PI: [redacted]	Title: Control of FES and an Electric Motor Drive for a hybrid gait neuroprosthesis	
Received: 02/19/2015	FOA: PA13-304	Council: 10/2015
Competition ID: FORMS-C	FOA Title: NIH SMALL RESEARCH GRANT PROGRAM (PARENT R03)	
1 R03 HD086529-01	Dual:	Accession Number: 3793246
IPF: 2059802	Organization: UNIVERSITY OF PITTSBURGH AT PITTSBURGH	
Former Number:	Department: Mechanical Eng & Materials Sci	
IRG/SRG: CHHD-K	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 50,000 Year 2: 50,000	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N	New Investigator: N Early Stage Investigator: N
Senior/Key Personnel:	*Organization:*	*Role Category:*
[redacted] Ph.D	University of Pittsburgh	PD/PI
[redacted] M.D.	University of Pittsburgh	Co-Investigator
[redacted] Ph.D	VA Medical Research & Education Foundation	Consultant
[redacted]	VA Medical Research & Education Foundation	Consultant
[redacted] Ph.D	VA Medical Research & Education Foundation	Consultant

OMB Number: 4040-0001
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier**

1. TYPE OF SUBMISSION*	**4.a. Federal Identifier**
❍ Pre-application ● Application ❍ Changed/Corrected Application	**b. Agency Routing Number**
2. DATE SUBMITTED / **Application Identifier**	**c. Previous Grants.gov Tracking Number**

5. APPLICANT INFORMATION — **Organizational DUNS*:** 004514360

Legal Name*:	University of Pittsburgh
Department:	Office of Research
Division:	Engineering
Street1*:	123 University Place, B21
Street2:	
City*:	Pittsburgh
County:	Allegheny
State*:	PA: Pennsylvania
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	15213-2303

Person to be contacted on matters involving this application

Prefix: Dr. First Name*: Jennifer Middle Name: E. Last Name*: Woodward Suffix: Ph.D

Position/Title:	Assoc. Vice Provost for Research Operations
Street1*:	123 University Place, B21
Street2:	
City*:	Pittsburgh
County:	Allegheny
State*:	PA: Pennsylvania
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	15213-2303

Phone Number*: 412-624-7400 Fax Number: 412-624-7409 Email: offres@offres.pitt.edu

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 1250965591A6

7. TYPE OF APPLICANT* X: Other (specify)

Other (Specify): Private Non-Profit State Related Educational Inst.

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ❍ Resubmission

❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).

❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration

❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Control of FES and an Electric Motor Drive for a hybrid gait neuroprosthesis

12. PROPOSED PROJECT

Start Date*	Ending Date*
09/01/2015	08/31/2017

13. CONGRESSIONAL DISTRICTS OF APPLICANT
PA-014

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Dr. First Name*: [redacted] Middle Name: Last Name*: [redacted] Suffix: Ph.D

Position/Title:	Assistant Professor
Organization Name*:	University of Pittsburgh
Department:	Mechanical Eng & Materials Sci
Division:	Engineering
Street1*:	636 Benedum Hall
Street2:	3700 O'Hara Street
City*:	Pittsburgh
County:	Allegheny
State*:	PA: Pennsylvania
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	15261-0001

Phone Number*: 412-624-9746 Fax Number: 412-624-4846 Email*: nis62@pitt.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$140,846.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$140,846.00
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ❍ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ❍ PROGRAM IS NOT COVERED BY E.O. 12372; OR

● PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or [redacted] statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: Dr. First Name*: Jennifer Middle Name: E. Last Name*: Woodward Suffix: Ph.D

Position/Title*:	Assoc. Vice Provost for Research Operations
Organization Name*:	University of Pittsburgh
Department:	Office of Research
Division:	Engineering
Street1*:	123 University Place, B21
Street2:	
City*:	Pittsburgh
County:	Allegheny
State*:	PA: Pennsylvania
Province:	
Country*:	USA: UNITED STATES
ZIP / Postal Code*:	15213-2303

Phone Number*: 412-624-7400 Fax Number: 412-624-7409 Email*: offres@offres.pitt.edu

Signature of Authorized Representative*	**Date Signed***
Brittany Croker	02/19/2015

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:1244-Cover letter.pdf

424 R&R and PHS-398 Specific
Table Of Contents

Page Numbers

OMB Number: 4040-0010
Expiration Date: 06/30/2016

Project/Performance Site Location(s)

Project/Performance Site Primary Location

❍ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name:	University of Pittsburgh
Duns Number:	0045143600000
Street1*:	636 Benedum Hall
Street2:	3700 O'Hara Street
City*:	Pittsburgh
County:	Allegheny
State*:	PA: Pennsylvania
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	15261-0001
Project/Performance Site Congressional District*:	PA-014

File Name

Additional Location(s)

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: __ 1 __ 2 __ 3 __ 4 __ 5 __ 6

If NO, is the IRB review Pending? ● **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00006790

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	1239-Project_Description.pdf
8. Project Narrative*	1240-PROJECT NARRATIVE.pdf
9. Bibliography & References Cited	1241-References.pdf
10.Facilities & Other Resources	1242-Facilities.pdf
11.Equipment	1243-Equipment.pdf

Functional electrical stimulation (FES) and a powered exoskeleton are among some of the technologies that aim to restore walking in individuals with paraplegia. FES can be used to obtain desired muscle contractions in the lower limbs through external application of low-level repetitive electrical currents. A powered exoskeleton uses electric motor drives to move the lower-limb joints. Alone, each has limitations. We aim to combine these two technologies to create a hybrid neuroprosthesis that is more advantageous than an FES-based walking system or a powered exoskeleton alone. Because of improved torque reliability, the hybrid walking orthosis can be used for a longer time or over longer distances. Moreover, the use of FES in the hybrid neuroprosthesis may provide therapeutic benefits associated with its use. Specifically, we propose to design and evaluate a new automatic controller for a hybrid walking neuroprosthesis that is composed of an FES system and a semi- powered exoskeleton.

Little research has gone into the design and evaluation of control methods for a hybrid walking neuroprosthesis. However, research on its control methods is important for ensuring operational efficiency, gait stability, and torque reliability. In our preliminary results, we show that a model predictive control-based dynamic control allocation can simultaneously control FES and an electric motor to produce a knee extension task, despite the aforementioned challenges. We also show that the new controller can adapt to muscle fatigue in the quadriceps muscle and can sustain knee extension movements for a longer period of time. The proposal's hypothesis is that the new controller can sustain limb movements for a longer period of time compared to a sole FES system and the overall power requirement will be lower than an electric motor system. The specific aims of the proposal are: (1) To physically validate the model predictive control (MPC) method that optimizes the torque contribution from FES and an electric motor in a modified hybrid leg extension machine; and (2) To physically validate the MPC method on a hybrid walking device to elicit walking in persons with spinal cord injury.

The proposed project, if successful, will lead to a hybrid walking orthosis that will be lighter and can be used for a longer time or over longer distances. Moreover, the use of FES in the hybrid neuroprosthesis will provide therapeutic benefits; e.g., application of electrical stimulation improved cardiovascular fitness and increased muscle mass and fatigue resistance.

PROJECT NARRATIVE

The proposed project will evaluate a method to control a hybrid walking device composed of functional electrical stimulation (FES) and a lower-limb powered exoskeleton. By enhancing the powered exoskeleton with FES, the research aims to maximize the time and distance a user can walk with the hybrid device. The research may increase physical activity and ambulation capacity of individuals with mobility impairments, which may lead to their higher levels of community participation and quality of life.

Facilities and other Resources

Neuromuscular and Robotics laboratory

The Neuromuscular and Robotics laboratory (NCRL), overseen by Dr. [redacted] is located in the Department of Mechanical Engineering and Materials Science at the University of Pittsburgh. It occupies an area of 550 square feet on the second floor of the Benedum Hall. The experiments on participants and their training with the hybrid brace will be conducted in NCRL. The participants using wheelchair have easy access to the Benedum Hall. The laboratory contains all the necessary equipment and software related to the project. The PI has his own secured office on the 5th floor of the Benedum Hall and has private computer and laptop. NCRL currently hosts 2 PhD students, 5 M.S students, and 2 undergraduate students. These students have access to their own desktop computers. The PI has also access to Swanson School of Engineering's machine shop. The shop has equipment for rapid prototyping, additive manufacturing, machining, etc.

The University of Pittsburgh Medical Center (UPMC), Dept. of Physical Medicine and Rehabilitation (PM&R)

The UPMC Dept. of PM&R is one of the leading academic Rehabilitation practices in the country, consistently ranks in the top 3 Departments in National Institutes of Health funding for rehabilitation research. Our practice consists of over 40 physiatrists and PhD faculty and a residency program with 38 residents and interns. Our Department is affiliated with the University of Pittsburgh School of Medicine**,** which is one of the highest ranking and heavily funded medical schools in the nation. Our Department houses NIDRR Model Centers for Spinal Cord Injury and Traumatic Brain Injury. We have 7 inpatient rehabilitation units and several outpatient specialty clinics which comprise the UPMC Rehabilitation Institute. Some of these clinics are described below.

The Adult and Pediatric Spinal Cord Injury Clinics

The Pediatric Spinal Cord Injury Clinic at Children's Hospital of Pittsburgh (CHP) is a multidisciplinary clinic that serves individuals from newborn to age 21 years. The Adult Spinal Cord Injury Clinic is located at UPMC Mercy Hospital and sees patients age 16 and up. Combined, these clinics serve over 700 individuals with spinal cord injury and are a regular source of recruitment for Dr. [redacted] studies.

The UPMC Center for Assistive Technology

The UPMC Center for Assistive Technology (CAT) is a joint partnership between UPMC and the University of Pittsburgh. Dr. [redacted] is the Medical Director. During a clinic visit, a team of physiatrists, assistive technology practitioners, therapists, engineers, and durable medical equipment suppliers evaluate both pediatric and adult patients for all types of assistive technology including manual and power wheelchairs, and equipment for computer access, environmental control, adaptive driving, augmentative communication, audiology, and adaptive sports. CAT serves approximately 40 unique individuals with various disabilities, including spinal cord injury, every week. A satellite clinic, the Durable Medical Equipment Clinic at the Children's Pine Center, provides similar services exclusively to pediatric patients.

Center for Spinal Cord Injury

The UPMC Rehabilitation Institute is nationally designated as center of excellence in spinal cord care. The center is involved in research studies relating to cutting-edge drugs that minimize the impact of trauma to the spine Interventions meant to improve and repair connections in a damaged spinal cord.

Research Registries

We have research registries which will serve as additional sources of recruitment. These registries contain individuals who have already expressed interest in being contacted about potential research studies. The UPMC research registry contains over 3200 unique individuals. Of these, over 600 have spinal cord injury.

Equipment

1. Two eight channel functional electrical stimulators (FNS 8/16, CWE, Inc)
2. Instrumented hybrid walking neuroprosthesis with two low profile electric motors (Harmonic Drive, LLC) and a custom-designed wrap-spring clutch
3. Instrumented leg extension machine for model identification and closed-loop control during FES- elicited leg extension. LEM is integrated with an electric motor drive to generate redundancy in the system
4. A Windows machine with 12-core Intel processor for running optimization algorithms
5. IMPROV motion capture system (Phase Space Inc, USA)
6. QPIDe (Quanser, Inc., Canada) - real-time control and data acquisition system for Windows
7. A physical therapy table
8. xPC Target Machine (Speedgoat GmbH)
9. Aluminum track-based body unweighing system to support 30 feet of walking
10. Instrumented walker to measure load on a user's arm
11. Baxter Robot-Rethink Robotics

OMB Number: 4040-0001
Expiration Date: 06/30/2016

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: Dr. First Name*: [redacted] Middle Name Last Name*: [redacted] Suffix: Ph.D

Position/Title*:	Assistant Professor
Organization Name*:	University of Pittsburgh
Department:	Mechanical Eng & Materials Sci
Division:	Engineering
Street1*:	636 Benedum Hall
Street2:	3700 O'Hara Street
City*:	Pittsburgh
County:	Allegheny
State*:	PA: Pennsylvania
Province:	
Country*:	USA: UNITED STATES
Zip / Postal Code*:	15261-0001

Phone Number*: 412-624-9746 Fax Number: 412-624-4846 E-Mail*: nis62@pitt.edu

Credential, e.g., agency login: [redacted]

Project Role*: PD/PI Other Project Role Category:

Degree Type: Ph.D. Degree Year: 2010

	File Name
Attach Biographical Sketch*:	1234-[redacted] [redacted] nih-biosketch 02-17 15
Attach Current & Pending Support:	

Tracking Number: GRANT11841465 Funding Opportunity Number: PA-13-304 . Received Date: 2015-02-19T12:54:22.000-05:00

PROFILE - Senior/Key Person			
Prefix: Dr. First Name*: Brad	Middle Name E.	Last Name*: [redacted]	Suffix: M.D.

Position/Title*: Associate Professor
Organization Name*: University of Pittsburgh
Department: Physical Medicine & Rehab.
Division: Medicine
Street1*: Kaufmann Medical Bldg., Suite 202
Street2: 3471 Fifth Avenue
City*: Pittsburgh
County:
State*: PA: Pennsylvania
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 15261-0001

Phone Number*: 412-648-6138 | Fax Number: 412-692-4410 | E-Mail*: [redacted]pitt.edu

Credential, e.g., agency login:

Project Role*: Co-Investigator	Other Project Role Category:
Degree Type: M.D.	Degree Year: 2001
	File Name
Attach Biographical Sketch*:	1235-BIOSKETCH_[redacted]pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person			
Prefix: Dr. First Name*: Ronald	Middle Name J.	Last Name*: [redacted]	Suffix: Ph.D

Position/Title*: Professor
Organization Name*: VA Medical Research & Education Foundation
Department: Orthopaedics & Biomedical Eng.
Division:
Street1*: VA Advanced Platform Technology Center
Street2: 10701 East Blvd.
City*: Cleveland
County:
State*: OH: Ohio
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 44106-1702

Phone Number*: 216-791-3800 | Fax Number: 216-231-3433 | E-Mail*: ronald[redacted]case.edu

Credential, e.g., agency login:

Project Role*: Consultant	Other Project Role Category:
Degree Type: Ph.D.	Degree Year: 1986
	File Name
Attach Biographical Sketch*:	1[redacted]ketch_[redacted] 150127 [redacted]pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person				
Prefix: Mr.	First Name*: Rudi	Middle Name	Last Name*: [redacted]	Suffix:

Position/Title*: Senior Biomedical Engineer
Organization Name*: VA Medical Research & Education Foundation
Department:
Division:
Street1*: VA Advanced Platform Technology Center
Street2: 10701 East Blvd.
City*: Cleveland
County:
State*: OH: Ohio
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 44106-1702

Phone Number*: 216-791-3800 Fax Number: 216-231-3433 E-Mail*: [redacted]fescenter.org

Credential, e.g., agency login:

Project Role*: Consultant	Other Project Role Category:
Degree Type: M.S.	Degree Year: 1980

	File Name
Attach Biographical Sketch*:	1 [redacted]Biosketch_Feb2015_[redacted]pdf
Attach Current & Pending Support:	

PROFILE - Senior/Key Person				
Prefix: Dr.	First Name*: Musa	Middle Name L.	Last Name*: [redacted]	Suffix: Ph.D

Position/Title*: Research Associate Professor
Organization Name*: VA Medical Research & Education Foundation
Department:
Division:
Street1*: VA Advanced Platform Technology Center
Street2: 10701 East Blvd.
City*: Cleveland
County:
State*: OH: Ohio
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 44106-1702

Phone Number*: 216-791-3800 Fax Number: 216-231-3433 E-Mail*: musa.[redacted]case.edu

Credential, e.g., agency login:

Project Role*: Consultant	Other Project Role Category:
Degree Type: Ph.D.	Degree Year: 1985

	File Name
Attach Biographical Sketch*:	1 [redacted]Biosketch_02122015.pdf
Attach Current & Pending Support:	

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: [redacted]

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted]

POSITION TITLE: Assistant Professor, Mechanical Engineering and Materials Science, University of Pittsburgh

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Alberta, Edmonton, AB	Postdoctoral Fellow	09/2012	Walking rehabilitation
University of Florida, Gainesville, FL, USA	PhD	08/2010	Mechanical Engineering
University of Florida, Gainesville, FL, USA	M.S.	05/2008	Mechanical Engineering
Thapar University, India	B.E.	06/2004	Industrial Engineering

A. Personal Statement

My long term research goal is to improve quality of life and community participation of individuals with paraplegia by using a hybrid walking exoskeleton. This type of exoskeleton uses functional electrical stimulation (FES) and a lower-limb powered exoskeleton. This combination may increase walking distance and time spent using the device. I am an expert in control system engineering, robotics, and modeling of dynamical systems. My PhD dissertation was on new nonlinear control methods for FES. My postdoctoral training, under the supervision Dr. Richard Stein (inventor/co-inventor of C-Leg and WalkAide), was on optimizing walking movements of individuals with spinal cord injury using an FES-based walking brace. I will be using these skills to design an innovative automatic control method to control FES and the semi-powered lower-limb orthosis. I am extremely motivated to do the proposed research. Since I have joined the University of Pittsburgh as an Assistant Professor, my research group has raced to complete two hybrid neuroprosthesis platforms. Both of these platforms will be used to evaluate the proposed control methods. To perform this project, I am also teaming with a physiatrist who specializes in spinal cord injury. I will be mentored and will get consultation from a team of experts in hybrid walking neuroprosthesis. The project will also hire a physical therapist who will provide consultation as well as provide physical therapy services. Overall, for the project's success, I believe that the project has access to necessary physical resources, expertise in control theory and robotics; consultation from a team for experts who specializes in walking restoration in paraplegia and collaborators who have clinical experience in spinal cord injury.

1. [redacted] **N**, Dani A. Nonlinear Estimation of Gait Kinematics during Functional Electrical Stimulation and Orthosis-based Walking. American Control Conference; 2014 Jun 4-6; Portland, Oregon. 4778-83 (invited). doi: 10.1109/ACC.2014.6859342
2. Alibeji N, Kirsch N, [redacted] **N**. Dynamic Surface Control of Neuromuscular Electrical Stimulation of a Musculoskeletal System with Activation Dynamics and an Input Delay. American Control Conference; Chicago, IL. 2015. (accepted).

