cord injuries (SCI) increased muscle mass and improved the trophic situation of the lower extremities (1). Furthermore, structural altered muscle into fat- and connective tissue could be restored into contractile muscle tissue by stimulation (2). However it has been shown that

an extended time after SCI hinders the stimulation impact (3,4). The denervation process can be divided in four chronologically running steps. Muscle fibrillations are present some days after lesion followed by a loss of tension during electrical evoked tetanic contraction. After months a severe disorganization of the contractile structure in the muscle occurs and finally ends after years in a replacement of muscle fibers into fat tissue and collagen (4). The best results have been seen within three years after SCI (5). The stimulation protocol was set up to start with single twitches combined with tetanic stimulation patterns according to the patients' improvements (6). The progression in stimulation training to elicit a tetanic contraction - 40 ms pulse duration with a pulse pause of 10 ms and bursts of 2 sec – could last some month in chronic stage after SCI (1). In most of the investigated studies the stimulation of the M. quadriceps, Mm. ischiocrurales and the M. gluteus maximus was performed to achieve a certain stand or walking function. Therefore those muscles must have been trained by daily (six times a week) stimulation for at least 30 minutes each muscle. This is a high time expenditure by considering that only two muscles technically can be stimulated at the same time. Hence, the benefit of the stimulation is in contrast to the practicability in clinical and domestic setting. The question of priority of the necessarily stimulated muscles arises. Furthermore, the benefit that justifies the expenditure yields as a criteria to perform this time intensive treatment.

The aim of the data analysis is to illustrate the application area of electrical stimulation in denervated muscle during rehabilitation.

Methods

A retrospective data analysis of stimulation protocols between 2010 and 2017 was performed.

The stimulation protocols were screened regarding stimulated muscles and muscle groups, target of stimulation, onset time of stimulation after lesion, changes in ASIA impairment scale (AIS) and number of treatment.

Stimulation parameters were performed within two years after lesion with 35 ms pulse duration, biphasic rectangular, 17.5 ms per phase, 10 sec pause (22 Hz) and bursts of 2 sec (2 sec pause). Stimulation was applied 5 times a week, 30 minutes. In contrast to the stimulation protocol used from two years after lesion began with 100 ms pulse duration, 400 ms pause (2 Hz) with burst of 4 sec. Patients were tested regularly every four weeks if a tetanic contraction could be elicited. In case of a tetanic contraction, stimulation parameters were changed to 35 ms pulse duration, 10 ms pause (22 Hz) and bursts of 2 sec (2 sec pause). Stimulation was also applied 5 times a week. Stimulation time was increased from 10 to 30 minutes. Only those data of patients that gave their informed consent were included.

Results

167 stimulation protocols were analysed. The data of 128 male and 29 female were included. The overall median age was 52 ± 17 years. The stimulation was mainly performed in the upper (30%) and lower limb (70%) muscles. None was performed in the trunk muscles.

Data of 147 patients were completed regarding stimulated muscle, target of stimulation and onset time of stimulation after lesion. An AIS as a baseline assessment and at the end of treatment was only performed in 15 cases that performed stimulation for motor learning/reinnervation (Table 1). In all 15 cases there was an improvement in the AIS of at least one grade. The onset stimulation time after lesion was during primary rehabilitation 3 (Median) ± 3.1(SD) month.

Pat. ID	Gender	Age	AIS initial	AIS final	Level of lesion	Stimulated muscles	Time between lesion and stimulation (month)	Number of treatment
1	m	64	C	D	L1	Gluteal muscles, hamstrings	1	17
2	m	52	A	C	L3	Gluteal muscles, hamstrings	3	36
3	w	28	A	B	T10/L1	Gluteal muscles, hamstrings	3	43
4	m	42	B	D	T12	Gluteal muscles, hamstrings	3	43
5	w	18	C	D	T12/L2	Gluteal muscles, hamstrings	3	33
6	m	30	B	D	T10/T12	Gluteal muscles, hamstrings	1	24
7	m	63	A	C	T77	Gluteal muscles, hamstrings	3	33
8	w	59	B	C	T9/T11	Gluteal muscles, hamstrings	1	27
9	w	80	C	D	L1	Tibialis anterior	3	15
10	m	19	C	D	C4/C3	Delta muscle	13	7
11	w	80	C	D	L1	Quadriceps	3	15
12	m	64	C	D	C4	Finger-handextensors	1	32
13	m	29	C	D	L1	Gluteal muscles, hamstrings	1	22
14	m	59	B	C	L3	Gluteal muscles, hamstrings	2	7
15	m	75	C	D	C4	Finger-handextensors	6	22

Table 1: Patient chart, including baseline and final AIS, stimulated muscles, onset time of stimulation and number of treatments
Abbreviation: m = male, f=female, AIS = ASIA impairment scale

The number of treatments were available for 102 patients. Those data had a wide range – from two to 139 treatments - and were not valid because of the lack of documentation. Most of the stimulation was applied in the acute and subacute phase after lesion (Table 2). The acute and subacute phase were defined within two years after LMN and the chronic phase (Table 3) from two years up without a terminal date. In the acute and subacute phase the median onset stimulation time was 3 ± 5.0 month after the lesion. In contrast the median onset stimulation time in the chronic phase was 10 ± 3.95 years.

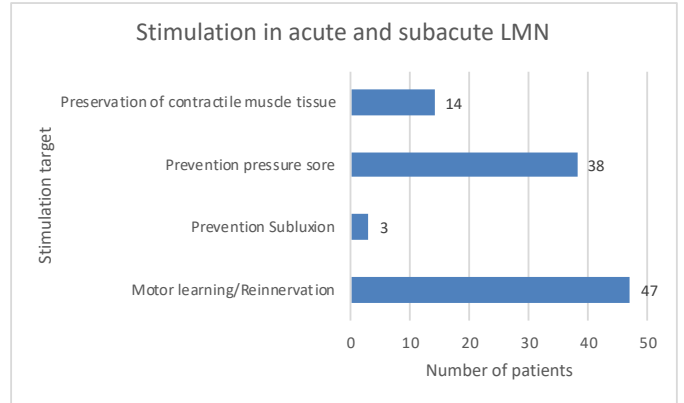


Table 2: Number of patients and stimulation targets in acute and subacute LMN

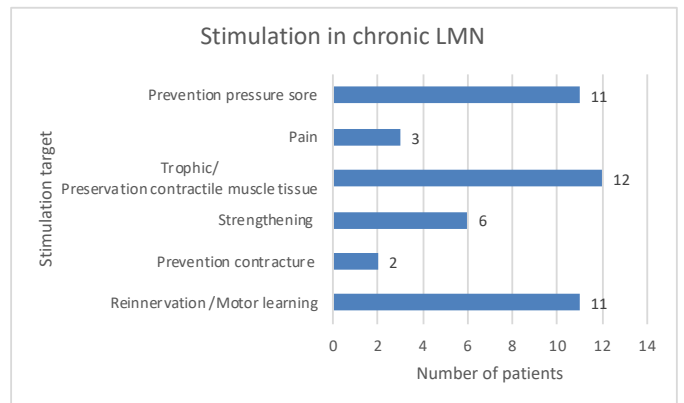


Table 3: Number of patients and stimulation targets in chronic LMN

In 2016 and 2017 upper limb muscles in 24 patients were stimulated (Table 4).

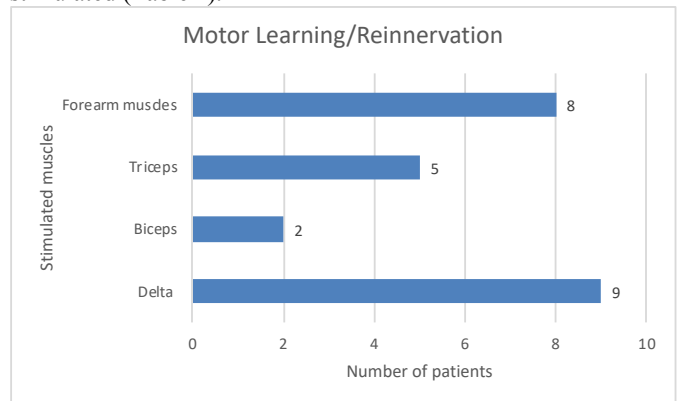


Table 4: Number of patients and stimulated muscle in the upper limbs

The application area for stimulation of denervated muscle is focused mainly on the lower limbs (70%) in contrast to the upper limbs. However our data showed a noticeable increase of stimulation of denervated muscles in the upper limbs targeting motor learning and reinnervation in the last two years.

The data of the 15 patients give a representative image where stimulation is applied for motor learning/ reinnervation. In contrast to the existing literature in clinical setting the quadriceps muscle is seldom stimulated (4,7-10). That might cause of the relatively poor functional outcome that could be achieved regarding standing or walking ability for a com-

plete paraplegic patient (T12-L1). Patients desire to relearn walking or standing is very often based on their capacity they had before the lesion. Furthermore, walking is often associated with a certain gait speed and the ability to use at least one hand for carrying something or other maneuvers. Our clinical experience has shown, that this patients regard themselves less handicapped in daily and social life using a wheelchair. In contrast to the motor incomplete patients (AIS C or D) or patients with an lower lesion, L2 and below, with some voluntary activity in the quadriceps muscle and less or no voluntary muscle activity in the hamstrings and bottom muscles. This population notices after regularly stimulation of the hamstrings and bottom muscles more stability in standing and walking due to structural changes (1,11) and in some cases an increase in voluntary muscle activity (12).

The T10-L1 motor complete patient population is affected by the risk to get pressure sores, mainly under the ischial tuberosity. In the first year after discharge from rehabilitation the cumulative incidence for getting a pressure sore represents 41% (13). A pressure sore is associated with hospitalization combined with immobilization and high health costs and not at least an enormous reduction in quality of life (14). Hence the stimulation should at best start during primary rehabilitation or at least offered during this period to the patient as an effective prevention to minimize the risk of pressure sores. The onset of stimulation after lesion regarding to the denervation process should be taken into account and encourage clinicians and therapists to start as early as possible after lesion. It was shown that the cross sectional area of the quadriceps muscle was reduced approximately 40 % of its normal value 1-2 years after denervation (1). Even in long term denervation the atrophy is partially reversible but to achieve a tetanic muscle contraction under stimulation takes month to sometimes years (4). Hence achieving the cushioning effect of the bottom muscles and hamstrings that is necessary to minimize the pressure peaks under the ischial tuberosity, takes a long time.

The stimulation of denervated muscles of the upper extremities gets more attention. It has been investigated that the cross sectional area of denervated muscle fibers could have been increased by early electrical stimulation. Furthermore, the changes in myosin heavy chain isoform, following denervation could be reversed (12). That indicates that early onset of stimulation could preserve the contractile muscle structure for possible reinnervation or further treatment options. Specially for tetraplegic patients who could benefit from nerve transfers, could win time for their decision (15). If a nerve branch is transferred into a denervated or partially denervated muscle it might be beneficial if the muscle consists of a contractile muscle structure.

In the present data analysis there are some limitations. No quantitative valid assessment was used to evaluate the benefit of the treatment. Furthermore, there were several lacks because of data missing in the documentation. This is a quite common problem in clinical practice. On the documentation sheets therapists noted personal remarks from patients and how they evaluated their benefit. The mode comments were, in case of bottom stimulation, longer mobilization time, more stability in sitting position and less fear to get pressure

sores. However standardized measurements are required. Portable ultrasound devices could be used to measure muscle thickness. Using calipers might also be possible. They are cheap, easy to handle but less accurate. The assessments are required not at least to give evidence to the insurances to pay for the treatment and the stimulation devices. In conclusion, stimulation of denervated muscles is mainly applied during primary rehabilitation for motor learning and the support of reinnervation. A further goal is the prevention of pressure sores. Based on the focus to improve motor learning and reinnervation, the number of stimulation of the upper limb muscles is increasing. Quantitative assessments to provide evidence in clinical setting are missing.

Acknowledgement

Our thanks go to all therapists who helped us to implement the stimulation of denervated muscles into clinical practice.

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Effect of Neuromuscular Electrical Stimulation on Masseter Muscle in Oral Phase Dysphagia after Stroke

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Abstract: Oropharyngeal motor dysfunction and sensory impairment is an important cause of dysphagia after stroke. This study was conducted to investigate the effect of neuromuscular electrical stimulation (NMES) on masseter muscle in oral phase dysphasia after subacute stroke. Subacute stroke patients who were diagnosed as oropharyngeal dysphagia by videofluoroscopy swallowing study were enrolled. Study group received NMES on masseter muscle and suprahyoid muscle simultaneously. Control group received NMSE only on suprahyoid muscle. After 2 weeks treatment, study group showed improvement in the scores of oral phase dysphagia scale. Thus, our study suggest that MNES on masseter muscle could be a treatment option for oral phase dysphagia after stroke.

Keywords: Neuromuscular electrical stimulation, oral dysphagia, Masseter muscle, Stroke

Introduction

Oropharyngeal motor dysfunction and sensory impairment is an important cause of dysphagia after stroke. There are many previous studies [1-2] about neuromuscular electrical stimulation (NMES) therapy as a treatment for pharyngeal dysphagia in stroke patients. However, few studies have been conducted about NMES effect in oral phase dysphagia after stroke [3]. Thus, the aim of our study was to investigate the effect of NMES on masseter muscle in oral dysfunction after subacute stroke patients.

Methods

This study was designed as pilot randomized controlled trial. Among the subacute stroke patients who were diagnosed as oropharyngeal dysphagia by Videofluoroscopy swallowing study (VFSS), those with oral dysfunction were enrolled. Oral dysfunction includes any abnormality of lip closure, and bolus formation, residue in oral cavity after swallowing, and delayed in oral transit time. Subjects were randomly assigned to one of the two groups: Study group received NMES (Vitalstim[®], Chattanooga group, Hixon, TN, USA) on masseter muscle and suprahyoid muscle simultaneously (Fig. 1-A). Control group received NMES only on suprahyoid muscle (Fig. 1-B). The amplitude of the electrical current level was approximately 7mA. The NMES therapy sessions were applied 30 minutes per time, 2 times per day for 10 days, total 20 sessions.

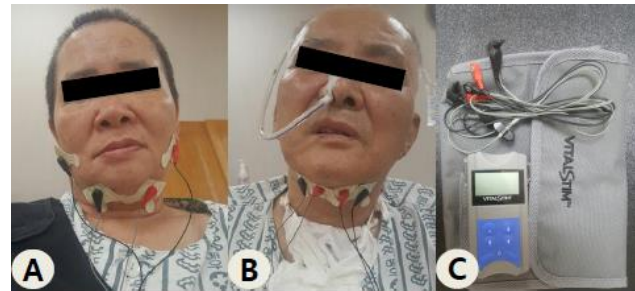


Figure 1: Neuromuscular electrical stimulation therapy. (A) Study group received MNES on masseter muscle and suprahyoid muscle simultaneously. (B) Control group received NMES on suprahyoid muscle. (C) Vitalstim[®](Chattanooga group, Hixon, USA) was used for NMES therapy.

And both group received conventional dysphagia therapy during study period. All enrolled patients were evaluated by VFSS before and after 2 weeks of treatment. Oropharyngeal swallowing function was evaluated by penetration aspiration scale (PAS), functional dysphagia scale (FDS), and American speech-language-hearing association-national outcome measurement system swallowing scale (ASHA-NOMS) based on the results of VFSS.

Table 1: Demographic characteristics of subjects

Characteristics	Study group (n=8)	Control group (n=8)	p-value
Sex (Male/Female)	2/6	3/5	
Age	64.45±18.58	66.78±12.84	0.846
Types of Stroke hemorrhagic/ ischemic	5/3	3/5	
Days from stroke onset	15.84±11.82	19.45±9.23	0.758
ASHA-NOMS (1-7)	2.84±1.52	2.68±1.38	0.832
FDS (total, 0-100)	32.75±13.42	34.55±11.56	0.663
FDS (oral, 0-33)	7.45±3.25	7.90±4.25	0.325
FDS (pharyngeal, 0-67)	24.85±9.48	27.45±8.96	0.802
PAS (1-8)	7.72±0.45	7.35±1.65	0.422

Values are presented as mean ± SD or numbers

Results

Eight patients were randomly assigned to study group and eight patients were assigned to control group. There were no significant differences in the baseline characteristics and initial values between the two groups (Tab. 1).

After 2 week, all groups showed improvement in the scores of total FDS and pharyngeal FDS. Additionally study group showed improvement in oral phase FDS (Tab. 2).

The changes of oral phase FDS were significantly improved in the study group (Tab. 3)

Table 2: Changes of measurements after the treatment

	Study group (n=8)			Control group (n=8)		
	Pre	Post	p-value	Pre	Post	p-value
ASHA-NOMS (1-7)	2.84±1.52	3.70±2.45	0.031	2.68±1.38	3.92±1.45	0.063
FDS (total, 0-100)	32.75±13.42	22.42±6.45	0.048	34.55±11.56	23.42±11.27	0.035
FDS (oral, 0-33)	7.45±3.25	2.25±2.38	0.042	7.90±4.25	4.00±3.58	0.105
FDS (pharyngeal, 0-67)	24.85±9.48	17.66±5.71	0.038	27.45±8.96	20.22±9.22	0.034
PAS (1-8)	7.72±0.45	5.45±0.78	0.063	7.35±1.65	5.68±1.35	0.082

Values are presented as mean ± SD or numbers

Table 3: Comparison of the treatment effect between two groups

	Study group (n=8)	Control group (n=8)	p-value
Δ ASHA-NOMS	1.50±0.45	1.44±0.64	0.612
Δ FDS (total)	-12.23±5.38	-12.16±3.37	0.425
Δ FDS (oral)	-5.10±0.75	-3.15±2.25	0.035
Δ FDS (pharyngeal)	-8.65±5.49	-7.46±2.92	0.288
Δ PAS	-2.23±0.87	-1.66±0.46	0.525

Values are presented as mean ± SD or numbers

Discussion

In this preliminary study found that NMES on masseter muscle have a therapeutic effect in oral phase dysfunction after subacute stroke. Chewing might plays an important role as a stimulus in initiation of swallowing process[4]. NMES on masseter muscle could enhance chewing process in oral phase and this improvement of oral phase may facilitate swallowing process[1,2,5]. Thus,our study suggest that NMES on masseter muscle could be a treatment option for oral dysfunction after stroke.

Acknowledgement

No.

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Reinforcement Learning Control of Functional Electrical Stimulation of the upper limb: a feasibility study

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Abstract: *Controllers for Functional Electrical Stimulation are still not able to produce natural movements of the paretic arm. In this work, Reinforcement Learning was used to design a non-linear controller for a hybrid upper limb robotic system thought for stroke rehabilitation. The performance of the controller was tested on one healthy subject during elbow extensions in the horizontal plane. Experimental results showed an absolute position error $< 0.7^\circ$ for a maximum range of motion of 40° and stability against perturbation induced by simulated muscle spasms. Promising results must be confirmed on a broader population.*

Keywords: *Functional Electrical Stimulation, Reinforcement Learning, Rehabilitation, Hybrid Robotic Systems.*

Introduction

Functional electrical stimulation (FES) is an effective technology used in rehabilitation to restore impaired motor functions in people affected by neurological disorders [1]. Following stroke, spinal cord injuries or multiple sclerosis, patients often have difficulties in performing functional movements with the upper limb as well as in grasping and manipulating objects. Rehabilitative treatments, based on FES, aim at restoring motor functions of the impaired upper extremity [2]. Recently, different robotics solutions have been proposed to be coupled with FES, the so-called “hybrid robotic systems”, in order to facilitate the execution of motor exercises and increase the rehabilitative outcomes [3]. However, reliable controllers driving accurate and natural movements through FES are still under investigation. The electrically stimulated human muscle is a nonlinear system whose physiological properties are difficult to be modelled [4]. Moreover, it is a strongly time-variant system: spasticity and fatigue can significantly influence the performance in the short period, while muscle strengthening and motor relearning can improve performance in the medium/long period.

Classical control solutions [5] rely on the accuracy of the model by which the system is described. Due to the complexity of the electrically stimulated muscles response, linear assumptions are frequently made. More advanced techniques, such as non-linear [6] and adaptive control systems [7], have been tested in real environments. However, the increased complexity of the controllers implicates more onerous calibration procedures [8], not suitable for clinical settings and non-technically trained operators. Recently, reinforcement learning (RL) [9] has been investigated to

solve upper limb FES control problems in simulation [10]. RL is a sub-field of machine learning which studies how agents can learn from experience collected by interacting with the environment. To achieve desired performances, RL algorithms can directly learn an optimal non-linear control law without prior knowledge about the system. In this work, we used the Proximal Policy Optimization (PPO) RL algorithm [11] to control a FES-driven elbow extension movements supported by a passive exoskeleton. We identified a common initial position and we trained the controller to reach different target angles. The training was made off-line simulating the subject’s arm dynamics with an artificial neural network (ANN) model. The performance of the controller was tested in a real environment, with one healthy subject who was asked to be completely passive. Moreover, we evaluated the stability of the control system in presence of simulated muscles spasms.

Methods

Apparatus: The robotic system for the upper limb [12] consisted of a lightweight passive exoskeleton for the right arm characterized by 3 degrees of freedom, each equipped with an angle sensor (Vert-X 13 E, ConTelec AG) to measure the angle position and an electromagnetic brake to lock a desired target position. The exoskeleton, exploiting the use of the brakes, was configured to allow only elbow flexion/extension movements in the horizontal plane, in the range of 60° (maximum flexion) to 170° (maximum extension). Trains of biphasic pulses were sent through surface patch electrodes (Pals® electrodes, Axelgaard Manufacturing Co., Ltd.) by means of a current-controlled stimulator/EMG recorder device (RehaMovePro, Hasomed GmbH). Only two channels were used, one connected to the biceps brachii and one to the triceps brachii. We controlled the stimulation of the two channels by modulating the pulse width, while the current amplitude and the stimulation frequency were fixed. The raw EMG signals recorded from the two stimulated muscles were filtered using an adaptive linear prediction filter in order to estimate the volitional EMG component [13]. The exoskeleton and the stimulator were controlled by the embedded processor BeagleBoneBlack ®™.

The RL problem statement: Considering a discrete time setting (where i is the discrete time instant), we formally described the episodic RL problem as a Markov decision

process (MDP) with the tuple $\langle S, A, P, R, \gamma, \mu \rangle$, where: S is a continuous set of states $\mathbf{s}_i = [\phi_i, \dot{\phi}_i, \ddot{\phi}_i, (\phi^t - \phi_i)]' \in \mathbb{R}^4$ composed of the elbow angular position, ϕ_i , the instantaneous angular velocity, $\dot{\phi}_i$, the instantaneous angular acceleration, $\ddot{\phi}_i$, and the difference between the target angle (ϕ^t) and the actual position; A is the continuous set of actions $\mathbf{a}_i = [pw_i^{ch1}, pw_i^{ch2}] \in \mathbb{R}^2$ composed of the instantaneous values of pulse width (PW) in the two stimulation channels within the interval $[0, 400] \mu\text{s}$; P is the transition probability kernel such that $P[\mathbf{s}_{i+1} | \mathbf{s}_i, \mathbf{a}_i]$ represents the probability of reaching the state \mathbf{s}_{i+1} from state \mathbf{s}_i , by performing action \mathbf{a}_i , R is the reward function $r(\mathbf{s}, \mathbf{a}) = E[r | \mathbf{s}, \mathbf{a}]$; $\gamma = 0.99$ is the discount rate and μ is the initial state distribution. Our scenario can be formalized as an episodic RL problem. An episode defines a finite time interval $I = 60, 0 \leq i \leq I$: at every time instant i , the agent is in the state \mathbf{s}_i , and makes an action \mathbf{a}_i to reach the next state \mathbf{s}_{i+1} . At the same time, the environment produces a scalar reward r_i . The agent goal is to find a policy $\pi(\mathbf{a} | \mathbf{s})$ that maximizes the sum of the collected discounted rewards, as described in Eq. 1:

$$J(\pi) = E_{\pi}[G_0 | \mathbf{s}_0 \sim \mu] \quad (1)$$

where G_0 is the return at the time instant $i = 0$, as described in Eq. 2:

$$G_0 = \sum_{k=0}^T \gamma^k r_k \quad (2)$$

The reward function defines the learning goal, i.e. it defines what the agent has to learn. Hence, we defined the reward function as in Eq. 3:

$$r_{i+1} = -(\phi^t - \phi_i)^2 \quad (3)$$

The effect of such reward function was that to penalize the distance from the target in each time instant.

To solve the RL problem, we used the PPO policy gradient method, implemented in rllab [15] (available at <https://github.com/rll/rllab>). We used a Multi-Layer Perceptron (MLP), characterized by two hidden layers with 10 hyperbolic tangent (tanh) neurons and a tanh output layer, to estimate a Gaussian policy. In order to design a controller able to generalize the control strategy to reach different target angles starting from the same initial position, we defined a set of 3 target angles $\phi^t = [130^\circ, 145^\circ, 160^\circ]$, equally spaced in the elbow extension range of motion, and then we separated the total number of learning iterations (750) in batches of 50. At the beginning of each batch, the state was reset to $\mathbf{s}_0 = [\phi_0, 0, 0, (\phi^t - \phi_0)]'$, where ϕ_0 is the initial position, and the target angle was randomly selected from the set ϕ^t . In every iteration, the algorithm simulated an episode in which the agent, starting from the initial state \mathbf{s}_0 , has to reach the actual target angle, in I time instants. The policy is then updated using the data collected during a batch.

The ANN model of the subject arm: Our RL environment consisted of an ANN model of the electrically stimulated subject's arm. We chose a feedforward architecture and we trained it with data collected during a 20-minute acquisition session. The model estimated the state transition dy-

namics of the environment given the agent's action, as defined in Eq. 4:

$$\mathbf{s}_{n+1} = \mathbf{f}_{\mathbf{w}}(\mathbf{s}_n, \mathbf{a}_n) \quad (4)$$

where $\mathbf{f}_{\mathbf{w}}(\cdot)$ is the estimated dynamics of the environment, \mathbf{w} is the vector of the neural network weights, $\mathbf{s}_n = [\phi_n, \dot{\phi}_n, \ddot{\phi}_n, h_n^{ch1}, h_n^{ch2}]'$ is the enlarged state, and n is a discrete time index. To increase the amount of input information, and also considering the whole stimulation sequence and muscle fatigue, we extended the state \mathbf{s}_n with two additional signals, defined as in Eq. 5:

$$h_n^{ch} = \begin{cases} \sum_{c=1}^n a_c, & \text{if } a_n \neq 0 \\ 0, & \text{otherwise} \end{cases} \quad (5)$$

where $ch \subset \{1, 2\}$ indicates the stimulation channel.

We designed an ad-hoc experimental protocol to collect data for ANN training. During the acquisition, the subject wore the exoskeleton and elbow flex-extension movements in the horizontal plane were only allowed. The subject was asked to remain passive, while stimulation sequences were sent to both muscles. We used the volitional EMG signals, estimated from the raw EMG recordings, to monitor the capability of the subject to remain passive during data collection [13]. The current amplitude of the two stimulation channels were identified at comfortable values for the subject able to induce visible muscle contractions (8 and 10 mA for the biceps and the triceps, respectively) and the stimulation frequency was set at 25 Hz. The pulse width was modulated with a predefined sequence of ramps, ranging between 0 and 400 μs , with an inter-ramp interval of 5s. The stimulation ramps were alternated between the two channels, but we also stimulated the two channels simultaneously to collect information related to the dynamics of co-contraction. The acquisition procedure lasted 20 minutes and a total number (N) of 35000 samples were collected. We used the data sampled at each time instant n to compute the extended state \mathbf{s}_n . Then, we defined the inputs matrix $X [N \times 8]$, whose n^{th} row is $\mathbf{x}_n = [\mathbf{s}_n', \mathbf{a}_n]$, and the targets matrix $Y [N \times 3]$, whose n^{th} row is $\mathbf{y}_n = \mathbf{s}'_{n+1}$, for training the ANN model.

We implemented and trained a single-layer feedforward ANN with 9 hidden tanh neurons with Keras (<https://keras.io>). The mean squared error (MSE) was set as performance function and the Adam optimization algorithm was chosen [15].

Experimental protocol and performance measures: We identified the initial position ϕ_0 , equal to 120° , as the position at which the subject was completely relaxed. The interval $[120^\circ, 170^\circ]$ was considered as the range of motion for the elbow extension movement and the angles $130^\circ, 140^\circ, 150^\circ$ and 160° were chosen as target positions for testing the controller. The trained control system was used in the real environment (one healthy male subject, 26 years old). The subject was asked to remain completely passive while executing 10 repetitions of four target elbow extensions movements, always starting from ϕ_0 .

