

AWARD NUMBER:

W81XWH-14-2-0132

TITLE: Restoration of Bladder and Bowel Function Using Electrical Stimulation and Block after Spinal Cord Injury

PRINCIPAL INVESTIGATOR: Graham Creasey, MD, FRCSEd

RECIPIENT: VA Palo Alto Health Care System/PAVIR , Palo Alto, CA

REPORT DATE:

October 2020

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Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) VA Palo Alto Health Care System/PAVIR 3801 Miranda Ave Palo Alto, CA 94304				8. PERFORMING ORGANIZATION REPORT NUMBER	
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13. SUPPLEMENTARY NOTES					
14. ABSTRACT The purpose of the project is to evaluate the restoration of bladder function using electrical stimulation and block after spinal cord injury in human subjects. Regulatory compliance has been maintained with the Institutional Review Boards and the Human Research Protection Office and Investigational Device Exemption has been maintained with the Food and Drug Administration. Nine subjects have been enrolled and undergone urodynamic evaluation, six of these have undergone neuromodulation by electrical stimulation via skin surface electrodes. and four responded to this neuromodulation. Two did not wish to proceed with surgical implantation of a bladder stimulator, one is considering implantation and one has undergone implantation. In this subject the implant has been successful in restoring micturition without catheterization and continence without medication or rhizotomy for the first time in 41 years. Two additional sites have been added to the trial. Recruitment is continuing and has identified several more suitable subjects who will be evaluated when the pandemic allows.					
15. SUBJECT TERMS Spinal Cord Injuries, Neurogenic Bladder, Electric Stimulation					
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1. INTRODUCTION:

This is a Phase 1 clinical trial of an implanted electrical stimulator to improve both continence and voiding in human subjects with chronic spinal cord injury. It will use the existing FDA-approved Vocare stimulator and electrodes, implanting electrodes on the sacral nerves as usual but without performing posterior sacral rhizotomy. Conventional low frequency stimulation will be applied to the sacral nerves at a low amplitude to activate large afferent axons with the aim of inhibiting bladder contraction by neuromodulation, and bladder capacity and continence will be measured. Higher frequency stimulation will be applied at low amplitude and tested for its effectiveness in blocking sphincter contraction for the purpose of improving micturition.

2. KEYWORDS:

Spinal Cord Injuries, Neurogenic Bladder, Electric Stimulation

3. ACCOMPLISHMENTS:

What were the major goals of the project?

1. Maintain regulatory compliance
2. Coordinate study staff for clinical trial
3. Participant recruitment, screening & surgery
4. Evaluation of continence
5. Evaluation of voiding
6. Data analysis and publication

What was accomplished under these goals?

- 1) Major activities
 - Regulatory compliance maintained
 - Study staff for clinical trial maintained
 - Participant recruitment and screening continued
 - First non-veteran subject implanted
- 2) Specific Objectives
 - To improve continence by electrical stimulation in human subjects with SCI
 - To improve voiding by electrical stimulation in human subjects with SCI
- 3) Significant results
 - Regulatory compliance maintained
 - a. FDA approval maintained
 - b. IRB approval maintained for Stanford University IRB, Santa Clara Valley Medical Center IRB and MetroHealth Medical Center (Cleveland) IRB
 - c. HRPO approval maintained for VA Palo Alto, Santa Clara Valley Medical Center and MetroHealth Medical Center
 - d. Information on clinicaltrials.gov has been updated
- 4) Coordinate study staff for clinical trial
 - a. Staff training maintained at VA Palo Alto and Santa Clara Valley Medical Center, San Jose
 - b. Staff training at MetroHealth Medical Center, Cleveland, OH is in process
- 5) Participant recruitment, screening and surgery
 - a. First non-veteran subject has been successfully implanted at Santa Clara Valley Medical Center and has undergone programming of the device and urodynamic evaluation and one year follow-up.
 - b. Other veteran and non-veteran subjects being recruited within limits of pandemic
- 6) Evaluation of continence
 - a. The implant has been able to produce continence without anticholinergic medication or rhizotomy in non-veteran subject for the first time in 41 years.
- 7) Evaluation of micturition
 - a. External controller has been modified for micturition
 - b. FDA Amendment approved for modification of external controller
 - c. The implant has been able to produce micturition without catheterization or rhizotomy in non-veteran subject for the first time in 41 years
- 8) Data analysis and publication
 - a. Data collection and analysis for the non-veteran subject with implant
 - b. Publication in Operative Neurosurgery
 - c. Presentation at International Neuro Urology Society
- 9) Other achievements
 - a. Funding of routine costs of clinical trial at Santa Clara Valley Medical Center under CMS National Coverage Determination 310.1 has been confirmed
 - b. A request for extension without funding for the next 12 months has been approved, and a request has been made to DOD for an additional site at the University of New Mexico

What opportunities for training and professional development has the project provided?

The Biomedical Engineer has received training from the biomedical engineering collaborators in the VA Functional Electrical Stimulation Center in Cleveland Ohio, and the Neurosurgeon and Urologist in Santa Clara Valley Medical Center have received training allowing them to carry out implants in non-veterans.

How were the results disseminated to communities of interest?

A journal article and video was published by the journal Operative Neurosurgery in January 2020
A presentation was given to the International Neuro Urology Society conference in Istanbul, Turkey in January 2020.

What do you plan to do during the next reporting period to accomplish the goals?