3. Kirsch N, Alibeji N, [redacted] **N**. Model Predictive Control-based Dynamic Control Allocation in a Hybrid Neuroprosthesis. In: ASME 2014 Dynamic Systems and Control Conference. 2014 Oct 22-24; San Antonio, Texas. ASME, 2014 Oct. 8 (invited). doi: 10.1115/DSCC2014-6133
4. Kirsch N, Alibeji N, Fisher LE, Gregory C, [redacted] **N.** A Semi-Active Hybrid Neuroprosthesis for Restoring Lower Limb Function in Paraplegics. In: 2014 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. 2014 Aug 26-30; Chicago, IL. IEEE, 2014. 2557-2560. doi: 10.1109/EMBC.2014.6944144
5. Wang Q, [redacted] **N**, Johnson M, Gregory CM, Dixon WE. Adaptive Inverse Optimal Neuromuscular Electrical Stimulation. IEEE transactions on cybernetics. 2013 Jan 9; 43 (6):1710-1718.
6. Wang Q, [redacted] **N**, Johnson M, Gregory CM, Dixon WE. Adaptive Inverse Optimal Neuromuscular Electrical Stimulation. IEEE Transactions on Cybernetics. 2013; 43 (6):1710-1718.
7. Fischer N, Dani A, [redacted] **N**, Dixon WE. Saturated Control of an Uncertain Nonlinear System with Input Delay. Automatica. 2013; 49 (6):1741-1747.
8. Fisher N, Kamalapurkar R, [redacted] **N**, Dixon W. RISE-Based Control of an Uncertain Nonlinear System With Time-Varying State Delays. IEEE Conference on Decision and Control; 2012 Dec 10-13; Maui, Hawai. 2012. 3505-3507.
9. [redacted] **N.** Predictor-based Compensation for Electromechanical Delay during Neuromuscular ElectricalStimulation-II. American Control Conference; Montreal, QC. 2012. 5604-5609.
10. Downey RJ, Bellman M, [redacted] **N,** Wang Q, Gregory CM, Dixon WE. A Novel Modulation Strategy to Increase Stimulation Duration in Neuromuscular Electrical Stimulation. Muscle & nerve. 2011 Sep; 44 (3):382-7.
11. Gregory C, Bickel CS, [redacted] **N**, Dixon W. Comparing the Force and Excursion-Frequency Relationships in Human Skeletal Muscle. Muscle and Nerve. 2008; 38 (6):1627-9.

B. Positions and Honors

<u>Positions and Employment</u>

9/2012 - Present	Assistant Professor, Mechanical Engineering and Materials Science, University of Pittsburgh, Pittsburgh, PA
2010 - 2012	Postdoctoral Fellow, Physiology, University of Alberta
6/2004 - 6/2006	Assistant Manager, Production Engineering, Maruti Suzuki India Ltd, Gurgaon, India

<u>Other Experience and Professional Memberships</u>

2011 - Present	Member, EMBS
2007 - Present	Member, IEEE

<u>Honors</u>

2011	Alberta Innovates Health Solutions Fellowship Award
2011	MAE Department Best Dissertation Award
2010	Best Presentation in Session Award at the American Control Conference, Baltimore, MD
2009	O. Hugo Schuck Award
2009	Best Student Paper Award in Robotics
2008	Finalist for Best Student Paper Award at the IEEE Multi-Conference on Systems and Control, San Antonio, Texas

C. Contribution to Science

1. New Nonlinear Control methods for FES. The objective of this research was to design an automatic controller for FES to elicit muscle contractions as per a user-specified desired command; e.g., an FES controller designed to compute stimulation current amplitudes to produce desired lower-limb movements. However, the control of FES is complicated due to nonlinear and time-varying musculoskeletal dynamics. Existing automatic controllers cannot produce desired limb movements due to these challenges. This research has led to the development of FES control designs that have superior performance in terms of producing desired limb motions when compared to existing FES controllers. These results have potential applications in various FES-elicited tasks such as arm reaching, gait retraining or restoration, etc.
    a. [redacted] **N,** Patre P, Gregory C, Dixon W. Nonlinear Control of NMES: Incorporating Fatigue and Calcium Dynamics. ASME Dynamic Systems and Control Conference; Hollywood, CA. ASME 705-712.
    b. [redacted] **N**, Gregory CM, Johnson M, Dixon WE. Closed-loop Neural Network- based NMES Control for Human Limb Tracking. IEEE Transactions on Control Systems Technology. 2012 May; 20 (3):712-725.
    c. [redacted] **N**, Gregory CM, Dixon WE. Predictor-based Compensation for Electromechanical Delay during Neuromuscular Electrical Stimulation. IEEE transactions on neural systems and rehabilitation engineering. 2011 Dec; 19 (6):601-11.
    d. [redacted] **N**, Stegath K, Gregory CM, Dixon W. Nonlinear Neuromuscular Electrical Stimulation Tracking Control of a Human Limb. IEEE Transactions on Neural Systems and Rehabilitation Engineering. 2009; 17 (6):576-584.

2. Dynamic Optimization of FES-based Walking. This research has looked into the problem of dynamic optimization for FES-based walking neuroprostheses. In this project, a mathematical model that captures the dynamics of FES, a passive or active orthosis, and the body segmental dynamics of a user with a walker was developed. An optimization technique was employed to compute the desired gait parameters and stimulation profiles based on the computer model of walking. These model-based optimal solutions overcome the current limitations of walking control algorithms such as dependence on the gait parameters of an able-bodied person or mimicking EMG activity of able-bodied persons to tune stimulation profiles. The advantage of the model and the optimization technique is that the optimal gait parameters such as optimal step length, specific to a user can be identified and can be used as a reference trajectory or can be used to optimize a user's gait with an FES and passive orthosis system
    a. [redacted] **N**, Mushahwar V, Stein R. Dynamic Optimization of FES and Orthosis- based Walking using Simple Models,. IEEE Transactions on Neural Systems and Rehabilitation Engineering. 2014; 22 (1):114-126.
    b. Kirsch N, Alibeji N, [redacted] **N**. Optimized Control of Different Actuation Strategies for FES and Orthosis aided Gait. ASME Dynamic Systems and Control Conference; 2013 Oct 21-23; Palo Alto, CA. 2013. (accepted) (invited).
    c. [redacted] **N**, Stein R. Gait Planning and Double Support Phase Model for Functional Electrical Stimulation-based Walking. in the conference proceedings of Annual International Conference of the IEEE Engineering in Medicine and Biology Society. 2012; 1904-7.
    d. [redacted] **N**, Stein R. Optimal Trajectory Planning for a Constrained Functional Electrical Stimulation-based Human Walking. in the conference proceedings of Annual International Conference of the IEEE Engineering in Medicine and Biology Society. 2011; 603-7.

3. Nonlinear control of time-delayed systems. This research has primarily focused on compensating time delays in general nonlinear systems. Time delay is an effect caused by mechanical or chemical or biological processes that take a finite time to influence or produce change in system dynamics. Unaccounted delays complicate the control design for the system dynamics, which means obtaining a desired behavior from the dynamics is difficult. Existing control designs for delay compensation are meant for linear systems, which means their performance to deal with nonlinearities may not satisfactory. I developed the first-ever predictor type controllers for an unknown Euler-Lagrange system (a robotic or an automated mechanical system) with a known constant input delay. The controllers compensate for input delay without requiring knowledge of the nonlinear system dynamics. The control design has been successfully shown to stabilize and produce accurate desired behavior in FES-controlled lower limbs and a robotic system.
    a. Alibeji N, Kirsch N, [redacted] **N**. Control of Functional Electrical Stimulation in the Presence of Electromechanical and Communication Delays. 6th International IEEE EMBS Conference on Neural Engineering; 2013 Nov 6-8; San Diego, CA. IEEE 299-302.
    b. Alibeji N, Kirsch N, Sethi A, [redacted] **N.** A State Synchronization Controller for Functional Electrical Stimulation-Based Telerehabilitation. In: ASME 2014 Dynamic Systems and Control Conference. 2014 Oct 22-24; San Antonio, Texas. ASME V003T43A004; 9 pages (invited). doi: 10.1115/DSCC2014-6139
    c. [redacted] **N**, Bhasin S, Wang Q, Dixon WE. RISE-based Adaptive Control of a Control Affine Uncertain Nonlinear System with Unknown State Delays. IEEE Transactions on Automatic Control. 2012 Jan; 57 (1):255-259.
    d. [redacted] **N**, Bhasin S, Wang Q, Dixon W. Predictor-Based Control for an Uncertain Euler-Lagrange System with Input delay. Automatica. 2011; 47 (11):2332-2342.

Complete List of Published Work in MyBibliography:
http://engineering.pitt.edu/Sub-Sites/Labs/[redacted]Lab/Publications/

D. Research Support

Ongoing Research Support

([redacted] 07/01/14 - 07/01/16
Central Research Development Fund (internal)
Model Predictive Control for a Hybrid Neuroprosthesis
The overall goal of the project is develop a model predictive control for a hybrid neuroprosthesis.
Role: PI (sole)

([redacted] 07/01/14 - 07/01/16
Central Medical Research Fund
Modeling and Optimization for a Personalized HybridWalking Neuroprosthesis
Role: PI (sole)

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Brad Edward [redacted] MD	Associate Professor, Physical Medicine and Rehabiliation
eRA COMMONS USER NAME [redacted]	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training)*

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
University of Pittsburgh, Pittsburgh, PA	BS	July 1993-June 1997	Ecology & Evolutionary Biology
University of Pittsburgh, Pittsburgh, PA	BA	July 1993-June 1997	History & Philosophy of Science (HPS)
University of Pittsburgh School of Medicine Pittsburgh, PA	MD	July 1997-June 2001	Medicine
University of Pittsburgh, Pittsburgh, PA	MS	July 2005-Dec 2008	Bioengineering

Professional Certifications

Specialty Certification: 2006 — American Board of Physical Medicine & Rehabilitation

Medical Licensure: 2004 – present — Pennsylvania MD-423047

A. Personal Statement: I am an Associate Professor an in the Dept. of Physical Medicine & Rehabilitation (PM&R) at the University of Pittsburgh Medical Center (UPMC). I am a physiatrist and bioengineer. I serve as the Medical Director of the Center for Assistive Technology, which is a multidisciplinary clinic that provides state-of the art technology, including wheelchairs and advanced seating systems, to children and adults with a variety of disabilities including spinal cord injury. I have been first author or co-author on a number of clinical practice guidelines related to the provision and medical efficacy of wheelchairs and related technology, which were published by the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA). I also am the Medical Director of the Human Engineering Research Laboratories, where I direct a number of different studies on mobility assistive equipment with the goal of enhancing mobility in those with disabilities including spinal cord injury. On this project, my role will be to assist with recruitment and provide medical oversight of gait experiments.

B. Positions and Honors

Selected Research and/or Professional Experience

2001-2005	Medical Residency, full-time, Univ. of Pittsburgh Medical Center (UPMC) Dept. of Physical Medicine & Rehabilitation (PM&R)
2004-2005	Administrative Chief Resident, full-time, UPMC Dept. of PM&R
2004-2008	Phase I Trainee, full-time, Rehabilitation Medicine Scientist Training Program, National Institutes of Health (NIH), National Institute of Child Health Human Development (NICHD), National Center for Medical Rehabilitation Research (NCMRR), & Association of Academic Physiatrists (AAP), Rory A. Cooper, PhD-Chair
2005-2006	Investigator, full-time, Human Engineering Research Laboratories, VA Pittsburgh Health Care System & University of Pittsburgh, Pittsburgh, PA , Rory A. Cooper, PhD-Chair
2005-2006	Clinical Instructor, full-time, UPMC Dept. of Physical Medicine and Rehabilitation
2005-present	Director full-time, UPMC Adult Spina Bifida Outpatient Clinic
2005-present	UPMC Physician Advisory Committee on the implementation and use of Electronic Medical Records
2006-present	Associate Medical Director, full-time, Human Engineering Research Laboratories, VA Pittsburgh Health Care System & University of Pittsburgh, Pittsburgh, PA , Rory A. Cooper, PhD-Chair
2006-present	Assistant Professor, full-time, entered tenure-stream August 2006 UPMC Dept. of PM&R
2006-present	Medical Director, full-time, UPMC Center for Assistive Technology
2007-present	Assistant Professor-Secondary Appointment, full-time, University of Pittsburgh, Dept. of Rehabilitation Science & Technology, Rory A. Cooper, PhD-Chair

2007-present Medical Advisory Committee, Spina Bifida Association of Western Pennsylvania
2009-present Director, Medical Student Research and Education, UPMC Dept. of PM&R
2011-present Director, UPMC Center for Wellness for Individuals with Spina Bifida and Spinal Cord Injury
2012-present Associate Professor, full-time, tenure-stream UPMC Dept. of PM&R
2015-present Medical Director, Human Engineering Research Laboratories

Selected Honors

1999 AAP Award for Best Paper Presentation, AAP National Conference, Orlando, FL
2001 AAP Award for Best Paper Presentation, AAP National Conference, Hilton Head, SC
2004 AAP Award for Best Paper Presentation, AAP National Conference, Albuquerque, NM
2008 AAP Award for Best Paper Presentation, AAP National Conference, Anaheim, CA
2008 Innovative Design Award, Dept. of Rehabilitation Science and Technology, Univ. of Pittsburgh
2010 *AAP Award for Best Paper Presentation, AAP National Conference, Bonita Springs, FL
2010 University of Pittsburgh "Big Idea" Competition Award
2010 Wellspring Worldwide "What If" Competition Award
2011 AAP Young Academician Award
2012 Research Award, First Place, 2nd World Congress on Spina Bifida Research and Care
2012 Medicaid Health Plans of America Annual Best Practices Compendium Award Finalist.
2013 UPMC Health Plan Award for Outstanding Contribution to Innovation in Patient Care and Clinical Outcomes, UPMC Health Plan Conclave, Nemacolin, PA, June 6, 2013.
2014 Pitt Innovator Award, for inventing technologies that were licensed to a startup company

Professional Societies

1997 Conceptual Foundations of Medicine Certificate in Medical Ethics, Univ. of Pittsburgh
1997-2001 Area of Concentration in Disabilities Medicine Certificate, Univ. of Pittsburgh School of Medicine
2001-present Member, Association of Academic Physiatrists (AAP)
2001-2011 Member, American Academy of Physical Medicine and Rehabilitation (AAPMR)
2005-present Member, Rehabilitation Engineering and Assistive Technology Society of North America
2005-present Spina Bifida Assoc. of Western PA Medical Wellness Advisory Committee
2006-present Clinician Task Force: Coalition to Modernize Medicare Coverage of Mobility Devices
2007-present Director, Rehabilitation Research Experience for Medical Students, AAP
2007-present Nurses and Health Professional Committee, Spina Bifida Association (national)
2007-2010 Centers for Disease Control Summit Panel on Transitional Care in Spina Bifida
2010-present Spina Bifida Assoc. of Western PA Housing and Planning Committee
2010-present Spina Bifida Association Professional Advisory Council (national)
2010-present Planning and Education Committee, Spina Bifida World Congress (international)
2011-present Committee for Science and Publication, National Spina Bifida Patient Registry
2011-present Coordinating Committee, National Spina Bifida Patient Registry
2012-present Chair, Krainak Program on Adult Care, Spina Bifida Association (national)
2014-present Medical Director of Adult Care, Spina Bifida Clinical Care Network (national)

SELECTED PEER-REVIEWED JOURNAL ARTICLES:

*Dr. [redacted] has over 40 published or in press peer-reviewed journal articles, ***** indicates corresponding author status, § indicates mentorship on student or resident publication*

Peer Reviewed Articles

1. Stepanczuk B, § [redacted] BE, Webb T. Young adults with Spina Bifida may have higher occurrence of prehypertension and hypertension. Am J Phys Med Rehabil. PMID: 24088776. In Press.
2. Crytzer TM, §* [redacted] BE, Fairman AD. Effectiveness of an upper extremity exercise device and text message reminders to exercise in adults with spina bifida: a pilot study. Assistive Technology 2013. 25(4). In Press.
3. Bellin MH, [redacted] BE, Osteen P, Dosa N, Aparicio E, Braun P, Zabel AT. Longitudinal Analysis of Family Satisfaction, Pain, and Quality of Life in Young Adults with Spina Bifida. Am J Phys Med Rehabil. 2013. Aug;92(8):641-55. PMID: 23867887.