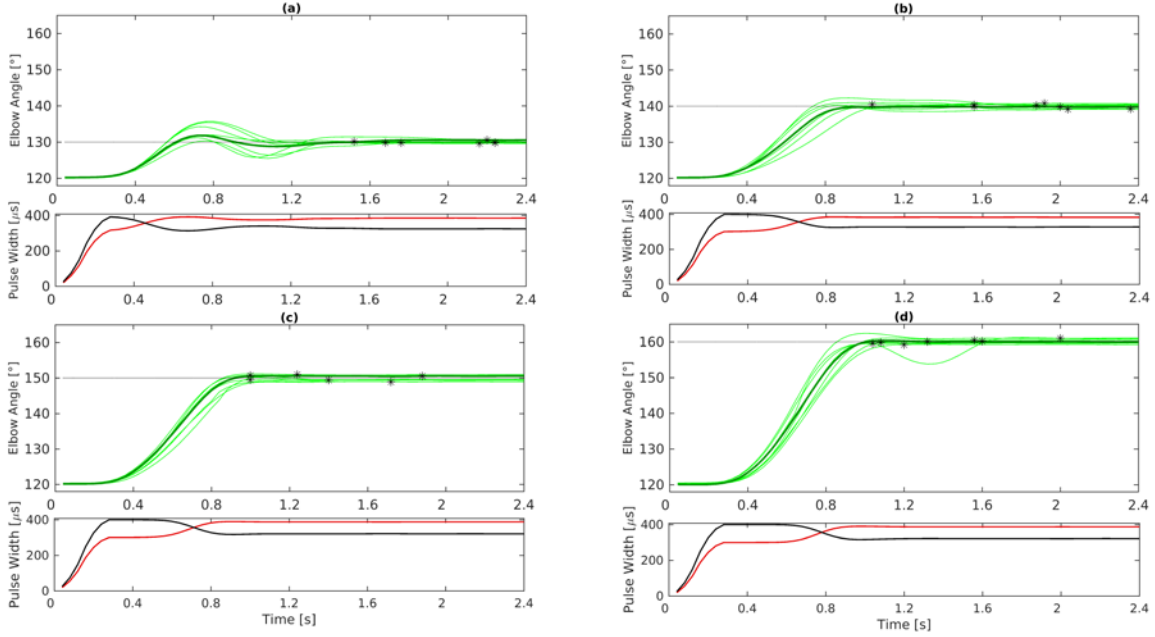


Figure 1: Controller performances in reaching 4 different targets of the elbow extension.

As for the data acquisition protocol (described in the previous section), the volitional EMG signal was monitored to check the capability of the subject to remain passive. Each repetition was evaluated in terms of time needed to reach the target and stop the arm in that position, i^{set} , the absolute position error, e^{abs} , and the smoothness, sm as in Eq. 6:

$$sm = \frac{\phi_{\text{mean}}}{\phi_{\text{max}}} \quad (6)$$

Where ϕ_{mean} and ϕ_{max} are the mean and the maximum instantaneous velocity within the repetition, from the beginning to the time i^{set} .

We also simulated muscle spasms during the executions of the elbow extension (from 120° to 140°), with the aim to verify the stability of the controller against intra-subject dynamical disturbances. Once reached the target position, we asked the subject to make a quick voluntary muscle contraction which moved the arm away from the target position. Then the subject had to relax again and let the control system bring back the arm to the target. We checked the elbow angle after 2s from the disturbance occurrence.

Results

We used the standardized data, collected from the subject, to train the ANN model of the arm dynamics and we achieved MSEs values of 0.001, 0.016 and 0.021 for the three outputs of the model, respectively. The model was then used as the simulated environment for the RL experiment. The optimal policy was obtained by running the PPO algorithm for 750 iterations, as described in the Methods section. Such number of epochs was enough to let the average returns (over a batch) converge to acceptable values of -944.28, -2471.21 and -14305.84, considering 130° , 145° and 160° respectively as the target angle to reach in the episodes simulated in that batch.

Tab. 1 reports the performance measures achieved by the

RL control for the four targets. The low values of the absolute position error showed the capability of RL control to drive accurate movements. However, the amount of dispersion around the mean suggested a consistent variability in the performance of the controller. Overall, the four tasks achieved low values of smoothness, which were previously found in healthy subjects who performed similar movements with the help of a passive exoskeleton for weight relief [16].

Table 1: Performance measures of the RL control.

Target Angle	$e_{\text{abs}} [^\circ]$	$i_{\text{set}} [s]$	sm
130°	0.29 ± 0.17	1.93 ± 0.22	0.12 ± 0.03
140°	0.47 ± 0.29	1.69 ± 0.31	0.25 ± 0.09
150°	0.67 ± 0.24	1.61 ± 0.37	0.30 ± 0.10
160°	0.53 ± 0.38	1.52 ± 0.34	0.31 ± 0.08

In Fig. 1, we reported the angular trajectories during the execution of the movements. Each panel represents the performance of the controller for a different target angle: 130° in (a), 140° in (b), 150° in (c) and 160° in (d). The upper panels show the superimposed repetitions to reach the same target, shown with a dashed line. The control actions, corresponding to the highlighted (dark green) single repetition, are displayed in the lower panels (red line for the biceps and black line for the triceps). The black asterisks indicate the setting time of each movement.

Fig. 2 shows an experiment in which a muscles spasm was simulated by the subject's volitional activation. The angular trajectory is plotted in panel (a), where the target angle (140°) is indicated with a dashed line. Panel (b) displays the volitional EMG signals of the subject (red for the biceps and black for the triceps) during the experiment. At the onset of the stimulation, the subject's arm is in the initial position (120°) and the volitional EMG signals of both muscles are lower than $20 \mu V$, which can be considered as the subject's relax threshold. After 1.7s, the subject made a

quick muscle contraction which moved the arm away from the target. The volitional activation is clearly visible in the rapid and consistent increase of the EMG signals. Following the induced disturbance, the subject relaxed his muscles and the arm was driven again by the controller in the target position, with a final absolute position error equal to 0.2° .

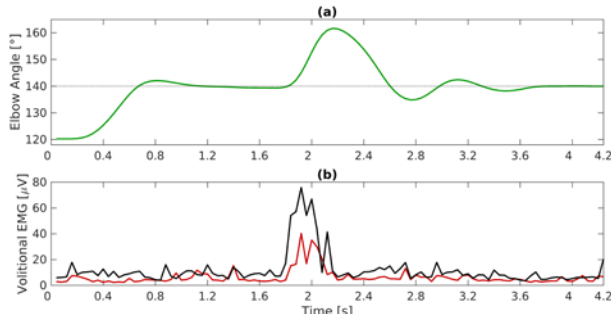


Figure 2: Robustness of the controller to “simulated” muscle spasms (at about 2s).

Discussion and conclusions

Our results showed the ability of reinforcement learning to drive very accurate flexion extension angles in a real environment combining an exoskeleton for weight relief with upper limb FES. The control system revealed good stability and disturbance rejection properties in reaching different target angles within an overall range of motion of 40° on a single healthy subject.

The control actions (pulse width of the biceps and triceps muscles) were modulated to rapidly reach the angle target. Then, to hold the position, high values of pulse width, resulting a massive co-contraction, were used. This control strategy cannot be considered efficient from a physiological point of view, since the overstimulation can accelerate the muscle fatiguing process. The obtained overstimulation might depend on the reward function choice. Indeed, we penalized the distance of the arm from the target in each time step. Therefore, the goal of the agent was to find the optimal policy which drove the arm to the target position as fast as possible, also increasing the stiffness to avoid large overshoots. To modify this behaviour, additional penalty terms for the speed or the stimulation integral should be investigated. Exoskeleton brakes can also be exploited to avoid co-contractions to keep the target position once achieved. Based on the good accuracy achieved by the RL controller in reaching different target angles, methods based on machine learning seem to be promising in overcoming the typical problems of more traditional control solutions. Further investigations on both healthy and impaired subjects need to be done to ascertain its performance and its future suitability in clinics.

To improve the system, the generalization properties of the policy could be enhanced by adding more initial conditions and on-line learning can be exploited to let the controller follow the physiologic time-varying dynamics.

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In-silico Biophysical Myelinated and Unmyelinated Autonomic Nerve Fiber Models

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Abstract: Over the past few decades, *in-silico* modeling has become accurate and insightful. The current work proposes a physiologically accurate nerve fiber model for rat unmyelinated and myelinated autonomic nerve fibers. The model predicts the temporal aspects to high degree of accuracy and generates a self-propagating action potential allowing the spatial-temporal visualization of the propagating action potential. Using previous data from patch clamp work on a nodose sensory ganglia, well defined channel dynamics are placed on a classical cable model. The cable model was generated piecing together individual material electrical properties of a nerve fiber to create a self-scaling model as a function of fiber diameters. The SFAP is allowed to propagate at a conduction velocity set by its own electrical properties. Nerve fibers simulated in this paper were unmyelinated fibers: (0.5, 1 μm dia.) and myelinated fibers: (1, 3 μm dia.). The resulting action potential conducted at 0.4, 1.1, 3.3 and 7.3 m/s, respectively. With the ability to test electrode designs realistically *in-silico*, a needle electrode was implemented and tested on its ability to stimulate a 0.5 μm unmyelinated and 12 μm myelinated nerve fiber. A theoretical strength-duration was simulated to predict characteristics for a near and far nerve fiber.

Keywords: Active Fiber Model, Autonomic Nerve Fibers, Neural Electrode Design, Computer Simulation

Introduction

The advent of the use of micro-electro-mechanical systems (MEMS) microfabrication techniques to produce neural interface structures has led to the possibility of instantiating extremely precise, patterned structures. Flexible multi-channel structures can be reproducibly implemented with feature sizes approaching 1 μm [1]–[4] to be used as high-resolution interfaces to the nervous system. However, the designs and specifications used as the basis for these structures are currently largely based on the intuition formed by empirical, *in-vivo* and *in-vitro* trial-and-error experience by investigators who are developing devices and new applications.

In-silico simulations of novel neuroprosthetic interface designs are a means to predict the performance, design, optimize and characterize the stimulation and recording behavior of putative advanced indwelling interfaces [5]. They allow a large number of new designs to be varied and modified to identify critical characteristics before going through

the expense of realizing and testing the microfabricated structures in the animal model. This ultimately reduces the number of animals used to refine and perfect the neural interface. They also aid in the exploration of unexplained or interesting results coming from animal trials and a means to identify putative mechanisms of these results [6].

A research focus in our laboratory is to develop electrode structures to reach the peripheral nerve fibers in the autonomic nervous system. In contrast to the fibers in somatic peripheral nerves, those in the autonomic nerves are thinner in caliber and largely unmyelinated. Myelinated fibers are between 1 and 12 μm in diameter, while unmyelinated fibers which comprise up to 80% of the nerve are between 0.5 and 3 μm . Initial attempts to use techniques developed for characterizing the recording and stimulation behavior in somatic peripheral nerves [5], [7]–[9] resulted in simulations with poor agreement to the experimental data (unpublished work).

The accuracy and fidelity of a biophysical model to the animal model depends on the accuracy of the physical parameters and fidelity of the dynamic equations used to model the bioelectric phenomenon. Our modeling framework consists of a **1**) volume conductor model, used to model the current density and potential distribution to predict the electrode sensitivity function and **2**) an active nerve fiber model used to either model the effect of stimulation through the electrode, or reciprocally the potential coupled to the electrode given the activity of a nerve fiber in the volume conductor. The volume conductor half of this modeling framework is well characterized. Thus, we focus on the active nerve fiber model.

Various nerve fiber models have been proposed since the seminal work by Hodgkin and Huxley [10]–[13]. Each model has subtle differences, strengths and limitations on their scope. HH modelled the giant squid axon membrane, FH the myelinated frog nerve, CS the myelinated rabbit nerve, etc. There were, however, no autonomic nerve fiber models. The experimental observational basis for the autonomic nerve fiber, especially the unmyelinated fibers is extremely limited. Most are based on somatic membrane or whole cell recordings [14].

In the present paper, the development of active autonomic myelinated and unmyelinated nerve fiber models is described. The models were used to predict the shape of single fiber action potentials recorded through a needle electrode, and the shape was compared with *in-vivo* single fiber

action potentials recorded in the rat cervical vagus nerve, and are presented in a companion paper.

Methods

Ionic Channels

The nerve fiber models were based on Schild et al's [14] characterization of the somatic ion channels of a rat nodose sensory neuron. An assumption was made that a subset of the channels expressed at the soma are shuttled to the axon to form the set of channels embedded in the axonal membrane. Thus, the set of somatic channels were trimmed by eliminating channels that are not known to be found in the axon, such as those related to Ca^{2+} . Two subsets of channels were defined, listed in Figure 1, and incorporated in an unmyelinated and a myelinated nerve fiber cable model [14]. Briefly, the channels included were as follows:

Na⁺ Channels: Fast Acting TTX Sensitive (Nav1.7) and Slow Acting TTX Insensitive (Nav1.8), **K⁺ Channels:** Inward Rectifying K⁺ (K2.1), Slowly Inactivating Delay (D), K⁺ Delayed Rectifier (K), Tx Sensitive K⁺ (DTX) and Early Transient Outward K⁺ (A), and the **Passive Ion Channels:** Sodium-Potassium exchange pump (NaK), Background (B), and Membrane passive leakage (L).

The models take on the temporal-spatial dynamics of a nerve fiber, along with the non-linear activation dynamics of the channels and gives rise to a spatial-temporal representation of the membrane dynamics of the fiber. The spatial aspect was achieved by segmenting the axon into many serial segments. For the described work 1 μm segments were used for the unmyelinated fiber model. The myelinated fiber models was split into 10 segments, a single 1 μm Node of Ranvier (NoR) segment and 9 equally spaced internodal segments, larger due to lack of any active or passive channels. Each individual segment, with its membrane dynamics, is linked in series. The effects are spread out to the other surrounding segments and extracellular media via the second spatial derivative present in the nerve cable model.

Active Fiber Model Implementation

Both fiber models were implemented using Matlab (Matlab 2014, Natick MA) using the built in ordinary differential equation solvers (ODE23 and ODE45) to solve the gating variables and transmembrane potential in both temporal and spatial dimensions. Sodium, potassium and passive channel equations used were modified from Schild, based on new unpublished results [14].

An alteration was made at the Nodes of Ranvier (NoR) to account for the geometries seen in Figure 1 [15] by pinching the nodes to 2/3 the axonal radius. Additionally, channel densities were adjusted to match sodium channel counts shown by Waxman [16].

Four models were produced: 0.5 μm and 1 μm unmyelinated, and 1 μm and 3 μm myelinated fibers. These calibers roughly correspond to the typical minimum and maximum fiber diameters seen in the autonomic nervous system (ANS). To test the models, the model's state variables and transmembrane potentials were bootstrapped, and allowed to settle to steady state values until the input and output steady state values of the ODE were within 1% of each

other for a 1 second simulation epoch. Action potentials/currents were initiated at the initial segment of the ca-

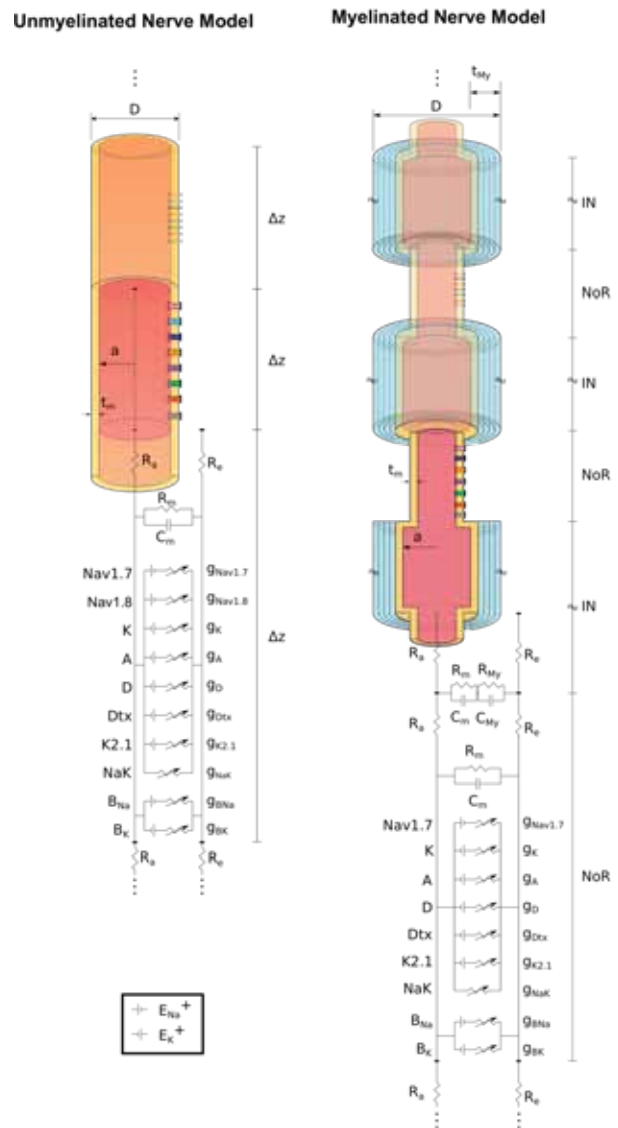


Figure 1: Cable model representation of the two nerve fiber types simulated. Shown are the channel locations, channel types used and model parameters for the unmyelinated nerve fiber model (left) and the myelinated nerve fiber model (right).

ble using a sufficiently large transmembrane potential clamp, approximating a 0.2ms long depolarizing discontinuous voltage clamp pulse at the initial segment. The resulting propagating action potential propagated from one end of the fiber to the other.

The extracellular stimulation response of the active fiber models were tested by running a strength-duration experiment *in-silico*. The potential distribution for rectangular pulses ranging from 5 - 1000 μA and 0.2 - 100 μs originating from an intrafascicular multi-electrode needle array were presented to both a 0.5 μm unmyelinated and a 12 μm myelinated nerve fiber. The adequate stimulus to activate and generate a propagating action potential was found for a nerve fiber adjacent to the needle and at the margins of a 500 μm diameter nerve fascicle.

Results

The Nerve Fiber Models

The activation of the initial segments of the two unmyelinated and two myelinated active nerve fiber models produced action potentials that propagated down their respective fibers (Figure 2).

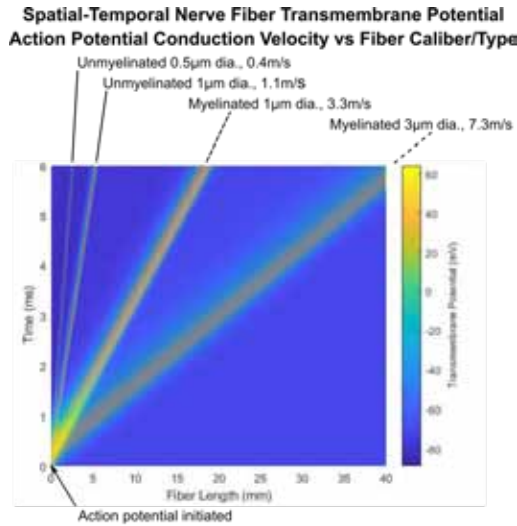


Figure 2: Spatial-temporal nerve fiber transmembrane potential showing differences in conduction velocity and spatial width of action potentials.

The conduction velocities of the unmyelinated fibers were 0.4m/s and 1.1m/s for the 0.5µm and 1µm fibers respectively. Those of the myelinated fibers were 3.3m/s and 7.3m/s for the 1µm and 3µm fibers. These velocities agree nearly exactly to the conduction velocities measured in *in-vivo* experiments [17] Figure 2. also shows how the wavelength of the action potential increases with increasing conduction velocity and with fiber type.

Taking the transmembrane potential at a specific time point in the middle of the nerve fiber, results in the temporal action current and spatial action potential/currents (Figure 3).

In the left panels show the temporal action currents and constituent channel action currents. The right panels show the transmembrane action potential and currents comparing the spatial distribution of the action potential/current and their amplitudes. Note that the amplitude and timing of the action currents for both unmyelinated and myelinated fibers are generally similar per unit area, while the spatial distribution, total currents and potentials are quite different. These characteristics are in general agreement with what is known about these autonomic peripheral nerve fibers.

In-silico Electrode Design

The micro needle electrode structure was tested for its ability to stimulate certain fiber types and diameters and was found to have a difference in its ability to stimulate one fiber type over another (Figure 4). In this particular case, it is shown that the electrode is more likely to stimulate a myelinated nerve fiber at a lower threshold.

Discussion

Presented in this paper was a physiologically accurate representation of two classes of autonomic nerve fibers. This can be used as a tool to help determine such things as shape of single fiber action potentials recorded and aid in the design of electrode structures to interface with the simulated nerve fiber. An insight between the myelinated and unmyelinated fibers predicted by the model is the vastly different spatial wavelength between the myelinated and unmyelinated nerve fibers in Figure 3. The unmyelinated nerve fibers have a spatial wavelength on the order of eight times narrower than that of the myelinated nerve fiber. The spatial narrowness of the unmyelinated action potential can explain the difficulties in recording from these fibers, and suggests that electrodes must have spatial sensitivity functions that are finer than the wavelength of the target fiber type's action potential. (Figure 3B, starting from the right of the figure), it is around 1-3mm in width. Thus, myelinated fibers can be measured by gross electrode structures, like a cuff or hook electrode with a contact, less than 1mm for best results. However, unmyelinated fibers present an

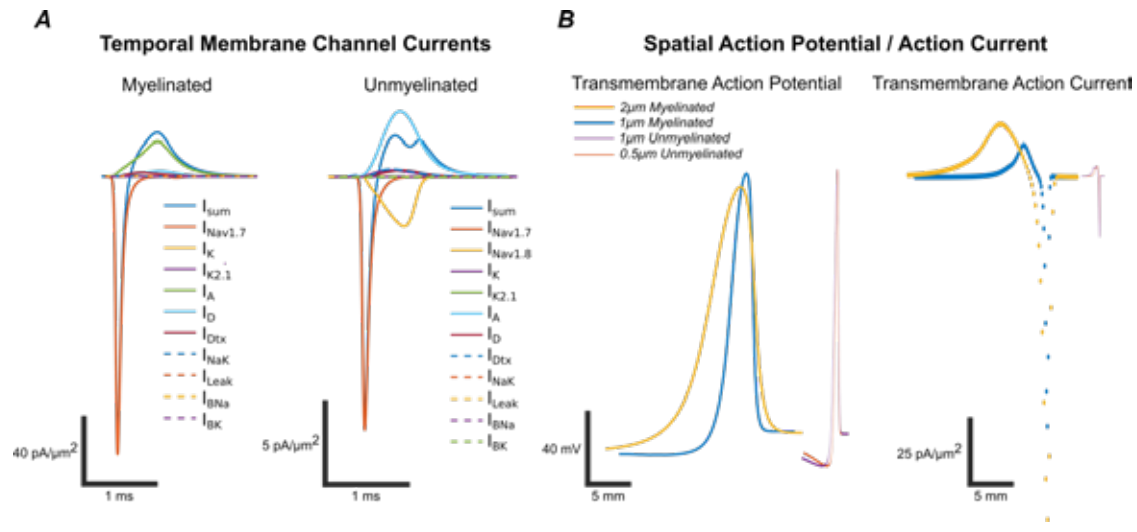


Figure 3: A) Shows the total temporal transmembrane action currents as a sum and individual ion channel contributions. B) Shows the spatial transmembrane action potential and current showing the drastic difference in spatial domain between nerve fiber types.

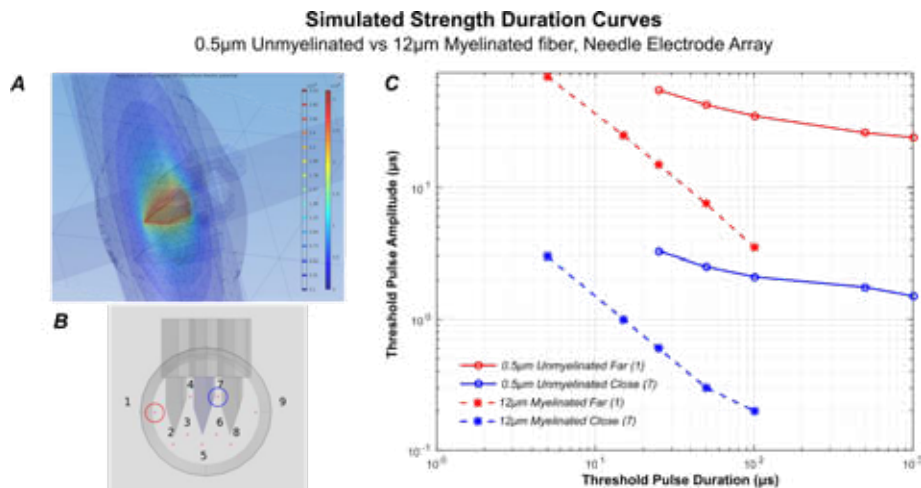


Figure 4: A) Is the volume conductor potential field to a monopolar stimulation of the middle needle of the multi-needle array. B) Depicts the location of nerve fibers extracted for comparison. Fiber 1 (Distant) and Fiber 7 (near) C) Shows the strength duration curve of two selected nerve fibers. It can be seen that the slope of the two different fibers are different. The unmyelinated fiber has a shallower slope as compared to the myelinated fiber. Distance from the electrode displaces the threshold pulse amplitude by about an order of magnitude for both fiber types.

entirely different story. Here the sub-mm wavelength of the initial phases of the sodium depolarization makes it unlikely that that same cuff structure can measure the activity of these fibers. Taking this into account one can start to understand the need for microscale intrafascicular electrodes or needle electrodes to pick up activity from these slower nerve fibers. An electrode design and implementation workflow that takes advantage of these types of *in-silico* fibers can inform adequate electrode design structures and reduce ad-hoc guesses on what structures should look like. In doing so, animal usage will be reduced in addition to the benefit of saving both time and money for testing a multitude of electrode designs.

Acknowledgement

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Difference between tonic and phasic pinch contractions in facilitation of responses elicited by cervical transcutaneous spinal cord stimulation

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Abstract: Transcutaneous spinal cord stimulation (tSCS) can be used to evoke reflex responses of the lower-limb muscles. In this study, we evoked responses in the upper-limb muscles using cervical tSCS. Specifically, we showed that the evoked responses were suppressed if the inter-stimulus interval was 50 ms. Moreover, we showed that both tonic and phasic contraction of muscles facilitated the responses. These results suggest reflexive nature of the evoked responses and that motoneuron excitability facilitated the evoked spinal responses. Non-invasive stimulation of the cervical spinal cord could potentially be used for neuro-modulation of spinal excitability to improve upper-limb motor function after neurological injury.

Keywords: transcutaneous spinal cord stimulation, cervical vertebra, upper-limbs, H-reflex.

Introduction

Transcutaneous spinal cord stimulation (tSCS) of the lumbar posterior root has been used to induce responses in the lower-limb muscles [1], [2], [3]. These responses were shown to be reflexive in nature, with evidence suggesting they are likely monosynaptic [1], [2]. tSCS-induced spinal reflexes share common features with the well-known Hoffmann's reflex (H-reflex) [3]. While it is sometimes difficult and time consuming access the nerves required to induce H-reflex response, tSCS has the ability to induce responses in multiple muscles simultaneously since stimulation is applied on the dorsal root of the spinal cord. Most studies have used tSCS to evoke responses in the lower-limbs, however it is also possible to induce upper-limb responses [4], [5]. Therefore, the objective of this study was to examine the effects of cervical tSCS (ctSCS) on the upper-limb responses and investigate modulation effects on the evoked responses.

Methods

Participants

Ten able-body individuals were recruited in this study (age: 23-35 years). The study protocol was approved by the local institutional ethics committee at the University of Tokyo. Participant remained in the supine position for the duration of the experiment.

Cervical transcutaneous spinal cord stimulation (ctSCS)

Spinal excitability was evaluated simultaneously in multiple upper-limb muscles using tSCS on the cervical spinal cord. Responses were recorded the on: i) first dorsal

interosseous (FDI); ii) abductor pollicis brevis (APB); iii) flexor carpi radialis (FCR); and iv) extensor carpi radialis (ECR) muscles unilaterally using surface electromyography (EMG) electrodes (Ag/AgCl; Vitrode F-150S, Nihon Kohden, Japan). A reference electrode was placed on the elbow. A constant current electrical stimulator (DS7A, Digitimer Ltd., UK) was used to deliver a single monophasic pulse (2 ms pulse width) with stimulation amplitudes of 70 - 90 mA. The anode (5x9 cm) was positioned along the midline of the anterior side of the neck, while the cathode (5x5 cm) was positioned over the 7th cervical vertebra on the posterior side of the neck. The cathode was adjusted, if necessary, such as to induce maximal responses in all muscles.