4. Parmanto B, Pramana G, Yu DX, Fairman AD, [redacted] BE, McCue MP. iMHere: A Novel mHealth System for Supporting Self-Care in Management of Complex and Chronic Conditions JMIR Mhealth Uhealth 2013;1(2):e10. URL: http://mhealth.jmir.org/2013/2/e10/.
5. Fairman AD, § [redacted] BE, Datt N, Garver A, Parmanto B, McCue M. Outcomes of Clinicians, Caregivers, Family Members and Adults with Spina Bifida Regarding Receptivity to use of the iMHere mHealth Solution to Promote Wellness. International Journal of Telerehabilitation. Jun. 2013. URL: http://telerehab.pitt.edu/ojs/index.php/Telerehab/article/view/6116.
6. Kamaraj DC, § [redacted] BE, Cooper RA, Hunter J, Tang JL. Acute Mountain Sickness in athletes with neurological impairments. J Rehabil Res Dev. *2013* Apr;50(2):253-62. PMID: 23761006.
7. Bellin MH, Dosa N, Zabel TA, Aparicio E, [redacted] BE, Osteen P. Self-management, satisfaction with family functioning, and the course of psychological symptoms in emerging adults with spina bifida. J Ped Psych 2013; 38(1): 50-62. PMID: 22976508.
8. Mahmood D, § [redacted] BE, Bellin MH. Self management, preventative conditions, and assessment of care among young adults with myelomeningocele. Child Care Health Dev. 2011 Nov;37(6):861-5. PMID: 22007986.
9. Wilson R, Lewis SA, [redacted] BE. Targeted preventive care may be needed for adults with congenital spine anomalies. PM&R. 2011; Aug;3(8):730-8. PMID: 21871417.
10. Bellin MH, Zabl TA, [redacted] BE, Levey E, Dosa N, Roux G, Marben K. Interrelationships of gender, level of lesion, and transition outcomes among young adults with myelomeningocele. Dev Med Child Neurol. 2011 Jul;53(7):647-52. PMID: 21410695.
11. Chan W, § [redacted] BE. Virtual socialization in adult spina bifida. PM&R. 2011; 3(3):219-25. PMID: 21402368.
12. Garcia AM, § [redacted] BE. The frequency of lymphedema in an adult spina bifida population. Am J Phys Med Rehabil. 2011;90(2):86-96. PMID: 21173682.
13. [redacted] BE, Wilson R. Hospitalizations of adults with spina bifida with congenital spinal cord anomalies. Arch Phys Med Rehabil. 2010; 91: 529-35. PMID: 20382283.
14. Bellin MH, Zabel TA, [redacted] BE, Levey E, Garver K, Linroth R, Braun P. Correlates of depressive and anxiety symptoms in young adults with spina bifida. J Pediatr Psychol. 2010; 35(7): 778-89. PMID: 19880443.
15. § [redacted] BE, Kurowski B, Yang J, Chancellor M, Bejjani G, Fairman A, Lewis N, Sotirake J. Rehabilitation and medical management of the adult with spina bifida. Am J Phys Med Rehabil. 2008; 87(12): 1027-50. PMID: 15923330
16. § [redacted] BE, Aguila ED, Cooper RA, Pasquina PF, Clark MJ, Collins DM, Fitzgerald SG, Wichman TA. Acute mountain sickness in disability and adaptive sports: preliminary data. JRRD. 2009; 45(4): 479-87. PMID: 18712635.
17. Sporner ML, Fitzgerald SG, § [redacted] BE, Collins DM, Teodorski E, Pasquina PF, Cooper RA. Psychosocial impact of participation in the National Veterans Wheelchair Games and Winter Sports Clinic. Disabil Rehabil. 2009; 31(5): 410-8. PMID: 18608391.
18. [redacted] BE, Tovey E. Power mobility device provision: understanding Medicare guidelines and advocating for clients. Arch Phys Med Rehabil. 2007; 88(6): 807-16. PMID: 17532908.
19. § [redacted] BE, Spaeth DM, Cooper RA, Fitzgerald SG, Boninger ML, Brown KW. Force control strategies while driving electric powered wheelchairs with isometric and movement-sensing joysticks. IEEE Trans Neural Sys Rehab Eng. 2007; 12(1): 144-50. PMID: 17436887.
20. [redacted] BE, Spaeth DM, Cooper RA, Fitzgerald SG, Boninger ML. Advancements in power wheelchair joystick technology; effects of isometric joysticks and signal conditioning on driving performance. Am J Phys Med Rehabil. 2006; 85(8):631-9. PMID: 16865017.

21. Boninger ML, [redacted] BE, Cooper RA, Towers JD, Koontz AM, Souza AL. Shoulder magnetic resonance imaging abnormalities: wheelchair propulsion, and gender. Arch Phys Med Rehabil. 2003; 84(11):1615-20. PMID: 1463950.

22. Boninger ML, Cooper RA, Fitzgerald SG, Lin J, [redacted] BE, Liu B. Investigating neck pain in wheelchair users. Am J Phys Med Rehabil. 2003; 82(3): 197-202. PMID:12595772.

23. Boninger ML, Towers JD, Cooper RA, [redacted] BE, Munin MC. Shoulder imaging abnormalities in individuals with paraplegia. J Rehabil Res Dev. 2001; 38(4): 401-8. PMID: 11563493.

24. Pegoraro E, Mancias P, Swerdlow S, Raikow R, Garcia C, Marks H, Crawford T, Carver V, [redacted] B, Hoffman E. Congenital muscular dystrophy with primary laminin alpha-2 (merosin) deficiency presenting as inflammatory myopath. Ann Neurol. 1996: 782-91. PMID: 8957020.

Invited Reviews

1. Arledge S, Armstrong W, Babinec M, [redacted] BE, et al. RESNA Wheelchair Service Provision Guide. Assist Technol. 2013; *in press.*

2. [redacted] BE, Morgan A, Lieberman J, Rosen L. RESNA Position on the Application of Wheelchair Standing Devices: 2013 Current State of the Literature. http://www.resna.org/resources/position-papers/RESNAStandingPositionPaper_Dec2013.pdf

3. Crytzer TM, [§*][redacted] BE. Physical Activity, Exercise and Health Related Measures of Fitness in Adults with Spina Bifida: A Review of the Literature. PM&R. 2013; Dec;5(12):1051-62. PMID: 24332229.

4. [§][redacted] BE, Peele P, Lovelace J, Fairman A, Smyers D, Halgas M, Burkholder K, Boninger ML. Specialty medical homes and wellness services in congenital and acquired spinal cord injury. American Medical Group Association Compendium of Chronic Care Practices. 2013. http://www.amga.org/Research/Research/CCI/compendiums_cci.asp.

5. [§][redacted] BE, Fairman AD, Braun PG, Zabel TA. Using the spina bifida lifecourse model in clinical practice: an interdisciplinary approach. Pediatr Clin North Am. 2010; 57(4):945-57. PMID: 20883884.

6. Swanson ME, [redacted] BE. Physiatrists and developmental pediatricians working together to improve outcomes in children with spina bifida. Pediatr Clin North Am. 2010; 57(4): 973-81. PMID: 20883886.

7. Fairman AD, Thibadeau JK, [§][redacted] BE, Parmanto B. Implementing a specialty electronic medical record to document a life-course developmental model and facilitate clinical interventions in spina bifida clinics. Pediatr Clin North Am. 2010; 57(4): 959-71. PMID: 20883885

8. [redacted] BE, Cooper RA, Coltellaro J. Joystick control for powered mobility: current state of technology and future directions. Phys Med Rehabil Clin North Am. 2010; 21(1): 79-86. PMID: 19951779.

9. Arva J, Paleg J, Lange M, Liberman J, Schmeler M, [redacted] B, Babinec M, Rosen L. RESNA position on the application of wheelchair standing devices. Assist Technol. 2009; 21: 161-8. PMID: 19908680.

10. [redacted] BE, Lieberman J, Schmeler M, Souza A, Phillips K, Lange M, Cooper R, Davis K. RESNA SIG-09 position on the application of tilt in space, lateral/rotational tilt, reclining backrest, and elevating leg rests for wheelchair users. Assist Technol. 2009; 21: 13-22. PMID: 19719059.

11. Cooper RA, [§][redacted] BE, Brewer B, LoPresti E, Ding D, Simpson R, Grindle G, Wang H. A perspective on intelligent devices and environments in medical rehabilitation. Med Eng Phys. 2008; 30(10):1387-98. PMID: 18993108.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
[redacted] Ronald J.	Professor Orthopaedics & Biomedical Engineering Case Western Reserve University
eRA COMMONS USER NAME [redacted]	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Villanova University, Villanova PA	B.S.E.E.	1976 - 1980	Electrical Engineering
Drexel University, Philadelphia PA	M.S.B.E.	1980 - 1982	Biomedical Engineering
Drexel University, Philadelphia PA	M.S.E.E.	1982 - 1984	Electrical Engineering
Drexel University, Philadelphia PA	Ph.D.	1980 - 1986	Biomedical Engineering

A. Personal Statement.

This is to confirm my availability and willingness to serve as a consultant to Dr. [redacted] on his proposal to investigate the applicability of model predictive control (MPC) to hybrid systems combining electrical stimulation with actuated exoskeletons.

I am a Tenured Full Professor in the Departments of Orthopaedics and Biomedical Engineering at Case Western Reserve University and serve as the Director of the Motion Study Laboratory (MSL) at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center, and the Advanced Platform Technology (APT) Center of Excellence in the VA Rehabilitation R&D Service.

I have been a researcher in the field of assistive, restorative and rehabilitation technology for almost 25 years. During this time I have conducted Phase II multicenter clinical feasibility trials of implanted neuroprostheses for standing and walking, developed new multicontact peripheral nerve electrodes and exploited their selectivity to delay the onset of fatigue, and pursued original research directed toward providing new and clinically useful options for automatically regulating standing and seated balance, and designing powered exoskeletons for walking and stair climbing after paralysis. These efforts have been funded by the Department of Veterans Affairs, the National Institutes of Health, the Department of Defense and the Office of Orphan Product Development of the USFDA.

I have dedicated my professional efforts to the development and assessment of medical technologies to enhance mobility after limb loss or neurological dysfunction, including implanted neuroprostheses and robotic exoskeletons, as well as analysis and assessment tools such as fully three dimensional and anatomically realistic biomechanical models of the trunk, spine, pelvis and lower extremities. I have developed automatic control systems to maintain seated posture and balance and improve the efficiency of manual wheelchair propulsion with implanted neuroprostheses. As such, I can lend my expertise in rehabilitation engineering, biomechanics, human motor control, prosthetic and orthotic design, and evaluation of neuroprosthetic technologies to the successful completion of this worthwhile project.

B. Positions and Employment.

1986-1994	Director of Research, Philadelphia Unit of Shriners Hospitals & Clinical Assistant Professor, Department of Orthopaedic Surgery, Temple University, Phila. PA
1994-2002	Assistant Professor, Departments of Orthopaedics and Biomedical Engineering, Case Western Reserve University, Cleveland OH
2002-2009	Tenured Associate Professor, Departments of Orthopaedics and Biomedical Engineering, CWRU & Research Career Scientist, US Department of Veterans Affairs
2005-Present	Director, Advanced Platform Technology Center of Excellence, Rehabilitation R&D Service - US Department of Veterans Affairs
2007-Present	Senior Career Research Scientist, US Department of Veterans Affairs
2009-Present	Tenured Full Professor, Departments of Orthopaedics and Biomedical Engineering, CWRU

Other Experience and Professional Memberships

Associate Editor, *Journal of Rehabilitation of Rehabilitation Research & Development*, 2006 – present

White House Committee on Emerging Technologies in Support of the New Frontiers Initiative, 2004.
International Functional Electrical Stimulation Society (IFESS) – Board of Directors 2002-2005
Associate Editor, *IEEE Transactions on Neural Systems & Rehabilitation Engineering,* 1999 – 2009
IEEE Engineering in Medicine & Biology Society (EMBS), 1980 - present

Honors and Awards
Elected Fellow, American Institute of Medical and Biological Engineers, 2014
Maurice Saltzman Award for Clinical/Academic Excellence, Mount Sinai Foundation, 2004
Professional Achievement Award, Villanova University, 1992
Selected to Sigma Xi, Scientific Research Society, 1984

C. Selected Peer-Reviewed Publications (Total = 111).
Most recent relevant publications

1. [redacted] M, Lombardo L, Schenellenberger J, Foglyano K, Miller M, [redacted] **R**, A neuroprosthesis for control of seated balance after spinal cord injury, *Journal of NeuroEngineering and Rehabilitation* 15, 12-8
2. Lombardo L, Bailey S, Foglyano K, Miller M, Pinault G, [redacted] **R**, A preliminary comparison of myoelectric and cyclic control of an implanted neuroprosthehsis to modulate gait speed in incomplete SCI, *Journal of Spinal Cord Medicine* 38(1): 115-122, 2015.
3. Schiefer MA, Freeberg M, Pinault GJC, Anderson J, Hoyen H, Tyler DJ, [redacted] **RJ**, Selective activation of the human tibial and common peroneal nerves with a flat interface nerve electrode, *Journal of Neural Engineering* – (in press).
4. Bulea T, [redacted] R, [redacted] M, Schnellenberger J, Pinault G, [redacted] **R**, Forward stair descent with hybrid neuroprosthesis after paralysis: single case study demonstrating feasibility, *Journal of Rehabilitation Research & Development,* 51(7):1077-1094, 2014.
5. Bulea TC, [redacted] R, [redacted] ML, Schnellenberger JR, Pinault G, [redacted] **RJ**, Stance phase knee flexion improves stimulation driven walking after spinal cord injury, *Journal of NeuroEngineering and Rehabilitation* 2013, 10:68 DOI: 10.1186/1743-0003-10-68, PMID: 23826711, PMCID: PMC3708761
6. Murphy J, [redacted] M, Lombardo L, Foglyano K, [redacted] **R,** Feasibility of a closed-loop controller for righting seated posture after spinal cord injury, *Journal of Rehabilitation Research and Development*, 51(5): 747-760, 2014.
7. [redacted] **RJ**, Lombardo LM, Nogan-Bailey S, Miller M, Foglyano K, [redacted] ML, Effects of trunk stimulation on manual wheelchair propulsion mechanics after spinal cord injury," *Archives of Physical Medicine & Rehabilitation* 94(10):1997-2005, 2013 DOI:10.1016/j.apmr.2013.04.010, PMID: 23628377.
8. Fisher L, Tyler D, [redacted] **R**, Optimization of selective stimulation parameters for multi-contact electrodes, *Journal of NeuroEngineering and Rehabilitation* 10:25, 2013 - (in press). DOI: 10.1186/1743-0003-10-25, PMID: 23442372, PMCID: PMC3599334
9. [redacted] **R**, Lombardo L, Miller M, Nogan-Bailey S, [redacted] M, Effects of stimulating hip and trunk muscles on seated stability, posture and reach after spinal cord injury, *Archives of Physical Medicine & Rehabilitation* 94(9):1766-75, 2013. DOI: 10.1016/j.apmr.2013.02.023, PMID: 23500182
10. Bulea TC, [redacted] R, [redacted] ML, Schnellenberger JR, [redacted] **RJ**, Finite state control of a variable impedance hybrid neuroprosthesis for locomotion after paralysis. *IEEE Transactions on Neural Systems and Rehabilitation Engineering* 21(1):141-151, 2013.
11. Bulea TC, [redacted] R, To CS, [redacted] M, Schnellenberger J, [redacted] **RJ**, A variable impedance knee mechanism for controlled stance flexion during pathological gait. *IEEE Transactions on Mechatronics* 17(5):822-832, 2012.
12. Nataraj R, [redacted] M, [redacted] **R**, Center of mass acceleration feedback control of standing balance by functional neuromuscular stimulation against external postural perturbations. *Journal of Rehabilitation Research & Development* 49(6): 889-912, 2012.
13. To C, [redacted] R, Bulea TC, [redacted] ML, Schnellenberger JR, Pinault G, [redacted] **RJ**, Sensor-based stance control with orthosis and functional neuromuscular stimulation for walking after spinal cord injury. *Journal of Prosthetics and Orthotics*, 24(3):124-132, 2012.
14. Nataraj R, [redacted] M, [redacted] **R**, Comparing joint kinematics and center of mass acceleration for feedback control of standing by functional neuromuscular stimulation. *Journal of NeuroEngineering and Rehabilitation*, 9:25, 2012. Doi:10.1186/1743-0003-9-25.

15. [redacted] **RJ**, Bailey SN, Miller ME, Rohde L, Andersons JA, Davis JA, Abbas JJ, Diponio la, Forrest GP, Gater DR, Yang LJ. Longitudinal performance of a surgically implanted neuroprosthesis for lower extremity exercise, standing, and transfers after spinal cord injury. *Archives of Physical Medicine and Rehabilitation.* 93(5):896-904, 2012.

Additional recent relevant publications

1. Rohde L, Bonder B, [redacted] **R**, An exploratory study of perceived quality of life with implanted standing neuroprostheses. *Journal of Rehabilitation Research & Development* 49(2):265-278, 2012
2. [redacted] M, Nataraj R, Gartman S, [redacted] **R.** Posture shifting after spinal cord injury using functional neuromuscular stimulation – a computer simulation study, *Journal of Biomechanics*. 44: 1639-1645, 2011.
3. Schiefer MA, Polasek KH, [redacted] **RJ,** Pinault GC, Tyler DJ. Selective stimulation of the common human femoral nerve with a flat interface nerve electrode. *Journal of Neural Engineering,* 7(2010): 1-9; 026006, 2010.
4. Bailey SN, Hardin E, [redacted] R, Boggs L, Pinault G, [redacted] **R**. Neuroprosthetic and neurotherapeutic effects of implanted electrical stimulation for ambulation after incomplete spinal cord injury. *Journal of Rehabilitation Research & Development* 47(1): 7-16, 2010.
5. [redacted] ML, To C, [redacted] R, [redacted] **R**. Gait evaluation of a novel hip constraint orthosis with implication for walking in paraplegia. *IEEE Transactions on Neural Systems and Rehabilitation Engineering* 18(6): 610-618, 2010
6. Polasek KH, Schiefer MA, Pinault GCJ, [redacted] **RJ**, Tyler DJ. Intraoperative evaluation of the spiral nerve cuff electrode for a standing neuroprosthesis. *Journal of Neural Engineering*, 6(2009) 066005, 1-6, 2009.
7. Gustafson KJ, Pinault GCJ, Neville J, Syed I, Davis JA, Jean-Claude J, [redacted] **RJ**. Fascicular anatomy of the human femoral nerve: implications for standing neural prostheses utilizing nerve cuff electrodes," *Journal of Rehabilitation Research & Development*, 46(7):973-984, 2009.
8. [redacted] R, To C, Schnellenberger J, [redacted] ML, Bulea T, Gaudio R, Tashman S, [redacted] **RJ**. Development of a hybrid orthosis for standing, walking & stair climbing after spinal cord injury. *Journal of Rehabilitation Research & Development* 46:447-62, 2009.
9. [redacted] **RJ**, Boggs L, Miller M, Nagy J, Nemuanitis G, Nogan-Bailey S. Implanted electrical stimulation of the trunk for seated postural stability & functional mobility after cervical SCI: A single case study, *Archives of Physical Medicine & Rehabilitation* 90(2), 2009.
10. Fisher L, Tyler D, Anderson J, [redacted] **RJ**, Chronic stability and selectivity of four-contact spiral nerve-cuff electrodes in stimulating the human femoral nerve. *Journal of Neural Engineering* 6(2009) 046010.
11. Gartman S, [redacted] ML, Kirsch RF, [redacted] **RJ.** Selection of an optimal muscle set for a 16-channel standing FES system, *Journal of Rehabilitation Research & Development.* 45(7): 1007-1017, 2008.
12. Fisher L, Miller M, Nogan S, Davis JA, Anderson J, Murray L, Tyler D, [redacted] **RJ**, Standing after SCI with four contact nerve-cuff electrodes for quadriceps stimulation, *IEEE Transactions on Neural Sys & Rehab Eng* 16:473-8, 2008.
13. Dutta A, [redacted] R, [redacted] **R**. Ambulation after incomplete spinal cord injury with EMG-triggered functional electrical stimulation, *IEEE Trans Biomed Engr* 55(2): 791-794, 2008.
14. Mushahwar VK, Jacobs PL, Normann RA, [redacted] **RJ**, Kleitman N. New functional neuromuscular stimulation approaches to standing and walking, *Journal of Neural Engineering* 4(2007) S181-S197 - JNE/244402/SPE/114677
15. Hardin E , [redacted] R, Murray L , Corado-Ahmed M, Pinault G, Sakai J, Nogan S, Ho C , [redacted] **R**. Ambulation after incomplete spinal cord injury with an implanted FES system , *Journal of Rehabilitation Research & Development.* 44(3):333-346, 2007.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
[redacted] Rudi, M.S.B.E.	Senior Biomedical Engineer
eRA COMMONS USER NAME (credential, e.g., agency login) [redacted]	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Case Western Reserve University, Cleveland OH	B.S.	1977	Biomedical Engineering
Case Western Reserve University, Cleveland OH	M.S.	1980	Biomedical Engineering

A. Personal Statement

For over 30 years my professional effort has been dedicated to improving the lives and personal mobility of individuals paralyzed by spinal cord injuries (SCI), stroke or other disabling neurological conditions by means of electrical stimulation. I have focused on the biomechanics of stimulated muscle, the control of posture and gait and the construction of effective patterns of stimulation to restore or facilitate movement of paralyzed lower extremities with and without bracing. I have devised systems for delivering electrical stimulation to the key muscles and combine them with sensor based controllable bracing/exoskeletons to enable walking and other maneuvers important for independence of persons paralyzed from SCI. To further improve function of these systems, I contributed significantly to the design, evaluation and ongoing development of a novel hybrid neuroprosthesis (HNP) incorporating an advanced sensor-based controlled hip and knee mechanisms for walking in paraplegia. The HNP system was designed to reduce energy consumption by regulating posture through reciprocal coupling of the hips and stance phase knee flexion control during walking, to provide body weight support, adjust stimulation on a stride-to-stride basis, and restore stair ascent and descent function by controlling the resistance to knee flexion while lowering of the body during stair descent. This approach has the potential to significantly lower the energy requirement of walking and improve safety in terms of gait stability with lesser risk of falls in people disabled by SCI. I am committed to developing and evaluating the performance of the implanted HNP that I have been instrumental in developing and applying the knowledge and techniques I helped create to understanding the long-term consequences of their application. I believe many individuals with complete paralysis from SCI can benefit from HNP by improving their access to community and improve their quality of life. I am excited to join Dr. [redacted] and his team to develop controllers for a HNP which will use person's paralyzed muscles as main source of power and use motors to aid power to hips only when needed. As a consultant on the project, I will apply my knowledge and expertise to system specifications, tuning stimulation, developing stimulation patterns and adding on demand electric motor power for testing and evaluation of gait in persons with SCI using HNP. I am excited about the possibility of improving quality of life of paralyzed individuals and looking forward to overcoming challenges that may come my way in this endeavor.

B. Positions and Honors

<u>Positions and Employment</u>

1980-Present	Supervisory Biomedical Engineer, Motion Studies Laboratory, Veterans Affairs Medical Center, Cleveland, Ohio.
1979-1980	Research Engineer, Applied Neural Control Laboratory, Case Western Reserve University, Cleveland, Ohio.
1977-1978	Research Technician, Electronics Design Center, Case Western Reserve University, Cleveland, Ohio.

<u>VA Committee Membership</u>

2011-present	LSCDVAMC Research and Development Committee
2008-present	LSCDVAMC Subcommittee on Research Safety

Patents
Bachmann R, Kern N, [redacted] **R**, Polinkovsky A, Quinn RD, [redacted] RJ, inventors; Case Western Reserve University,assignee. Orthotic Brace. USA US 8,235,924 B2. 2012 August 07.

Honors
Top 10 poster presentation at the 52nd annual APS conference, Sep 2006.

C. Selected Peer-reviewed Publications
Most relevant to the development of hybrid neuroprosthesis

1. Bulea TC, [redacted] **R**, [redacted] ML, Schnellenberger JR, Pinault G, [redacted] RJ. Forward stair descent with hybrid neuroprosthesis after paralysis: Single case study demonstrating feasibility. *J Rehabil Res Dev*. 51(7) 2014. doi: 10.1682/JRRD.2013.12.0257.
2. To CS, [redacted] **R**, Bulea TC, [redacted] ML, Schnellenberger JR, Pinault G, [redacted] RJ. Sensor-based hip control with hybrid neuroprosthesis for walking in paraplegia. *J Rehabil Res Dev*. 51(2)229-44, 2014. http://dx.doi.org/10.1682/JRRD.2012.10.0190.
3. Bulea TC, [redacted] **R**, [redacted] ML, [redacted] RJ. Stance controlled knee flexion improves stimulation driven walking after spinal cord injury. *Journal of NeuroEngineering and Rehabilitation*, 10:68, 2013.
4. Kern NI, [redacted] JR, [redacted] **R**, [redacted] M, Quinn RD. A convertible spinal orthosis for controlled torso rigidity, *Applied Bionics and Biomechanics*, 10:59-73, 2013.
5. Bulea TC, [redacted] **R**, [redacted] ML, Schnellenberger JR, [redacted] RJ. Finite state control of a variable impedance hybrid neuroprosthesis for locomotion after paralysis. *IEEE Trans Neural Syst Rehabil Eng*. 2013 Jan;21(1):141-51. doi: 10.1109/TNSRE.2012.2227124. Epub 2012 Nov 15.
6. To CS, [redacted] **R**, Bulea TC, [redacted] ML, Schnellenberger JR, Pinault G, [redacted] RJ. Sensor-based stance control with orthosis and functional neuromuscular stimulation for walking after spinal cord injury. *J of Prosthetics and Orthotics*, 24(3):124-132, 2012.
7. Bulea TC, [redacted] **R**, To CS, [redacted] M, Schnellenberger J, [redacted] RJ. A variable impedance knee mechanism for controlled stance flexion during pathological gait. *IEEE/ASME Transactions on Mechatronics*, 17(5):822-832, 2012. DOI:10.1109/TMECH.2011.2131148.
8. Bulea TC, [redacted] **R,** [redacted] RJ. Restoration of stance phase knee flexion during walking after spinal cord injury using a variable impedance orthosis. *Conf Proc IEEE Eng Med Biol Soc*, 2011:608-11, 2011.
9. To CS, [redacted] **R**, Bulea TC, [redacted] ML, Schnellenberger JR, Pinault G, [redacted] RJ. Stance control knee mechanism for lower-limb support in hybrid neuroprosthesis. *J Rehabil Res Dev*, 48(7):839-850, 2011. DOI:10.1682/JRRD.2010.07.0135.
10. [redacted] ML, To CS, [redacted] **R**, [redacted] RJ. Gait evaluation of a novel hip constraint orthosis with implication for walking in paraplegia. *IEEE Trans. Neural Syst Rehabil Eng*. 18(6):610-618, 2010. DOI:10.1109/TNSRE.2010.20047594.
11. [redacted] **R**, To CS, Schnellenberger JR, [redacted] ML, Bulea TC, Gaudio R, Pinault G, Tashman S, [redacted] RJ. Development of hybrid orthosis for standing, walking, and stair climbing after spinal cord injury. *J Rehabil Res Dev.* 46(3):447-462, 2009. DOI:10.1682/JRRD.2008.07.0087.
12. Kern NI, Majewski TJ, [redacted] RJ, [redacted] **R**, Quinn RD. A locking compliant device inspired by the anatomy of the spine. *J Mechanical Design*. Vol 131, Jan 2009. DOI: 10.1115/1.2991143.
13. To CS, [redacted] **R**, Schnellenberger J, [redacted] M, [redacted] RJ. Design of a variable constraint hip mechanism for a hybrid neuroprosthesis to restore gait after spinal cord injury. *IEEE/ASME Transactions on Mechatronics*, 13(2):197-205, 2008.
14. To CS, Kirsch RF, [redacted] **R**, [redacted] R. Simulation of a functional neuromuscular stimulation powered mechanical gait orthosis with coordinated joint locking. *IEEE Trans Neural Sys and Rehab Eng,*13(2):227-235, June 2005.
15. [redacted] **R**, Marsolais EB, [redacted] RJ, Davy DT, Gaudio R, Tashman S. Development of a hybrid gait orthosis: a case report. *J Spinal Cord Medicine* 26(3):254-258, Fall 2003.
16. Marsolais EB, [redacted] **R**, Polando G, Ferguson K, Tashman S, Gaudio R, Nandurkar S, Lehneis HR. The Case Western Reserve University Hybrid Gait Orthosis, *J Spinal Cord Medicine* 23(2):100-108, 2000.
17. Ferguson KA, Polando G, [redacted] **R**, [redacted] RJ, Marsolais EB: Walking with hybrid orthosis system, *Spinal Cord* 37:800-804, 1999.

Additional publications relevant to electrical stimulation of paralyzed muscle

1. Ho CH, [redacted] RJ, Elias AL, Kilgore KL, DiMarco AF, Bogie K, Vette AH, [redacted] ML, [redacted] **R**, Chang SR, Chan KM[1], Dukelow S, Bourbeau DJ, Brose SW, Gustafson KJ, Kiss ZH, Mushahwar VK. Functional Electrical Stimulation and Spinal Cord Injury. *Phys Med Rehabil Clin N Am*. 2014 Aug;25(3):631-654. doi: 10.1016/j.pmr.2014.05.001.
2. Hardin EC, [redacted] **R**, [redacted] RJ. Ambulation and spinal cord injury. *Phys Med Rehabil Clin N Am*. 2013 May;24(2):355-70. doi: 10.1016/j.pmr.2012.11.002. Epub 2013 Jan 21. PubMed PMID: 23598268.
3. Dutta A, [redacted] **R**, [redacted] R. Walking after partial paralysis assisted with EMG-triggered or switch-triggered functional electrical stimulation--two case studies. *IEEE Int Conf Rehabil Robot*. 2011;2011:5975383. doi: 10.1109/ICORR.2011.5975383. PubMed PMID: 22275587.
4. Dutta A, [redacted] **R**, [redacted] RJ. An objective method for selecting command source for myoelectrically triggered lower-limb neuroprostheses. *J Rehabil Res Dev*, 48(8):935-948, 2011.

2. Foglyano KM, Schnellenberger JR, [redacted] **R**. Development of a self-contained accelerometry based system for control of functional electrical stimulation in hemiplegia. *Conf Proc IEEE Eng Med Biol Soc*, 2011:5448-51, 2011.
3. Bailey SN, Hardin EC, [redacted] **R**, Boggs LM, Pinault G, [redacted] RJ. Neurotherapeutic and Neuroprosthetic effects of implanted functional electrical stimulation for ambulation after incomplete spinal cord injury. *J Rehabil Res Dev* 47(1):1-16, 2010. DOI:10.1682/JRRD.2009.03.0034.
4. Dutta A, [redacted] **R**, [redacted] RJ. Gait initiation with electromyographically triggered electrical stimulation in people with partial paralysis. *Journal of Biomechanical Engineering* 131:0810021-0810029, Aug 2009.
5. Dutta A, [redacted] **R**, [redacted] RJ. Ambulation after incomplete spinal cord injury with EMG-triggered functional electrical stimulation. *IEEE Trans Biomed Engr* 55(2):791-794, 2008.
6. Hardin E, [redacted] **R**, Murray L, Corado-Ahmed M, Pinault G, Sakai J, Nogan S, Ho C, [redacted] RJ. Walking afert incomplete spinal cord injury using an implanted FES system: A case report. *Jour Rehab Res and Dev* 44(3):333-346, 2007.
7. Agarwal S, [redacted] RJ, [redacted] **R**, Miller M, Bieri C, Kukke S, Rohde L, Davis J. Long-term user perceptions of an implanted neuroprosthesis for exercise, standing, and transfers after spinal cord injury. *J Rehab Res Dev* 40(3):1-12, May/June 2003.
8. Agarwal S, [redacted] **R**, Nandurkar S, Marsolais EB. FES for walking in paraplegia:17 year follow up of 2 cases. *J Spinal Cord Medicine,*26(1):86-91, 2003.
9. Nandurkar S, Marsolais EB, [redacted] **R**. Percutaneous Implantation of Iliopsoas for Functional Neuromuscular Stimulation, *Clin Orthop and Rel Res,*389:210-217, 2001*.*
10. [redacted] RJ, May QL, [redacted] **R**, Uhlir J. Selectivity of intramuscular electrodes in the lower limbs, *J Rehabil Res Dev* 38(5):533-544, 2001.
11. [redacted] RJ, Wibowo M, Uhlir J, [redacted] **R**, Kirsch R. Effects of stimulated hip extension moment and position on upper-limb support forces during FNS-induced standing- A technical note. *J Rehabil Res Dev.* 38(5):545-555, 2001.
12. Uhlir JP, [redacted] RJ, [redacted] **R**. The use of selective electrical stimulation of the quadriceps to improve standing function in paraplegia, *IEEE Trans Rehab Eng,* 8(4):514-522, Dec 2000.
13. [redacted] **R**, [redacted] RJ, Uhlir J, Bieri C, Wibowo M, Polando G, Marsolais EB, Davis JA, Ferguson K, [redacted] M. Implanted functional electrical stimulation system for mobility in paraplegia: A follow-up case report. *IEEE Trans Rehab Eng*, Dec 1999.
14. Kagaya H, [redacted] M, [redacted] **R**, Marsolais EB. Ankle, knee, and hip moments during standing with and without joint contractures; Simulation study for Functional Electrical Stimulation. *Am J Phys Med Rehabil* 77(1):49-54, 1998.
15. Zhenxing J, [redacted] **R**. Rail supporting transducer posts for three-dimensional force measurement. *IEEE Trans Rehab Eng* 5(4):380-387, 1997.
16. [redacted] **R**, [redacted] R, Marsolais EB. Muscle selection and walking performance of multichannel FES systems for ambulation in paraplegia. *IEEE Trans Rehab Eng* 5(1):23-29, 1997.
17. [redacted] RJ, Bieri C, Uhlir J, [redacted] **R**, Scheiner A, Marsolais EB. Implanted functional neuromuscular stimulation systems for individuals with cervical spinal cord injuries: Clinical case report. *Arch Phys Med Rehabil* 77:1119-1128, 1996.
18. [redacted] **R**, Marsolais EB. Synthesis of paraplegic gait with multichannel functional neuromuscular stimulation. *IEEE Trans Rehab Eng* 2(2):66-79, 1994.
19. [redacted] **R**, Marsolais EB, Miller PC. Function and strength of electrically stimulated hip flexor muscles in paraplegia. *IEEE Trans Rehab Eng* 2(1):11-17, 1994.

20. [redacted] **R**. Advancing step by step. *IEEE Spectrum* 27-31, October 1994.
21. Marsolais EB, Sheiner A, Miller PC, [redacted] **R**, Daly JJ. Augmentation of transfer for a quadriplegic patient using an implanted FNS system. Case report. *Paraplegia* 32:573-579, 1994.
22. Doyle J, [redacted] **R**, Marsolais EB. Effect of Functional Neuromuscular Stimulation on Anterior Tibial Compartment Pressure. *Clin Orthop and Rel Res* 284:181-188, November 1992.
23. Marsolais EB, [redacted] **R**, Chizeck HJ, Jacobs J. Orthoses and electrical stimulation for walking in complete paraplegia. *Jour Neuro Rehab* 1(5):13-22, 1991.
24. Marsolais EB, [redacted] **R**, Barnicle K, Jacobs J. FNS application for restoring function in stroke and head-injury patients. *Jour Clin Eng* 15(6):489-496, December, 1990.
25. Carroll SG, [redacted] RJ, Chizeck HJ, [redacted] **R**, Marsolais EB. Tetanic Responses of Electrically Stimulated Paralyzed Muscle at Varying Interpulse Intervals. *IEEE Trans Biomed Eng* 36(7):644-653, 1989.
26. Borges G, Ferguson K, [redacted] **R**. Development and Operation of Portable and Laboratory Electrical Stimulation Systems for Walking in Paraplegic Subjects. *IEEE Trans Biomed Eng* 36(7):798-801, 1989.
27. Marsolais EB, [redacted] **R**. Development of a practical electrical stimulation system for restoring gait in the paralyzed patient. *Clin Orthop* 233:64-74, 1988.
28. Chizeck HJ, [redacted] **R**, Marsolais EB, Abbas JJ, Donner IH, Simon E. Control of functional neuromuscular stimulation systems for standing and locomotion in paraplegics. *Proc IEEE* 76(9):1155-1165, 1988.
29. Marsolais EB, [redacted] **R**. Functional electrical stimulation for walking in paraplegia. *J Bone & Joint Surg* 69A(5): 728-733, 1987.
30. Marsolais EB, [redacted] **R**. Implantation techniques and experience with percutaneous intramuscular electrodes in the lower extremities. *J Rehabil Res Dev* 23(3):1-8, 1986.
31. Marsolais EB, [redacted] **R**. Functional walking in paralyzed patients by means of electrical stimulation. *Clin Orthop* 175:30-36, 1983.