Data acquisition and processing

Data was recorded at the sampling frequency of 4,000 Hz (Powerlab, AD Instruments, Australia) after filtering (15-1000 Hz) and amplification (1000x) using an EMG amplifier (MEG-6108, Nihon Kohden, Japan). Peak-to-peak amplitude was calculated in 200 ms window after ctSCS. Background EMG was compared 50 ms before ctSCS.

Experiment

In the study two different experimental protocols were tested: 1) Double pulse stimulus (DPS): participants remained at rest while two stimulation pulses with 50 ms inter-stimulus-interval were delivered; 2) Pinch: participants were asked to pinch a force sensor (20% of their maximal effort) using their index finger and thumb in the following conditions: a) continuous (Tonic); b) as fast as possible in response to an audio signal (Phasic; note: ctSCS response was evoked 300 ms after the audio cue); and c) control condition at rest (Rest). Eight trials were tested and averaged for each condition and protocol.

Statistics

Responses were analysed using the paired samples T-test to compare first and second response of the DPS protocol and background EMG between Tonic and Phasic tasks. Moreover, repeated measures analysis of variance (ANOVA) with LSD post-hoc multiple comparisons was used to compare Rest, Tonic, and Phasic responses of the Pinch protocol. Significance was set to $p < 0.05$.

Results

Results of the DPS protocol (Figure 1) indicate that the second response was significantly suppressed compared to the first response for the FDI ($t(9) = 3.927$; $p = .003$), APB

($t(9) = 5.460$; $p < .001$), FCR ($t(9) = 4.905$; $p < .001$), and ECR ($t(9) = 2.500$; $p < .034$) muscles.

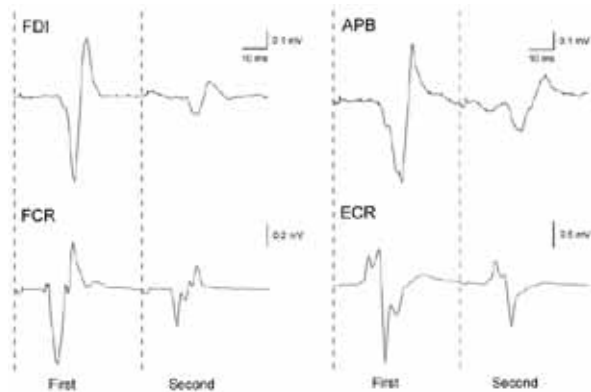


Figure 1: DPS protocol sample responses for all muscles.

Results of the Pinch protocol (Figure 2) indicate that responses were significantly different for FDI ($F(2,18) = 6.620$; $p = .007$) with post-hoc differences between Rest-Tonic, Rest-Phasic and Tonic-Phasic conditions; APB ($F(2,18) = 6.335$; $p < .008$) with post-hoc differences between Rest-Tonic and Rest-Phasic conditions; and ECR ($F(2,18) = 10.389$; $p < .001$) with post-hoc differences between Rest-Phasic and Tonic-Phasic conditions. No differences were shown in the FCR ($F(2,18) = 2.482$; $p < .112$). Results also indicate that background EMG was larger during the Phasic task compared to Tonic for FDI ($t(9) = 3.966$; $p = .003$), APB ($t(9) = 3.900$; $p < .004$), FCR ($t(9) = 2.372$; $p < .042$), and ECR ($t(9) = 4.096$; $p < .003$).

Discussion

Our results demonstrated that ctSCS can evoke responses in the upper-limb muscles. Although pain wasn't evaluated systematically, none of the participants reported discomfort using this technique. Specifically, we showed that the evoked responses were suppressed in the DPS protocol. The refractory period of 50 ms was not sufficient to re-polarize the nerves, therefore inhibiting the responses as we expected [1], [2], [3]. Moreover, when muscles were contracted, evoked responses were generally facilitated. Specifically, Phasic task facilitated the responses more compared to the Tonic task, while background EMG was also larger in the Phasic condition. Therefore, phasic contractions facilitated motoneuron excitability to a larger extent, which was reflected in facilitation of spinal excitability. Overall, these results suggest reflexive nature of the evoked responses in the upper-limb muscles using ctSCS, which is analogous to the H-reflex. Involvement of spinal reflexes is vital for driving neuroplasticity in the central nervous system. Stimulation of the cervical posterior root could perhaps be used for neuromodulation of spinal excitability [4], which could affect upper-limb motor function in individuals with neurological injury.



Figure 2: Pinch protocol sample responses during Rest (control), Tonic (continuous), and Phasic (audio cued) conditions.

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FES SYSTEM FOR HAND OPENING AND GRASPING WITH AUTOMATIC CONTROL BASED ON THE MICROSOFT KINECT SENSOR

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Abstract: *The goal of this work was to develop and evaluate a FES system to assist hand opening and cylindrical grasp automatically controlled by information provided by a Kinect sensor. The system was evaluated by 9 hemiparetic subjects that grasped, lifted, displaced, and released 2 cylinders of different diameters with and without assistance of the FES system. Results showed that the percentage of successful grasps increased by 10% when using the system, the execution time was shorter, and the timing of stimulation was appropriate.*

Keywords: *Functional Electrical Stimulation, stroke, grasping, Kinect, rehabilitation*

Introduction

Functional Electrical Stimulation (FES) can assist hemiparetic patients performing functional hand movements [1]. Improvements in functionality were observed immediately but also persisted in time [2]. Diverse sensors, e.g. switches, movement, EMG, have been used to control the stimulation parameters; video recordings allow measuring body and object positioning without body-mounted sensors. A perception system based on a Kinect sensor able to decode hand and object positions was tested previously on one healthy subject [3]. This study presents the development and test of a Kinect sensor controlled FES system for supporting functional movements of the hand.

Methods

System: The computer-controlled closed-loop FES system consisted of a four-channel electrical stimulator (200 μ s square pulses, 30 Hz) and a Microsoft Kinect sensor. Information provided by the sensor was used to determine the onset and offset of stimulation to support hand opening and grasping. The Kinect sensor captured an 8 bit RGB image and a 16 bit depth image at a rate of 30 frames per second. The sensor was placed above a table allowing recording images of the hand and the object to grasp, which consisted of two cylinders (height: 10 cm, diameter: 4 and 7.5 cm; weight: 300gr). The cylinders had the lid coloured green. To detect them, the green pixels in the RGB images were found. Then, a two-dimensional median filter was applied and if the area of the green pixels was between 50 and 200% of the area of the lid, the pixels were labelled as the cylinder. Pixels with a depth value larger than 3 cm above the surface of the table and not belonging to the cylinder were labelled as the hand.

To open the hand before grasping, stimulation targeting m. extensor digitorum communis, m. extensor pollicis longus, and m. abductor pollicis was triggered when the distance between the hand and the center of the cylinder was 3-30 cm. When the hand was positioned appropriately, grasping was initiated by stimulating m. flexor digitorum profundus, m. flexor digitorum superficialis, and m. adductor pollicis. The hand was opened again when the cylinder was placed on a specific area in the working space.

Test of the system: The performance of the closed-loop FES system was evaluated on 9 sub-acute stroke subjects (6 male, 56-78 years old). The study was approved by the local ethical committee (approval no. N-20130053). Subjects had to reach, grasp, lift, displace, and release one of the cylinders. The task was repeated 20 times which each cylinder, with and without FES. Wilcoxon signed-rank tests were performed with a significance level of 0.05. Results are presented as median [25% Q; 75% Q].

Results

Three subjects were able to complete the task only with FES support and two of them could only do it using the small cylinder.

For the 4 cm diameter cylinder, the median percentage of successful grasps increased by 10% [4%;53%] ($p=0.02$), when using FES. No changes in the percentage of successful grasps were observed for the 7.5 cm cylinder, when comparing tests with and without FES. The onset and offset of FES was timed appropriately on average in 96% and 92% of all cases, respectively. When comparing repetitions without and with FES, the grasp-and-hold time decreased for the 7.5 cylinder (-1.23 s [-1.9 s; -0.3 s], $p = 0.046$) and the hold-and-release time decreased for the 4 cm cylinder -0.9 s [-6.3 s; -0.4 s] ($p = 0.04$). No changes were detected in the other cases.

Discussion

The test of this closed-loop FES system automatically controlled by a Kinect sensor showed its usability in assisting hand grasp and release of cylindrical objects. Stroke patients, assisted by the FES system, were more successful performing this task and decreased the execution time. Furthermore, the stimulation was appropriately timed in more than 95% of the trials.

Acknowledgement

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3D printed hinged multi-contact cuff electrodes for rapid prototyping and testing

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Abstract: Multi-contact cuff electrode (MCC) structures were implemented using a 3D laser stereolithographically (SLA) printed, rigid poly (methyl methacrylate) hinged cuff design with stainless steel-poly(3,4-ethylenedioxythiophene) polystyrene sulfonate (SS PEDOT:PSS) contacts. The method offers a means to rapidly implement a complex MCC as a robust and precise structure for ex-vivo and acute in-vivo testing of novel electrode structures and designs. Verification testing was carried out by employing 3D printed MCCs in in-vitro and in-vivo studies, which included stimulation and recording of action potentials. These MCCs were used in in-vivo and ex-vivo nerve experiments to test their handling and usability. The electrode impedance spectrum of each contact was characterized before and after each experiment. They indicated that there were no notable changes. Collectively, 3D printed rapid prototype MCC functionally behaves identically to classical silicone MCCs, but with increased robustness, improved implantability, and lower production cost and faster production turn around.

Keywords: Multi-contact cuff electrode; rapid prototyping; neural interface; poly(methyl methacrylate) (PMMA); 3D printed; poly(3,4-ethylenedioxythiophene) polystyrene sulfonate (PEDOT:PSS)

Introduction

The manipulation and measurement of the bioelectrical activity within peripheral nerves is an essential tool to further our understanding of the nervous system towards developing and improving bioelectric therapies such as neuroprosthetics and functional electrical stimulation (FES). Access to the information flow within the peripheral nerves can be gained through the use of appropriately designed and placed electrodes, such as multi-contact cuff electrodes (MCC). MCCs consist of a cylindrical outer insulative material, and multiple electrode contacts seated along the inner surface. These contacts extend around a large portion of the epineurium of the nerve. Design specifications of the cuff electrode that can be influenced by experimental minutiae are: the inner diameter of the cuff, number of contacts, width of each contact, distance between contacts, and distance from outer contacts to end of insulative material [1]–[7].

Advancing neuroprosthetics by exploring techniques such as velocity selective recording, electrical nerve block or developing methods that target small caliber fibers, such

as those in the autonomic nervous system required changes and customization of electrodes from the standard circumferential tripolar configuration that was optimized for large caliber sensory and motor fibers in the somatic peripheral nerves in order to improve electrode selectivity, recording signal-to-noise ratios, and stimulation selectivity. Recent *in-silico* work in our lab to develop spatial-temporal filtering suggested various non-standard electrode configurations. While standard cuff electrodes are commercially available, electrodes with custom geometries such as contact pattern, contact size, and structural features, are expensive to realize with long lead times through commercial producers making them cost/time prohibitive for this research. A rapid means to produce *in-silico* informed test structures for first *in-vitro* or *in-vivo* experimental verification was needed.

In standard cuff electrode designs, a flexible sheath such as silicone has been used in fabrication using a variety of methods. Although in-house facilities to produce custom structures are available, we found limitations in the precision of structures that can be produced, as well as issues in durability during reuse with the silicone structures problematic. A 3D printing technique, stereolithography (SLA) was explored to rapidly create MCC structures, using Poly(methyl methacrylate) (PMMA) to produce robust, reproducible, dimensionally accurate structures for repetitive, acute *in-vivo* and *ex-vivo* research purposes.

Methods

PMMA MCC Design

In-silico simulations defined the inner diameter of the cuff and the contact dimensions and placement. To allow application of the rigid MCC structure to an intact peripheral nerve bundle, the normal slit tube of a silicone structure was divided into two semi-circumferential shells with a hinge integrated into the design, similar to the closure design of [8], to enable articulation of the two hemi-circumferential shells to articulate. Structures were designed with and without a second hinge for use a closure. A 3D CAD program (Fusion 360 Ultimate Student v2.0.3800, Autodesk) was used to capture the design of the structure, including coiffers to accommodate electrode contacts, and a via to enable feedthrough of the lead-out wire attached to the metal film electrode contacts (Fig.1A).

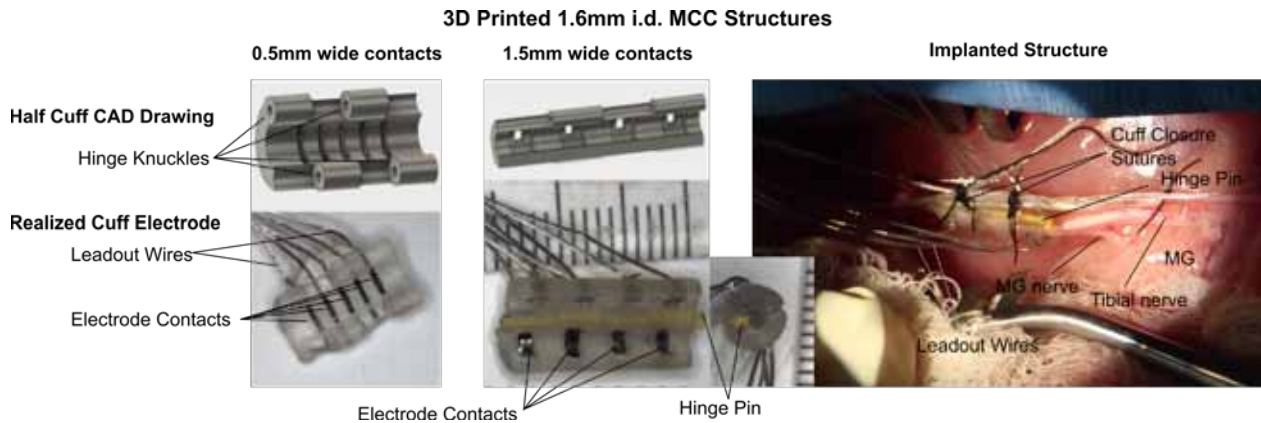


Fig. 1: Illustration of multi-contact cuff structure implementation. Two 1.6mm i.d. MCC structures are shown. The left panel shows the CAD rendering and implemented half cuff leaf of a 10-pole MCC with 0.5mm wide contacts. The middle panels show an 8-pole MCC with 1.5mm wide contacts. The lower realized 8-pole cuff is shown with the hinge in the open and closed states. Both MCC structures were implemented with PEDOT:PSS coated stainless steel contacts. The right panel shows the 8-pole electrode structure implanted on the tibial nerve of an anaesthetised rabbit during an acute experiment.

In a second design, grooves were used to accommodate wire contacts comprising of the stripped ends of the PFA insulated stainless steel bioelectric cable (Fig.1B). In both designs, stainless steel contacts were used instead of standard platinum contacts in order to explore lower cost materials. However, to eliminate the polarization problems associated with stainless steel interfaces, they needed to be surface modified to lower overall impedance and eliminate low frequency reactance. Electroplated PEDOT:PSS was used for this purpose.

3D Printing

A stereolithography (SLA) 3D printer (Form 1+, Formlabs Inc.) to print the cuff structures using the clear photopolymer resin (FLGPCL02, Formlabs Inc.). The CAD design was imported into the 3D printer software (Pre-Form v2.11.3, Formlabs Inc) to set up and drive the 3D printer. Immediately following the completion of each print, the structures were soaked in denatured alcohol for approximately 20 minutes to eliminate excess resin and hardened through exposure to a sunlight, a UV dental resin curing lamp (Optilux VCL 401, Demetron), or halogen lamp house (Intralux 5100, Volpi).

Electrode Contacts

Stainless steel contacts were applied to the 3D printed MCC structures. Wire contacts were implemented using multi-stranded stainless steel wire (AS634, Cooner Wire) that was sewn via holes and grooves on the inner surface of the 3D printed cuff structures, as shown in Figure 1. In cases where larger contacts were defined, stainless steel metal foil (Type 304 - 41580, Alfa-Aesar) was cut to fit within the printed coffers on the inner surface of the cuff wall, multi-stranded stainless steel wire was micro-welded onto the back side of the contacts and the contact/lead wire assembly was glued into cuff wall coffer using cyanoacrylate glue. In both cases, the exposed wire on the back side of the cuff wall was insulated using a small amount of 3D print media, which was UV light cured with a hand held UV lamp.

Since stainless steel was used as contacts in the two designs, PEDOT:PSS was electroplated [9] to improve the contact impedance characteristics.

Testing

After assembling and preparing the cuff electrodes, the MCC structures were tested by 1) measuring the impedance spectra in normal saline, 2) tested for implantability and usability by surgical implantation of the structure around the tibial nerve and 3) used to record compound and spontaneous nerve activity in an acute *in-vivo* experiment.

Results

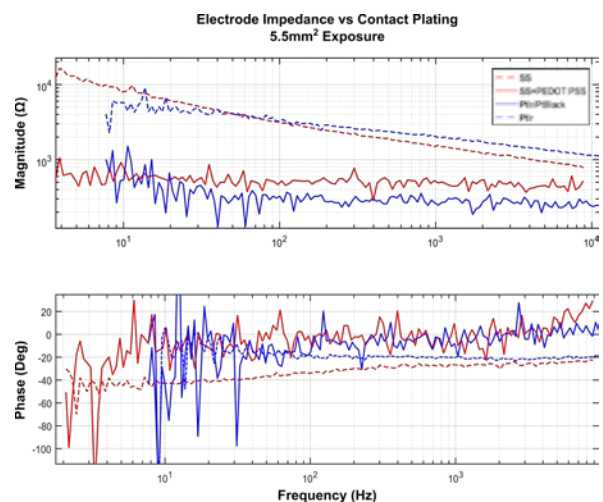


Fig. 2: Impedance of electrode contacts (1.5mm wide) in a 1.6mm diameter multi-contact cuff. The contacts are comparing one made of platinum and one made of stainless steel. Both are measured before and after electroplating. The platinum electrode was plated with platinum black using Kohrausch's solution. The stainless steel contact was plated with PEDOT:PSS. There is a significant reduction in impedance following plating, especially in the low frequency reactance.

Impedance

The impedance spectra from the 1.5mm wide foil based design implemented with stainless steel and platinum contacts is shown in Fig.2. Measurements made after PEDOT:PSS and platinum black electroplating shows a significant reduction in the overall impedance, notably the reduction/elimination of the low frequency reactance.

This indicates that the PEDOT:PSS plating modified the interfacial properties to provide a galvanic pathway that enables the classically polarizable stainless steel contact to pass a galvanic current into the media. The efficiency of that pathway compares favorably against platinum contacts coated with platinum black.

Surgical Handling

Electrode structures were implanted around the tibial nerve at a level just above the popliteal fossa in an acute anaesthetised rabbit hind limb preparation. The articulated hinge structure made the implant easier and with manipulation of the nerve as compared a traditional silicone cuff electrode. The joint could be disassembled to enable placement of the leads on either side of the nerve. The rigidity of the structure also facilitated the ease of placement around the nerve (Fig.1 right) and minimized the handling, reducing the time needed to place and secure the structure as compared to traditional MCC electrodes.

Neural Recordings

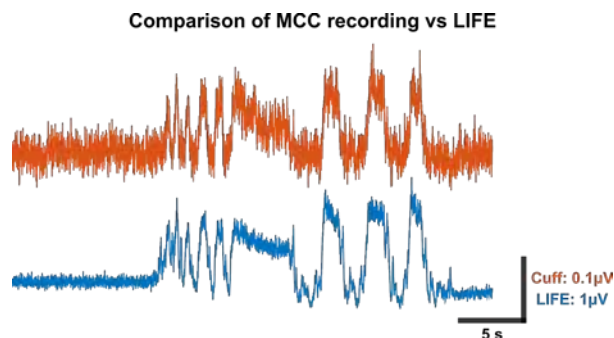


Fig. 3: Comparison of simultaneously recorded electro-neurograms originating from MCC and LIFE implanted on the tibial nerve and MG nerve respectively showing muscle mechanoreceptor activity in response to stretching of the triceps surae muscle. The raw records were bandpass filtered (300 - 10kHz), rectified and envelope filtered to show the modulation of the neural activity.

PMMA cuff electrodes that were produced in this study were used to stimulate and record activity in peripheral nerves in *in-vivo* and *ex-vivo* procedures. Fig.3 shows a recorded action potential obtained using the cuff electrode shown in Fig.1. Although the comparison is between an intrafascicular electrode and the multi-contact cuff, an extrafascicular electrode, the modulation of the neural activity is clearly visible, despite an approximately 10x reduction in amplitude.

The recorded action potential shown in Fig.3 serves as verification that the PMMA cuff electrode used in experimentation has the ability to capture neural activity.

Discussion

The motivation for accelerating the production of cuff electrodes for rapid prototyping and testing arose from recent work with *in-silico* simulations which indicated that spatial and temporal filtering characteristics of a neural interface could be manipulated by adjusting the electrode sensitivity function by varying the electrode geometry and shape. Having the ability to faithfully reproduce electrode designs in a short amount of time can reduce the total time as well as cost of experiments.

The cuff electrodes produced using laser SLA had feature fidelity to $<100\mu\text{m}$ to the CAD designs, which proved to be sufficient for the structures manufactured in this study. This method enables multiple identical structures to be rapidly produced in small volumes. Thus far, cuff electrodes with inner diameters of 1.6 mm, 2 mm, 2.5 mm, 3 mm, and 4mm have been fabricated and have demonstrated functional characteristics that are equivalent to a more traditional MCC electrode design. The structures produced in this study were consistently successful in stimulating and recording action potentials in peripheral nerves.

A limitation of the approach is the rigidity and unknown biocompatibility of the SLA printed polymer which prevents the chronic application of the approach. Although we are investigating softer custom photoinitiated polymers to translate the approach to softer materials, the currently used media produces excellent devices for acute and *ex-vivo* use. In the current workflow, once a MCC cuff design is perfected and tested using the rigid SLA printed structures, the features and design can be translated to traditional materials by working with commercial producers for long term testing and application of the design.

Acknowledgements

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Abdominal Functional Electrical Stimulation (ABFES) for the Treatment of Functional Constipation in Multiple Sclerosis: A Case Series

22. Annual IFESS Conference

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Abstract: Functional constipation is a common manifestation in neurological conditions such as multiple sclerosis (MS) and first line treatments are frequently ineffective. The current study sought to explore the use of abdominal functional electrical stimulation (ABFES) as a potential treatment for constipation in neurological conditions over a six week treatment period for 14 participants. The main outcome measure was the Patient Assessment of Quality of Life (PACQoL). Qualitative analysis was also conducted using semi-structured interviews. A within subjects analysis revealed a significant improvement in constipation related quality of life. Reported benefits included a long term therapeutic effect, reduction in the use of laxatives and improved sexual functioning.

Keywords: constipation, abdominal functional electrical stimulation, upper motor neuron disorders,

Introduction

Chronic constipation is estimated to affect 70% of people who have Multiple Sclerosis (MS) (Hinds et al., 1990). Chronic constipation is reported as a distressing, painful and often debilitating condition leading to a lower quality of life. Patients are often unresponsive to first line treatment and achieve inadequate control of their constipation, which predisposes them to impaction, pseudo-obstruction, volvulus, megacolon and bowel perforation which are emergencies requiring surgical intervention. Hence there is an unmet clinical need for novel treatment modalities to be developed to appropriately manage chronic constipation.

There is little research examining the use of electrical stimulation for treating constipation. One case series (n=5) conducted over six weeks by Singleton et al (2016) using abdominal electrical stimulation found a reduction in colonic transit and whole gut transit time in people with MS. An improvement in constipation related quality

of life, frequency and comfort of bowel movements was also found. Two of the participants in the study who continued to use the treatment after the study for approximately two years, have reported no further constipation symptoms and have stopped using the device and previous medications. A further two studies have explored the use of abdominal electrical stimulation in people with SCI Hascakova-Bartova et al (2006) found 70% of participants improved their colonic transit time. An improvement in bowel function was reported by 80% of participants. A further study by Fajardo et al. (2004) found a significant reduction in time to first stool with abdominal electrical stimulation (n=8).

The objective of the current study was to replicate the study methodology and design of the Singleton et al., 2016 study using the patient assessment of constipation related quality of life (PACQoL) questionnaire as the main outcome measure.

Methods

14 people with MS and constipation (ROME IV criteria) were included from Birmingham (n=9) and Salisbury (n=5) FES centres. Electrical stimulation was delivered using the Microstim II device (Odstock Medical Ltd.). The stimulation was delivered at 40 Hz, 300µ pulse width, and 40–50 mA simultaneously (8s contraction with 2s ramps and 3s off period) from both channels. Participants were instructed on electrode placement (see Fig. 1) and the level of stimulation was set to achieve visible contraction of the abdominal muscles. Participants performed six weeks of home administered stimulation of 2x30 minute sessions each day.

Outcome measures included the patient assessment of constipation related quality of life (PACQoL) (Marquis et al., 2005) questionnaire completed at baseline and after six weeks of treatment. Semi-structured telephone interviews were conducted four weeks after completing treatment for five participants seen in Salisbury. The other

participants continued with treatment following the study.

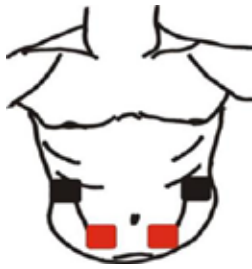


Fig. 1.
Electrode
positioning for
abdominal FES

Results

The scores for the different sub-scales of the PACQoL (28 items) which include physical discomfort, psychosocial discomfort, worries and concerns and satisfaction were calculated individually. The PACQoL uses a five point likert scale. Wilcoxon signed rank tests (two tailed) were used to analyse the data. All sub-scales showed significant improvement over the six week treatment period (Tab.1).

Table 1: Results for PACQoL Sub-Scales
*significant (p<0.05)

Sub-Scales	Median	Z	p	IQR
Satisfaction	8	89	0.003*	6.25-11
Psychosocial Discomfort	7.5	84	0.008*	2.25-12.75
Physical Discomfort	6	105	0.001*	4-8
Worries and Concerns	12	78	0.003*	6.75-14.25

Qualitative Semi Structured Interviews

Improvements from FES

All five interviewed participants reported improvements. The most commonly reported improvement was frequency of bowel movements (n=5) and improvements related to comfort and decrease in bloating (n=5). Participants reported the most important change to be related to an improvement in comfort and reduced bloating (n=3), increased frequency of bowel opening (n=3), an increase in control over their bowel movement and the associated freedom (n=1). The two male participants interviewed both reported improvements in sexual functioning.

Carry Over or Training Effect

Four participants interviewed experienced some carry over when they had stopped using FES. One participant continued to experience a training effect for three months up to the time of reporting. The latter participant report-

edly changed from not opening their bowels for sometimes up to 10-14 days to opening their bowels every 2-3 days.

Comfort of FES compared to Laxatives

All participants reported that FES was associated with more comfortable bowel movements compared to laxatives. All participants reported some level of dissatisfaction with laxatives in terms of their effectiveness and the associated degree of discomfort.

Additional Benefits

Additional improvements reported by participants using FES included improved core strength, sexual functioning, energy, walking and bladder functioning.

Adverse Events

Three participants reported accidentally increasing the power on the stimulator rather than decreasing thus providing themselves with a brief uncomfortable burst of stimulation. One person reported skin irritation which was easily managed through using hypoallergenic electrodes.

Discussion

The findings from the case series suggests that abdominal FES to treat chronic constipation related to neurogenic bowel in people with MS is worthwhile exploring with a feasibility study followed by a fully powered randomised controlled trial. It is encouraging that all constipation related quality of life sub-scales showed a significant improvement. This finding along with the qualitative interviews suggests that the treatment may influence the development of a more natural, comfortable bowel movement. Of particular interest is the participant who suffered from chronic constipation for 10 years yet remarkably was constipation related symptom free for more than three months after the end of the six week intervention. Furthermore, two of the participants from the Singleton et al., 2016 study who continued with treatment for a further two years are now no longer using ABFES and are constipation symptom free. The potential underlying mechanisms for a long term therapeutic effect are unknown but suggest that the treatment may have more than a mechanical influence on the bowel and could potentially activate and strengthen damaged pathways on a neurological level.

Of further interest is the unexpected additional benefits reported. All male participants interviewed reported improvements in sexual functioning. Impairments in sexual functioning is commonly reported in upper motor neuron conditions. Other additional benefits included improvements in bladder functioning, core stability and

walking. Further work in this area should include an assessment to measure any changes in these areas.

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Postural Perturbations induced by Peroneal and Tibial Nerve Electrical Stimulation

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Abstract: Balance assessment and training has been proven to reduce the risk of falling in elderly and frail populations. Balance training consist of instability exercises where postural perturbations are either generated by unstable passive platforms or externally applied to the subject. The current work presents a preliminary study where a novel approach based on electrical stimulation has been used for generating balance perturbations on two healthy subjects. Two different intensity stimulations were applied to both the peroneal nerve and the tibial nerve. The tibial nerve stimulation resulted in a greater CoP variation when compared to the peroneal nerve stimulation for both subjects and both intensities. The application of electrical stimulation to the lower-limbs seems a suitable approach for generating balance perturbations.

Keywords: Balance, Postural Control, Electrical Stimulation, Perturbation-based Training, Lower Limb

Introduction

Frailty is a clinically recognizable state of increased vulnerability resulting from aging-associated decline in functions, which carries an increased risk of falls [1].

Both walking and maintaining balance are complex tasks mediated by a common set of neural muscle synergies [2]. In fact, postural stability is affected in the elderly and frail population due to different causes [3-5]. Assessment methods (proactive/anticipatory tasks as well reactive responses to perturbations) have been proposed to identify the cause of the limitations [[6],[7]]. Several training programs have been proposed to improve postural control and reduce falling risk in elderly and frail populations [8,9]. Especially, balance assessment training based on instability exercises or external balance perturbation applications have shown to be successful [10,11].

In parallel, electrical stimulation has also shown to induce physiological and functional improvements, including increased postural control, in the elderly and frail populations [12-15].

Despite the benefits of balance or instability training programs and the benefits of the application of electrical stimulation in these populations, to our knowledge, no solution has been presented for combining both concepts in electrical-perturbation-based assessment or balance training programs. Apart from the possible benefits induced by the application of electrical stimulation, it could have an additional usability advantage compared to existing mechanical-perturbation-based systems, as it is a compact and portable solution that does not present the

spatial and cost disadvantages associated with other existing solutions.

Thus, in this preliminary study, we checked the feasibility of applying electrical stimuli to the lower leg in order to generate postural perturbations during two-leg standing for possible balance assessment and training applications. These first trials were carried out with two healthy subjects to investigate the effect of two different stimulation sites and two different stimulation intensities on Centre of Pressure (CoP) position.

The hypotheses tested were the following:

- electrical perturbation applied to the shank can generate balance perturbations
- the higher the electrical intensity the stronger the perturbation

Methods

Material

In this pilot study two different systems were used: i) the ESPert Lower system for delivering electrical perturbations to the lower limbs, and ii) the commercial baropodometrix Tekscan sensor for estimating the CoP during standing.

The ESPert Lower system was an adaptation of the Fesia Walk device [16] (Fig. 1), for delivering electrical pulses to the peroneal and tibial nerves during two-leg standing and elicit balance perturbations.

The stimulator delivered current-controlled stimuli to 20 electrode fields that could be activated independently. The multi-field electrode aimed at covering the posterior and lateral sides of the knee in order to stimulate the peroneal and tibial nerves. A textile garment ensured the electrode-skin contact. It was designed to be placed right under the knee, adapting to different leg sizes and shapes. The stimulation parameters and electrode activation were controlled by means of a software application and Bluetooth wireless communication.



Figure 1: ESPert Lower system. (Top) Outer view - stimulator and garment. (Bottom) Inner view - multi-field electrode and garment.

On the other hand, the Tekscan 5330 [17] pressure sensor together with the Body Pressure Measurement System (BPMS) Research software was used for analysing the pressure distribution of the feet and estimate the CoP.

Protocol

In this pilot study the influence on balance of different stimuli were analysed in two healthy volunteers. For this, the subjects were standing in two legs on top of the Tekscan mat while wearing the ESPert Lower system on their leg, as shown in Fig. 2. Both systems were controlled by their respective software applications, which were running simultaneously in a single laptop.



Figure 2: Experimental setup – Subject wearing the ESPert Lower system on the left leg while standing on top of the baropodometrix Tekscan sensor mat.

The stimulation parameters were set to biphasic symmetric waveform, 300us pulse-width, 50Hz frequency, and 10 pulses of duration for all the trials. ESPert and Tekscan data were synchronised using computer clock. Data from the Tekscan were collected at 100Hz by the BPMS Research software and was then postprocessed by means of functions developed in Matlab environment.

Four different stimuli were tested, which consisted in the combination of strong/medium intensity and peroneal/tibial nerve stimulus, referred as “Dorsi-Strong”, “Dorsi-Medium”, “Plantar-Strong”, “Plantar-Medium”. These were defined in a calibration stage, which was comprised by the following steps: i) don the ESPert Lower system on the support-dominant leg, ii) manually set the two electrode configurations for generating a dorsal flexion (peroneal nerve) and a plantar flexion (tibial nerve) while the subject was sitting with straight legs, iii) for each electrode configuration start at 5mA and increase in 1mA steps until reaching motor thresholds (MT) and pain thresholds (PT), iv) calculate the stimuli intensities for each electrode configuration according to Eq. 1.

$$\begin{aligned}
 &strong = PT \\
 &medium = \frac{PT - MT}{2} + MT \tag{1}
 \end{aligned}$$

Once electrode configurations and amplitudes were defined, subjects were asked to stand on two legs during all the trials. At the beginning each subject was asked to stand still 30 seconds without stimulation. The recorded CoP was used as baseline. Then the four stimuli were applied at random order and random times for 1 minute. This was repeated 6 times per subject with 5 minutes of rest between the stimulation blocks. At the end of the session, each participant was asked to stand still again without perturbations for 30 seconds. The postline CoP data were used to check an eventual muscular fatigue.

Data analysis

The first post-processing step consisted on estimating the dependant variables: Anterio-Posterior (AP) and Medio-Lateral (ML) CoP positions and velocity. When done, the ESPert Lower perturbation onsets were added (Fig. 3). A 1.5 sec time window was set before and after perturbation onsets in order to analyse its impact on CoP data. Postural perturbations trigger oscillatory compensatory mechanisms to recover a stable state. We therefore extracted both the minimum and maximum values of CoP (AP and ML) before and after perturbations.

Finally, since we were interested in investigating the variation of CoP, we computed the difference between the baseline and the postline.

Results

In this experiment we used the following electrical stimulation parameters (Tab. 1) established during the calibration procedure.

Table 1: ESPert Lower stimulation amplitudes used for the two subjects.

Subject #	Stimulation type	Amplitude (mA)	MT (mA)	PT (mA)
1	Dorsi Strong	36	14	36
1	Dorsi Medium	25		
1	Plantar Strong	32	18	32
1	Plantar Medium	25		
2	Dorsi Strong	38	18	38
2	Dorsi Medium	28		
2	Plantar Strong	38	18	38
2	Plantar Medium	28		

Fig.4 presents the CoP AP accumulated data of the two subjects. We can see that baseline condition did not lead to major variation as expected (0,06 cm. in Tab. 2). On the contrary, tibial nerve stimuli led to anteroposterior variations. In fact, strong intensity stimulus (“Plantar” in Fig. 3.and 1.95cm in Tab. 2) seemed to generate slightly stronger perturbations than the medium intensity stimulus (1.83 cm). Concerning the peroneal nerve stimulus, it led to less anteroposterior CoP variation for strong intensities (“Dorsi” in Fig. 3.and 0.86 cm in Tab. 2) and no perturbation was generated with medium intensity (-0.06 cm). Finally, the postline data didn’t show any variation (<0,01 cm) outlying that the realization of all trials did not lead to muscular fatigue and/or any postural alteration.

Even if the stimulation of the peroneal and tibial nerves aimed at introducing anteroposterior postural perturbations, we also analysed the mediolateral component of CoP positions (see Fig. 5 and Tab. 2) and noticed that stimuli on both nerves introduced small lateral CoP perturbations (around 0.45 cm on average). Again, we can observe that baseline data didn’t present any significant variation. Postline variations are small (equivalent to baseline) demonstrating no medium-term effect on CoP mediolateral position.

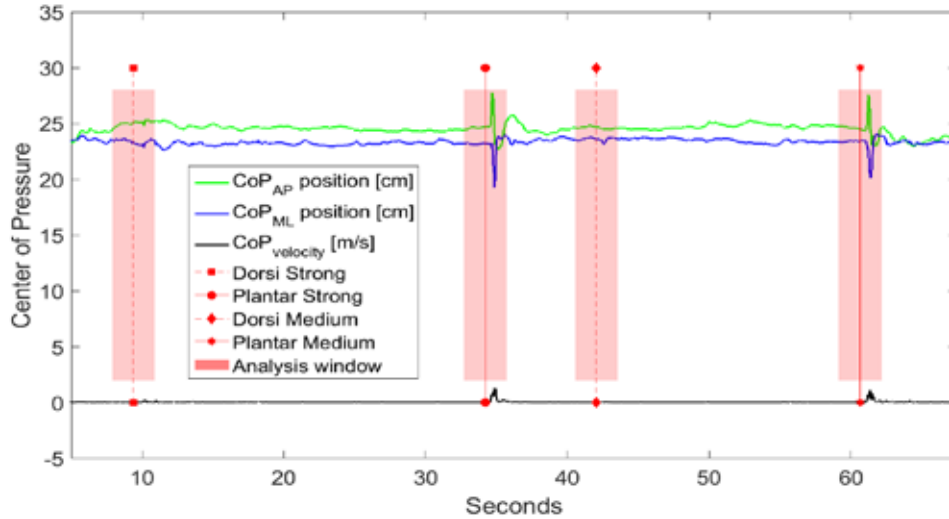


Figure 3: Illustration of a recorded CoP time series (CoP_{AP}, CoP_{ML}, CoP_{velocity}) together with onsets of ERPert perturbations (strong/medium dorsiflexion, strong/medium plantarflexion)

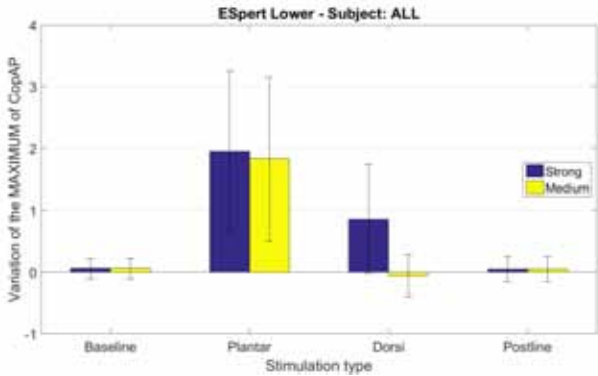


Figure 4: Anteroposterior maximum CoP variation [cm] for baseline, plantarflexion (tibial nerve), dorsiflexion (peroneal nerve) and postline condition.

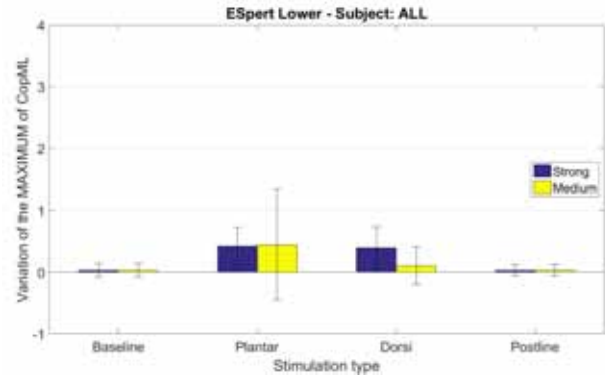


Figure 5: Mediolateral maximum CoP variation [cm] for baseline, plantarflexion (tibial nerve), dorsiflexion (peroneal nerve) and postline condition.

Table 2: CoP variations across the situation (baseline, plantar strong, plantar medium, dorsi strong, dorsi medium, postline), the subjects (subject 1, subject 2, overall) and the dependant variables (variation of the Max, Min, AP, ML)

		BASELINE		PLANTAR (Tibial nerve)				DORSI (Peroneal nerve)				POSTLINE	
				Strong		Medium		Strong		Medium			
		AP	ML	AP	ML	AP	ML	AP	ML	AP	ML	AP	ML
Subject 1	Max	0,1 (0,16)	0,04 (0,12)	2,5 (1,22)	0,5 (0,31)	2,78 (0,15)	0,84 (1,16)	0,55 (0,68)	0,3 (0,38)	-0,19 (0,20)	-0,02 (0,26)	0,12 (0,15)	0,04 (0,13)
	Min	0,1 (0,16)	0,04 (0,12)	-2,26 (0,89)	-3 (1,39)	-3,38 (2,29)	-3,14 (0,26)	-0,47 (0,59)	-1,48 (1,06)	0,10 (0,23)	-0,02 (0,26)	0,12 (0,15)	0,04 (0,13)
Subject 2	Max	0,02 (0,17)	0,02 (0,12)	1,4 (1,29)	0,35 (0,33)	0,88 (1,29)	0,04 (0,30)	1,16 (1,05)	0,49 (0,31)	0,08 (0,43)	0,23 (0,33)	-0,01 (0,24)	0,02 (0,04)
	Min	0,02 (0,17)	0,02 (0,12)	-2,21 (0,47)	-2,07 (1,5)	-0,87 (0,6)	-1,34 (1,39)	-1,15 (0,46)	-2,01 (1,21)	-0,06 (0,21)	-0,36 (0,84)	-0,01 (0,24)	0,02 (0,04)
OVERALL	Max	0,06 (0,16)	0,03 (0,11)	1,95 (1,3)	0,42 (0,31)	1,83 (1,32)	0,44 (0,90)	0,86 (0,88)	0,39 (0,34)	-0,06 (0,34)	0,11 (0,31)	0,05 (0,20)	0,03 (0,09)
	Min	0,06 (0,16)	0,03 (0,11)	-2,23 (0,66)	-2,54 (1,43)	-2,12 (2,04)	-2,24 (1,33)	-0,81 (0,61)	-1,74 (1,09)	0,02 (0,22)	-0,19 (0,61)	0,05 (0,20)	0,03 (0,09)

AP: average CoP anteroposterior variations in cm, ML: average CoP mediolateral variations in cm. Data in brackets correspond to standard deviations

Discussion

In this preliminary study we presented a portable approach for generating electrical postural perturbations while standing. Compared to baseline CoP data, we have shown that both tibial nerve stimulation and peroneal nerve stimulation can perturb a two-leg standing posture as the CoP variation increases in both AP and ML axes in both cases. The CoP variation is higher in the AP axis because the tested stimulations aimed at knee or ankle flexion/extension movements. ML variations could come either from a small misalignment of human anatomical planes with respect to the Tekscan device axes and/or from residual eversion/inversion components of the electrically induced movements of the ankle. Finally, we found out that plantarflexion or tibial nerve stimulation affected in a greater magnitude to the balance when compared to dorsiflexion or peroneal nerve stimulation. As during the stance posture the ankles were supporting the full body weight, the tibial nerve stimulation did not induce an ankle plantarflexion but a knee flexion, which affected considerably to the overall postural stability. On the other hand, the peroneal nerve provoked an ankle dorsiflexion, and if subjects stood with a quite posterior CoP position (i.e. most of the forces passed through the calcaneus bone) lifting the forefoot would not affect tibia and fibula orientation.

This preliminary study showed that it is possible to use electrical stimulation for generating balance perturbations and that tibial nerve stimulation seems to be more suitable than peroneal nerve stimulation. Further research needs to be carried out to define best stimulation parameters and sites, and to test the approach on target population such as frail subjects.

Acknowledgement

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FES DRIVEN CYCLING BY DENERVATED MUSCLES

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Abstract: Paraplegic individuals performed FES assisted lower limb cycling on a tricycle, which has been adapted for this purpose. Two persons with complete spinal cord injury and denervated muscles performed the trainings 2 times a week for 6 weeks. It was assumed that the trainings motivates them to reach higher cycling speed from training to training. Their cycling speed was monitored and compared during each training. The average speed increased during the 6 weeks period. Within trainings the speed was the highest in the first part of the training than decreased and slightly increased again. This was found for both participants. Results suggests that the quantitative difference between the participants, regarding cycling speed reflects more differences in their level of motivation and less their level of injury and muscle condition.

Keywords: Tricycle, Speed

Introduction

It is known and reported that functional electrical stimulation (FES) helps to regenerate denervated muscles [1]. Denervated muscles after FES treatment show improvement in cross sectional area and in structure, and this treatment results in rescue of muscle mass and tetanic contractibility [2]. Recovery from muscle degeneration after denervation can be reached by appropriate FES training. FES is the only option for denervated muscles to have active contraction. [3]. FES trainings for lower limb muscles have been performed on stationary cycle ergometers and also on mobile tricycles [4, 5, 6]. Here we present that a sequence of FES trainings on a special tricycle for persons with flaccid paraplegia, make them able and motivated to propel it and increase cycling speed and distance over time.

Methods

Participants with complete spinal cord injury, lesion in the cauda equina, used a tricycle which has been adapted for this purpose (Reha-Funtrike, OVG, Munich, Germany). One participant (P1), 32 years old, level of injury T10,

and a second participant (P2), 45 years old, level of injury T12, started the training 3 respectively 6 months post-injury. We examined whether the cycling speed increased during a period of 6 weeks, performed twice a week, and how speed changed within individual trainings.

The tricycle, was equipped with a custom build 4 channel electrical stimulator, capable of delivering biphasic rectangular long-duration pulses (15 - 100 ms per phase, +/- 80 V), as necessary for activating denervated muscles (Figure 1). Two channels and pairs of large size (200 cm²) conductive rubber electrodes (Schuhfried Inc., Vienna Austria) with wetted foam pads were used to activate the quadriceps muscle groups on both legs for knee extension. Synchronous bilateral knee extension is used to actively pushing back the seat, coupled to the driving chain, and driving the bike forward; passive knee flexion is generated by pulling body and decoupled seat forward along gliding rails towards the firm steering bar by active arm flexion ("rowing mode"). The stimulation is activated and deactivated by a push button next to the left handle.

Each training was performed on flat surface of a straight corridor over a distance of about 50 meters, back and forth, with reversing zones at both ends. The subjects continued cycling in these loops for about 30 minutes.

Table 1: Basic data on both participants

	P1	P2
Gender	male	male
Age	32	45
Level of injury	T10	T12
	3 months	6 months
ASIA score	A	A
Avg Velocity	5 km/h	4 km/h
Avg Distance	2.51 km	2.01 km



Figure 2: Custom build 4-channel stimulator



Fig 2: Left: Bilateral knee extension starts and actively drives the tricycle as the quadriceps muscles are stimulated; Right: The end of quadriceps stimulation (start of "rowing mode").

Results

The speed was computed for 3 equal phases of the total cycling time. The speed in the first and third phases were similar but in the middle phase it appeared generally lower. Average speed for P1 in the 1st, 2nd and 3rd phase was 5.5 km/h, 4.4 km/h, 5.1 km/h respectively, the same values for P2: 4.4 km/h, 3.7km/h, 3.9km/h. The average cycling speed for a whole session (total cycling time)

were 5.0 and 4.0 km/h for P1 and P2 (Figure 3.). The distances cycled in the 12 trainings are shown at Figure 4. The first participant achieved higher cycling speed and cycled longer distance (Figure 5.) Average speed increased for both participants during the training period with slopes of 0.22 and 0.23 for P1 and P2 (Figure 6.).

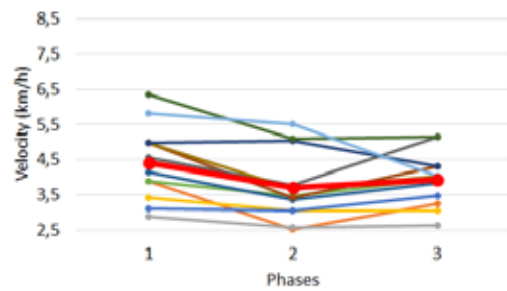
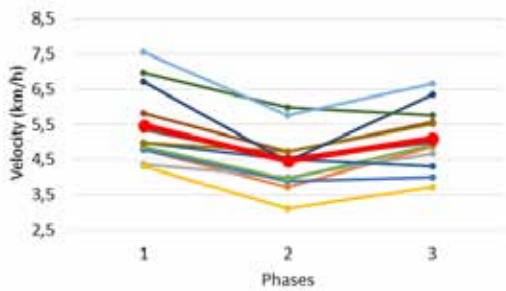


Fig 3: The average (across trainings) velocity is represented by large red dots representing the average of the first second and third phases of the training (dots connected by thick lines). Small dots and thin lines represent velocity values for 12 separate trainings for the participants P1 (left) and P2 (right).

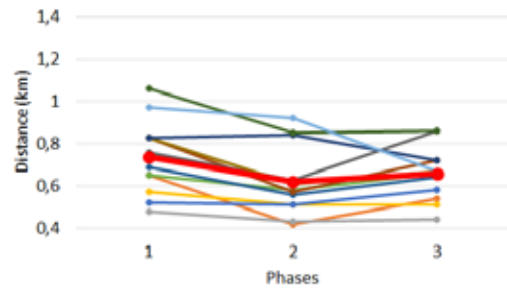
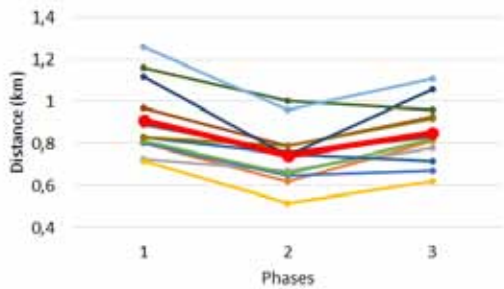


Fig 4: The average (across trainings) cycling distance is represented by large red dots (dots connected with thick red lines). The small dots and thin lines represent twelve 12 separate trainings for P1 (left) and P2 (right).

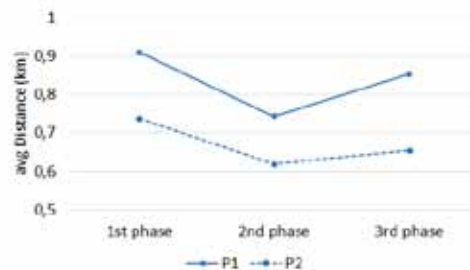
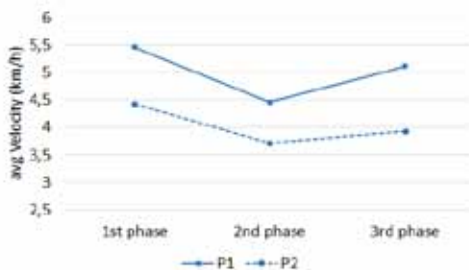


Figure 5. Comparison of average cycling speed (left) and cycled distance (right) of the two participants.

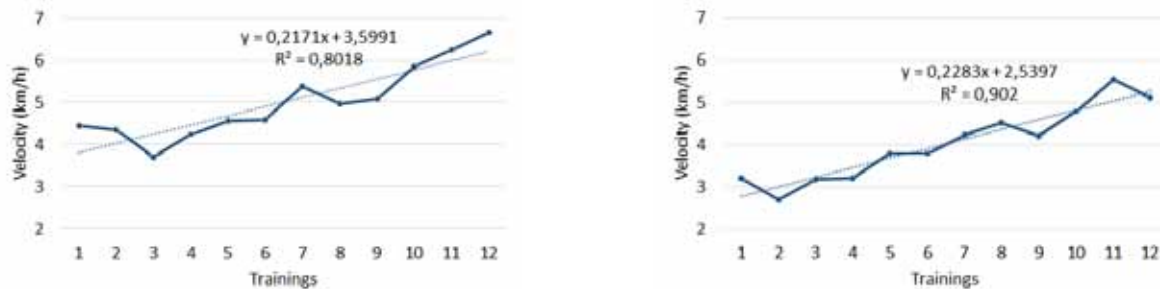


Figure 6. The speed in 12 consecutive trainings increased in both cases. left: P1, right P2.

Discussion

The speed increased during the series of trainings for both participants. Aware of all limitations of just preliminary observations in the 2 single cases we assume that the throughout higher values for participant P1 originate mainly from his higher motivation of using the tricycle to achieve as long cycling distance and as high cycling speed as possible. With T10 P1 had a higher level of injury (P2 had T12), but had a younger age and shorter time since injury. In both cases significant improvements were observed with progress of training, which is encouraging for further systematic studies with a higher number of participants.

Acknowledgement

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A NOVEL THERAPEUTIC TOOL FOR STANDING BALANCE: A CASE STUDY

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Abstract: *Incomplete spinal cord injury (iSCI) can impair balance control during standing. Here we developed a novel therapeutic tool integrating visual feedback training and non-invasive functional electrical stimulation for ankle muscles. We have developed the therapeutic tool consisting of a force plate, two electrical stimulators activating plantarflexors and dorsiflexors, and a computer controlling the visual feedback and the electrical stimulation. This tool was tested with an individual with iSCI. The participant was successfully used the tool for twelve training sessions, without having any adverse events. The results of the case study demonstrated that this tool is promising in improving the postural control of iSCI individuals. Future steps include validating the effectiveness of this system using experimental data from more participants.*

Keywords: *Visual Feedback Training, Functional Electrical Stimulation, Posture Control, Incomplete Spinal Cord Injury, Proportional and Derivative Feedback Control, Active Ankle Torque, Closed-Loop Control, Balance Training*

Introduction

Incomplete spinal cord injury (iSCI) can impair muscle control and mobility, including balance control during standing. Recovering standing ability can increase personal autonomy in individuals with iSCI, increasing their independence and quality of life.

We have previously explored the potential of visual feedback training (VFT) for rehabilitating balance control during standing in individuals with iSCI [1]. VFT involves displaying participant centre of pressure (COP) on-screen to a participant standing on a force platform. The participant would then be instructed to move their COP to satisfy provided tasks. We have previously found that VFT can improve standing balance control in individuals with iSCI [1].

We have also demonstrated that the use of non-invasive lower-limb functional electrical stimulation (FES) successfully improves standing balance control in an individual with iSCI [2]. We first showed that a proportional-derivative (PD) closed-loop feedback controller can mimic the physiological control system [3,4], and then we

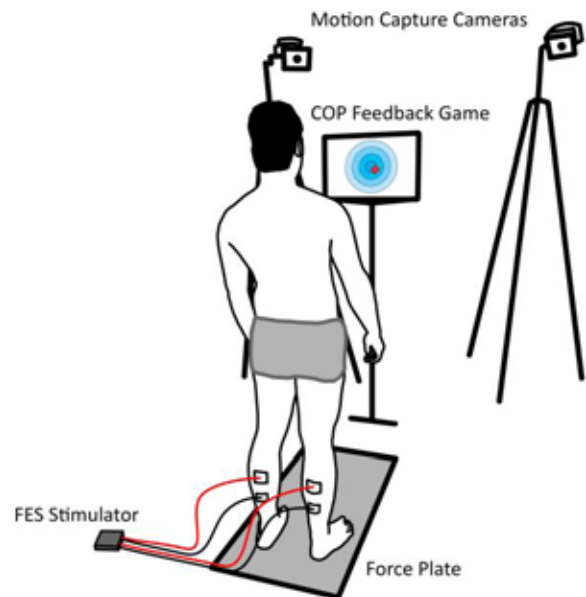


Figure 1: Therapeutic Tool

demonstrated that a FES system that used the closed-loop PD controller and regulated active ankle torque successfully improved balance control during standing for an individual with von Hippel-Lindau Syndrome [2] and stabilized an artificial inverted pendulum with able-bodied participants in a standing frame [5]. As therapies using FES effectively improve motor functions [6], we hypothesized that integrating VFT with FES would synergistically improve balance control during standing in individuals with iSCI.

Thus, the objectives of this study were to develop a therapeutic tool integrating VFT and FES for ankle muscles, and to perform a case study with an individual with iSCI to test whether the VFT indeed improve one's ability to stand independently.