Book Chapters

1. Nemunaitis G, [redacted] R, [redacted] **R**, Kilgore K, Creasey G, Anthony DiMarco A. Spinal Cord Injury Medicine. Edited by S Kirschblum, D Campagnolo, J Delisa, et al.; Philadelphia, Pa. Lippincott, Wiliams & Wilkins. 2011. Chapter 25, Neuromuscular Electrical Stimulation in Spinal Cord Injury. p. 360-388.
2. Marsolais EB, [redacted] RJ, [redacted] **R**, Nandurkar S. The Spinal Cord Injured Patient. 2nd ed. Lee BY, Ostrander LE, editors. New York: Demos; 2002. Chapter 16, The Role of Electrical Stimulation in Management of Spinal Cord Injured Patients; p.201-230. 432p.
3. [redacted] RJ, [redacted] **R**, Betz RR. Human Motion Analysis. Harris GF, Smith PA, editors. New York, NY: IEEE Press; 1996. Chapter 17, Standing and Walking with FNS: Technical and Clinical Challenges; p.318-350.
4. [redacted] **R**, Marsolais EB, Semame P, Borges G. Human Walking. 2nd ed. Rose J, Gamble JG, editors. Baltimore, Maryland, USA: Williams & Wilkins; 1994. Chapter 10, The Next Step: Artificial Walking; p.225-263.

D. Research Support

Ongoing Research Support

B7692R (Principal Investigator) 10/12-9/15
Department of Veterans Affairs "Improving Ambulatory Community Access after Paralysis"
The objective of this feasibility study of safety and effectiveness of an implanted multichannel functional electrical stimulation (FES) gait system is to correct gait instability and increase walking speed to improve ambulatory community access of persons with lower extremity paralysis due to incomplete spinal cord injury.

B0608-R (Principal Investigator) 1/13-12/16
Department of Veterans Affairs "Hybrid Neuroprosthesis with a Variable Knee for Walking in SCI"
The objective of this study is to determine whether a novel hybrid neuroprosthesis combining functional neuromuscular stimulation and incorporating an advanced sensor based controlled variable impedance knee mechanism for walking in persons with paraplegia from spinal cord injury can: 1) reduce impact forces during loading, improve forward momentum, reduce the fluctuations in vertical trunk motion, and improve foot-ground clearance during walking, and 2) restore stair descent and stand-to-sit functions by controlling the resistance to knee flexion while lowering of the body.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
[redacted] Musa L.	Research Associate Professor
eRA COMMONS USER NAME (credential, e.g., agency login) [redacted]	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Ahmadu Bello University, Zaria - Nigeria	B. Eng	06/1977	Mechanical Engineering
Ahmadu Bello University, Zaria - Nigeria	M. Eng	08/1980	Mechanical Engineering
Case Western Reserve University, Cleveland, OH	Ph.D.	01/1985	Biomechanics

A. Personal Statement

The goal of the proposed research is to design an automatic control system that engages FES, a limited force producing and fatigable power source, and an electric motor drive, a high force producing and non-fatigable power source, to accommodate for a change in force demand or to compensate for loss of muscle force caused by FES-induced muscle fatigue. The proposed feedback control algorithm can adapt to compensate for the rapid onset of muscle fatigue; thus ensuring consistent control performance. I have a broad background in experimental biomechanics, musculoskeletal modeling and design of control systems for applications in functional electrical stimulation. I have been working at the Cleveland FES Center for the last 14 years where I was the chief consultant for all experimental and musculoskeletal modeling and computational issues for several senior researchers and graduate students. In this role I have produced or participated in producing several peer-reviewed publications in the areas of biomechanical modeling, control systems design and experimentation with application to FES and other interventions. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of helping to construct realistic research plans and implementation of timelines and budgets. In summary, I have a demonstrated record of successful and productive research projects in an area of FES control, and my expertise and experience have prepared me to provide mature advise on the implementation of the proposed research project.

B. Positions and Honors

Positions and Employment

1978 – 1988: Graduate Assistant to Senior Lecturer, Department of Mechanical Engineering, A.B.U.
Zaria – Nigeria.
1988 – 1992: Associate Professor (Reader) and Director, Center for Industrial Studies, Abubakar Tafawa Balewa University, Bauchi – Nigeria
1992 – 2000: Rector (President), The Federal Polytechnic, Bauchi - Nigeria
2000 – 2012: Principal Researcher, Department of Biomedical Engineering, Case Western Reserve University, Cleveland, OH.
2012 - Present: Research Associate Professor, Department of Biomedical Engineering, Case Western Reserve University, Cleveland, OH, USA.

Other Experience and Professional Memberships

1. Member American Society of Biomechanics.
2. Corporate Member, The Nigerian Society of Engineers
3. Registered Engineer with Council for the Regulation of Engineering in Nigeria (COREN)
4. Member IFESS: International FES Society

Honors

1. Shell-BP Prize for "Best Final Year Mechanical Engineering Student". A.B.U. Zaria - Nigeria, 1977.
2. Mobil Oil Prize for "Best Final Year Mechanical Engineering Design Project". A.B.U. Zaria - Nigeria, 1977.
3. U. A. C. Prize for "Best All round Student in the Faculty of Engineering". A.B.U. Zaria Nigeria, 1977.
4. Nigerian Breweries Limited Prize for "Best Final Year Mechanical Engineering Student's Overall Performance over Three Years". A.B.U. Zaria - Nigeria, 1977.

C. Selected Peer-reviewed Publications (Selected from 45 peer-reviewed publications)

1. [redacted] **M.L.**, Lombardo, L.M., Schnellenberger, J.R., Foglyano, K.M., Miller, M.E. and [redacted] R.J., "A neuroprosthesis for control of seated balance after spinal cord injury". Journal of NeuroEngineering and Rehabilitation, vol. 12:8, pp:1-12, 2015.
2. Murphy, J.O., [redacted] **M.L.**, Lombardo, L.M., Foglyano, K.M., [redacted] R.J. "Feasibility of closed-loop controller for righting seated posture after spinal cord injury", Journal of Rehabilitation, Research and Development, vol. 51, No. 5, Pages 747–760, 2014.
3. [redacted] **M.L.**, Gartman, S.J., Nataraj, R. and [redacted] R.J, "Posture dependent control of stimulation in a standing neuroprosthesis: a simulation feasibility study", Journal of Rehabilitation Research and Development, vol. 51, No. 3, pp:481-496, 2014.
4. Bulea, T.C., [redacted] R., [redacted] M.L. and [redacted] R.J., "Stance controlled knee flexion improves stimulation driven walking after spinal cord injury", Journal of NeuroEngineering and Rehabilitation, vol. 10:68, pp:1-11, 2013.
5. [redacted] R.J., Bailey, S.N., Miller, M.E., Lombardo, L.M. and [redacted] **M.L.**, "Effects of Stimulating Hip and Trunk Muscles on Seated Stability, Posture, and Reach After Spinal Cord Injury", Archives of Physical Medicine and Rehabilitation, vol. 94, pp:1766-1775, 2013.
6. Nataraj, R., [redacted] **M. L.**, Kirsch, R. F. and [redacted] R. J., "Trunk Acceleration for Neuroprosthetic Control of Standing – a Pilot Study". *Journal of Applied Biomechanics*, vol. 28, No. 1., pp 85 – 92, 2012.
7. To, C. S., [redacted] R., Bulea, T. C., [redacted] **M. L.**, Schnellenberger, J. R., Pinault, G., [redacted] R. J. "Sensor-Based Stance Control With Orthosis and Functional Neuromuscular Stimulation for Walking After Spinal Cord Injury", *Journal of Prosthetics & Orthotics*, vol. 24, Issue 3, p 124–132, 2012.
8. Bulea T.C., [redacted] R., To C.S., [redacted] **M.L.**, Schnellenberger J., [redacted] R.J. "A Variable Impedance Knee Mechanism for Controlled Stance Flexion During Pathological Gait", *IEEE Transactions on Mechatronics*, vol. 17, no. 5, pp. 822-832, 2012.
9. Nataraj, R., [redacted] **M. L.**, Kirsch, R. F. and [redacted] R. J., "Center of mass acceleration feedback control for standing by functional neuromuscular stimulation: A simulation study", *Journal of Rehabilitation, Research and Development*, vol. 49, No. 2, Pages 279-296, 2012.
10. Nataraj, R., [redacted] **M. L.** and [redacted] R. J., "Center of mass acceleration feedback control of functional neuromuscular stimulation for standing in presence of internal postural perturbations", *Journal of Rehabilitation, Research and Development*, vol. 49, No. 6, Pages 889-912, 2012.
11. To CS, [redacted] R, Bulea TC, [redacted] **ML**, Schnellenberger JR, Pinault G, [redacted] RJ. Stance control knee mechanism for lower-limb support in hybrid neuroprosthesis. *Jour Rehab Res and Dev* 48(7):839-850, 2011.
12. Bulea TC, [redacted] R, To CS, [redacted] **M**, Schnellenberger J, [redacted] RJ: A variable impedance knee mechanism for controlled stance flexion during pathological gait." *IEEE/ASME Transactions on Mechatronics*, in press (*accepted 02.12.2011*). doi: 10.1109/TMECH.2011.2131148, 2011.
13. [redacted] **M. L.,** To, C. S., [redacted] R. and [redacted] R. J., "Gait evaluation of a novel hip constraint orthosis with implication for walking in paraplegia", IEEE Trans. Neural Syst Rehabil Eng. Vol 18, No.6, pp.610-618, 2010.

D. Research Support

Ongoing Research Support

SC090230 /W81XWH-10-2-0141 09/2010 – 03/2015 60%
Department of Defense (DOD/SCIRP): $ 909,865.00
"Control of a Seated Balance with Functional Neuromuscular Stimulation (FNS)".
Function: PI.

The objective of this project is to develop novel control systems to automatically regulate posture and actively restore balance to users of neuroprostheses for standing after spinal cord injury. A sensor-driven "artificial vestibular system" combining innovative feed-forward, feedback and adaptive control techniques will actively monitor posture, anticipate perturbations and automatically modulate stimulation to keep the user upright. A model-based approach to controller design will be utilized that relied on computer simulation and optimization prior to human testing with a 16 channel implanted neuroprosthesis.

B0608R 01/2013 – 12/2016 20%
Department of Veterans Affairs (Rehab R&D): $ 798,980.00
"Hybrid Neuroprosthesis with a Variable Knee Control for Walking in SCI"
Function: co-Investigator.

The main objective of the proposed study is to restore functions normally provided by eccentric muscle contractions during walking, stair descend and stand-to-sit maneuver in individuals with paraplegia from thoracic spinal cord injury (SCI) by means of a novel hybrid neuroprosthesis (HNP). The proposed HNP combines advantages of functional neuromuscular stimulation (FNS) for generating power for forward propulsion with the user's own musculature and stability provided by a controllable lower extremity brace with a variable impedance knee mechanism (VIKM).

R01 NS040547-04A2 07/2011 – 07/2016 20%
National Institutes of Health (NIH): $ 2,366,690.00
"Automatic Control of Standing Balance with FNS"
Function: co-PI.

The objective of this project is to develop novel control systems to automatically regulate posture and actively restore balance to users of neuroprostheses for standing after spinal cord injury. A sensor-driven "artificial vestibular system" combining innovative feed-forward, feedback and adaptive control techniques will actively monitor posture, anticipate perturbations and automatically modulate stimulation to keep the user upright. A model-based approach to controller design will be utilized that relied on computer simulation and optimization prior to human testing with a 16 channel implanted neuroprosthesis.

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

1. Project Director / Principal Investigator (PD/PI)

Prefix: Dr.
First Name*: [redacted]
Middle Name:
Last Name*: [redacted]
Suffix: Ph.D

2. Human Subjects

Clinical Trial? ● No ❍ Yes
Agency-Defined Phase III Clinical Trial?* ❍ No ❍ Yes

3. Permission Statement*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

● Yes ❍ No

4. Program Income*

Is program income anticipated during the periods for which the grant support is requested? ❍ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Budget Period*	Anticipated Amount ($)*	Source(s)*

PHS 398 Cover Page Supplement

5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?* ● No ❍ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): Specific stem cell line cannot be referenced at this time. One from the registry will be used.

6. Inventions and Patents (For renewal applications only)

Inventions and Patents*: ❍ Yes ❍ No

If the answer is "Yes" then please answer the following:

Previously Reported*: ❍ Yes ❍ No

7. Change of Investigator / Change of Institution Questions

❏ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

First Name*:

Middle Name:

Last Name*:

Suffix:

❏ Change of Grantee Institution

Name of former institution*:

PHS 398 Modular Budget

OMB Number: 0925-0001

Budget Period: 1

Start Date: 09/01/2015 End Date: 08/31/2016

A. Direct Costs

	Funds Requested ($)
Direct Cost less Consortium F&A*	50,000.00
Consortium F&A	
Total Direct Costs*	50,000.00

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
1.	MTDC	54.00	38,000.00	20,520.00
2.				
3.				
4.				

Cognizant Agency
(Agency Name, POC Name and Phone Number): Department of Health and Human Services Steven Zuraf 301-492-4855

Indirect Cost Rate Agreement Date: 06/18/2014

Total Indirect Costs: 20,520.00

C. Total Direct and Indirect Costs (A + B)

Funds Requested ($): 70,520.00

Funding Opportunity Number: PA-13-304. Received Date: 2015-02-19T12:54:22.000-05:00

Tracking Number: GRANT11841465

PHS 398 Modular Budget

Budget Period: 2

Start Date: 09/01/2016 End Date: 08/31/2017

A. Direct Costs

	Funds Requested ($)
Direct Cost less Consortium F&A*	50,000.00
Consortium F&A	
Total Direct Costs*	50,000.00

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
1.	MTDC	54.00	37,640.00	20,326.00
2.				
3.				
4.				

Cognizant Agency
(Agency Name, POC Name and Phone Number)
Department of Health and Human Services Steven Zuraf
301-492-4855

Indirect Cost Rate Agreement Date 06/18/2014

Total Indirect Costs 20,326.00

C. Total Direct and Indirect Costs (A + B)

Funds Requested ($) 70,326.00

Tracking Number: GRANT11841465
Funding Opportunity Number: PA-13-304. Received Date: 2015-02-19T12:54:22.000-05:00

PHS 398 Modular Budget

Cumulative Budget Information

1. Total Costs, Entire Project Period

Section A, Total Direct Cost less Consortium F&A for Entire Project Period ($)	100,000.00
Section A, Total Consortium F&A for Entire Project Period ($)	
Section A, Total Direct Costs for Entire Project Period ($)	100,000.00
Section B, Total Indirect Costs for Entire Project Period ($)	40,846.00
Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period ($)	140,846.00

2. Budget Justifications

Personnel Justification	1245-Budget Justification.pdf
Consortium Justification	
Additional Narrative Justification	

Budget Justification

[redacted] PhD, Principal Investigator, will devote 1.67% of his effort to this project during Years 01 and 02. Dr. [redacted] is an Assistant Professor in the Department of Mechanical Engineering and Materials Science at the University of Pittsburgh. He has specific training in key research areas for this project: control theory, dynamic optimization, and modeling of mechanical systems. He will be involved in the design, implementation, and interpretation of all aspects of this study. He will supervise and train the graduate student involved in the following research activities: modeling and designing of control algorithms for the knee extension and the walking device. He will regularly meet with the co-investigator and team consultants for project updates and discussion on research findings. He will be involved in literature review, writing, and editing manuscripts. He will also train students for their conference presentations as well as he will be attending and presenting at the conferences/meetings for the dissemination of the proposed research findings.

Brad E [redacted] MD, Co-Investigator, will devote 1.67% of his effort to this project in Years 01 and 02. Brad [redacted] is the Human Engineering Research Laboratories Medical Director and Associate Professor in the Department of Physical Medicine and Rehabilitation at the University of Pittsburgh Medical Center. As a staff physician at the University of Pittsburgh Medical Center, he evaluates patients with disabilities for assistive technologies such as wheelchairs and addresses the complex assistive technology and rehabilitation needs of individuals with complex disabilities including spinal cord injury. His research interests focus on developing and studying interventions targeted to improving health and wellness in individuals with complex disabilities (wheelchairs, adaptive sports, telemedicine, virtual reality, and preventative care programs). Dr. [redacted] will help us recruit an individual with SCI, train and familiarize the participant with SCI with the hybrid walking device, and supervise and conduct the gait experiments.

Graduate Student: One PhD student will devote 12.0 calendar months of his effort to this project in Years 01 and 02. This PhD student will focus on the theoretical design of the control algorithms for the hybrid walking device and leg extension machine; e.g., control development of model predictive control-based dynamic allocation. Also, he will work on the gait experiments on the hybrid walking neuroprostheses. This involves parameter identification of the recruited subjects, writing MATLAB codes, and collection and analysis of limb angle and control performance data.

Consultant team comprising of Ron [redacted] PhD; Rudi [redacted] MS; and Mussa [redacted] PhD will provide mentoring and consultation to the project. The PI will regularly meet (once a semester) with the consultant team in the Louis Stokes Cleveland Department of Veterans Affairs Medical Center in Cleveland, PA to update them on the project. The team members will also visit the PI's laboratory to oversee the progress and provide feedback to the PI and his research team members. The feedback will primarily improve the control methods, gait experiments, and leg extension experiments and the data analysis. The budget allocates $3000, for 2 years, for the team's travel and consultancy expenses.

Christopher Venus, PT, NCS will be hired on an hourly basis to provide his physical therapy services during the experiments. He will assist participants in various ways including transferring from the wheel chair, assist in donning on/off the walking brace, collecting and monitoring the participant's vital information such as heart beat and blood pressure. Mr. Venus will be reimbursed for his services @$100/hr.

Materials/Supplies: This cost mainly constitutes cost of electrodes for functional electrical stimulation, printing and publication, and machining and fabrication costs of adding a torque sensor in the hybrid leg extension machine and the walking brace.

Payment to participants: Participants with spinal cord injury will be compensated for any costs that they incur while traveling to and from the PI's laboratory for each session. In addition, they will be compensated up to $75 (including travel cost) for participating in each session. They will be compensated for each session completed regardless of completing the whole study.

Travel: Travel costs include expenses to attend domestic conference meetings.