Methods

Therapeutic Tool Design: A therapeutic system integrating VFT and ankle-regulating FES was created. A graphic abstract on this system was published in [7]. The VFT component consisted of four games designed in LabVIEW which were displayed to the participant, along with their COP, using a conventional monitor (Fig. 1). Four

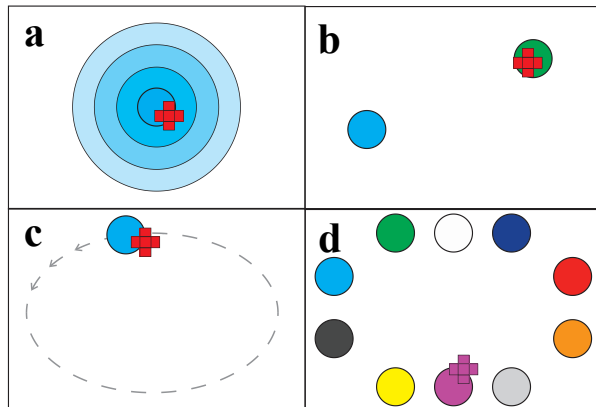


Figure 2: VFT Game Interfaces
a) Target, b) Hunting, c) Ellipse, d) Colour Matching

COP-based games were created based on literature [1], each requiring different movement patterns. Of the games used in literature by Sayenko et al. [1], the “Target” and “Hunting” games were reproduced identically, the “Circle” game was modified into an “Ellipse” game to use an elliptical instead of circular orbit, and the “Basketball” game was modified into a “Colour-Matching” game that included movement between the boundaries of the subject’s base of support in both the anterior-posterior (AP) and medial-lateral (ML) directions (Fig. 2).

The designed FES controller was an extension of the PD controller developed in our previous studies [2,3]. In addition to PD control, the FES controller included gravity compensation and directional biasing [5]. The PD controller served to regulate ankle torque to assist the subject in moving their COP to the onscreen target. In addition to this, a gravity compensation component acted to regulate ankle torque to supporting the subject, helping them maintain their current lean in the AP direction. The degree of stimulation to their plantarflexors for gravity support varied based on ankle joint angle. As well, the PD controller in our previous studies [2,3,5] only considered movement in the AP direction, and as such a single set of motor commands to control both ankle torques was sufficient. In this system however, the ML direction also requires consideration. In our preliminary experiments with able-bodied standing data, a pattern of asymmetric ankle muscle activation when a person voluntarily moved their COP in the ML direction was revealed. For instance, leaning to the left would cause an increase in left ankle muscle activations and a reduction in right ankle muscle activations. Based on preliminary data, the directional biasing component to the FES controller was designed to behave similarly, increasing stimulus for the left leg and decreasing stimulus for the right leg when leaning left of the median plane, and increasing stimulus for the right leg while decreasing stimulus for the left leg when leaning to the right. The percent maximum increase-decrease in stimulus from the directional biasing, as well as the values for the PD controller, were optimized in another study using able-bodied experimental data.

Experimental Study: In order to examine the effect of our designed VFT and FES system, we conducted a case study where we recruited an individual with a non-traumatic iSCI (68 year old female participant with paraplegia, 4.5 years post-symptom onset). The study involved twelve training sessions where the participant played the four games 1 to 3 times per session. In addition, quiet standing trials were recorded before and after the training.

For all of these sessions, the participant stood on a force plate while we recorded the COP fluctuation that was fed back into the VFT and FES controller in real-time. When the participant was playing VFT, the ankle muscles were activated by the FES system depending on the participant’s posture. The game scores were used for subsequent stability analyses. We also assessed the participant’s static balance by measuring COP fluctuation during quiet standing before and after the twelve training sessions. The participant performed quiet standing on the force plate for 30 seconds twice (Pre-Training) or three times (Post-Training) with eyes opened. As the measure of stability, we quantified the root-mean-squared value of the COP as well as the mean velocity in both AP and ML directions during the quiet standing trials. The averages of two or three trials were calculated.

Results

The game scores throughout the training are shown in the Figure 3. The scores for the colour-matching game and the hunting game showed gradual improvement throughout the training sessions (see Figure 3a), while the scores for the target and the ellipse game stayed consistent (see Figure 3b).

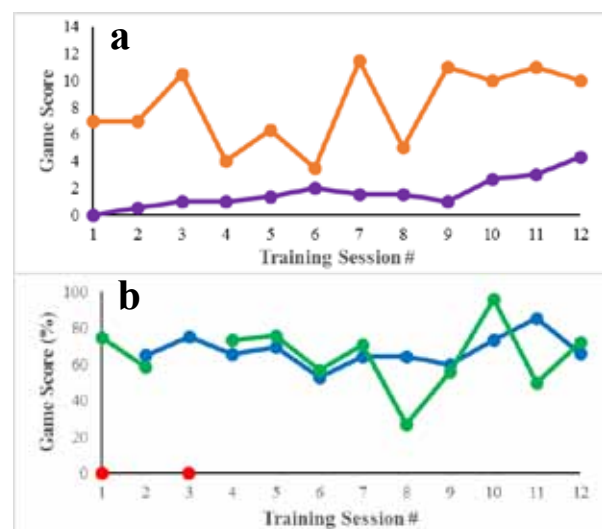


Figure 3: The game scores recorded throughout the training sessions for: a) Hunting (orange) and Colour Matching game (purple), and b) Target (green) and Ellipse (blue). The red plots represent the training sessions where the participant did not complete the game at all.

Figure 4 shows the time-series of the COP displacement in AP direction pre- and post-trainings. The figure suggests that the COP fluctuations measured after the training were reduced compare to what were seen prior to the trainings.

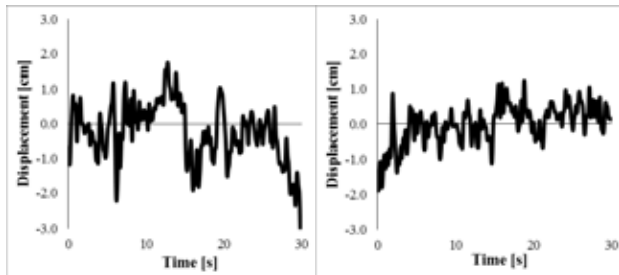


Figure 4: Example time-series of the COP displacement in AP direction (left) before the training sessions and (right) after the training sessions

The RMS and mean velocity values during the static balance test are summarized in Table 1. Compared to the pre-training measurements, we saw a reduced RMS values and mean velocity in both directions in the post-training measurements.

Table 1: Static balance measurements in Pre- and Post-Training

Case	RMS (cm)		Mean Vel (cm/s)	
	AP	ML	AP	ML
Pre-Training	0.720	1.513	2.778	2.787
Post-Training	0.612	0.605	2.167	1.752

Discussion & Conclusion

We have successfully developed a prototype of the proposed VFT and ankle FES tool. This tool was tested with an individual with iSCI. The participant used the tool for twelve training sessions, without any adverse events. The feedback from the participant, and the observations made regarding the VFT game characteristics and scoring will be used to modify future iterations of the tool.

From the case study, we saw that the postural control can be improved using our novel therapeutic system that integrates both VFT and closed-loop PD controlled FES, in agreement with our initial hypothesis. Future studies are required to validate the feasibility of this tool with more participants with iSCI, and to investigate the effect of FES in a randomized control trial.

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Closed-loop Proprioception Training System Based on Wireless Hand Kinematics Sensor and Electrotactile Stimulation

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Abstract: *The aim of this paper is to present a system for closed-loop training of dynamic electrotactile stimulation patterns for proprioceptive feedback. The developed system allows the user to perform two hand movements (hand opening/closing and rotation) while equipped with a hand kinematics sensor, and receive electrotactile proprioception feedback on the contralateral forearm. Spatially coded dynamic stimulation patterns that are mimicking hand movements are used for communicating the state of the hand to the user. The developed system is a tool for self-paced learning of electrotactile patterns, which will be used in further studies on feedback learning and closed-loop control. An extension of the learning paradigm to a system for mirror therapy is considered in the future.*

Keywords: *Feedback, electrotactile stimulation, closed-loop control.*

Introduction

Tactile displays are commonly used for providing feedback to the user by stimulating the skin mechanically (e.g., vibration motors) or electrically. They are used as feedback interfaces in virtual reality applications [1, 2], teleoperation [2, 3], mobile environment communication [4], and in prosthetics, for providing sensory information from the missing limb (artificial touch) [5, 6].

In electrotactile (electrocutaneous) displays, low-intensity electrical current is delivered to the skin to activate nerve fibers and elicit tactile sensations [7]. The advantages of electrotactile interfaces, compared to other types of tactile displays, are thinness, deformability, low weight, low energy consumption, and mechanical robustness [8]. Additionally, electrodes can be customized in shape and size, adapting the design to a specific application and body location. They can integrate a large number of tactile electrodes and allow independent modulation of stimulation parameters (e.g., location, intensity and frequency), thus providing high resolution tactile feedback and/or communicate multiple variables simultaneously. Its applications include assistive devices for the visually impaired applied to various body parts (back [9], tongue [10], forehead [11], fingertips [12] or palm [13], sensory substitution for amputees with hand prosthesis [14-20], virtual reality and telexistence [21], and touch panels with haptic feedback [22]. The presented

electrotactile displays for haptic feedback and vision substitution mainly rely on 2 dimensional stimulation matrices and spatial information coding. Mixed frequency and spatial coding was used for providing the myoelectric prosthesis users with grasping force feedback [19].

Recently, a novel system for electrotactile stimulation with dynamic stimulation patterns for closing the loop in modern multi-DOF hand prostheses [18] was proposed. The patterns can be superimposed to intuitively and simultaneously transmit multiple feedback variables. The psychometric evaluation was conducted in able-bodied subjects and also in trans-radial amputees. It showed that subjects were able to reliably (>90%) adopt and identify 6 spatial locations, 4 frequency levels and 8 dynamic patterns after brief training [18, 23]. In order to develop a proprioception training system, we extended the presented system for closing the loop by providing the feedback on hand aperture and rotation, measured by wireless hand kinematics sensor. Here we present the developed setup.

Methods

System setup

The system is conceived as a training tool that allows the user to perform two desired hand movements (hand opening/closing and pronation/supination), while provided with real-time proprioceptive feedback delivered to the contralateral forearm or the stump of unilateral a trans-radial amputee. The system setup (Fig. 1) comprises the following components: 1) an own developed hand IMU based kinematics estimator (BEAGLE, Tecnalia R&I, San Sebastián, Spain), 2) a custom-made multichannel electrotactile stimulation system, and 3) a laptop PC.

The BEAGLE glove can be used for estimation of hand kinematics and it was developed for purpose of recording fingers and wrist movements during FES therapy. It consists of five 6 DoF IMUs that are placed on the wrist and four fingers (thumb, index, middle and ring). For the purpose of this study number of sensors was reduced to two, one being placed on the wrist and the other on middle finger (labeled in Fig. 1). Kalman filter algorithms for assessment of sensor orientation were used for threshold analysis, state identification and parameters reset to increase the robustness of the estimation.

The laptop PC ran the online control loop implemented using LabVIEW 2017 (National Instruments Corp., Austin, TX, USA). The control loop used the hand kinematics signals from the BEAGLE glove as input, and generated the stimulation parameters for the electrotactile stimulator as output.

The current state of the hand (aperture and rotation) was processed to stimulation parameters and transmitted via Bluetooth to the stimulation system. The Maxsense stimulation system is a fully-programmable and integrated electrotactile interface comprising a stimulation unit and a flexible array electrode [18]. The electrotactile feedback was delivered to the user through the array electrode comprising 16 circular cathodes and a single adjacent anode. The array was circumferentially placed on the forearm. The electrode was made of a polyester layer, an Ag/AgCl conductive layer, and an insulation coating covering the conductive leads. To improve the electrode-skin contact, the pads were covered with conductive hydrogel pads (AG730, Axelgaard, DK).



Fig. 1. Positioning of the BEAGLE glove (right hand) and the Maxsens stimulation system (left forearm). The glove comprises 4 finger sensors, but only the one on the middle finger (marked with red rectangular) was used for fingers angle estimation.

Electrotactile feedback coding

The state of the hand was transmitted to the subject using the set of dynamic stimulation patterns presented in [18]. In order to make the patterns as intuitive as possible, the spatial codes resembling the performed movements were designed. Initial state of the hand (fully opened hand with zero rotation) was coded with active pads 4 and 13.

Full range of rotation ($\sim 180^\circ$) was divided into 7 equal zones. Wrist rotation from initial position was coded by activating two pads (pads 4 and 13), and moving them together circumferentially until the end of the electrode in the direction of hand rotation (clockwise or counter-clockwise, depending on the side).

Full range of aperture ($\sim 180^\circ$ from hand fully opened to fully closed) was divided into 5 zones. Hand closing was

represented by activating two initial pads (pads 4 and 13 - hand fully closed) and moving circumferentially together until the middle of the electrode (pads 8 and 9 - hand fully closed). Hand opening was analogously represented, with opposite starting position and direction of the movement of the active pads.

The patterns for hand opening/closing and rotation were designed so that they can be combined, thus providing feedback regarding two or more states of the prosthesis. For example, as the user closes the hand, the two electrodes come close together. If the user then starts rotating the wrist, the two adjacent electrodes start rotating around the forearm (rotation pattern).

Movement detection algorithm

The subject should perform hand movements with his/her forearm parallel and opened hand orthogonal to the ground, in order to ensure the correct calibration of the system. To mimic the prosthesis behavior, only one movement can be performed at the time (sequential control) and all transmissions are allowed. In order to allow the transition from hand rotation to opening/closing and vice versa, hand must be still for 0.2 s.

The range between maximal pronation and maximal supination ($\sim 180^\circ$) was divided into 7 equal zones. Roll angle of the sensor placed on the dorsal portion of the hand was used for detecting wrist rotation. Selected starting position of the hand (orthogonal to the ground) allowed us to use the absolute orientation of the wrist. When the zone changes due to hand supination, two active pads on the electrode are shifted laterally by one pad, keeping the same distance between. Active pads are shifted medially when the zone is changed due to hand pronation.

The approximated range between hand opening and closing was 180° . When the hand is fully opened, active pads were separated by 8 pads, and when the hand is fully closed the 2 adjacent pads were active, which gives the possibility for generating 5 zones. Unlike wrist rotation, where the absolute orientation was used, hand opening and closing depended on wrist position, so relative angles were used. At the beginning of the session i.e. the calibration of the system, hand should be fully opened. This position was considered as middle finger's zero value. Fingers flexing angle is calculated relative to the previously described angle. Since wrist and fingers cannot be moved at the same time, if the wrist is moving (hand rotation), the current value of the fingers angle is stored. Once the wrist is still again and the fingers are moving, new fingers angle is calculated as a sum of a stored angle and movement relative to the position of the fingers when the wrist was stopped. This enables preservation of achieved fingers angle.

Results and Discussion

We have developed a closed-loop proprioception training system based on a custom hand kinematics sensor and

stimulation system for electrotactile stimulation. A set of dynamic stimulation patterns were used to provide the user with real-time proprioceptive feedback. The system allowed the user to select and perform the desired movement while wearing the kinematics sensor, and simultaneously learn the corresponding electrotactile stimulation pattern delivered through the electrode array on the contralateral forearm.

The identification of dynamic stimulation patterns was previously tested in able-bodied subjects and in trans-radial amputees, which during extensive testing showed a high recognition rate [18]. In the previous study, the subjects were presented with the pattern and asked to identify the movement and the direction. The system, however, allows a combination of the patterns and transmitting multiple feedback variables intuitively and simultaneously. In order to take full advantage of the design of the stimulation patterns the users must be able to identify numerous combinations of proprioceptive variables. Therefore, the here presented system provides an opportunity for self-paced learning of electrotactile patterns, which is necessary component of any future system for closed-loop control of myoelectric prosthesis. Another for the future envisioned application is the provision of electrotactile supported mirror neuron training system that would be able to enhance the visual feedback with proprioceptive, i.e. electrotactile transmitted proprioceptive feedback.

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Practical effects of using electrodes with different hydrogels and grid patterns in surface electrical stimulation

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Abstract: We designed 4 electrodes with different electrode grids for surface stimulation to investigate the influence of these grids on stimulation parameters and the resulting stimulus. The electrodes were covered with two types of hydrogels as a skin-electrode interface, with different ranges of volume resistivity (1.5 k Ω /cm and 300 k Ω /cm respectively). In our experiment, electrodes were positioned, one at a time, on the same spot of the forearm and sensory and motor thresholds were identified on 7 subjects. A current regulated stimulation unit delivering biphasic rectangular pulses was used for stimulation. In the pilot tests, the open square electrode required the highest voltage from the current source, while differences between the filled square and different density grid mesh were insignificant. Differences in the stimulation voltages between different hydrogels over the same grid pattern were less than 10%. Variations in sensory and motor thresholds for all electrodes were smaller when the gel with higher resistivity was used.

Keywords: Electrical stimulation, electrode grid pattern, hydrogel, motor threshold, sensory threshold

Introduction

Over the years, electrical stimulation (ES) has found numerous applications. ES is used for inducing functional movements of the paretic limbs [1], muscle strengthening [2], analgesia [3], spasticity reduction [4], feedback control [5], and more. Depending on their purpose, electrodes for ES can vary in size, shape or material. Alon et al. experimentally investigated sensations and motor responses as a function of electrode size [6]. Also, several groups steer their research to examine the effects of changing different stimulation parameters on basic excitatory responses [7-9]. Small electrodes improve selectivity, but larger ones are more comfortable for the same level of muscle activation on larger muscles. Forming a desired size and shape of the electrode can be done by activation of multiple pads within a multi-pad electrode [10]. Besides influencing functionality and user comfort [11-13], these parameters have a profound effect on the current distribution. Characteristics of the hydrogel needed for a well coupled electrode-skin interface, and the size of the gap between electrode elements additionally influence the current flow [13, 14]. This is important because depending on current distribution in the stimulated tissue, superficial and also deeper nerves are activated.

The goal of our study was to investigate whether grid patterns can influence the elicited sensation and/or the resulting motor activation function. We manufactured 4 surface electrodes and tested their performance with 2 types of hydrogel.

Methods

Four custom electrode types were designed and developed for the purpose of this study. The electrodes consisted of a polyester carrier, a printed Ag/AgCl conductive layer with different inner grid patterns, and an insulation coating covering the conductive leads. All electrodes were produced to have 1.7 x 1.7 cm square shape, and thus size that is in line with the commercial electrodes used for surface stimulation (the diagonal of these pads (2.4 cm) is approximately equal to the diameter of Axelgaard's PALS® Electrode - J10R00). Electrodes are shown in Fig. 1.

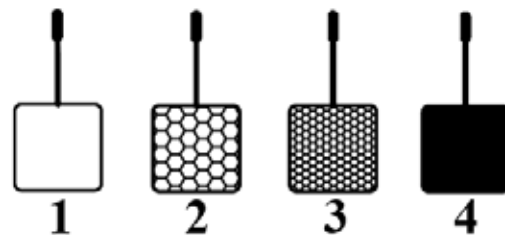


Figure 1: Four electrodes used in the study

Experimental setup: For our tests, a 9 x 5 cm anode was placed on the forearm, proximal to the wrist, while the electrodes shown in Fig. 1 served as cathodes and were placed on the forearm in the zone that produced wrist extension [10]. The stimulation unit delivered symmetrical biphasic current controlled pulses of 350 μ s at a frequency of 30 pulses per second. The cathode was covered with one of the two tested types of commercially available hydrogel: AG725 with low volume resistivity (1.5 k Ω /cm) and AG835 with high volume resistivity (300 k Ω /cm), both produced by Axelgaard Manufacturing Co. Ltd. All electrodes were used for the first time and applied on previously cleaned skin. The order of the electrodes was randomized in all tests.

Test 1: Outcome measure of this test was the voltage over the current source when electrodes from Fig. 1 were used with hydrogels AG725 and AG835. The current intensity was fixed at 8 mA, with 350 μ s pulse duration and 30 pulses per second. One subject participated in this test.

Test 2: Sensory and motor thresholds were determined for each of the 4 electrodes by gradually increasing the current intensity by 0.1 mA steps. In this test we used the hydrogel with high resistivity. Electrodes (cathodes) were positioned on the same, marked position. Seven healthy subjects with no sensory or motor deficits participated in the test.

Results

To ensure a desired current intensity independent of the connected impedance, the stimulator adjusts the produced voltage, thus is current regulated. The voltage that was measured between anode and cathode differed by less than 10% between the 2 types of hydrogels for all measurements. For both hydrogels, the absolute voltages were similar for electrodes 2, 3 and 4 when the same gel was applied. The highest voltage difference was found when electrodes 1 and 4 were used.

Sensory and motor thresholds were determined for 7 subjects using 4 electrodes. Standard deviations within a subject for all electrodes were less than 0.2 mA for the sensory thresholds and less than 0.7 mA for motor thresholds. All subjects reported the sensations produced by different electrodes to be comparable.

Discussion

In this study we analyzed the effects of electrode grid patterns on sensory and motor thresholds, as well as the effect of hydrogels with different resistivity.

The biggest difference in stimulation voltage was found between electrodes 1 and 4 (open and filled square), which was expected. We assumed that the stimulation voltages for the electrodes 2 and 3 (narrow and wider mesh) would also be different from these 2 values, but they were almost the same as for the fully filled square.

Based on the results from test 1, we expected to have similar results in test 2 for electrodes 2-4 and slightly different for electrode 1, however this was not the case. The results when electrode 1 was used did not differ regarding neither for sensory nor for motor threshold. These results are preliminary and a more in-depth analysis is necessary. Future tests should include testing in more controlled conditions, and observation of current density and distribution using methods like FEM modeling or spatial current distribution measurements. Such experimental voltage and current measurements in conjunction with sensory and motor threshold determination can be of importance for the design of electrical stimulation electrodes [15].

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Close-loop system to restore movement in upper-limb after paralysis

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Abstract: High spinal cord injuries disrupt communication between the motor cortex to the muscles via the cervical spinal cord. We are developing a neuroprosthetic device to deliver closed-loop cortical control of spinal cord stimulation and act as an artificial bypass to restore motor function. Our approach uses local field potentials from premotor cortex to trigger real-time stimulation of the spinal cord via an epidural cuff electrode. Here we demonstrate that such a connection can restore ability to make arm movements to a monkey after temporary paralysis induced by reversible inactivation of primary motor cortex by muscimol. We conclude that this method could provide a simple and robust approach to restoring motor function with brain-to-spine interfaces

Keywords: intraspinal microstimulation, closed-loop neuro-prosthetics devices, spinal cord injury, brain-computer interface, pull, electrical stimulation, non-human primate model

Introduction

Quadriplegia caused by a spinal cord injury (SCI) or stroke has a lasting impact on quality of life. One approach to restoring motor function is via a neuroprosthetic link from the brain to the spinal cord [1-4]. Previously we demonstrated that spiking activity recorded from premotor cortex could be used to control intraspinal stimulation in real-time to restore reach-to-grasp movements after drug-induced upper-limb paralysis [2]. However, neural interfaces based on spiking activity suffer instabilities and require continuous recalibration [5], and the invasiveness of penetrating intraspinal electrodes may limit clinical translation.

To overcome these problems we have developed a cortical interface based on low-frequency features of the local field potential (LFP), which are stable over time and reliably reflect both the neural activity in a cortical area [6] as well as the timing of upper-limb movements [7]. We trigger spinal cord stimulation from the areal velocity of the instantaneous LFP when projected onto the plane defined by the first two principal components (PCs) as we have previously shown this to be a good indicator of movement [5, 7]. In addition, we use a less invasive cuff electrode based on our previous finding that ventral epidural stimulation could evoke robust movements of the upper-limb [8].

Here we tested whether a neural prosthesis based on low-frequency LFP recordings and epidural stimulation could be used to restore volitional pulling movements in a monkey (monkey U) following reversible inactivation of the primary motor cortex (M1) using muscimol.

Methods

Experiments were approved by the local ethics committee at Newcastle University and appropriate UK Home Office licenses in accordance with the Animals (Scientific Procedures) Act 1986.

BEHAVIORAL TASK

A female, purpose-bred Rhesus macaque monkey (*Macaca mulatta*) was trained to perform a self-paced grip-and-pull task for food reward (Fig 1A). The task was designed to require simultaneous grasping and elbow extension as these movements are often impaired by SCI and are important for activities of daily living such as transfer from a wheelchair. The task required grasping and pulling a spring-loaded lever to exceed an experimenter-defined threshold for a duration of 200-400 ms.

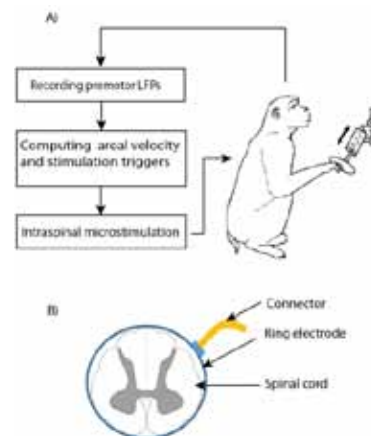


Figure 1: Brain control spinal cord stimulation after reversible paralysis due to muscimol injection

After each successful trial, the monkey has to return the lever to the start position to initiate a new trial. Auditory feedback signalled when the lever was in target and when a trial had been successfully completed.

SURGICAL PROCEDURES

In total, three implant surgeries were performed on our monkey, each separated by about 1 month. In the first surgery, six electromyogram (EMG) patch electrodes were implanted over hand and forearm muscles (1DI, *first dorsal interosseus*; APB, *abductor pollicis brevis*; FDS, *flexor digitorum superficialis*; FDP, *flexor digitorum profundus*; FCU, *flexor carpi ulnaris*; ECR, *extensor carpi radialis*) and tunnelled subcutaneously to a connector on the head. In the second surgery, 32-channel

floating microelectrode arrays (Microprobe FMAs) were implanted in the dorsal and ventral premotor cortices and a recording chamber was implanted over primary motor cortex (M1). A head case was fixed with titanium screws and dental cement to protect the M1 chamber and electrode connectors. In the third surgery, a laminectomy of vertebrae C5-C6 and half of C7 was performed, and vertebrae C4-C7 were fused using screws inserted into the lateral mass. An 8-channel cuff electrode (Cortec, AirRay Fetz Spinal Cord 8) was placed around the C7 segment by first tunnelling sutures under the spinal cord and then using these to pull the electrode under and around the cord without penetrating the dura (Fig 1B). The electrode was connected to a subcutaneous lead running to the head.

PHARMALOGICAL INACTIVATION

The hand area of M1 was identified by low threshold microstimulation responses in arm/hand muscles. Muscimol (Sigma-Aldrich, M1523 dissolved in sterile saline to 0.5%) was injected into arm/hand area of M1 (Fig 1C) under ketamine/medetomidine sedation before stimulation experiments using 2.5 μ l injected slowly over 30 s at 3 different depths. Once the injection was completed, the sedation was reversed to ensure the monkeys was sufficiently alert (around 45 min) to perform the task while the muscimol inactivation was still in effect.

HARDWARE SETUP

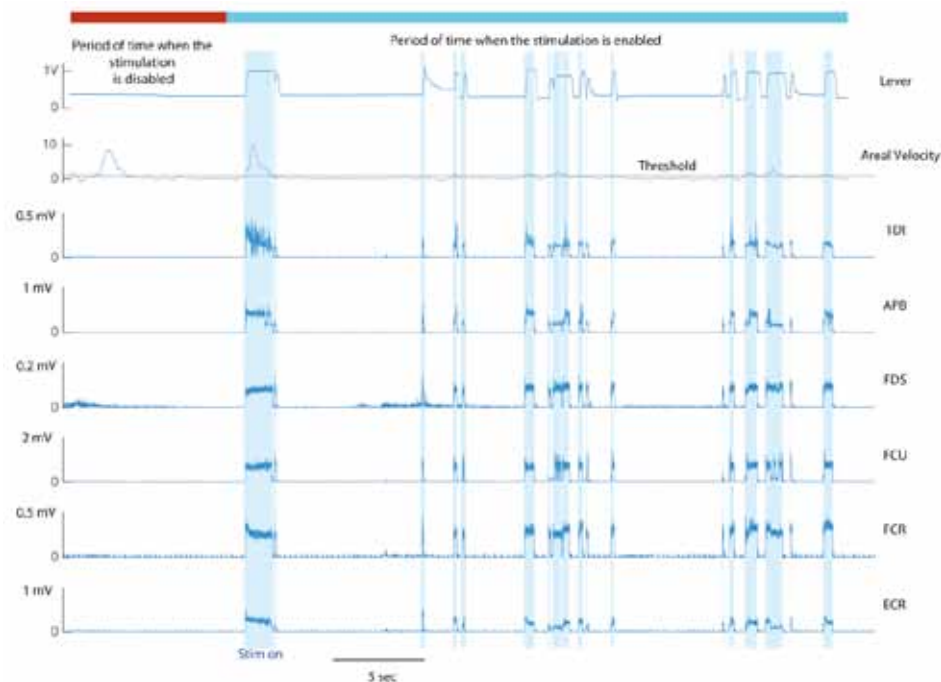


Figure 2: Brain-controlled spinal stimulation.

Results

The dataset comprises seven experimental sessions using muscimol with monkey U, spread over 19 days. Figure 2 shows an example of lever position, areal velocity and EMG during the task. As can be seen, with stimulation

We used a National Instrument DAQ (NIDAQ) card to digitise lever positions to send to a computer that run the task using custom Matlab code. LFPs were amplified and digitised by System3 (Tucker-Davis Technologies) hardware prior to low-pass filtering at 5 Hz. The digital signal processors (DSPs) in the TDT System3 were configured to project the multichannel LFP onto the plane defined by the first two PCs (established from a previous recording session) and calculate in real-time the areal velocity (Eq 1):

$$AV = \frac{1}{2} (l_1 \cdot \frac{d}{dt} l_2 - l_2 \cdot \frac{d}{dt} l_1) \quad (1)$$

where l_1 and l_2 are the first two PCs of the LFP.

STIMULATION PROTOCOL

Whenever the areal velocity exceeded a user-defined threshold, we delivered biphasic stimuli (0.2ms per phase) with an intensity of 100-200 μ A at a rate of 50 Hz to the spinal electrode via a model 2100 stimulator (AM Systems). Isolated cathodal-first stimuli were delivered to the electrode on the ventral surface of the spinal cord, with the return electrode on the dorsal surface.

Within each session, we interleaved periods with stimulation enabled and periods with stimulation disabled in order to assess whether stimulation could restore the animal's ability to complete the task.

enabled, increasing areal velocity triggered the stimulation which elicited robust EMG responses and movement of the lever. By contrast, with stimulation disabled, there was little EMG or movement of the lever, despite the peaks in the areal velocity signal indicating that the animal was still attempting to perform the task.

We performed a combined analysis of all sessions in which closed-loop spinal stimulation was attempted, by calculating the overall rate at which successful trials were completed when stimulation was on with trials with no stimulation. Over the 7 sessions, monkey U performed 904 trials in 144 minutes when the stimulation was on and 78 trials in 153 minutes without stimulation. This corresponds to an average rate of trial completion of 6.27 trials per minute with stimulation and 0.51 trials per minute without stimulation. A paired t-test indicated that this difference was significant ($n=7$, $t=4.9$, $P=0.003$).

Figure 3 shows the rate of trial completion over the 7 sessions individually. Note that there is an increase over successive sessions in the rate of trial completion which could indicate that the animal was learning to use closed-loop stimulation more effectively. However, there is also an increase in the rate of trial completion when stimulation was disabled. This likely reflects the decreasing efficacy of the muscimol block after repeated injections. Therefore we cannot at this stage dissociate the improved performance over time from the reduced paralysis. Note however that in all sessions, the rate of trial completion was higher when stimulation was enabled compared to when stimulation was disabled.

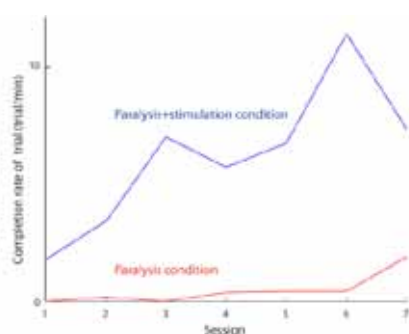


Figure 3: Evolution of the completion rate of trials over the different muscimol sessions.

Discussion

These results suggest that our approach of LFP recording and ventral epidural stimulation can provide a simple and robust link from the brain to the spinal cord that was able to restore volitional control of simple upper-limb movements. We used areal velocity decoding [5] as this provides a reliable and robust indication of movement time [7]. In this experiment (over 19 days), once the PC projection had been calculated, we did not subsequently recalibrate our control algorithm. Since LFPs are more stable over time than spikes [5, 6, 9], this approach could be suitable for clinical translation without the need for regular recalibration. A further advantage of the low-frequency LFP is that low sampling rates are required, so this algorithm could be implemented in a low-power implantable device.

Stimulation via the epidural electrode was capable of eliciting strong contractions at relatively low current levels (100-200 μ A). This is likely due to the stimulating electrodes being positioned directly over the ventral roots.

Over our experimental period, the threshold current required to elicit movement did increase steadily, and a longer experiment will be required to establish whether these electrodes are sufficiently stable for long-term clinical use.

Finally, we acknowledge that short-term muscimol inactivation does not model damage to spinal circuitry involved in SCI, or longer-term plastic changes following injury. Nevertheless, we feel our present results reflect several important advances towards a robust and reliable brain-to-spine neuroprosthesis for the upper-limb.

Acknowledgement

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MEASURES OF EXCITABILITY IN CORTICOSPINAL AND SPINAL PATHWAYS BEFORE AND AFTER FES SUPPORTED WALKING

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Abstract: *Electrical stimulation of the sole of the foot has been used to elicit the withdrawal reflex. When synchronized with the gait cycle providing hip, knee, and ankle flexion during swing, it has been shown to result in improved gait of hemiparetic individuals. This effect outlasted the 20 days training period suggesting that plastic changes occurred. The purpose of this study was to investigate the neural pathways involved in this process. After a single 30 minute walking session, results showed changes in spinal excitability that could be attributed to walking but not to the electrical stimulation.*

Keywords: *Withdrawal reflex, hemiparetic gait, plasticity, TMS, stretch reflex*

Introduction

Stroke survivors typically suffer from hemiparesis, which is characterized by weakness in one side of the body consequent to damage of neural structures in the contralateral side of the brain [1]. The hemiparesis results in abnormal gait and reduced endurance [2] due to decreased muscle strength [3] and abnormal patterns of muscle activation [4]. Reduced hip, knee, and ankle flexion during swing, and reduced knee extension during early-stance in the most affected side are usually observed [5]. This problem affects approximately 50% of stroke survivors, of which 18% are still unable to walk independently after 11 weeks of rehabilitation [6]. The restricted mobility and increased risk of falls [7] have direct consequences on the patients' quality of life. Therefore, regaining the ability to walk is a primary goal for stroke patients [8].

Intensive exercising supported by synchronized functional electrical stimulation of relevant paretic muscles has shown to improve gait function [9, 10]. This modality of stimulation relies primarily on the use of multichannel stimulation systems that target different muscles or groups of muscles involved in the production of the desired movements. A different modality of electrical stimulation, sensory stimulation, can be otherwise used to activate the withdrawal reflex and thereby obtain flexion of the three main joints of the leg [11]. In the sitting position, the nociceptive withdrawal reflex elicited from the sole of the foot has been shown to produce ankle plantarflexion, dorsiflexion, inversion, and eversion depending on the precise location of the stimulation site, in addition to knee and hip flexion [12]. Hemiparetic patients had increased hip and knee flexion and ankle dorsiflexion when stimulated on the arc of the foot and forefoot after heel-off [13] compared to no stimulation walking. Functional electrical therapy based on activation of the with-

drawal reflex to train the hemiparetic gait resulted in more symmetric gait and improved gait velocity after 20 sessions [14]. The improvements were measured immediately after the end of the treatment, and at one and six months follow up [14], suggesting that plastic changes might have happened. The mechanisms behind these changes are however unknown.

Investigating the changes in excitability of neural pathways consequent to an intervention is an approach to understand plasticity. To this end, Transcranial Magnetic Stimulation (TMS) has been used to evaluate the corticospinal and corticocortical pathways [15] and the H-reflex and stretch reflex have been used to investigate the spinal pathways [16, 17]. TMS pulses applied to the primary motor cortex evoke motor evoked potentials (MEP) in the target muscle; these are measured in the EMG and provide information about the overall integrity of corticospinal pathways and do not differentiate between the spinal and cortical mechanisms [18]. A quick stretch of a muscle elicits a stretch reflex; its fastest pathway consists of the receptors (velocity sensitive muscle spindles), Ia-afferent fibers going from the muscle to the spinal cord, and the synapses in the spinal cord to the alpha-motoneurons innervating the muscle.

The purpose of this study was to investigate the possible changes in excitability of the corticospinal and spinal pathways following elicitation of the nociceptive withdrawal reflex using electrical stimulation during gait.

Methods

Twenty-six healthy participants were recruited for the experiment; two were immediately excluded because they were not eligible for TMS (assessed with a transcranial magnetic stimulation adult safety screening questionnaire). The remaining participants were randomly allocated to two groups: an intervention group and a control group. In the intervention group, three participants were excluded because they presented adverse effects of TMS (n=1) or had a motor threshold larger than 80% of the maximum stimulator output (n=2). In the control group, four participants were excluded because of the same reasons (n=1 and n=3, respectively). The remaining 17 participants had an age of 24.5±1.8 years and six were female. The study was approved by the local ethical committee.

Experimental protocol: Participants in both groups walked on a treadmill (Technogym, Italy) for 30 minutes at a velocity of 2.5 km/h. For safety reasons, participants wore a harness that did not support any body weight.

Participants in the intervention group (n=9) were additionally stimulated on the sole of the foot to elicit the nociceptive withdrawal reflex at each step and thereby facilitate the initiation and execution of the swing phase [14]. The cathode (Ambu® Neuroline 700, 20 mm x 15 mm) was placed at the arch of the dominant foot, while the anode (Axelgaard, PALS®, 7.5 cm x 10 cm) was placed on the dorsum of the same foot [12, 14]. A foot-switch was used to detect heel-off and trigger the electrical stimulation at each step. The stimulation consisted of a burst of five 1 ms pulses delivered at 200 Hz, repeated four times at 15 Hz [20]. The stimulation was delivered by a constant-current stimulator (NoxiTest, Denmark) controlled by the computer program Mr. Kick III (Knud Larsen, SMI®, Aalborg University, Denmark).

After familiarization with the electrical stimulation, the stimulation intensity was determined as the intensity that resulted in a visible kinematic response consisting of flexion of the hip and knee and dorsiflexion of the foot. The mean stimulation intensity across participants was 9.1 ± 2.0 mA.

Evaluation of corticospinal and spinal excitability was performed before, immediately after, and 30 minutes after the 30 minutes' walk on the treadmill. Corticospinal excitability was assessed by eliciting MEPs with TMS, while spinal plasticity was assessed by eliciting the stretch reflex.

The TMS measures were performed with the participants in a sitting position. To elicit MEPs in the Tibialis Anterior (TA) muscle, a monophasic transcranial magnetic stimulator (Magstim 200, Magstim Inc., Morrisville, US) with a focal figure-of-eight stimulating coil (custom-made Magstim Alpha Coil Flat Range, 1.5 T, diameter of each loop: 70mm) was used. A tracking system (Brainsight TMS Navigation, Rogue Resolutions, Cardiff, UK) was used to ensure preciseness of the stimulation location across evaluation sessions. The tracking system was calibrated to the head (marker placed on the forehead). Additionally, a marker was placed on the handle of the coil to track its movements. Surface EMG was recorded from the TA of the dominant leg using a bipolar configuration (Ambu® Neuroline 720 electrodes) with the reference electrode placed on the tibia. The EMG signal was amplified (SENS-003-001 and Brainsight® 2 EMG Isolation Unit, Rogue Research Inc.), band-pass filtered (16-550 Hz, Brainsight®, Rogue Research), digitized, and saved from 100 ms before TMS to 300 ms after TMS.

To find the hotspot for TA, the center of the coil was positioned on the top of the head such that the induced current was in the anterior/posterior direction. TMS pulses at 65% of the magnetic stimulator output were applied while moving the coil around. The location where TMS elicited the largest and most consistent MEPs was defined as the hotspot for TA [21]. The resting motor threshold (rMT) was determined as the lowest stimulation intensity needed to evoke a MEP with a peak-to-peak amplitude of at least 50 μ V in 5 out of 10 consecutive magnetic stimuli. To examine the corticospinal excitability, the input/output (I/O) curve was obtained for intensities of 90-140% of the

rMT with steps of 10 %. Eight stimuli were delivered at each intensity (order was randomized) with an interstimulus interval of at least 5-7 s. If the rMT increased during the process, an additional stimulation was given at 150 % of the rMT.

The peak-to-peak amplitude of the individual MEPs was obtained and the mean for each stimulation intensity was calculated. Since the rMT was re-established for pre, post and 30min post intervention, the data was fitted to a Boltzmann equation (Trust-Region algorithm, Curve Fitting Toolbox, MATLAB). The goodness of the fit was measured by the R-square of every Boltzmann fit. For statistical analysis, three parameters: K (maximum slope), S50 (stimulus intensity needed to obtain a MEP with an amplitude of 50 % of the MEPmax), and MEPmax (maximum value of the curve or plateau) were obtained from each I/O curve.

The stretch reflex was elicited with the participants standing on two pedals on a servo-controlled hydraulic actuator (MTS Systems Co., Minnesota, USA). The TA of the dominant leg was stretched mechanically while surface TA EMG was recorded. The EMG was band-pass filtered (5-1000 Hz) and amplified 10000 times. The amplitude of the stretch was 6 degrees and the rise/fall time was 24 ms with a hold time in the stretched position of 460 ms [22]. Thirty stretches were performed with random intervals of 5-7 s between stretches. The computer program Mr. Kick III (Knud Larsen, SMI®, Aalborg University, Denmark) initiated the perturbations and recorded the TA responses. Thirty recordings corresponding to 30 stretches performed prior to, immediately following and 30 minutes after the cessation of the intervention.

The raw TA EMG signals were rectified and low pass filtered (Butterworth, 40 Hz) and the average of the EMG obtained. The averaged signals were visually inspected and the peak amplitude and the peak latency of the first two peaks of the stretch reflex response (M1 and M2) were quantified.

A two-way repeated measures ANOVA with Time (pre, post, and post 30) as within-participant factor and Group (intervention and control) as between-participant factor was carried out on the outcome measures: rMT and, K, MEPmax, and S50 of the Boltzmann fit, and the peak latency and peak amplitude of M1 and M2. A significance level of 0.05 was considered.

Results

Measures of corticospinal excitability: The rMT depended significantly on the time factor (RM-ANOVA, main effect, $p=0.015$); the rMT immediately post walking ($60.3 \pm 6.6\%$) was significantly larger than the rMT 30 minutes post walking ($56.6 \pm 6.5\%$) ($p=0.003$). No other significant differences were found in the pairwise comparisons.

Fig 1. shows the I/O curves prior to, immediately following and 30 minutes after the cessation of the intervention for one representative participant of each group. The overall goodness of the Boltzmann fit ranged from 0.86 ± 0.14 to 0.97 ± 0.03 (R-square).

No significant effects of time and group were detected for K and S50. The MEP-max depended only on the time when it was measured (RM-ANOVA, main effect, $p=0.018$). At pre-walking, the MEP-max was largest compared with the MEP-max measured immediately post walking ($P=0.02$) and 30 minutes post walking ($p=0.002$).

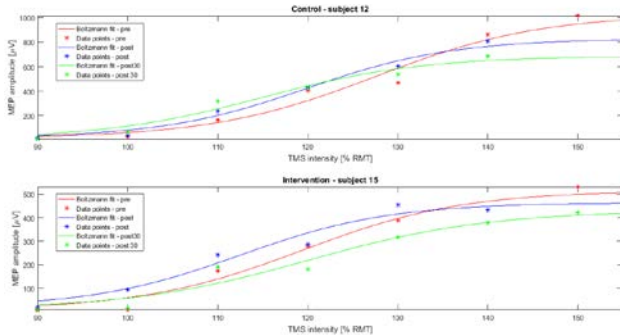


Figure 1: I/O curves from one participant in the control group (top panel) and one in the intervention group (bottom panel). The stars are the measured data points and the lines represent the Boltzmann fit. Red: pre-walking, blue: immediately post walking, green: 30 minutes post walking.

Measures of spinal excitability:

An example of the mean TA EMG stretch reflex response is shown in Fig. 2.

The amplitude of the M1 peak (Fig. 3) depended only on the time factor (RM-ANOVA, main effect, $p=0.001$). Post-hoc analyses showed that the mean M1 amplitude pre-walking ($193.0 \pm 135.7 \mu\text{V}$) was significantly larger than the mean M1 amplitude immediately post walking ($107.8 \pm 68.7 \mu\text{V}$) and 30 minutes post walking ($119.0 \pm 94.7 \mu\text{V}$) ($p < 0.005$).

The amplitude of the M2 peak depended only on the time factor (RM-ANOVA, main effect, $p=0.043$). Post-hoc analyses showed that the mean M2 amplitude pre-walking ($399.9 \pm 334.8 \mu\text{V}$) was significantly larger than the mean M2 amplitude 30 minutes post walking ($291.6 \pm 209.7 \mu\text{V}$) ($p=0.048$).

No significant effects of time or group were detected for the latency of the M1 and M2 peaks.

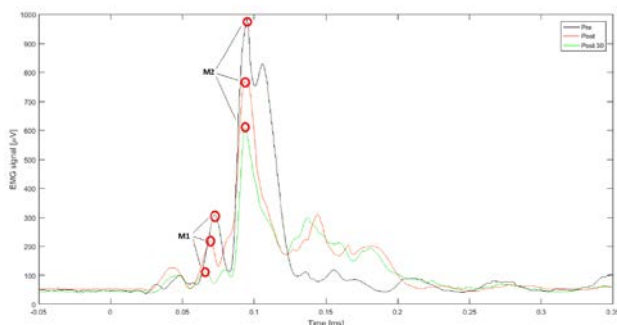


Figure 2: Mean stretch reflexes for a participant in the intervention group. The red circles indicate the M1 and M2 peaks. Black: pre-walking, red: immediately post walking, green: 30 minutes post walking.

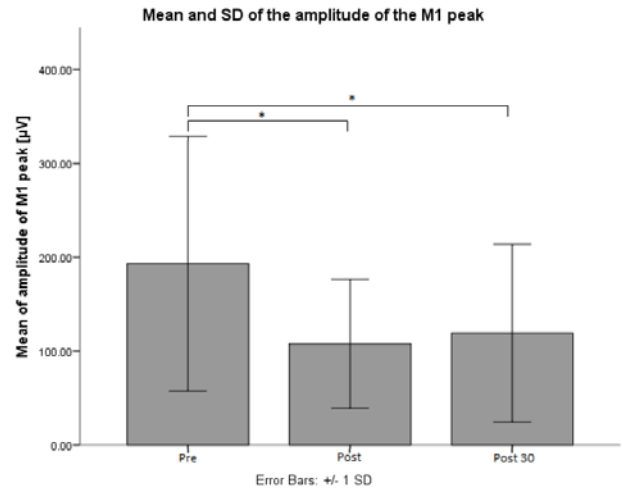


Figure 3: The amplitude of M1. Significant differences are marked with an *.

Discussion

The significant decrement of the MEPmax-value over time is in line with previous findings [24, 25]. In these studies, the decrease in MEPmax was associated to central fatigue induced by walking, e.g. 15 minutes at a comfortable pace [24]. No differences in MEPmax were detected between groups, neither the slope K nor the s50 value showed any dependency on time or group, suggesting that the temporal decrease of MEPmax might indeed be associated to central fatigue caused by walking. Changes in corticospinal excitability have only been shown in relation to skilled training [26], which might explain why no changes were detected in this study that involved only healthy participants for whom the task of walking on the treadmill probably does not result in skilled training.

The first component of the stretch reflex, M1, showed a reduction after walking indicating that the excitability of the pathway generating this component was reduced; however, no difference between groups was detected. The pathway includes the muscle spindles, Ia afferent fibers, and their synapse to the alpha-motorneurons and the alpha-motorneuron projections to the muscle [19], but does not include the cortical level. One of the possible sub-cortical mechanisms which could result in a reduction of the M1 amplitude is a reduction of the monosynaptic excitation of the motorneurons in the spinal cord [27]. Another possibility is that post synaptic changes in the membrane properties could alter the responsiveness of the motorneuron to the inputs derived from the Ia-afferents [28]. In both cases, this result suggests that treadmill walking could induce spinal changes up to 30 minutes after walking.

The second component of the stretch reflex, M2, was reduced 30 minutes after walking. This component is mediated by group II muscle afferents and/or group Ib afferents and was shown to both increase and decrease depending on training [28].

In conclusion, a single 30 minutes walking session showed a persistent (30 minutes) reduction of the peak amplitude of the M1 and M2 components of the stretch reflex in healthy participants, regardless of whether they received electrical stimulation or not. Further studies should involve multiple

walking sessions and individuals for whom walking represents a challenge.

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ELECTRICAL STIMULATION THERAPY BRINGS NEUROLOGICAL AND FUNCTIONAL CHANGES IN TOE-WALKING GAIT OF CHILDREN WITH SPASTIC CEREBRAL PALSY

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Abstract: *The present study enquires improvement of toe-walking gait which is often exhibited by children with spastic Cerebral Palsy (CP) with the application of Electrical Stimulation (ES) therapy on Triceps Surae (TS) muscles. The neurological and functional outcomes are investigated before and after 12 weeks of study. Sixteen children with spastic CP with unilateral toe-walking gait problem participated, and were divided into intervention group that received both ES therapy along with conventional physiotherapy and the control group that received only conventional physiotherapy treatment. Both groups were treated for 60 (30 + 30) minutes per day, for 5 days a week, up till 12 weeks. The results indicates that those who received the intervention had a significant difference in both functional and neurological assessments.*

Keywords: ES Therapy, EEG, Gait, ROM, GMFM score

Introduction

Cerebral palsy (CP) is the term for a range of posture and motor impairments that results from an insult to the developing central nervous system [1]. Statistical incidence of CP around the world is approximately 2 to 3 cases per 1000 live births [2]. Children with CP often have several gait deviations. When the calf muscle (Triceps Surae) is spastic, problem is seen in normal dorsiflexion of the foot giving rise to toe-walking [3-4]. Hence, toe-walking is a common gait abnormality seen in children with spastic CP.

Electrical stimulation (ES) has evolved in recent studies, in which short electric pulses may be delivered to the muscles to produce contractions in the muscles [5]. The electrical stimulation of muscles simultaneously activates sensory and motor pathways and may bring both functional and neurological recovery. This may reduce the spasticity of the muscle and facilitate normal dorsiflexion.

Several studies are now focusing on the rehabilitation of CP using ES therapy, but studies showing the cortical changes seen in the motor cortex due to use of ES therapy is not much explored. There are evidences that ES therapy promotes neurological and functional recovery in stroke patients. Many studies in stroke survivors have been registered but that on cerebral palsy is very limited.

The aim of this study is to enquire the neurological and functional outcome of ES therapy in children with unilateral spastic CP exhibiting toe-walking problem. The motor cortical changes in terms of Power Spectral Density (PSD) of electroencephalography (EEG) have been investigated along with functional changes through gait parameters, Gross Motor Function Measure (GMFM) score and Range of Motion (ROM) changes.

Methods

A. Participant Allotment

Twenty children with spastic hemiplegic unilateral CP exhibiting toe-walking were recruited in this study. Inclusion criteria for the study [6] were, (i) Age between 5-14 years; (ii) Gross Motor Function Classification System (GMFCS) up to level III and Modified Ashworth Scale (MAS) of equal or less than 2; (iii) Having controlled or no seizure; (iv) Keeping 6 months of minimum gap period post botulinum toxin injections; (v) Absence of significant medical problems (juvenile diabetes or cardiac) or metallic/electronic implants. Finally only sixteen children agreed to regularly take the treatment sessions and were divided randomly into two groups of eight each in control and in intervention (ES therapy) group.

B. Study Treatment Protocol

The 12 week study was approved by Institute Ethical Committee of the Indian Institute of Technology, Kharagpur, and registered with the Clinical Trials Registry India (CTRI/2016/07/007066) [7]. The parents/caregivers of each participating child willingly gave written consent for the study.

The treatment session was for 60 minutes total of which 30 minutes were conventional physiotherapy and 30 minutes more of ES therapy or conventional physiotherapy as per the group (ES therapy group and Control). The protocol for ES therapy was 30 minutes daily on all 5 days a week. It was delivered through a multichannel stimulator (Mega-XP, Cyber Medic Corp, Korea). A biphasic rectangular pulse of 200 microseconds, 40 Hz frequency, and the current intensity varying within 0 to 30 mA depending on the endurance limit of the individual, was used to bring a twitch in the Triceps Surae (TS) muscle [6].

C. Initial and Final Assessments

The study can be broadly divided into three phases: initial assessment, treatment sessions and final assessment. Both neurological and functional tests were done for the complete assessment of the participants. Functional assessment was enquired through Gait parameters, ROM changes and GMFM score. For neurological test, EEG recording was done during the period the patient dorsiflexed their ankle of the leg which exhibited toe-walking.

Functional Assessments

The Gait data were collected through a microcomputer-based, small portable device to measure physical activities, the Intelligent Device for Energy Expenditure and Activity system (IDEEA™, MiniSun, LLC, Fresno, California, USA). After the attachment of the sensors the total system was calibrated to reject any initial offsets by sitting in a position such that the knees are perpendicular to the ground, and ankle at neutral position. Each participant had to walk a 50 meters walkway, followed by climbing a flight of 12 stairs for recording the desired gait data. The raw gait data collected was processed by the ActView™ software, which was provided by the manufacturer.

The motor functioning can be evaluated with a clinical tool Gross Motor Function Measure (GMFM) [8]. The Gross Motor Ability Estimator (GMAE 2) is a software program based on java that was designed to evaluate GMFM. It is openly available online and helps in easy calculation of the GMFM-66 score. We use the program GMAE 2 to calculate the GMFM-66 score. There are 4 assessment types (Item sets) available; Assessment 1 has 15 set of tasks, assessment 2 has 29 set of tasks, assessment 3 has 39 set of tasks, and assessment 4 has 22 set of tasks. One among the 4 assessment set was chosen and the scores for the tasks were filled within the program. Those tasks that were not performed were marked as ‘not tested’. In order to maintain similarity and homogeneity between data sets, same assessment type was used for all stages of data recording. The GMFM-66 score was calcu-

lated at the beginning and at the end of the 12th week both in the control and intervention groups.

The ROM of the right and the left ankle during dorsi and planter flexion was measured using a goniometer. The participant was made to sit with knee flexed 90 degrees; and, in neutral or 0 degrees of inversion/eversion. This allows maximum passive dorsiflexion. The Fulcrum of the device is aligned along the lateral malleolus, the stationary arm up along the fibula, and the moveable arm parallel to the fifth metatarsal bone. At this starting position the patient were asked to dorsiflex and plantarflex their foot for measuring the range of motion.

Neurological Assessment

EEG was recorded with the Flex Comp Infiniti (Thought Technology Inc., Toronto, Canada), a multichannel data acquisition hardware. The 9-channel EEG signals were investigated for this study. The BioGraph software (Thought Technology, Inc.) was used to record the raw data. The EEG cap was put on the participant with the cup electrodes filled with conductive gel and gently fixed to the scalp. The reference electrodes were clipped to both the ear lobes, after applying conductive gel to the ear lobes. The participants performed ankle dorsiflexion during the process of the EEG data collection, which was done for 10 seconds. The power spectral distribution for different EEG bands were calculated and analyzed to enquire the neurological effect of ES therapy in bringing motor rehabilitation.

D. Statistical Analysis

All outcomes recorded at the beginning of the study was compared to that recorded at the completion of 12 weeks. Paired t-tests was used to determine the statistical significance within the same group and a 2-way analysis of variance (ANOVA) was conducted for between groups. We used SPSS statistics software (version 17.0), and those that had a P-value less than 0.05 were regarded as statistically significant.