Cost of Living Increases, Fringe Benefit Rates, and Indirect Costs:
Cost of Living Increases: A 3% cost-of-living increase was applied to current salaries effective July 1, 2014, and for each year thereafter.
Fringe Benefits: Fringe benefit rates for the University of Pittsburgh are based on a rate agreement with the Department of Health and Human Services.
Other Faculty: 30.3%
Medical Faculty: 22.8%
Graduate Student Researcher: 50%
Indirect Costs: Indirect costs are calculated at the federal on-site rate of 54% based on a rate agreement with the Department of Health and Human Services. The University of Pittsburgh uses a Modified Total Direct Cost Base which for this proposal excludes graduate student fringe benefits.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

OMB Number: 0925-0001

1. Introduction to Application (for RESUBMISSION or REVISION only)	
2. Specific Aims	1246-Specific Aims.pdf
3. Research Strategy*	1247-Research strategy.pdf
4. Progress Report Publication List	
Human Subjects Sections	
5. Protection of Human Subjects	1248-PROTECTION OF HUMAN SUBJECTS.pdf
6. Inclusion of Women and Minorities	1249-Inclusion of women and minorities.pdf
7. Inclusion of Children	1250-Inclusion of Children.pdf
Other Research Plan Sections	
8. Vertebrate Animals	
9. Select Agent Research	
10. Multiple PD/PI Leadership Plan	
11. Consortium/Contractual Arrangements	
12. Letters of Support	1251-Combined_letters.pdf
13. Resource Sharing Plan(s)	1252-Resource Sharing Plan.pdf
Appendix (if applicable)	
14. Appendix	

Specific Aims. Functional electrical stimulation (FES) and a powered exoskeleton are among some of the technologies that aim to restore walking in individuals with paraplegia. FES can be used to obtain desired muscle contractions in the lower limbs through external application of low-level repetitive electrical currents. A powered exoskeleton uses electric motor drives to move the lower-limb joints. Alone, each has limitations. We aim to combine these two technologies to create a hybrid neuroprosthesis that is more advantageous than an FES-based walking system or a powered exoskeleton alone. Because of improved torque reliability, the hybrid walking orthosis can be used for a longer time or over longer distances. Moreover, the use of FES in the hybrid neuroprosthesis may provide therapeutic benefits associated with its use. Specifically, we propose to design and evaluate a new automatic controller for a hybrid walking neuroprosthesis that is composed of an FES system and a semi- powered exoskeleton.

Little research has gone into the design and evaluation of control methods for a hybrid walking neuroprosthesis. However, research on its control methods is important for ensuring operational efficiency, gait stability, and torque reliability. The dynamics of FES and the electric motor are characteristically different. These dissimilarities, if unaccounted for in the control design, can cause instability during walking and operational inefficiency. Moreover, the system's adaptability with varying conditions to ensure reliable joint torque generation (e.g., during rapid onset of FES-induced muscle fatigue) remains an open research problem.

An intact neuromuscular system can engage low-force (fatigue resistant) and high-force (fatigable) generating muscle fiber types to accommodate for a change in force demand or to minimize muscle fatigue. This inspired us to design an automatic control system that engages FES, a limited force producing and fatigable power source, and an electric motor drive, a high force producing and non-fatigable power source, to accommodate for a change in force demand or to compensate for a loss of muscle force due to FES-induced muscle fatigue. In our preliminary study, we have shown that model predictive control may be able to simultaneously control FES and an electric motor. Despite their dissimilar dynamics, the developed methods can be used to optimally compute control inputs for FES and an electric motor. Further, the new algorithm can adapt to compensate for the rapid onset of muscle fatigue; thus ensuring consistent control performance.

Specific Aim 1: To physically validate the model predictive control (MPC) method that optimizes the torque contribution from FES and an electric motor in a modified hybrid leg extension machine. We hypothesize that the hybrid leg extension machine will have a lower power consumption, when compared to an electric motor, and can sustain knee extension movements for longer periods of time despite muscle fatigue induced by FES. The MPC method will be used to produce knee extension by simultaneously modulating the FES of quadriceps muscle and controlling an electric motor drive of a leg extension machine. A subject specific linear model of the FES-induced muscle fatigue and a subject specific musculoskeletal model of knee extension will be used in the control design. Three sets of experiments will be conducted on able-bodied subjects and participants with SCI using the hybrid combination of FES and electric motor, a sole electric motor drive, and FES of the quadriceps muscle.

Specific Aim 2: To physically validate the MPC method on a hybrid walking device to elicit walking in persons with spinal cord injury. We hypothesize that the hybrid walking device will have a lower power consumption, when compared to a semi-powered exoskeleton, and can sustain hip flexion movements for longer periods of time than common peroneal nerve (CPN). The MPC method will be used to produce hip flexion by simultaneously modulating the CPN stimulation and controlling a hip electric motor. A subject specific linear habituation model of withdrawal reflex during CPN stimulation will be developed. The habituation model along with a subject specific musculoskeletal model of hip flexion will be used in the control design. Three sets of walking experiments will be conducted on participants with SCI using the hybrid combination of CPN stimulation and hip electric motor drives, sole hip electric motor drives, and CPN stimulation.

The proposed work promises to provide an important automatic control method that can simultaneously operate an electric motor drive and FES. The adaptable algorithm will ensure reliable torque generation by using the electric motor drive to compensate for any reduction in the torque output, caused by the FES-induced muscle fatigue. We anticipate that the proposed control algorithm will aid in efficient operation of a hybrid walking neuroprosthesis, which is being designed in the principal investigator's laboratory. Potentially, this research will contribute to the emergence of an adaptable and lightweight hybrid exoskeleton technology that may be able surpass the limitations of current sole FES systems and powered exoskeletons.

Research Strategy

(a) Significance. Nearly 5.5 million people in the United States alone [1] are reported to be living with mobility impairments caused by spinal cord injury (SCI), stroke, transverse myelitis or progressive neurological diseases such as multiple sclerosis or, amyotrophic lateral sclerosis. Evidence has shown that post injury or disease, users of walking devices experience fewer secondary medical complications than wheelchair users [2]. Therefore, we are motivated to find innovative engineering solutions that look beyond the use of a wheelchair for mobility. Our long term research goal is to restore walking in mobility impaired individuals using a lightweight orthotic device that exploits a user's inherent muscle power via functional electrical stimulation (FES) as well as robotic power for additional assistance.

FES, which elicits desired muscle contractions using repetitive low-level external electrical currents, has been used to generate or improve walking [3–11] in persons with paraplegia. However, FES-based walking restoration systems have achieved limited acceptability due to the rapid onset of muscle fatigue and upper-body effort required to maintain balance while walking. To overcome these issues, FES can be combined with a passive orthosis [12–22]. Still, a passive orthosis combined with FES has the disadvantage that power cannot be added, especially when the muscle fatigue caused by FES sets in and leads to reduction in available muscle joint torque. A hybrid technology that combines an FES system with a powered exoskeleton [23–26] seems most promising for use as an assistive device. A powered exoskeleton is an active orthosis that provides joint torques using electric motor drives [27–30]. With such a system, the limitations of FES such as limited and unreliable muscle torque generation can be overcome by using an electric motor while using FES intermittently to get either its physiological benefits or to conserve the battery charge required for an electric motor; thus, the battery can be smaller and lighter.

For the hybrid neuroprosthesis technology to be successful, the design of its automatic control - an open research problem - needs to be addressed. This control problem is challenging and complicated due to the dissimilar dynamics of FES and the electric motor. An output from the slow and electromechanically delayed muscle dynamics is different from an output produced by the fast dynamics of the electric motor. The lack of coordination between FES and the electric motor can cause instability in the system that can lead to falling and potentially injuring a user. In our preliminary results, we show that a model predictive control (MPC)-based dynamic control allocation (DCA) can simultaneously control FES and an electric motor to produce a knee extension task, despite the aforementioned challenges. We also show that the new controller can adapt to muscle fatigue in the quadriceps muscle and can sustain knee extension movements for a longer period of time. The proposal's hypothesis is that the new controller can sustain limb movements for a longer period of time compared to a sole FES system and the overall power requirement will be lower than an electric motor system. The proposed project, if successful, will lead to a hybrid walking orthosis that will be lighter and can be used for a longer time or over longer distances. Moreover, the use of FES in the hybrid neuroprosthesis will provide therapeutic benefits; e.g., application of electrical stimulation improved cardiovascular fitness and increased muscle mass and fatigue resistance [3].

(b) Innovation. In his previous research, the PI has developed continuous robust nonlinear controllers for FES [31–35]. While these control techniques perform very well for FES for a certain period of time, they fail to deal with muscle fatigue. Recently, the PI has also looked into methods to dynamically optimize FES with a passive orthosis [36–39]. A major limitation in these systems is the inaccessibility of muscles that produce hip flexion during walking. A common method employed to produce hip flexion is through modulation of the withdrawal reflex elicited via stimulation of the common peroneal nerve (CPN) [11, 40, 41]. However, sensitivity of CPN stimulation is reduced over time due to habituation, which often leads to poor, unreliable, and insufficient hip flexion.

To overcome these technical issues, the PI has recently developed two hybrid neuroprosthesis platforms. A recently assembled prototype of the hybrid walking device uses an electric motor drive along with the withdrawal reflex, which is elicited via CPN stimulation, to elicit hip flexion movements. This feature improves reliability of the hip flexion movements during walking, because any lack in torque generation due to CPN stimulation can be compensated by the electric motor at the hip. A wrap spring clutch mechanism (WSC) [22, 42], controlled via a solenoid system, was included to lock and unlock the knee joint during the standing and stance phase of walking. This feature facilitates elimination of FES stimulation during the standing and stance phase of walking, which lowers the FES stimulation duty cycle and thus, helps to avoid the muscle fatigue. Additionally, as opposed to a fully powered exoskeleton, the developed walking device is a semi-powered device. Electric motors are used only to move the hip joints and the rest of the limb movements can be generated via FES. Potentially, the semi-powered feature of the device facilitates a lower power requirement for operation. The PI's laboratory has also developed a modified leg extension machine (LEM) where the knee joint torque can be generated by external stimulation of the quadriceps muscle as well as by using an electric motor gear drive. The electric motor drive in the LEM can be used to compensate for reduced force caused by muscle fatigue during quadriceps stimulation.

A major innovation of the proposed project lies in the use of 1) subject specific linear model of muscle fatigue induced during the quadriceps stimulation, 2) subject specific linear habituation model of withdrawal reflex during common peroneal nerve stimulation, and 3) subject specific musculoskeletal models of knee extension and hip flexion to control the hybrid neuroprostheses. This work is different from the pioneering control designs developed by Ha et al. [23] and Quintero et al. [25]. Firstly, the coordination of CPN stimulation and a hip electric drive to produce hip flexion has not been studied so far. Secondly, the controllers in Ha et al. [23] and Quintero et al. [25] may not be able to dynamically vary or adapt with changing load conditions on the limb or as a skeletal muscle fatigues. This is because a simplified muscle dynamics model was used and the control designs do not account for muscle fatigue. The proposed MPC-based DCA optimizes and adapts, based on the aforementioned subject-specific computer models, to allocate optimized control inputs to FES and the electric motor. This automatic controller is inspired by, although not exactly the same as, an intact neuromuscular system, where muscle fiber types of different characteristics can be engaged as force demand changes or to minimize muscle fatigue.

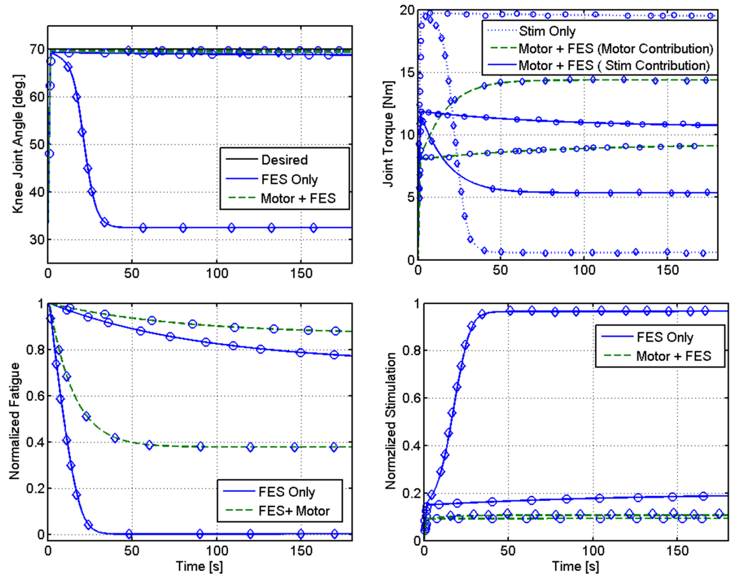

Figure 1: These computer simulations show knee extension movements elicited by a sole FES system and a hybrid system. Simulations representing an able-bodied person and a paraplegic are marked in 'o' and '◇', respectively. The top-left plots show desired knee angle vs actual knee angle; the top-right plots show joint torque contributions of electric motor and FES; and the bottom left and right plots depict normalized muscle fatigue and stimulation variables.

(c) Approach. *Preliminary results.* In our preliminary study, we used a computer model of knee extension movement to evaluate a new control method called dynamic control allocation (DCA) to simultaneously control an electric motor drive and FES. The DCA method, which relies on MPC [43, 44], has been designed to optimize engineering systems with multiple actuators [45–49]. The objective of the control algorithm was to elicit knee extension that follows a smooth function and reach a desired knee angle of 70°. Knee extension simulations were performed for an able-bodied person and a person with paraplegia. A normalized fatigue variable, which is an output of an analytical fatigue model and represents decay or recovery in the muscle force during FES [31, 50], was added to the musculoskeletal dynamics. The parameters of the fatigue model and musculoskeletal dynamics, as given in [redacted] et al. [31], of an able bodied participant were identified through a series of knee extension experiments (see details in Task 1 of Aim 1) and the model parameters for a person with paraplegia were taken from Riener et al. [50]. The MPC-based DCA method was simulated using an optimization solver generated by CVXGEN [51]. CVXGEN is software that generates a program code for solving MPC problems in real time. The results of the MPC-based DCA are shown in Fig. 1. These results show that the MPC-based DCA method can not only allocate control input between FES and an electric motor but also adapt as the muscle fatigue sets in (top right plot in Fig. 1). When only FES was used, the muscle fatigued more dramatically for a person with paraplegia than for the able-bodied participant (see Fig. 1 plots for *Normalized Fatigue*). This is consistent with the fact that muscles in able-bodied individuals are more fatigue resistant than in paraplegics. Importantly, for both able-bodied and paraplegic individuals, the hybrid combination of electric motor and FES achieved the desired knee angle and the muscle fatigue was less compared to the corresponding *'FES only'* cases.

Further, as shown in Fig. 2, a semi-active hybrid orthosis (SEAHO) that combines FES and a semi-active orthosis was recently tested by the PI's group on an able-bodied subject. The details on SEAHO and its finite state machine controller are given in Kirsch et al. [52].

Subject recruitment. We will recruit 2 able-bodied individuals and 3 persons with SCI after obtaining an approval from the Institutional Review Board of the University of Pittsburgh. Persons with SCI who have an incomplete or complete injury between the Thoracic-1 (T-1) and Thoracic-10 (T-10) levels will be recruited. The prospective participants will be recruited through advertisements. The inclusion criteria for the able-bodied persons are: 1) should be of the ages between 18 and 40 and 2) have no gait impairments. The exclusion criteria for able-bodied persons are: 1) a history of a neurological or an orthopedic condition that impairs normal lower limb movement, 2) any neurological or orthopedic condition that would impair knee extension, 3) absent sensation in the lower leg that would prevent sensation of the onset of FES or induced movements by an electric motor drive, and 4) pregnancy. The inclusion criteria for individuals with SCI are: 1) age 18 and older, 2) primary diagnosis of SCI between T1-T10, 3) at least 1-year post injury, 3) a medical clearance from his/her physician stating absence of any medical contraindications to the participation in the study, 4) accustomed to bearing weight on his or her lower limbs, and 5) experience in using a walking assistive device (e.g., a walking orthosis) in the past or recently. The exclusion criteria for individuals with SCI are: 1) another neuromuscular disease such as polio, stroke, or multiple sclerosis, 2) concurrent severe medical condition, pressure sore or other open wound, existing infection, unstable spine, unhealed limb or pelvic fractures, history of recurrent fractures, known orthopedic or neurological injury to the lower extremities, and osteoporosis, 3) presence of peroneal nerve injury, 4) weight that exceeds more than 240lb (weight limit on the body support system in the PI's laboratory), 5) insufficient knee or hip range of motion, i.e. contractures. For a person with contractures it may not be possible, or safe, to be in the device, 7) lack of minimum joint angle range of motion: knee flexion from 0-80°, hip flexion from 0-45° and hip extension 0-10°, and 8) uncomfortable with FES of quadriceps or inability to tolerate CPN stimulation.

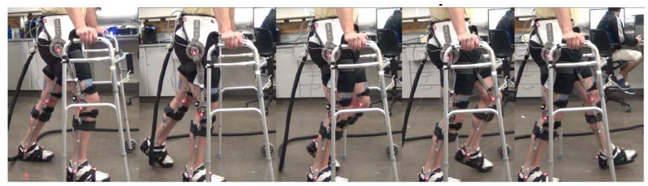

Figure 2: Testing of SEAHO on an able-bodied individual.

Aim 1. To physically validate the model predictive control (MPC) method that optimizes the torque contribution from FES and an electric motor in a modified hybrid leg extension machine. FES, when combined with an electric actuator, introduces actuator redundancy; i.e., a combined torque from an electric motor drive and FES of a muscle can be used to generate joint movement. Further, muscle fatigue during FES is a major technical challenge because over a short period of time the muscle loses its torque generation capability. To overcome these challenges, an MPC-based DCA method has been designed. The advantage of MPC is that it induces adaptation in the control allocation and at the same time controls FES and the electric motor despite their different characteristics. The method requires dynamic models of joint movement and muscle fatigue and a cost function to generate control inputs for FES and the electric motor. The computer model of the knee extension will be taken as $J\ddot{\phi}+G+\tau_p=-\tau_m-\tau_{ke}$, where ϕ is the anatomical knee joint angle, J and $G(\phi)$ are the inertial and gravitational terms, $\tau_p(\phi,\dot{\phi})$ is the joint torque due to passive muscle dynamics, torque τ_m is the torque of the motor, and $\tau_{ke}(\phi,\dot{\phi},a_{ke})$ is the knee extension torque due to stimulation of the quadriceps muscle. The analytical muscle fatigue model [31, 50] is modeled as $\dot{\mu}=\frac{(\mu_{min}-\mu)a_{ke}}{\tau_f}+\frac{(1-\mu)(1-a_{ke})}{\tau_r}$, where μ is the normalized muscle fatigue variable and τ_f and τ_r are the muscle fatigue and recovery time constants, respectively. The muscle fatigue model allows the MPC-based DCA method to predict the onset of muscle fatigue and thus, redistribute torque allocation to the electric motor drive and FES as the muscle fatigues. The cost function will be chosen as $\Pi=\sum_{k=1}^{H}Q(\phi(k)-\phi_d(k))^2+\sum_{k=0}^{H-1}u^T(k)Ru(k)$, where $\phi_d(k)$ is the desired knee joint angle at each discrete time k, $Q\in\mathbb{R}^+$ is a weight on the tracking error, and the matrix $R\in\mathbb{R}^{2\times 2}$ is a positive-definite matrix of weights on the input vector. The objective of this cost function is to minimize the tracking error, while simultaneously minimizing the amount of stimulation and motor torque used.