Table 1: Assessment of Functional Changes before and after the 12 week study program

Attributes		Control Group			ES Therapy Intervention Group			P-Value between groups at baseline	Change in Scores (%)	P-Value between groups post 12 weeks
		Pre (Mean ± SD)	Post 12 weeks (Mean ± SD)	P-Value (pre & post)	Pre (Mean ± SD)	Post 12 weeks (Mean ± SD)	P-Value (pre and post)			
Gait Speed (m/s)		0.52 ± 0.06	0.68 ± 0.05	0.047*	0.56 ± 0.05	0.81 ± 0.04	0.022	0.75	17.67	0.019*
Stride Length (m)		0.83 ± 0.05	0.79 ± 0.08	0.95	0.86 ± 0.06	0.71 ± 0.03	0.023*	0.945	10.25	0.037*
Pulling Acceleration (G)		0.479±0.07	0.601±0.09	0.62	0.53±0.06	0.808±0.05	0.041*	0.532	34.4	0.000***
Initial Contact (%)		0.4±0.03	0.7±0.02	0.379	0.5±0.02	1.3±0.06	0.003**	0.894	85.71	0.000***
Loading Response (%)		4.6±0.52	6.3±0.34	0.29	5.4±0.43	9.4±0.31	0.045*	0.168	49.2	0.005**
ROM	Range of Dorsiflexion (Degrees)	0 – 7 (± 2)	0 – 9 (± 1.5)	0.183	0 – 8 (± 2)	0 – 16 (± 3)	0.032*	0.753	75.3	0.004**
GMFM Score		70.9 ± 7.92	73.9 ± 9.8	0.042*	69.2 ± 6.7	76.5 ± 8.1	0.000***	0.218	3.5	0.005**

Statistical significance * $p < 0.05$; ** $p < 0.01$, *** $p < 0.001$

Results

There were distinct differences in scores between the control and intervention group after the completion of the 12 weeks study. There was a decrease in stride length by 10.25% ($p = 0.037$), and an increase in speed by 17.67% ($p = 0.019$). There was also an increase in pulling acceleration by 34.4% ($p = 0.000$), initial contact by 85.71% ($p = 0.000$), and loading response by 49.2% ($p = 0.005$), more in the intervention group after 12 weeks of ES treatment.

There was also a significant improvement seen in the ROM (Range of Dorsiflexion) of the ankle that was responsible for the unilateral toe-walking in the participant at the beginning of this study in the intervention group that received the ES therapy by 75.3% ($p = 0.004$).

The GMFM score for baseline and post-stimulation were compared, and there was a slight increase by 3.5% in the ES therapy treated group than that of control which was significant statistically ($p = 0.005$). The variation of the

functional changes are represented in table1, and all data were statistically significant ($p < 0.05$).

An example of EEG power spectrum and brain map for 10 seconds of EEG data recording, showing PSD distribution of different EEG bands, theta band (6Hz), alpha band (8Hz), Beta 1 band (14Hz) and beta 2 band (20Hz) for a typical patient from the intervention group during the period of ankle dorsiflexion after the 12 weeks of ES therapy is represented in figure1. We can notice that the motor cortex area is highlighted signifying motor movements taking place. The neurological effect of ES therapy is evident from the figure.

The variation of the EEG band PSD changes are represented in table 2. There was a significant decrease in alpha power by 34.4% ($p = 0.005$), beta 1 power by 49.2% ($p = 0.000$) and beta 2 power by 85.71% ($p = 0.000$) in the intervention group compared to that in the control group and the results were found to be statistically significant.

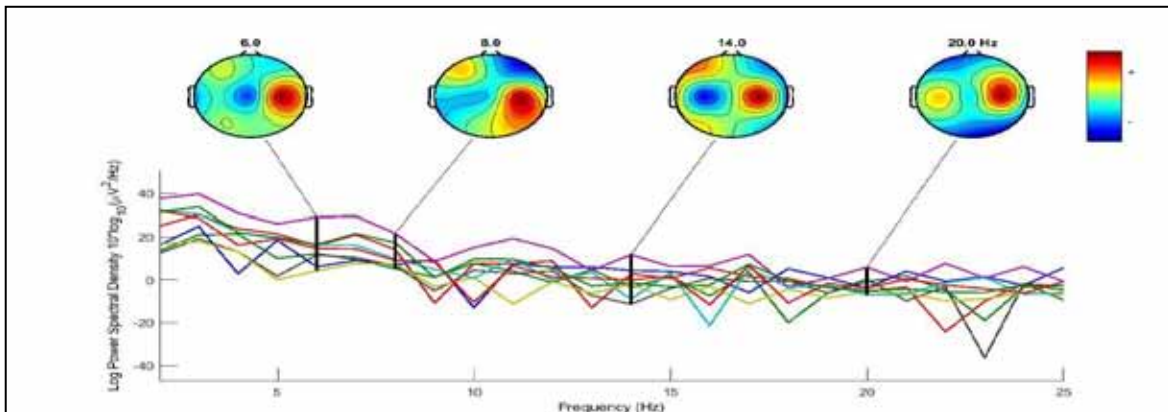


Figure 1: EEG power spectrum and brain maps at 4 different frequencies 6Hz, 8Hz, 14Hz and 20Hz representing motor activities (ankle dorsiflexion) of a participant with restricted ankle dorsiflexion after 12 weeks of ES therapy

Table 2: EEG Band Power Spectral Density Changes before and after the 12 week study program

EEG Band Power	Control Group			ES Therapy Intervention Group			P-Value between groups at baseline	Change in Scores (%)	P-Value between groups post 12 weeks
	Pre (Mean ± SD)	Post 12 weeks (Mean ± SD)	P-Value (pre & post)	Pre (Mean ± SD)	Post 12 weeks (Mean ± SD)	P-Value (pre and post)			
Theta Band (4 -7 Hz)	1.6 ± 0.3	1.82 ± 0.07	0.928	1.7 ± 0.4	1.95 ± 0.07	0.163	0.635	6.34	0.023*
Alpha Band (8 - 11 Hz)	0.53± 0.07	0.67± 0.08	0.132	0.59± 0.06	0.83± 0.05	0.0341*	0.932	34.4	0.005**
Beta 1 Band (12 – 16 Hz)	0.43 ± 0.04	0.201 ± 0.03	0.526	0.64 ± 0.15	0.099 ± 0.02	0.002**	0.864	49.2	0.000***
Beta 2 Band (16 – 24 Hz)	0.46 ± 0.1	0.104 ± 0.02	0.471	0.69 ± 0.1	0.003 ± 0.03	0.002**	0.827	85.71	0.000***

Statistical significance * $p < 0.05$; ** $p < 0.01$, *** $p < 0.001$

Discussion

The children with CP may have weak and spastic calf muscles, the spasticity causes the calf muscles to continuously contract and pull the foot so that the child is pointing the toes

during sitting posture or is up on the toes during standing position, and during walking he/she may walk on the toes instead of the whole foot as it is easier to do so (muscles might be tight and may not easily extend or contract due to

spasticity). Over time if the spasticity is not regulated or reduced the muscle may get used to being in this shortened position and become tight and harder to move out of the toe pointed position. Hence, it is essential to correct this toe-walking gait in children with spastic CP. ES therapy is a non-invasive assistive technique which when applied along with the conventional physiotherapy treatment could help in strengthening of the calf muscle, facilitate ankle dorsiflexion and improving the walking pattern such that there is a profound reduction in toe-walking in children with unilateral spastic CP.

Studies have shown that faster gait speed with smaller step lengths reduce the risk of falling down when encountered with a slipping down situation[9]. Thus a decrease in stride length and an increase in gait speed seen in the 12 week ES intervention group participants reduces the possibility of falling off easily, which is one of the main disadvantage of toe-walking. There is a significant increase in ROM. The ankle dorsiflexion range increases a lot in the ES therapy group. The children are able to freely dorsiflex their ankle, hence the foot is no longer in plantarflexion stretch as before, and the participants can touch the whole foot flat on the ground without much effort. GMFM-66 evaluates the gross motor function in children with CP. There was a statistically significant increase in GMFM-66 score in the intervention group, suggesting there might be a change in different functional abilities of the participants of the ES therapy intervention group.

Motor functions usually decreases the spectral amplitude of alpha and beta band in the corresponding motor cortex area. It is seen that planning and execution of motor activities can decrease alpha and beta band power [10]. The Beta 2 band is more affected in case of lower limb, hence mid beta frequencies are more influenced in this study. The decrease in the power signifies that motor activity was taking place. The more there was free ankle dorsiflexion, the more reduction in beta power is observed, indicating that there was functional changes.

Besides, the parents or guardians of the children who received the ES therapy also confirmed that the children were able to easy dorsiflex the ankle and were seen to walk more normally and less on toes. The results of this study indicates that those children who received the intervention had a significant difference in both functional and neurological assessments. Further assessments including large number of volunteers and enquiring the physiological changes seen in the muscles, evaluated through EMG may add to the results of this pilot study and the functional changes could be more explained at the muscular level.

Acknowledgement

The clinical trials to support the study was done in the National Institute for Locomotor Disability (NILD), Kolkata, India. We would like to thank our physiotherapist Avhijit Kumar, the clinicians and other paramedical staffs (at NILD, Kolkata) for their help in making the study possible. Last but not the least we would like to thank all the children and their caregivers who willingly were a part of the study and helped us to explore new direction to improve the toe-walking gait in spastic CP.

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Design of a Flexible Platform for prototyping of FES-based Motor Rehabilitation Systems

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Abstract: Impairment of motor function is a major problem among neurologically injured patients. Functional electrical stimulation (FES) systems are feasible technological alternatives for recovery of movement for that population. However, availability and adaptability of those systems are generally limited, which prevents fast development and updating of functions. Here is presented the design proposal of a platform for facilitating the prototyping process of FES systems. The platform is developed over MATLAB and SIMULINK software and is designed to be flexible enough to integrate commercial and prototype hardware for biopotential acquisition and electrical stimulation, and to implement offline and online signal processing and classification algorithms for generating command signals. Platform usefulness is shown by implementing FES stimulation sequences for five important upper-limb movements.

Keywords: FES, prototyping platform, motor rehabilitation, sEMG, upper limb

Introduction

Motor disabilities are among the most devastating sequelae suffered by people with Central Nervous System (SNC) injuries such as stroke and Spinal Cord Injury (SCI), causing dependence on caregivers and diminished quality of life.

In the past 50 years, several FES systems have been proposed as promissory alternatives for motor assistance and rehabilitation [1]. However, in spite of clear evidence of their benefits [2], there are currently only a few FES systems around the world being used as part of common rehabilitation practice [3]. This can be due to intrinsic characteristics of non-invasive FES stimulation, such as fatiguing, non-physiological contractions, and low spatial resolution/selectivity.

Furthermore, FES systems can be complex and cumbersome to configure and optimize, from prototyping/development stages, to daily use, in particular when additional sensing, processing and control elements are integrated as part of closed-loop on-command FES-based task-specific practice [4], an optimal approach to enhance long-term motor function recovery.

During initial design and testing stages of such prototype FES systems, the use of validated, commercial hardware and software elements is common practice, but later development stages requires migration to proprietary, application specific hardware, interfaces and algorithms.

Hence the need for a versatile and flexible platform for prototyping, testing and optimization of FES-based systems, capable of seamlessly integrating commercial, open-source, and prototype hardware and software building blocks, into practical applications. The aim of this work is presenting the design proposal of a platform intended to achieve such a purpose, and to demonstrate its usefulness by implementing a simple FES application.

Methods

The architecture of the proposed FES prototyping platform is shown in Fig.1. Below are detailed the general operating requirements for each of the building blocks, and the tools and procedures used to implement them.

Visualization and interaction: A graphical user interface is needed, where the experimenter can have contact with important operating parameters and see direct and immediately the effects of adjustments made on hardware and software blocks, or changes related to user behaviour/response. MATLAB®'s Graphical User Interfaces (GUI) Development Environment (GUIDE) is a feasible alternative for this task, given that all below requirements can also be implemented within MATLAB® and SIMULINK® mathematical and programming environment.

Signal Acquisition: FES-based rehabilitation applications need command signals to be operated by users in the right context. These commands can be as simple as a push button or as complex as continuous quantities derived from multichannel biosignals related to voluntary movement intention. A FES prototyping platform thus needs to allow robust connection of commercial and prototypes of analog and digital signal acquisition devices to use them as part of FES applications.

To cover a broad signal spectrum, two types of acquisition devices are planned to be available on the platform:

1. OpenBCI, a 24-bit, 8-16 multichannel open-hardware biosignal acquisition device with a 3-axis accelerometer sensor on the board, which can serve to devise FES applications based on bioelectrical and movement-related command and feedback signals.

2. A prototype, 8-channel FES compatible sEMG acquisition system, under current development, based on the same analog front-end chip that uses OpenBCI (ADS1299, Texas Instruments) but with greater sampling

rate (1 kHz per channel) and additional analog preprocessing (sEMG-specific, 10-480 Hz passive filter), to improve signal quality and reduce digital signal processing requirements.

Signal processing and classification: Signal processing and classification algorithms are necessary in order to extract useful information for FES command generation. MATLAB® is especially suited to this end, since a lot of algorithms and functions can be used directly from proprietary or open-source toolboxes, or implemented directly on M-language functions or in C-language as S-blocks over SIMULINK®, where soft-real time execution of the algorithms can be achieved, an important requisite for FES prototype development.

Electrical Stimulation Control: Multichannel, programmable electrical stimulation devices are at the core of FES systems and applications. Complete online control of stimulation parameters for each channel independently, is an important feature for implementing practical, complex FES applications for motor rehabilitation. For this platform, the integration of two different types of stimulation devices is considered (Fig. 1):

Rehastim 2 (HASOMED, GmbH), a commercial 8-channel, current-controlled, programmable electrical stimulator for FES applications, widely used on FES research. The Science Mode software allows configuration of parameters from any computing or processing device capable of implementing UART serial communication. Open-access SIMULINK® blocks for configuration and online operation of Rehastim 2 device are available on the web, which facilitates the prototyping process of FES systems.

A prototype, multichannel electrical stimulation device, currently under development, based on a prototyping platform for the FPGA chip Spartan 6 XC6SLX9. This prototype will allow independent control of 3 stimulation parameters on 6 stimulation channels: pulse width, frequency, and amplitude (current).

Integration of the platform: The core of the platform (grey central block of Fig. 1) must integrate the building blocks. The natural choice of development environment for this block is MATLAB®, since all other parts of the platform are to be developed over this environment or SIMULINK®.

It must manage data acquisition, interaction with signal processing and classification algorithms, control of stimulation parameters, communications with hardware devices, and control and updating of elements on the graphical user interface.

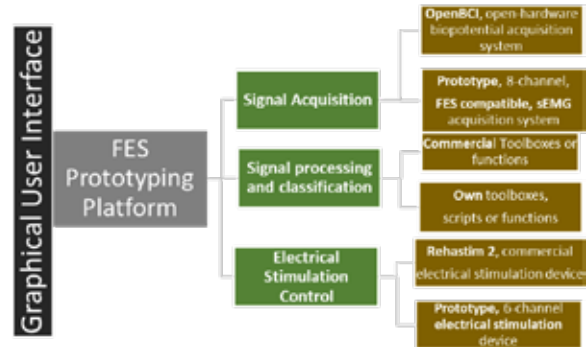


Figure 1: Blocks diagram of FES prototyping platform

Results

MATLAB® 2017a and SIMULINK® 8.9 were chosen as the software environment to develop the FES prototyping platform, running over 64-bit Windows 10 Pro OS, on a DELL T3420 workstation with a 3.4 GHz i7-6700 Processor and 32 Gb of RAM.

The solutions developed to meet the design specifications detailed on the Methods Section are given below for each building block:

Acquisition.

Data acquisition is managed in the platform for both signal acquisition systems by means of an *acquisition buffer function* implemented directly over MATLAB®.

For adaptation to the specific acquisition device to be used, the major adjustment is a change on the UART serial port baudrate (115,200 bps for OpenBCI and 460,800 bps for the prototype sEMG device) and data format, given the differences in sampling rate (8 channels@250 Hz VS 1 kHz) and data content of the two devices (OpenBCI includes 3-axis accelerometer data).

Acquisition buffer was tested and validated with the OpenBCI device, recording 30 consecutive windows of 300 samples of sEMG signal (1.2s) each and by plotting them online on the GUI without loss of samples (Fig. 2).

Preliminary acquisition tests were performed with the EMG device under development at 1 kHz sampling rate per channel, also with 30 consecutive windows of 300 samples each, which in this case corresponds to 300 ms. However, consistent behaviour is still to be optimized for this device, since occasional sample-loss and communication disconnection were found while testing the buffer.

Additionally, all signals acquired on-line are saved in .txt files for offline processing and analysis.

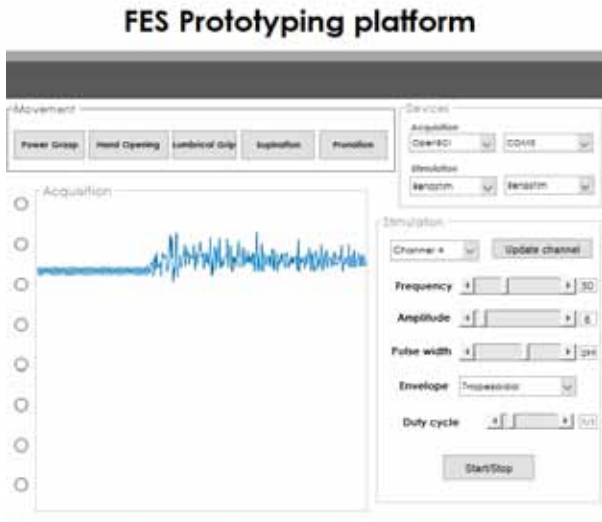


Fig. 2: sEMG recording with OpenBCI on Platform GUI

Processing.

Wavelet-based signal processing methods, and classifiers based on LDA and Neural Networks were implemented on MATLAB®, and tested offline, using sEMG signals acquired from the platform as inputs. However, considerations are currently being taken for translation of offline methods towards real time generation of command signals of FES systems [5], such as short window epoching and choosing fast algorithms over accurate, slow ones.

Stimulation command generator. A model for control and configuration was developed on SIMULINK® (Fig. 3), to allow setting of stimulation parameters (pulse width, intensity and frequency) for each channel of any of the two stimulation devices: Rehastim 2 and the prototype.

The model is designed to facilitate the implementation of predefined stimulation sequences, experimentation and testing of parameters by the user via the GUI, and can be adapted to allow update of parameters during online operation of FES applications. The system is designed to allow this functionality on any stimulation device.

The Rehastim 2 device is a commercial, programmable stimulator used in several FES projects worldwide. However, the prototype stimulation system under development has the potential, when completed, to have flexible application-specific stimulation parameters, to be dynamically configured for each channel, and to enable the development of complex, versatile FES systems, if combined with this command generator or a hardware version.

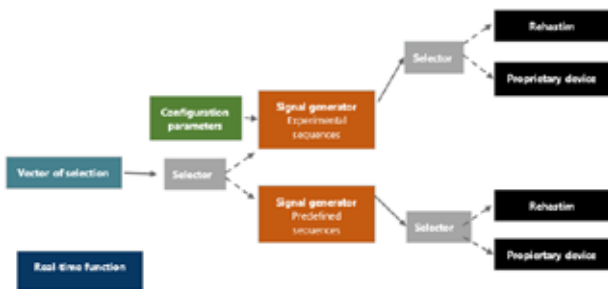


Fig. 3: Diagram of the stimulation command generator

FES application example.

Finally, an example of use of the prototyping platform is shown by the generation of stimulation sequences for the performance of four consecutive repetitions of five upper limb movements using Rehastim 2 FES system. Stimulation parameters are indicated in Table 1. SIMULINK® plots of amplitude envelope profiles for six stimulation channels are shown in Fig. 4 (adapted for visualization). The stimulation command generator block allows selection of movement/rest duration and amplitude envelope (square or trapezoidal). In this case a 7s/7s ratio and trapezoidal envelope (1s transition) were chosen (Fig. 4).

Table 1: Upper-Limb movement stimulation parameters

Movement	Pulse-width (μs)	Frequency (Hz)	Amplitude (mA)
Power Grasp	300	30	7-12
Hand Opening	300	30	7-12
Lumbrical Grip	500	30	7-12
Pronation	500	30	7-12
Supination	500	20	7-12

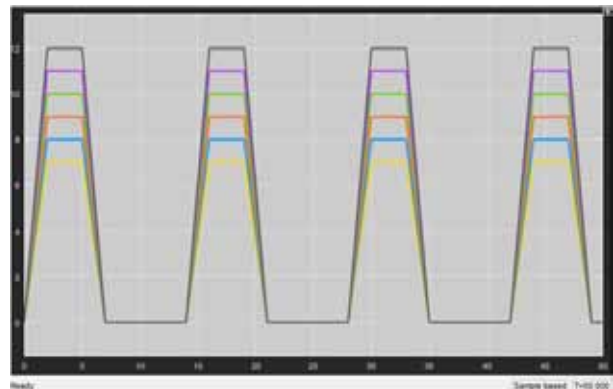


Fig. 4. Amplitude envelopes of stimulation sequences

Discussion

General operation requirements of a prototyping platform for the development of FES-based motor rehabilitation systems were identified, and the solution was implemented over MATLAB® and SIMULINK® software.

For validation of the platform, stimulation sequences for five upper-limb movements were developed, each in an individual stimulation channel of the Rehastim 2 device.

This prototyping platform is the starting point for developing FES applications at the Laboratory of the Division of Medical Engineering Research, National Institute for Rehabilitation, and is planned to be further developed to facilitate the integration of other sensing and feedback elements, such as Shimmers® EMG and inertial measurement sensors, Depth sensing cameras, and other hardware prototyping boards as Arduino or Raspberry Pi.

Beyond the use of commercial hardware for acquisition and electrical stimulation, we're interested in developing and integrating safe prototypes of stimulation and biopotential acquisition devices, which can give us much more flexibility and allow us to optimize FES systems for motor rehabilitation and other specific purposes, such as daily assistance or exercise.

Acknowledgement

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TOWARDS OPTIMIZATION OF ELECTRICAL STIMULATION PARAMETERS USING ULTRASONIC IMAGING: ASSESSMENT OF PARAVERTEBRAL MUSCLES DURING VOLUNTARY AND ELECTRICALLY INDUCED CONTRACTIONS

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Abstract: *Surface electrical stimulation was used to induce contractions of deep spinal muscles, and these contractions were compared to voluntary activation. We tested a novel methodology of simultaneous ultrasound (US) imaging and electrical stimulation for the assessment of induced contractions. The impact of spatial electrode configuration on muscle thickness change during elicited contraction was also analyzed. Our results show that FES is capable of inducing muscle activation comparable to voluntary isometric contraction. Comparing the two spatial configurations of stimulation electrodes, wider anode-cathode spacing was more efficient in activating deeper muscles. The US based method for assessment of electrically induced contractions of paravertebral muscles was successfully validated. Our results are a direct step toward application of US imaging for optimizing electrical stimulation parameters for targeting deep spinal muscles. Our findings imply that surface electrical stimulation might be an effective alternative for achieving the results of physical exercise of paravertebral muscles without its side effects.*

Keywords: *Electrical stimulation, paravertebral muscles, ultrasound measurements, stimulation parameters*

Introduction

Prolonged exposure to functional electrical stimulation has been shown to achieve muscle strengthening [1]. Exercise for strengthening deep spinal muscles is used in rehabilitation in severely disabled individuals, persons with vertebral fractures, osteoporosis, or back pain due to a wide range of spinal pathology. In addition to our previous work [2] we have identified a few studies describing the effects of electrical stimulation for isometric strengthening of paraspinal muscles [3][4][5]. These studies show that electrical stimulation therapy yields improvements in isometric muscle strength over time, but in these studies the stimulation amplitude was

set to a maximum tolerable value, while the actual paraspinal muscle contraction was not confirmed.

Surface electromyography (sEMG) is often used for assessment of muscle activity, but there are serious limitations in its application during electrical stimulation, such as signal contamination with stimulation artifacts [6], and interference of signals generated from surface muscle layers with the ones from deeper layers, making it difficult to identify the sources of sEMG activity. Ultrasound (US) imaging arises as a good alternative for adjusting the stimulation parameters and quantifying induced paravertebral muscle activation, as it provides a noninvasive, real-time assessment and quantification of activity in both surface and deep muscles and is immune to electrical interferences [6]. However, there are a limited number of studies employing US imaging of electrically evoked contractions of spinal muscles [7][8][9][10], wherein only the lumbar area was of interest.

This motivated us to test the feasibility of using US to optimize the stimulation parameters (pulse amplitude and spatial configuration of electrodes) for targeting deep spinal muscle layers and to compare artificially elicited contractions with voluntary isometric contractions in order to ensure that activation of the target muscles is achieved in a similar manner as with conventional isometric exercise [11]. We compared the effects of 2 different spatial-configurations of stimulation electrodes on electric field penetration depth at each stimulation site.

Methods

Eight healthy volunteers (2 males, 6 females; age 32 ± 2.5 years) participated in the tests after signing the informed consent approved by the local ethics committee. The tests were performed at the Clinic for Rehabilitation “Dr. Miroslav Zotović” in Belgrade, Serbia. The tests comprised US imaging of paravertebral muscle thickness at 3 spinal levels, in rest, during voluntary isometric contraction and electrically induced contractions (with two different electrode configurations).

Electrical stimulation system

The BoneSTIM system (Tecnalia Research & Innovation, Spain) was used for electrical stimulation. The system comprised a current controlled stimulator unit delivering symmetrical biphasic pulses (of 200 μ s pulse duration per phase) at the rate of 40 pulses per second, and a custom designed multi-pad stimulation electrode. The stimulator was controlled via Bluetooth, using a custom NI LabView application on a PC. Multi-pad stimulation electrode consisted of 16 pads (8 pads on each side of the back), but only the left side was tested in this study, and the active pads were chosen among the 8 pads of the left electrode side. The pads were of rectangular shape (with rounded angles and sides of 3.7 cm) with the distances between the edges of neighboring pads of 2.7 cm, and were covered with adhesive hydrogel (Axelgaard AG725) for interfacing with the skin. A sketch of the left electrode side is shown in Figure 2.

US measurement system

Toshiba Diagnostic Ultrasound System (Nemio SSA-550A, with 7.4 MHz linear probe) was used. The images were acquired in B-mode by an experienced examiner. Muscle thickness was measured using the on-screen calipers.

Protocol

The paravertebral muscle thickness was assessed in prone position with a pillow placed under the abdomen to reduce lumbosacral junction angle to less than 10 degrees. Three stimulation sites were tested for each subject: L4, Th10/11 and Th5/6 spinal levels. At each spinal level, corresponding multifidus muscles were targeted with electrical stimulation and US imaging. For the measurement at L4 level, the ultrasound transducer was positioned longitudinally in the midline of the spinal process of the L4 vertebra, and then moved slightly laterally and angled medially to obtain the image of zygapophyseal joint L4/5 [12]. Distance between the dorsal edge of the joint and the thoracolumbar hyperechoic fascia that separates the muscle from the subcutaneous fat tissue was considered the thickness of lumbar multifidus muscle (LM). No hyperechoic fascial thickness and joint-muscle boundaries were taken into account. The same procedure was repeated at levels Th10/11 and Th5/6.

The US measurements were taken at rest and during voluntary isometric contraction. The muscle was activated by lifting the contralateral arm and holding it at 120 degrees of shoulder abduction and 90 degrees of elbow flexion. Next, muscle thickness was measured at rest and during contraction induced by electrical stimulation in two spatial configurations (SC1 and SC2) comprising different anode-cathode positioning. In SC1, a single pad was chosen as cathode while a group of 2 neighboring pads acted as anode (Figure 2). SC2 featured a single pad

cathode and two neighboring pads acting as anode, separated with one pad (8.7 cm distance between anodes and cathodes, see Figure 2).



Figure 2: Sketch of the multi-pad stimulation electrode with dimensions marked in cm. Colored lines below/above the sketched pads mark the pads included in stimulation configurations SC1/SC2, respectively. Three colors (red, green and blue) represent different stimulation sites (L4, Th10/11 and Th5/6, respectively). Shorter lines underlying or overlying a single pad represent the inclusion of this pad in the configuration as a cathode, while longer lines underlying (overlying) two neighboring pads denote that those 2 pads acted as anode in the corresponding configuration.

The stimulation pulse amplitude for each subject and stimulation site was determined by increasing the intensity until the final amplitude value was determined. This value was reached when increase of current intensity did not produce significant further increase in muscle thickness during elicited contraction, or in case of pain or discomfort. The same current amplitude was used for SC1 and SC2 at each stimulation site.

Data analysis

As a measure of muscle activation, we used relative muscle thickness, calculated as the difference between thickness measured in contraction and thickness measured in rest, divided by thickness in rest, and multiplied by 100 to obtain percentages:

$$RelativeT = \frac{ContractionT - RestT}{RestT} * 100 [\%] \quad (1)$$

Statistical data analysis was performed using "R" statistical program version 3.4.4. Normality was assessed with Shapiro-Wilk test, which failed to reject the null hypothesis, allowing us to use parametric tests in further analyses. We performed repeated measures ANOVA with significance level set at 0.05, followed by paired t-tests with Bonferroni correction for multiple comparisons.