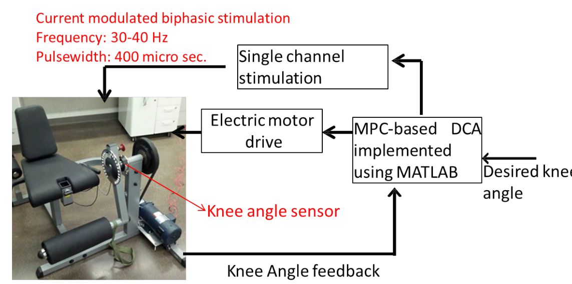

Figure 3: Experimental set-up for eliciting knee extension

We hypothesize that the hybrid LEM will have a lower power consumption, when compared to an electric motor,

<u>and can sustain knee extension movements for longer periods of time despite muscle fatigue induced by FES.</u> 2 able-bodied persons and 3 persons with SCI will be recruited for the knee extension experiments. These experiments will be performed on the hybrid LEM, as shown in Fig. 3. In the LEM, the knee joint torque can be generated by external stimulation of the quadriceps muscle as well as by using an electric motor gear drive.

Task 1. To find the parameters of the musculoskeletal and muscle fatigue dynamics during knee extension. The parameter identification is required because the dynamics of each human subject is unique and to implement the MPC control algorithm, the musculoskeletal and muscle fatigue dynamics must be known. The system identification experiments will be conducted to identify 1) geometrical and inertial properties of a user with the hybrid LEM, 2) viscosity and stiffness of the knee joint, 3) relationship of muscle torque with joint angle and joint-angular velocity, 3) muscle activation due to FES, and 4) muscle fatigue time constants. The geometrical, inertial and biomechanical parameters will be identified using joint angle measurements, pendulum tests, and pull tests [53]. Parameters of muscle activation due to FES will be measured by curve fitting the joint angle and angular velocity measurements and joint torques with controlled stimulation [54]. Muscle fatigue time constants will be identified by using as isometric knee contraction protocol as explained in Riener et al. [50]. Nonlinear model identification methods such as Grey Box modeling, which are available in MATLAB (Math Works, USA), will also be used.

Task 2. To experimentally validate the MPC-based DCA for eliciting knee extension. A participant will be asked to sit relaxed on the LEM while a computer generated control algorithm simultaneously commands an electrical stimulator (CWE Inc, USA) and an electric motor drive (Leeson Electric, USA) to generate involuntary leg extension movements. The MPC-based DCA method will be programmed in a MATLAB (MathWorks, USA) code. A code generator called CVXGEN [51,55] will be used for real-time implementation of the MPC-DCA method. The weights on the electric motor drive input and stimulation in the objective cost function will be tuned by a hit and trial method. The purpose of the weight tuning is to optimize control performance and the control inputs. More details about the proposed control algorithm are in Kirsch et al [56]. A real-time *hardware in the loop* system, QPIDe (Quanser, Canada), will be utilized to control the electric motor drive and the electrical stimulation of the quadriceps muscle. The knee extension angle will be measured by an optical encoder (Calt, China). The knee angle information will be used by the MPC-based DCA method to modulate stimulation current and the current to the electric motor drive. During FES, only current amplitude will be modulated while frequency (30 Hz) and pulsewidth (400μsec) will be kept constant. This process is illustrated in Fig. 3. Elicited lower-leg movements will be within normal range of knee angles and angular velocities. The leg extension machine has safety features (hard stops) to avoid any injury due to hyper knee extension/ flexion in the rare case of electric motor malfunctioning. Further, the software limits prevent the control signals to electric motor from inducing movements that go beyond the desired leg movement range.

Each participant will undergo the knee extension experiment on both of their legs. The control objective will be to make the lower leg follow or maintain a desired lower leg angle. Three sets of experiments will be randomly performed. The first set of experiments will only use FES to elicit knee extension. The second set of experiments will use the hybrid combination of electric motor and FES to elicit knee extension. The third set of experiments will use only electric motor to elicit knee extension. In all the experimental sets, only the MPC-based algorithm will be used to elicit knee extension. Each experiment will be run until the algorithm's performance, which is computed in terms of knee angle error (difference between the desired and the actual knee angle), drops below a predefined level. At the end of the experiments, a one-way analysis of variance (ANOVA) with repeated measures will be used to assess statistical differences in the following performance measures 1) root mean square (RMS) of knee angle error, 2) length of experimental run, and 3) average power consumption, which is defined as average current supplied multiplied with the applied voltage. Post-hoc testing consisting of paired t-tests with a Bonferroni correction will be performed when a significant ANOVA tests are identified.

Expected Results. The hybrid LEM serves as a general platform to evaluate computer algorithms to control FES and the electric motor drive. We expect that the hybrid combination of FES and the electric drive will have a lower power requirement to produce limb movements compared to a sole electric motor drive and also will provide the limb movement that can be sustained for a longer period of time compared to sole FES-based system. We are hopeful that the MPC-based DCA method and its experimental evaluation will provide insight to enhance a lower-limb exoskeleton with FES; e.g., during hip extension [23] and knee extension [25,26].

Aim 2: To physically validate the MPC method on a hybrid walking device to elicit walking in persons with

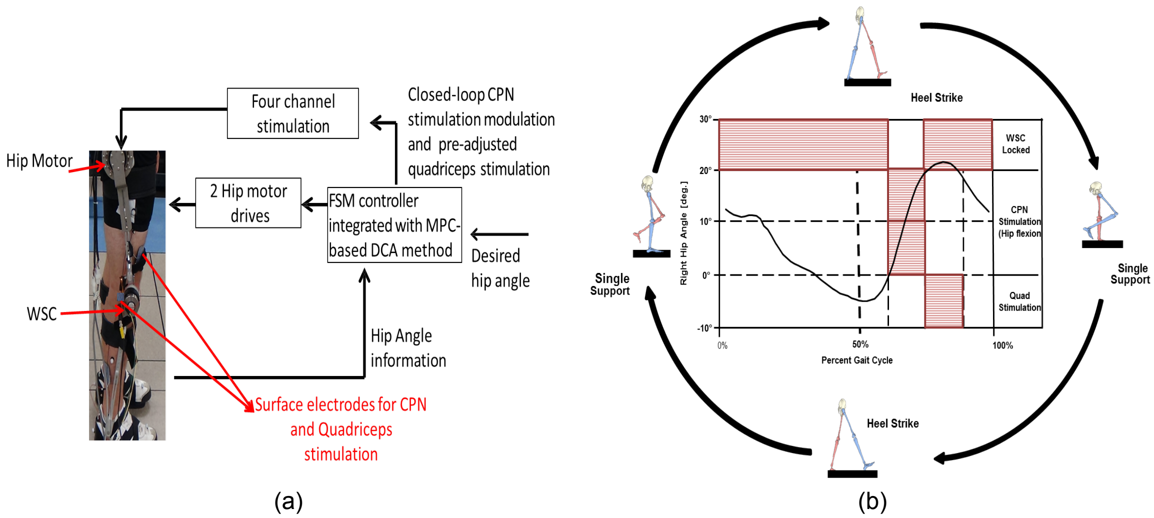

Figure 4: (a) Experimental set up for walking (b) FSM controller uses hip angle to actuate different components of SEAHO.

spinal cord injury. The walking platform (SEAHO) built in the PI's laboratory uses hip electric motors and CPN stimulation to produce hip flexion. The rationale for employing a hybrid combination for hip flexion is to use the hip motor to compensate for loss in the sensitivity of CPN stimulation. The CPN stimulation often habituates after constant stimulation [11], which causes insufficient hip flexion over a period of time. The MPC-DCA method will be used to simultaneously control CPN stimulation and the hip electric motor drive to elicit hip flexion. This method may also facilitate redistribution of torque allocation among the hip electric motor drive and the CPN stimulation when the CPN stimulation habituates.

<u>We hypothesize that the hybrid walking device will have a lower power consumption, when compared to a semi-powered exoskeleton, and can sustain hip flexion movements for longer periods of time than CPN stimulation alone.</u> The MPC algorithm will be validated on 3 individuals with SCI. The participant will come for 5 visits for the familiarization and training with the device and another 5 visits for the model identification experiments. Three additional sessions will be used to test the MPC-based DCA during walking. The main goal is to evaluate the method's performance during hip flexion and its ability to overcome habituation in the withdrawal reflex. The familiarization and training visits will allow us to customize and optimize the hybrid walking device according to the individual. All training sessions will be supervised by a physical therapist and/or physician. The following two tasks will be performed to achieve the aim.

Task 1 - To model common peroneal stimulation (CPN) and its habituation characteristics. External stimulation of the CPN elicits a primary response in the hip flexion muscles through the activation of high threshold pain afferent neurons. However, the model of the CPN stimulation is not available in the current literature, i.e., a model, defined by a set of differential equations that explains the CPN stimulation behavior has not been investigated. Therefore, the first task for Aim 2 is to develop an input and output model and habituation characteristics of the CPN using system identification techniques. The CPN stimulation will be modeled as $J\ddot{\phi} + G + \tau_p = -\tau_m - \tau_{he}$, where ϕ is the anatomical hip joint angle, J is the combined inertia of a user and SEAHO, $G(\phi)$ is the gravitational term, $\tau_p(\phi, \dot{\phi})$ is the joint torque due to passive muscle dynamics, torque τ_m is the torque of the hip motor, and $\tau_{he}(\phi, \dot{\phi}, a_{ke})$ is the hip flexion torque due to CPN stimulation. Similarly, the dynamics for CPN habituation, defined by variable ν, will be modeled as $\dot{\nu} = \frac{(\nu_{min} - \nu)a_{he}}{\tau_f} + \frac{(1-\nu)(1-a_{he})}{\tau_r}$, where τ_f is the habituation time constant and τ_r is the recovery time constant. The parameter identification experiments will be conducted to identify 1) geometrical and inertial properties of a user, while wearing SEAHO, during hip flexion, 2) viscosity and stiffness of the hip joint, 3) relationship of muscle torque with hip joint angle and hip joint-angular velocity, 4) muscle activation due to CPN stimulation, and 5) habituation time constants. The geometrical, inertial and biomechanical parameters will be identified using joint angle measurements, pendulum tests, and pull tests [53]. Parameters of muscle activation due to CPN stimulation will be measured by curve fitting the joint angle and angular velocity measurements and joint torques with controlled stimulation [54]. Time constants for CPN habituation will be identified by running a series of withdrawal reflex experiments over a period of 4 weeks. The reduction in the elicited hip angle will be used to find the habituation time constant. Nonlinear model identification methods such as Grey Box modeling methods, which are available in MATLAB (Math Works, USA), will also be used.

Task 2 - To synchronize CPN stimulation with the hip electric motor to produce walking in a person with SCI. A finite state machine (FSM) controller incorporating the MPC-DCA method will be designed to control the FES of the peroneal nerve and the actuation of the electric motors at the hip joint, as shown in Fig.4 (a). A preliminary version of the FSM controller was recently validated in a previous study [52]. The FSM divides walking into discrete phases to control or synchronize the individual components of the device, namely, FES of the quadriceps muscle and CPN, electric motors, and the knee locking and unlocking via a wrap spring clutch (WSC) (Warner electric, USA). designed for SEAHO. The timing of each phase is based on the hip angle information, as shown in Fig. 4 (b). The hip angle information will be taken from the angle encoder inbuilt in the hip electric motor (Harmonic drive LLC, USA). Quadriceps stimulation will be adjusted to achieve full knee extension before running an experiment; i.e., the knee extension movements will not use knee angle as feedback. An input from a user via a hand button on the walker will initiate motion; e.g., the right hand button will initiate hip flexion and knee extension movements in the right leg and hip extension in the left leg; vice versa for the left hand button. The participant will also be secured with a body support system to ensure safety or to prevent falls. Foot switches (Tekscan, USA) will be added to detect heel strike and maintain security of the participant.

Each participant will undergo a walking experiment. The sub-control objective will be to make the hip joint follow or maintain a desired hip angle during walking. Three sets of walking experiments will be randomly performed. The first set of experiments will only use FES of the CPN to elicit hip flexion. The second set of experiments will use the hybrid combination of hip motor and FES of the CPN to elicit hip flexion. The third set of experiments will use only hip motors to elicit hip flexion. In all of the experiments, only the MPC-based algorithm will be used to elicit hip flexion. Each walking experiment will be run till the participant fatigues or will be stopped based upon the participant's comfort level. The participant's blood pressure (BP) level and heart beat will be monitored to prevent overexertion and the experiment will be stopped, in case BP and heart beat levels cross limits. At the end of the experiments, ANOVA with repeated measures method will be used to assess statistical differences in the following performance measures 1) RMS of the hip angle error, 2) length of experimental run, and 3) average power consumption. Post-hoc testing consisting of paired t-tests with a Bonferroni correction will be performed when a significant ANOVA tests are identified.

Expected Results. SEAHO platform acts as a unique platform to evaluate the MPC-based DCA method to control CPN stimulation and the hip electric motor drives. We expect that SEAHO will have a lower power requirement to produce limb movements compared to a semi-powered exoskeleton and also will provide the limb movements that can be sustained for a longer period of time compared to a system with sole CPN stimulation. We are hopeful that experimental evaluation of the control method will provide insight to enhance the CPN stimulation with a hip electric motor drive during hip flexion.

Potential Problems and Alternative Approach. *Modeling.* Despite best efforts that would be made to identify the model of knee extension and CPN stimulation, unmodeled phenomena or modeling errors would affect the performance of the MPC-based algorithms. A feedback-based controller will be added to the system to compensate for unmodeled phenomena or modeling errors. *CPN stimulation modeling.* In addition to hip flexion, the withdrawal reflex also generates knee flexion and ankle dorsiflexion. We are ignoring these limb movements to keep the model simple. In future studies, knee flexion movement due to withdrawal reflex can be included; especially, when a knee electric motor needs to be synchronized with CPN stimulation during walking. Habituation of CPN stimulation may take several months to show considerable change in the hip flexion movement. And because the number of training and experimental sessions are limited, the identification of habituation constant may not be accurate. However, use of feedback control and adaptability of MPC will compensate for the modeling inaccuracy. *Voluntary effort:* To prevent voluntary interference from able-bodied participants, the participants will be instructed to relax as much as possible.

Summary. If successful, the proposed control methods can be used to combine FES with powered exoskeletons such as Indego, Ekso, and ReWalk. The hybrid walking system will have lower power consumption and will adapt to accommodate the adverse effects of muscle fatigue, which implies that limb movements with FES can be elicited for longer durations. This overall improves physical activity and ambulation capacity which may lead to higher levels of community participation and quality of life of individuals with mobility impairments [28, 57, 58].

PROTECTION OF HUMAN SUBJECTS

This study will recruit 2 able-bodied persons and 3 individuals with spinal cord injury (SCI) to conduct experiments as per Aims 1 and 2. There are no inclusion/exclusion criteria based on sex or race. The advertisements for recruiting able-bodied participants will be posted on the bulletin boards in the common areas of the Benedum Hall (location of the PI's research laboratory) at the University of Pittsburgh. The advertisement for a participant with SCI will be posted in the corridors of the UPMC Rehabilitation Institute. In addition, the study will be included in the research participant registry database, representative of population diversity in Pittsburgh, of the Clinical and Translational Science Institute at the University of Pittsburgh.

An approval to conduct the study has been obtained from the Institutional Review Board of the University of Pittsburgh. The leg extension experiments proposed in Aim 1 will involve 2 able-bodied subjects and 3 participants with SCI. The walking experiments proposed in Aim 2 will involve 3 participants with SCI. Persons with SCI who have an incomplete or complete injury between the Thoracic-1 (T-1) and Thoracic-10 (T-10) levels will be recruited.

The inclusion criteria for the able-bodied persons are: 1) should be of the ages between 18 and 40 and 2) have no gait impairments. The exclusion criteria for able-bodied persons are: 1) a history of a neurological or an orthopedic condition that impairs normal lower limb movement, 2) any neurological or orthopedic condition that would impair knee extension, 3) absent sensation in the lower leg that would prevent sensation of the onset of FES or induced movements by an electric motor drive, and 4) pregnancy.

The inclusion criteria for individuals with SCI are: 1) age 18 and older, 2) primary diagnosis of SCI between T1-T10, 3) at least 1-year post injury, 3) a medical clearance from his/her physician stating absence of any medical contraindications to the participation in the study, 4) accustomed to bearing weight on his or her lower limbs, and 5) experience in using a walking assistive device (e.g., a walking orthosis) in the past or recently. The exclusion criteria for individuals with SCI are: 1) another neuromuscular disease such as polio, stroke, or multiple sclerosis, 2) concurrent severe medical condition, pressure sore or other open wound, existing infection, unstable spine, unhealed limb or pelvic fractures, history of recurrent fractures, known orthopedic or neurological injury to the lower extremities, and osteoporosis, 3) presence of peroneal nerve injury, 4) weight that exceeds more than 240lb (weight limit on the body support system in the PI's laboratory), 5) insufficient knee or hip range of motion, i.e. contractures. For a person with contractures it may not be possible, or safe, to be in the device, 7) lack of minimum joint angle range of motion: knee flexion from 0-80°, hip flexion from 0-45° and hip extension 0-10°, and 8) uncomfortable with functional electrical stimulation of quadriceps or inability to tolerate common peroneal nerve stimulation.

Protection from potential risks in Aim 1

Electrode Placement: There is a rare risk of irritation, rash, and redness with application of the electrodes. This should go away after the electrodes are removed.

Functional Electrical Stimulation (FES): There is a likely risk of a tingling sensation near the electrode site. Also, most individuals experience muscle soreness after the experiments, just like an individual might experience after exercise. FES stimulation causes the muscle to fatigue more rapidly than volitional muscle contractions. For this reason sufficient rest periods will be provided between trials to allow participants to recover. FES can be perceived as uncomfortable. In some of the sessions, the participant may be stimulated for 8 minutes. FES that long period may not be tolerable. The participants may refuse to participate further if they do not feel comfortable.

Knee Joint Movements: Rarely, a sudden movement-related injury, i.e., sprain, strain may occur as a result of hyperextension of the knee joint. To ensure that this does not occur a strap has been added to the leg extension machine that prevents it from hyperextending the knee. The leg extension machine also has a mechanical stopper to prevent the leg extension arm from moving in the direction of flexion beyond a certain point.

Electric Motor: There is a very small chance that the circuit driving the motor that is attached to the leg extension machine could fail, causing unpredictable movements of the motor. The torque of the motor acting on the leg is constantly measured and monitored. The software prevents this torque from exceeding a healthy value, and the experimenter can immediately cut power to the driver should the conditions become unsafe. To ensure that this does not produce any harm to the participant, a strap has been added to the leg extension machine that prevents it from hyperextending the knee. The leg extension machine also has a mechanical stopper to prevent the leg extension arm from moving in the direction of flexion beyond a certain point.

Protection from potential risks in Aim 2

Electrode Placement: There is a rare risk of irritation, rash, and redness with application of the electrodes. This should go away after the electrodes are removed.

Functional Electrical Stimulation of quadriceps muscle: FES may feel uncomfortable or painful. In that case, a participant may refuse to participate in the study.

Common peroneal nerve (CPN) stimulation: CPN stimulation involves stimulation of sensory nerves at higher stimulation amplitudes. The purpose of the stimulation is to elicit withdrawal reflex leading to hip, knee, and ankle flexion. Due to higher amplitude stimulation, a participant may or may not feel pain. If the pain is unbearable, the participant may refuse to participate in the study.

Knee and Hip Joint Movements: Rarely, a sudden movement-related injury, i.e., sprain, strain may occur which may result due to hyperextension of the knee or hip joint. As a precautionary measure, safety features have been added to the software and hardware of the orthosis device. The hardware safety features are as follows:

1. Knee Joint Limiters: The orthosis has mechanical stoppers to prevent injury that might occur as a result of hyper extension of the knee.
2. Hip Joint Limiters: The orthosis has mechanical stoppers to prevent injury that might occur as a result of hyper extension/flexion of the hip.

The software safety features are as follows:

1. Emergency Stop: A participant will be given a button that can terminate the hybrid orthosis system should one feel that one can no longer continue, or if the system is not operating correctly and could be putting the participant at risk.
2. Hip Motor Position Limiters: Should the hip motors exceed a certain range of hip flexion/extension, the software sets the torque command signal to the motor to be zero. This means that the electric motors cannot be operated outside of a certain range of hip joint motion.

Risk of Fall: During the walking tests it is possible that participants may not be able to support themselves and may fall. The following measures ensure fall prevention.

1. Solo-Step: The Solo-Step system is a ceiling mounted body unweighing system that is tested and rated up to 240 lbs. This system will ensure that the participant is safe from falling to the ground.
2. Walker: The participants will use a walker to stabilize themselves during the tests.
3. Knee Joint Wrap Spring Clutch: Unidirectional wrap spring clutches are installed on the knee joint of the brace. This is done so that the brace may be locked in flexion, but always free in extension. When wrap spring clutches are engaged they will prevent a participant from falling while standing by preventing knee flexion.

Fall can also occur during transfers from wheelchair to table. A trained therapist who is trained in transfers will help in transfer you from your wheelchair to a cushioned chair or table.

Electric Motor: There is a very small chance that the circuit driving the motor that is attached to the hip joint could fail, causing uncontrollable or unpredictable movements of the motor. The maximum torque that the motor at the hip joint is capable of generating is large enough to generate the gait motion but not large enough to cause any harm to a participant. The mechanical stoppers will prevent the motors from causing any hyperextension or hyperflexion of the joint. Also, the experimenter, who will be closely monitoring the motor and driver system, can remove the power from the motor drivers with the push of a emergency stop.

Physical Exertion: If the participant's exertion level is high, the heart rate (HR) can exceed a certain limit, or the participant may have symptoms like chest pain. We will monitor each participant's HR and session will be halted once we find the HR exceeds a pre-calculated limit or if you feel and report that the exertion level is high, the study will be halted. Blood pressure (BP) will also be monitored. The BP will be taken initially and following testing and training activities during each session. The session will be halted in case the upper limit of systolic BP exceeds: 220 mm Hg during activity; goes below the lower limit: 90mm Hg or drop of >10mm from baseline; diastolic BP exceeds upper limit: 110 mm Hg; lower limit goes below: 60mm Hg.

Protection from risks common to both Aims

Videotaping: Participation may be video recorded and disseminated during conference presentations, seminars, or publications. However, the participant's face will not be included in a video recording to safeguard his/her identity. The participant may also choose not to be videotaped. The video recordings from the laboratory video camera, after recording a session, will transferred to the PI's office computer. The recording on the camera will be subsequently deleted. All the recordings from the sessions will be, thus, kept in a password protected folder on the PI's office computer. Each video recording and any electronic data will be identified only by recording date and the experiment type. Only research collaborators and graduate students working on the project will have access to these recordings.

Benefits: There might be no direct benefit to a participant. The objective of the study is to improve current knowledge on walking devices and understanding how to control the hybrid neuroprostheses better using computer algorithms.

Confidentiality: To protect the participant's privacy, only the PI and members of the research team will be aware of a subject's participation in this research study. We will not link the participant's name to any of the information we obtain. Any video recording, electronic research data, and any paper-based research records will be identified only by subject code (A, B, C, etc.), recording date, and the experiment type. The participant's identity will not be revealed in any description or publications of this research. Although we will do everything in our power to protect the participant's privacy and the confidentiality of participant's records, just as with the use of participant's medical information for health care purposes, we cannot guarantee the privacy of the participant's research records. Authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office may review the participant's data for the purpose of monitoring the conduct of this study.

It is possible that we may use the information obtained from this study in other research studies examining FES controllers for walking and upper limb restoration. This information may also be shared with other researchers here, and at other research centers, but those researchers will never be provided with any personal identifiers that would allow them to learn the participants. The research data will be kept indefinitely. Please note that the University of Pittsburgh policy is to maintain research records for 7 years following final publication and completion of the project.

The video recordings from the laboratory video camera, after recording a session, will transferred to the PI's office computer. The recording on the camera will be subsequently deleted. All the recordings from the sessions will be, thus, kept in a password protected folder on the PI's office computer. Each video recording and any electronic data will be identified only by recording date and the experiment type. Similar procedures will be followed for any electronic data collected during an experimental session. Only research collaborators and graduate students working on the project will have access to these recordings and data.

Payment for Participation: Participants with spinal cord injury will be compensated for any costs that they incur while traveling to and from the PI's laboratory for each session. In addition, they will be compensated up to $75 (including travel cost) for participating in each session. They will be compensated for each session completed regardless of completing the whole study.

INCLUSION OF WOMEN AND MINORITIES

INCLUSION OF WOMEN

In our clinics, average female to male prevalence is 42% female and 58% male, with breakdown of spinal cord injury as follows: 28% female, 72% male. In order to ensure that females are appropriately recruited according to the frequencies above, we will monitor participant enrollment quarterly. If enrollment is below targeted values for females (expected at 28%), we will specifically target recruitment of females to ensure targeted enrollment is attained. See Planned Enrollment Report attached. We will do this by encouraging clinicians who are assisting with recruitment (see letters of support) to inform female participants and their parents/guardians about our study and by posting advertisements in our recruitment locations where females access services such as attendant care or therapy.

INCLUSION OF MINORITIES

The race and ethnic representation of Pennsylvania compared to our clinic population is shown in the table below. Our clinic population represents mostly individuals from Western Pennsylvania with a small representation from Ohio and West Virginia. We will attempt to over-recruit participants of minority backgrounds into our study. Please see Planned Enrollment Report attached. We will monitor participant enrollment quarterly, and if enrollment is below targeted values for minorities in the 2012 Pennsylvania Census, we will specifically target recruitment of these groups to ensure targeted enrollment is attained.

	2013 Clinic Census	2012 Pennsylvania Census	Difference
Race			
Asian	0.6%	3.0%	-2.4%
Black or African American	6.6%	11.4%	-4.8%
Native Hawaiian and Other Pacific Islander	0.0%	0.1%	-0.1%
American Indian and Alaska Native	0.0%	0.3%	-0.3%
Multiracial	1.1%	1.7%	-0.6%
Caucasian	91.7%	83.5%	8.2%
Total	100.0%	100.0%	

Ethnicity			
Hispanic/Latino	0.6%	6.1%	-5.5%
Non-Hispanic/Latino	99.4%	79.5%	19.9%
No response	0.0%	14.8%	-14.8%
Total	100.0%	100.0%	

Table 4: Race and Ethnicity Comparisons for the 2012 Clinic Census vs Pennsylvania Census

OMB Number: 0925-0002

Planned Enrollment Report

Study Title: Control of FES and an Electric Motor Drive for a Hybrid Gait Neuroprothesis

Domestic/Foreign: Domestic

Comments:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	**0**
Asian	0	0	0	0	**0**
Native Hawaiian or Other Pacific Islander	0	0	0	0	**0**
Black or African American	1	1	0	0	**2**
White	2	1	0	0	**3**
More than One Race	0	0	0	0	**0**
Total	**3**	**2**	**0**	**0**	**5**

Study 1 of 1

Tracking Number: GRANT11841465

Funding Opportunity Number: PA-13-304. Received Date: 2015-02-19T12:54:22.000-05:00

Inclusion of Children

The proposed research will involve both adults and children of age 18 years and above. The rationale for including children is that persons between the ages of 16 and 30, according to National Spinal Cord Injury Association Resource Center, are predisposed to a higher risk of sustaining a spinal cord injury. Efforts will be made to enroll children in the age group of 18 – 21 years old from the pediatric and adult clinics.

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School of Health and Rehabilitation Sciences
Department of Rehabilitation Science and Technology

School of Medicine
Department of Physical Medicine and Rehabilitation

To the Grant Review Committee:

I am pleased to write this letter of support for Dr. [redacted] application entitled “Control of FES and an Electric Motor Drive for a hybrid gait neuroprosthesis” for consideration under the NIH Small Research Grant Program (R03). I am excited to lend my expertise to the project and feel strongly that hybrid neuroprosthesis technology holds promise for improving standing and gait in individuals with many types of disabilities including spinal cord injury.

I am the Medical Director of the Human Engineering Research Laboratories and Associate Professor in the Department of Physical Medicine and Rehabilitation at the University of Pittsburgh Medical Center (UPMC). My research focuses on assistive technology solutions to improve mobility and self-management skills in individuals with disabilities and chronic conditions, including spinal cord injury. On this project, my role will be to assist with recruitment and provide medical oversight of gait experiments.

My clinical interests focus around treating the assistive technology and rehabilitation needs of individuals with complex disabilities. Locally, I am the Director of the UPMC Adult Spina Bifida Clinic and the Medical Director of the UPMC Center for Assistive Technology. I also developed and directed a wellness program for individuals with spinal cord injury and spina bifida as part of a rare and chronic disease collaborative in a partnership with our integrated insurance division, UPMC Health Plan.

I have reviewed Dr. [redacted] proposal. This hybrid neuroprosthesis technology is highly innovative because the powered exoskeleton is enhanced with FES. As such, the technology may maximize the time and distance a user can walk with the hybrid device. I look forward to working with my colleagues on this important work. Please feel free to contact me with any questions or concerns.

Sincerely,

Brad [redacted] MD
Associate Professor
University of Pittsburgh Medical Center
Department of Physical Medicine and Rehabilitation

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Feb 13, 2015

TO: [redacted] Ph.D.
Mechanical Engineering and Materials Science
University of Pittsburgh
538C Benedum Hall
3700 O'Hara Street
Pittsburgh, PA 15261

FROM: [redacted] M.S.B.E.

RE: Letter of Support

Dear [redacted]

I am enthusiastic to consult on your proposed research project: "Control of FES and an Electric motor drive for a Hybrid Gait Neuroprosthesis". For the past 35 years my professional efforts have been dedicated to improving the lives and personal mobility of individuals paralyzed by spinal cord injury, stroke or other disabling neurological conditions. I have focused on the construction of effective patterns of stimulation to restore or facilitate movement of the lower extremities and the control of posture. I have devised systems for delivering electrical stimulation to the key muscles required for walking and combined them with orthoses into hybrid gait neuroprosthesis (HGN) and I am committed to thoroughly evaluating their performance. Due to fatigue limitations of electrically stimulated paralyzed muscles, I believe providing on demand power assist can significantly improve the performance of the HGN to restore functional mobility in people with paralysis, thus improving their access to community and improve their quality of life.

I will provide my expertise and skills in development and application of your HGN to help ensure success of your study. I am excited about development of advanced controllers combining electrical stimulation and power assist from electric motors for HGN with goal of improving walking in persons with paralysis and looking forward to overcoming challenges that may come our way in this endeavor.

[redacted]

CASE WESTERN RESERVE UNIVERSITY EST. 1826

[redacted]
Departments of Orthopaedics & Biomedical Engineering
And Senior Research Career Scientist,
Louis Stokes Cleveland Department of Veterans Affairs Medical Center
10701 East Boulevard, Cleveland Oh 44106

Date: February 13, 2015

From: Dr. Ronald J. [redacted]
Tenured Professor of Orthopaedics and Biomedical Engineering
Case Western Reserve University and
Director, Motion Study Laboratory and Senior Research Career Scientist,
Louis Stokes Cleveland Veteran's Affairs Medical Center

Re: Support for Model Predictive Control Proposal of Dr. [redacted] [redacted]

To whom it may concern:

This is to confirm my willingness and ability to serve as an expert consultant to Dr. [redacted] [redacted] as he pursues original and valuable research on the application of model predictive control to the coordination and integration of electrical stimulation and active motor assistance via actuated exoskeletal bracing hybrid systems for standing and stepping after paralysis.

I have been an active researcher and developer of neuroprosthetic systems to facilitate standing, walking, stair ascent/descent and automatic control of standing and seated posture and balance at Case Western University and the Cleveland VA Medical Center since 1994. As such, I have led and significantly participated in numerous externally funded research programs to design and test hybrid combinations of electrical stimulation and advanced bracing sponsored by the VA and Department of Defense. I also direct the Motion Study Laboratory at the Cleveland VA Medical Center, which is a state-of-the-art human motion capture and biomechanical analysis facility dedicated to the pursuit of advanced neuroprosthetic and orthotic interventions to facilitate daily function after neuromuscular disorders such as spinal cord injury, stroke and multiple sclerosis.

I am pleased to lend Dr. [redacted] the benefits of my experience with electrical stimulation and the design of control systems for hybrid neuroprostheses combining biological power and advanced bracing and look forward to participating in this worthwhile project.

[redacted]

Ronald J Triolo

[redacted]

CASE WESTERN RESERVE UNIVERSITY EST. 1826

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Department of Biomedical Engineering
Wickenden Building - Room 309

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http://bme.case.edu

February 12, 2015

[redacted] Ph.D.,
538C Benedum Hall,
3700 O'Hara Street,
Pittsburgh, PA 15261.

Dear Dr. [redacted]

I will be very glad indeed to participate as a consultant on your proposed project titled "Control of FES and an Electric motor drive for a Hybrid Gait Neuroprosthesis" which proposes to design a closed-loop control system for functional electrical stimulation (FES) applications. I will be prepared to commit some of my effort for consultation on the project.

I look forward to working with you on this important and interesting study.

Sincerely,

[redacted]
Research Associate Professor

Centers for Rehab Services
A Partner of UPMC

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South Side Outpatient Center
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Pittsburgh, PA 15203
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February 17, 2015

To whom it may concern:

This letter is written in support of my consultation for the NIH R03 grant application entitled "Control of FES and an Electric motor drive for a Hybrid Gait Neuroprosthesis." My consultation in this undertaking will be to provide physical therapy services in regards to supervision of transfers and also with gait training with the functional electrical stimulus enhanced bilateral lower extremity orthoses. I am also pledging my consultation for the entirety of the study, and as long as there is a need for the my consultation services.

[redacted]

We'll Get You Going Again

Physical Therapy • Occupational Therapy • Speech Therapy • Industrial Therapy

Resource Sharing Plan

Data sharing plan: Promising new control methods and gait restoration technologies may be developed during the course of the research. The research data and methods generated in this grant will be presented at national or international conferences and published in journals in a timely fashion. All final peer-reviewed manuscripts that arise from this proposal will be submitted to the digital archive PubMed Central.

Following data will be kept in digital or in hard copy format for minimum of 5 years post publication and can be made available, upon request to the corresponding author on a publication.

- Analysis of the research results from the human subject experiments; e.g., tables, graphs, plots
- MATLAB codes of control methods
- Project reports, poster, and power point presentations

Research data will be stored in a locked and secure location. Data entered into the computer will be protected by a password and firewalls. Subject participation during experiments may be video recorded and disseminated during conference presentations, seminars, or publications. However, a subject's face will not be included in a video recording to safeguard his/her identity. A subject may also choose not to be videographed. Also to protect a subject's privacy, only Dr. [redacted] and members of the research team will be aware of their participation in this research study. We will not link their name to any of the information we obtain. Their identity will not be revealed in any description or publications of this research.

Sharing Model Organisms: not applicable.

Genome wide studies: not applicable.