Paired t-test was used for assessing the effect of different stimulation configurations (SC1/SC2) on muscle thickness during induced contraction for the pooled data over all stimulation sites.

Results

No significant differences were found between relative muscle activation induced by electrical stimulation and voluntary activation, when the data were observed separately for all three positions on the back, except for differences between voluntary activation and SC1 at L4 where SC1 did not achieve equally potent contraction as

voluntary (Figure 3). Though mean SC2 electrically induced activation was greater than the voluntary one at the levels Th10/11 and Th5/6 (Table 1), there was not enough statistical power to support this finding.

Observed across the whole back, SC2 was significantly more effective than SC1 ($p=0.006$) in activating the muscles with the same pulse amplitude. The relative thickness achieved by using SC2 was greater than that of SC1 by 7.56 percentage points on average.

Discussion and Conclusions

Exercise of paravertebral muscles has shown positive effects on various disorders such as low back pain (LBP) [1], osteoporosis [11] and other degenerative spinal diseases [15]. Studies have shown that exercise enhances bone mineralization and can be used as a viable treatment in prevention of bone loss, which is characteristic of the elderly, particularly post-menopausal women [16]. Exercise in the form of short, repetitive mechanical loading has been shown to produce the greatest gains in bone strength [17]. Moreover, exercise increases skeletal mass primarily in the areas where the forces are applied, which is in accordance with Wolff's law [18].

However, certain subgroups of patients face limitations in the exercise regime. In case of spinal stenosis, for instance, dynamic extension of the lumbar spine is known to worsen the pain [19]. To pave the way for the use of electrotherapy as an alternative to exercise, we tested the feasibility of the electrical stimulation method combined with US imaging for targeting the multifidus muscles. Our goal was to use electrical stimulation for reproducing the desired voluntary isometric contraction of those muscles during exercise and to test the feasibility of ultrasonic imaging for optimizing the stimulation amplitude and spatial configuration for targeting specific muscle layers.

We have shown that electrical activation of paravertebral muscles using surface electrodes positioned on the back is feasible for all tested stimulation sites and cathode-anode configurations. Electrical stimulation of paravertebral musculature was effective in eliciting contraction, visible on the US as a distinct change in muscle thickness compared to the thickness measured in rest. This was true for all tested muscles and for both spatial configurations of the stimulating electrodes.

The absence of significant differences in relative change of muscle thickness during voluntary contraction and electrical stimulation with SC2 implies the possibility of testing this method for maintaining the trophic levels of paravertebral musculature in painful conditions, muscle dystrophies, osteoporosis and paralyses, that is, in all pathological conditions where movement of the spine is either contraindicated or difficult, but also as a supplementary treatment in cases that allow dynamic contraction.

Real time US imaging during electrical stimulation of paravertebral muscles has been reported in few studies [7][8][9][10], wherein only the lumbar region was observed, no comparison with voluntary activation and no

systematic spatial electrode configuration comparison was performed. The stimulation system employed in this study enables any subset of electrode pads to be activated as either cathode or anode, providing high flexibility of stimulation patterns.

Table 1. Mean and standard deviation of relative change in muscle thickness given in percentage points at three spinal levels. Comparison of the effects of voluntary contraction, stimulation with electrode configuration 1 and stimulation with electrode configuration 2.

	L4/5 [%]	Th10/11 [%]	Th5/6 [%]
Voluntary	23.1±10.2	21.8±21.2	23.6±15.1
SC 1	7.83±6.73	18.6±12.6	27.2±16.8
SC 2	16.1±11.6	26.3±14.7	34.0±14.9

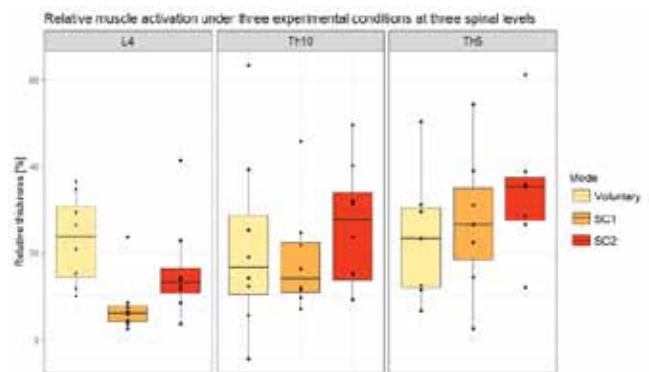


Figure 3: Relative muscle activation under three experimental conditions (Voluntary, SC1, SC2) measured at three spinal levels

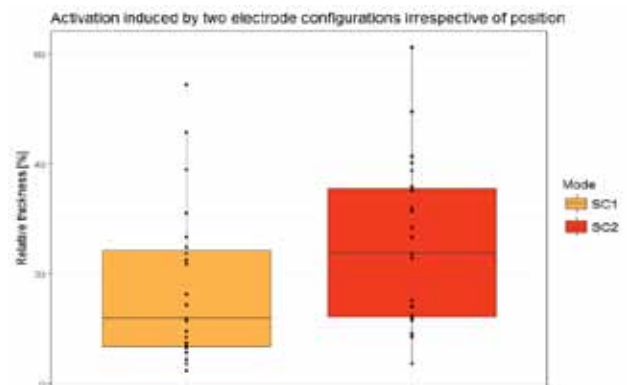


Figure 4. Relative muscle activation induced by two electrode configurations, irrespective of the position on the back.

Six out of eight subjects described the sensation as pleasant (massage-like). All the subjects confirmed that they would be able to tolerate the maximal tested current intensity if it were to be applied in a 30 min long session. Our study confirms the feasibility of assessing the effects of surface electrical stimulation on paravertebral muscle

activation in real time by using ultrasound imaging. Analysis of muscle activation under stimulation in comparison with voluntary activation, as well as feedback provided by the participants, suggest that electrical stimulation may be an adequate, safer alternative to isometric exercises of spinal muscles especially in population with contraindications for strength training.

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MOTOR LEARNING

How does the FES Therapy Improve Voluntary Function

22. Annual IFESS Conference

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Abstract: Since 1970ies when Roberto Merletti discovered that the use of Functional Electrical Stimulation (FES) might result in functional improvements that are permanent, many of the scientists in the field have tried to use FES as a therapeutic tool to improve walking, reaching or grasping. The purpose of the FES therapy is to use the FES technologies as a tool to help the central nervous system relearn to perform tasks it is not able to perform presently, but was able to carry out before a neurological injury. In other words, the FES therapy is used to evoke functional changes in the central nervous system that today would be attributed to neuroplasticity. Therefore, in this embodiment the FES has been used as a therapeutic tool to restore voluntary function in various neurologic patients. Some of the pioneers in the field are

Dejan and Mira Popovic, Richard Stein, Paul Taylor, Adam Thrasher, Thierry Keller and yours truly. Please note that this list of contributors is not comprehensive and I apologize in advance if I missed an early key contributor. The number of published articles in reputable journals, which are describing clinically relevant effects of the FES therapy, is growing rapidly. However, very few articles have been discussing the neurophysiological mechanisms behind the FES therapy and why this therapy works. In this lecture, I intend to present a number of mechanisms that can potentially help explain how the FES therapy works, why it is successful, and why it is capable of generating better rehabilitation outcomes compared to other competing rehabilitation approaches, such as constraint-induced therapy and robotic therapy.

KEYNOTE - SPINAL CORD STIMULATION

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Severe spinal cord injury (SCI) is a devastating condition, tearing apart the long tracts of the spinal cord and disrupting the communication within the nervous system. The consequences are disabilities of body functions below the lesion, including paralysis. Activity-based physical therapy is the common clinical practice for enhancing recovery of lost motor functions. However, the most affected patients who fail to produce active movements voluntarily experience minimal benefits and independent standing or walking is usually not achieved. Complementary approaches are continuously being sought to improve recovery by reactivating the intrinsic capacity of the spared lumbar sensory-motor circuitry distal to the lesion. Particularly, electrical spinal cord stimulation therapies have attracted tremendous attention during the past years [1,2]. Recent studies showed that stimulation of the lumbar spinal cord with implanted, epidural electrodes enabled paraplegic individuals to initiate movements of their paralyzed legs [3,4]. All studies of epidural stimulation for improving motor function to date have utilized neurostimulation technologies that had been originally developed for pain conditions. Once parameters are adjusted for a therapy, the stimulation is continuously applied from a fixed site and with constant amplitude and frequency in a so-called ‘tonic’ mode of operation.

To take full advantage of spinal cord stimulation to improve functional recovery from SCI, my lab was continuously engaged in studying the mechanisms through which the stimulation interacts with the spinal circuitries, as well as in further advancing implantable neurostimulation technologies [5-7]. As a result of our endeavors, we developed spatio-temporal epidural electrical stimulation (EES). This neuroprosthetic technology dynamically delivers short stimulus trains to specific spinal cord circuits to engage leg muscles with a temporal sequence that coincides with the natural flow of proprioceptive information and the intended motor command from the brain. In rodent and non-human primate models of SCI, spatio-temporal EES instantaneously restored robust locomotor movements in paralyzed hind limbs [8,9]. The focus of my presentation will be the First-in-Man study STIMO, our first effort to translate these pre-clinical findings into clinical applications. The intervention acts over two time scales. Combined with a robotic suspension system [10], spatio-temporal EES immediately enabled overground locomotion in non-ambulatory individuals with chronic SCI, and reestablished adaptive control over paralyzed muscles during walking. Over a period of five months of rehabilitation, the regained ability to sustain active

movements during an intense overground locomotor training promoted clinically meaningful functional improvements. Locomotor performance improved, and the participants regained voluntary control over previously paralyzed muscles even in the absence of EES. These preliminary results of our ongoing study provide encouraging insights into the potential of this intervention to augment neural plasticity and functional recovery in individuals after severe SCI.

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STIMULATION OF DENERVATED MUSCLEJarvis JC¹,¹School of Sport and Exercise Science, Liverpool John Moores University, Liverpool, UK

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Abstract: *Electrical stimulation of denervated muscle, though considered ineffective or even detrimental by some, is a promising means of rehabilitation in this setting.*

Keywords: *denervation, electrical stimulation, reinnervation, rehabilitation*

Introduction

It might be argued that since stimulation in persons with upper motoneurone lesions (spastic paralysis) is difficult enough, why would we even try to activate denervated muscle in flaccid paralysis in which lower motor neurones are damaged?

Denervated muscle quickly loses the ease of activation conferred in innervated muscle by the relatively low threshold for stimulation of the motor nerves and secure transmission of action potentials at the motor end plate. Therefore, stimulation of denervated muscle requires relatively high currents, and thus careful attention to safety, to activate the muscle membrane directly.

Methods

Several centres are using commercially available certified equipment to perform stimulation of denervated muscle in the clinical research setting.

The EU RISE project showed that stimulation of the lower limb muscle is effective to restore mass and some degree of function to the quadriceps and hamstring muscles. Enthusiastic users of regular stimulation in this setting include those who are convinced that it reduces the risk of pressure sores. We need to build the evidence base for this potential benefit by collecting evidence of effects on muscle thickness and quality over the ischial tuberosity as well as local blood flow. Muscle ultrasound examination has the potential to provide this evidence.

Muscle ultrasound can also be used to demonstrate the benefit of stimulation used to maintain the mass and quality of muscles during the

delay between peripheral nerve damage and either reinnervation or nerve grafting.

Results

This is a research area in which there are still conflicting opinions. We need to gather and expand the scientific evidence base for benefit or disadvantage of electrical stimulation of denervated muscle.

There is growing experimental evidence that stimulation does not necessarily reduce the chance of reinnervation, as has been suggested on the basis of work in rodent models [2]. We need to have a better informed debate, including full consideration of the type of stimulation that might be used and whether we refer to reinnervation via regrowth of the motor axons or via intramuscular sprouting. Chronic near-continuous stimulation may indeed reduce the chance of terminal sprouting but intermittent resistance style training has been shown to have no detriment regarding reinnervation in experimental studies in the horse, and in clinical research in facial nerve palsy.

Discussion

The use of tendon transfer and nerve graft techniques requires the maintenance of limb muscles during the time of rehabilitation after the initial trauma that causes a denervating injury. Electrical stimulation can maintain muscle mass and function during the time that reinnervation is progressing and may sometimes be indicated even where there is no likelihood of reinnervation.

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EFFICIENCY AND PERFORMANCE OF FES-CYCLING

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Abstract: *This document provides a brief summary of a keynote presentation that will be given at the IFESS 2018 conference. The purpose is to summarise the content of the talk and to provide a list of publications on which the talk is based.*

Keywords: *FES cycling, efficiency, performance, power output, metabolic cost, fatigue*

Introduction

The talk will discuss the energetics, efficiency and performance of FES-cycling. An important backdrop for this talk is the FES bike race which took place at the Cybathlon competition in Zürich in October 2016, where my team achieved the fastest time of any team which used surface stimulation (the race was won by team Cleveland which, uniquely, employed implanted stimulation technology).

The following paragraphs give an abbreviated summary of the sections of the talk, along with relevant citations for the work done in my lab.

Discussion of the energetics and efficiency of FES-cycling, including: a new framework for calculation of efficiency, and efficiency estimation in untrained spinal-cord-injured (SCI) participants [1]; and a systematic review of work on the efficiency of FES-cycling [2].

Investigation of the effect of long-term, intensive training on efficiency in SCI participants [3] and comparison of the efficiency of volitional and FES-cycling in able-bodied (AB) participants [4].

Stochastic (random) modulation of stimulation parameters (inter-pulse interval [frequency], amplitude, pulse width) [5,6].

Studies investigating the performance of multi-electrode configurations, viz. spatially distributed sequential stimulation (SDSS) in both AB [7,8] and SCI [9] participants.

Finally, the lessons that can be learned from our team's participation in the FES bike race at the Cybathlon 2016 competition will be discussed [10].

For completeness, although these aspects will not be considered in any detail in the talk, I also provide here additional background references on our early work on control strategies and testbeds for analysis of FES-cycling effi-

ciency and performance [11,12] and for comparison of different stimulation patterns [13].

We also concluded an intensive, long-term training study with clinical assessments which examined the effect of FES-cycling on bone density [14,15], cardiopulmonary fitness [16], muscle properties [17], and other energetics [18,19] and training/detraining [20] considerations; and we did a little bit of work on FES-cycling systems for children [21,22].

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**FUNCTIONAL ELECTRICAL STIMULATION IN NEURO-UROLOGY:
STANDARDS AND NEW TRENDS****Pannek J**

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Abstract: *Functional electrical stimulation is a standard treatment option for patients with non-neurogenic bladder dysfunction and/or incontinence. In the last decades, it has become increasingly important in patients with neurogenic lower urinary tract dysfunction as well. Besides temporary external stimulation of the genital region, implant-driven stimulation (e.g. sacral neuromodulation, sacral deafferentation and anterior root stimulation) are well established procedures in neuro-urology. Lately, spinal cord stimulation and stimulation of the tibial nerve provided promising results and may be useful non-invasive future treatment options.*

Keywords: neurogenic lower urinary tract dysfunction, incontinence

Introduction

The main task of the lower urinary tract (LUT) is to store and voluntarily evacuate the urine. To fulfill these tasks, complex regulation mechanisms at different levels of the the nervous system are involved. Any lesion of the nervous system may lead to a neurogenic lower urinary tract dysfunction (NLUTD). NLUTD may lead to symptoms, as urgency, incontinence, voiding difficulties, residual urine, or urinary retention. Especially if the suprasacral spinal cord is involved, e.g. in patients with spinal cord injury or multiple sclerosis, there is a risk of renal damage due to high intravesical pressures, which are not related to clinical symptoms. Therefore, treatment of NLUTD has two goals: protection of renal function and symptom control. As central nerve circuits are mandatory to use FES, its use is restricted to patients with preserved residual nerve function.

Types of FES

Basically, FES in urology is used as either as external stimulation or via implanted devices. Pelvic floor biofeedback and/or pelvic floor muscle stimulation are used for the treatment of stress urinary incontinence as well as to regain pelvic floor relaxation. Surface electrodes or intravaginal/intrarectal probes are applied. Intracavitary (rectal/vaginal) stimulation can also be utilised for the treatment of detrusor overactivity/urge incontinence.

Sacral neuromodulation is thought to work via afferent nerve stimulation. It is used either via

surface electrodes or, in selected cases, as a permanent implant with permanent electrodes located in the sacral foramina and a battery.

In patients with complete SCI, sacral deafferentation and anterior nerve stimulation via intradural electrodes can be used. By cutting the dorsal sacral roots, the afferent input of the urogenital tract is terminated, leading to an areflexic bladder. Using a hand-held device, patients can initiate voiding.

Lately, three interesting innovations have been introduced. First, percutaneous or transcutaneous tibial nerve stimulation has been demonstrated to be a successful treatment option in patients with neurogenic overactive bladder, especially in those suffering from multiple sclerosis. Second, on demand treatment of symptomatic detrusor overactivity with penil or clitoral electrodes could suppress detrusor overactivity for a sufficiently long time to allow bladder evacuation without urge incontinence. Third, and most important, early FES in the acute phase of SCI prevented the development of NLUTD in a small pilot study. A prospective trial to test this hypothesis with a non-invasive external device will start patient recruitment soon.

Last but not least, some weeks ago, a pilot study evaluating Transcutaneous Electrical Spinal Stimulation for LUT functional Augmentation (TESSLA), a non-invasive neuromodulatory technique has been published. In patients with chronic SCI, detrusor overactivity, and bladder capacity improved, whereas detrusor-sphincter dyssynergia decreased. If these results can be confirmed by larger studies, early electrical stimulation and/or TESSLA may significantly improve NLUTD in the future, which will improve patients' quality of life, will save renal function and, as a consequence, will reduce health care costs.

Towards non-invasive brain-computer interface for the control of the upper extremity in humans with spinal cord injury

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Abstract: *Spinal cord injury (SCI) can interrupt the communication pathways between the brain and the rest of the body, restricting the ability to perform volitional movements and other body functions. Neuroprostheses or robotic arms can enable individuals with high SCI to move independently, improving their quality of life. The control of restorative or assistive devices can be facilitated by brain-computer interfaces (BCIs), which convert brain activity into control commands.*

In this talk, I summarize the recent findings of our research towards the main aim to provide reliable and intuitive BCI control.

Keywords: *Brain-Computer Interface (BCI), Electroencephalogram, functional electrical stimulation (FES), spinal cord injury (SCI).*

Introduction

Many everyday goal-directed interactions, such as grasping a cup of coffee, are not possible for people who received a cervical spinal cord injury (SCI). The communication pathways between the brain and the peripheral nervous system can be affected, depending on the level and severity of the damage to the spinal cord. To improve the quality of life of individuals with SCI, and help them regain independence in movement, we aim to non-invasively record their electroencephalographic (EEG) brain signals and transform these signals into continuous control commands for a restorative neuroprosthesis or robotic arm.

We have shown that such control signals can be obtained from a brain-computer interface (BCI) and used for motor control [1]. For instance, one approach to switch between different grasp phases is the sustained motor imagery (MI) of hand or feet movements [2], [3]. Furthermore, we have shown that imagined movements with different durations could be used for motor control both in healthy users and in end-users with SCI [4]–[6].

The advantages of BCI for motor control can be augmented by adding other input modalities (e.g. shoulder position sensor) leading to a complementary system, the hybrid BCI [7]–[9]. Although such systems have shown promising results [10], [11], they still lack an intuitive control. This drawback could be overcome if the movements decoded by the system can closely reflect the user's intention [12].

This talk covers several concepts, methods and studies which were conducted in order to reach our aim of

providing a natural means of control for humans with high SCI.

Goal-directed movement intention detection: We are currently studying the cognitive processes which allow a decision on motor goals and lead to the initiation of movement. In [13], we investigated whether the detection of movement intention was influenced by the presence of a movement goal in a movement execution (ME) task. In another study [14], we designed a paradigm to separate target selection from the actual motor task, which allowed us to study the differences between externally and internally-driven target selection.

Classification of upper-limb, single joint movements and grasp types: Discrimination of several single and non-repetitive upper limb movements is also possible using the time-domain of low-frequency EEG signals [15]. Despite the large number of degrees of freedom of the human hand, most actions of daily life can be executed incorporating only palmar, pincer and lateral grasp. We showed that these three differently executed reach-and-grasp actions are discriminable using EEG signals [16]. Transferring the results to end users we investigated ten participants with high SCI. Furthermore, we are currently performing a clinical study on BCI-based neuroprosthetics control for grasp restoration. Preliminary results of an ongoing clinical trial will be presented, where people with SCI use a BCI to control their restored grasp.

Kinematics decoding: Complementary to classifying hand/arm movements, we have also investigated decoding of movement kinematics in a continuous self-paced arm movement task [17].

Error-related potentials detection: The incorporation of error-related potentials (ErrPs) detection into a BCI can improve its performance, contributing to a swifter interaction with the users [18].

Discussion

In conclusion, we evaluated our methods in a large number of healthy users, as well as in end-users with high SCI, and we obtained promising results. Future studies are needed to confirm whether attempted movements can be classified / decoded online and asynchronously from individuals with SCI and if the BCI performance is sufficiently high to reliably control a neuroprosthesis or a robotic arm. This holds also for complex arm-movement decoding. It also has to be determined if the BCI performance can be maintained and/or increased by user training. Furthermore, the translation of the ErrPs detection and kinaesthetic feedback delivery needs to be assessed in SCI end-users.

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FES Cycling for Fitness and Health Benefits

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Abstract: Functional electrical stimulation (FES) – elicited cycling activates large muscles in the lower limbs for the purpose of providing leg exercise in individuals with spinal cord injury (SCI). While FES was originally deployed to promote standing, the original purpose of FES-evoked exercise was to improve whole-body aerobic fitness in a way that re-activated muscles lacking neural innervation through ‘artificial’ recruitment via external neuromuscular stimulation. Later uses of FES-cycling investigated the augmentation of leg muscular strength (either by FES-alone or by combining FES with voluntary movements), possible health effects on skin and bone quality and most recently the potential benefits to maintain hormonal and muscle biochemical changes that might have health outcomes. Despite promising individuals studies in these physiological and functional outcomes, there is not strong evidence that FES-cycling benefits aerobic fitness and health outcomes. This Keynote presentation will review what is known and what may be surmised when individuals undertake FES-cycling for fitness and health benefits.

Keywords: aerobic fitness, muscular strength, cycling exercise.

Introduction

With longer survival times following spinal cord injury (SCI), later-life morbidity from cardiovascular disease, particularly coronary artery and other 'lifestyle' diseases, after SCI has reported to be higher relative to the healthy, ambulatory population, and may occur at an earlier age. This increased risk of cardiovascular disease is attributed to extant risk factors such as abnormal lipid profiles, obesity and diabetes, reportedly higher amongst individuals with SCI. Additional risk factors include an enforced sedentary lifestyle and reduced physical function due to wheelchair (and therefore small arm musculature) use as a primary means of ambulation.

FES-cycling elicits leg muscle contractions in an appropriate sequence to produce a cycling motion. Generally, the quadriceps, hamstrings, and gluteal muscle groups are recruited during FES-cycling. As the most popular (and commercially-deployed) mode of FES-evoked leg exercise, FES-evoked cycling is suitable for a wide range of persons with SCI.

This review and presentation will present some of the evidence supporting and refuting FES-cycling exercise as a beneficial means of promoting fitness and health benefits

Methods

This review will present isolated studies and some systematic reviews in investigating whether FES-cycling, by itself, or in combination with voluntary muscle exercise (either with arms or with legs) promotes health and fitness in users who exercise regularly using it.

FES-cycling devices can be very simple to construct (Figure 1) in a research or clinical laboratory, can be commercially sold (Figure) or may be included within very complex (and expensive) hospital neurorehabilitation systems (Figure 3). Yet, despite the level of technology, there is not strong scientific evidence from large sample-sized RCTs to support definitive benefits for users.



Figure 1: A laboratory-grade FES leg-cycling system (circa 2004, public domain source)



Figure 2: A commercial FES leg-cycling system (RehaMove, courtesy HASOMED GmbH, via website)



Figure 3: Neurorehabilitation assistive device (MotionMaker™, courtesy Swortec SA, via website)

Discussion

A number of isolated studies, a few well-designed RCT's and some systematic reviews have suggested that FES-cycling *may have* health and fitness benefits for its users. Yet positive results have not always been consistent.

Hamzaid and Davis [1] in their systematic review of 33 randomized and controlled studies concluded, "... available literature suggested that across a variety of outcome domains FES-evoked leg exercise promotes certain health and fitness benefits for people with SCI". Yet the authors cautioned that their conclusions were still speculative based on the number of studies and the quality of the evidence.

In contrast, a recent multicentre, randomized controlled, assessor-blinded trial was undertaken with 116 community-dwelling participants at six SCI units in Australia and New Zealand (NCT01236976; Galea et al, [2]). The authors' findings revealed no statistically significant between-group differences (exercise including FES-cycling versus upper body exercise alone) for any of the secondary outcome measures, including leg exercise capacity measured by FES-cycling, purportedly a composite of leg strength and leg aerobic metabolism.

In this presentation, the author will make a case that for FES-cycling to have putative health and fitness benefits, the exercise prescription needs to have strong "*dose-potency*" – that is, greater intensity and volume of leg exercise than is often deployed in rehabilitation centres or casually recommended to a home user by commercial interests selling such equipment. Indeed, the intensity and volume of FES-cycling must meet current international guidelines for aerobic exercise (greater than 50% whole-body VO_2 peak for longer than ~30 minutes) or muscle strength development (higher than 60% 1-RM of peak leg strength for sufficient repetitions and sets). Ultimately, a particular technology is much less important than how it is used by the client to promote aerobic fitness, muscle strength and health benefits. Some speculative guidelines for FES-cycling will be discussed based on the available scientific evidence.

Acknowledgement

The Swiss Paraplegic Centre and the IFESS Board is looking forward to welcoming you on behalf of 22. Annual Conference of the International Functional Electrical Stimulation Society held from 28-31 August 2018 in Nottwil, Switzerland.

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Keynote lecture: Spinal Cord Stimulation for Pain Therapy

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Spinal cord stimulation is a form of neuromodulation which has been defined by the International Neuromodulation Society as a «technology that acts directly upon nerves. It is the alteration or modulation of nerve activity by delivering electrical or pharmaceutical agents to a target area.»

The two most common ways to deliver something to a target area in the spine are the electrical stimulation of the dorsal column or the intrathecal application of drugs like opioids or baclofen.

Neuromodulation in general is used in a variety of clinical situations, and pain therapy is only one of them.

The beginning of neurostimulation as we know it dates back as far as over 50 years. The publication by Norman Shealy “Elektrical Inhibition of Pain by Stimulation of the Dorsal Columns” (Anesth and Analg, 1967 (4)) is said to be the first clinical description of modern spinal cord stimulation.

They report a case of abdominal and chest pain. They applied an epidural electrode at the level of Th3 and describe a pain reducing effect, unfortunately only for one and a half days, then the patient died of an intracerebral infarction.

Today we believe that there are two main ways of action of SCS: The first one includes activation of inhibitory interneurons that block transmission of signals by A δ - and C-fibers. The second one is an enhanced release of serotonin and norepinephrine which are essential for the function of the descending pain modulatory system.

The indication for a SCS treatment are manifold. Indications include a variety of neuropathic pain states like radiculopathy, phantom limb pain, post zoster neuralgia and others. Indications include also pain arising from low perfusion like peripheral vascular disease or coronary disease.

The material we use in SCS therapy includes the electrodes, leads, which can be either percutaneously or surgically implanted. In the second step we need an impulse generator. Modern impulse generators have a variety of programming options regarding frequency, amplitude or pulse width combined with the ability to sense the positioning of the patient.

Before a SCS system is implanted, a thorough clinical and psychological evaluation is performed. Once this is done and no contraindications exist, the leads are implanted and the effect of the therapy is trialed for 10 to 14 days. Only if the stimulation is effective, the definite generator is implanted.

One speciality of SCS therapy is the stimulation of the dorsal root ganglion (DRG).

Here the electrode is placed directly to the DRG. Therewith less current is needed and usually this form of neurostimulation is more effective. Indications are all neuropathic pain states where the pain has a dermatomal distribution and can be related to one or more defined nerve roots.

In the last years neurostimulation has been discussed as a possible therapy option for paraplegic or tetraplegic patients with an at-level or below-level neuropathic spinal cord injury pain. Here literature is very scarce and in Nottwil we are only at the beginning to implement this therapy in the therapeutic algorithm.

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Tetrahand Poster Area

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