1. Maintain IRB, HRPO and FDA approval for all three sites
2. Continue recruitment, screening, enrollment and evaluation of subjects at all three sites
3. Open additional site at the University of New Mexico
4. Confirm funding of routine costs of clinical trial at MetroHealth Medical Center under CMS National Coverage Determination 310.1
5. Implantation of additional stimulators
6. Evaluation of bladder capacity and continence with implanted stimulator
7. Evaluate micturition with implanted stimulator using higher frequencies

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

The use of electrical stimulation to restore both bladder continence and emptying without destructive surgery has generated considerable interest in the discipline of spinal cord injury particularly in Britain, France, Australia and New Zealand.

What was the impact on other disciplines?

Collaboration with biomedical engineers, particularly at the VA Functional Electrical Stimulation Center in Cleveland, Ohio, is defining new electrical stimulation parameters and protocols for management of the neurogenic bladder.

What was the impact on technology transfer?

The approval by the Food and Drug Administration of Investigational Device Exemption for evaluation of both continence and voiding in this project will facilitate progress of the project towards technology transfer of the implantable electrical stimulator.

What was the impact on society beyond science and technology?

Nothing to report yet.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

FDA approved expansion to a total of four sites in order to increase recruitment of non-veterans who more closely resemble current active duty service members than the population of veterans initially targeted who tend to be ageing and less interested in new techniques. We have set up three sites with IRB and HRPO approval and we plan to open a fourth site when approved by DOD.

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Identification of suitable veteran subjects was initially slow and therefore we obtained FDA approval to expand to non-veterans and to open up to three additional sites. At one of these, the Santa Clara Valley Medical Center, the first non-veteran subject was implanted in June 2018 and is successfully using the implant to produce micturition without catheterization and continence without medication. At another of these, the MetroHealth Medical Center in Cleveland, IRB approval has been obtained and they plan to evaluate subjects when the pandemic allows. We plan to open the third additional site at the University of New Mexico.

Changes that had a significant impact on expenditures

In response to the delays caused by the pandemic we have re-budgeted existing research funds to follow up existing subjects and recruit additional subjects, and have confirmed with the Centers for Medicare and Medicaid Services that the routine clinical costs of the trial can be charged to Medicare under National Coverage Determination 310.1. This has allowed expansion of the trial to non-veteran hospitals at no extra cost to DOD.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

Not applicable

Significant changes in use of biohazards and/or select agents

Not applicable

6. PRODUCTS:

• Publications, conference papers, and presentations

Presentation to the International Neuro Urology Society Annual Conference January 2020, Istanbul, Turkey
Publication in Operative Neurosurgery 2020: Implantation of Sacral Nerve Stimulator Without Rhizotomy for Neurogenic Bladder in Patient With Spinal Cord Injury: 2-Dimensional Operative Video. Ehsanian R, Creasey G, Elliott C, Abu-Eid C, Ali A, Prutton M & Singh H

Other publications, conference papers, and presentations.

Nothing to report

- **Website(s) or other Internet site(s)**

Clinicaltrials.gov NCT02978638

- **Technologies or techniques**

Technique being developed for application of high frequency alternating current block.

- **Inventions, patent applications, and/or licenses**

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

*Name: Graham Creasey
Project Role: Project Director
Nearest person month worked: 3.6
Contribution to Project: Dr. Creasey has worked on training and coordination of other personnel and on confirming and maintaining regulatory compliance and correspondence with the VA, IRB and DOD and FDA. He has met with potential subjects, provided information to allow them to give informed consent, and carried out screening urodynamics. He has also visited the new sites to select collaborators and educate them about the project.*

*Name: Zoia Latev
Project Role: Research Biomedical Engineer
Nearest person month worked: 3
Contribution to Project: Dr. Latev has assisted with maintaining regulatory compliance and preparing reports and supplements and amendments for the VA, the IRB, the DOD and the FDA. She has also visited the new sites to develop collaboration with the technical staff in those sites.*

*Name: Michael Prutton (Santa Clara Valley Medical Center)
Project Role: Research Coordinator
Nearest person month worked: 2
Contribution to Project: Screening and Recruitment. Scheduling and communication with subject and hospital. Data collection.*

*Name: Dennis Bourbeau (Case Western)
Project Role: Site PI
Nearest person month worked: 1
Contribution to Project: subject recruitment, equipment maintenance, running experiments, data collection and analysis*

Name: Kimberly Schach (Case Western)
Project Role: Site Study Coordinator
Nearest person month worked: 2
Contribution to Project: study coordination, subject recruitment

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Updated Other Support is attached.

What other organizations were involved as partners?

As planned in the grant application, collaboration has been established with the Functional Electrical Stimulation Center at the VA Medical Center in Cleveland Ohio, which is affiliated with the Bioengineering Department of Case Western Reserve University. This Center developed the technique of high frequency alternating current block in animals and has also studied the use of electrical stimulation for improvement of bladder capacity and continence after spinal cord injury. The biomedical engineering expertise available from the collaborators at the Functional Electrical Stimulation Center will be crucial in translating their basic research into clinical application in this project. Clinicians at the Santa Clara Valley Medical Center in San Jose and the MetroHealth Medical Center in Cleveland have collaborated in obtaining IRB approval at these sites and recruiting and evaluating subjects.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: See attached

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

CURRENT / PENDING SUPPORT

Creasey, Graham, MD, FRCS, Ed

Current Support

Project Title: **Restoration of Bladder and Bowel Function using Electrical Stimulation and Block after Spinal Cord Injury**

Time Commitment: 3.6 calendar months

Supporting Agency: Department of Defense (DoD)

Contact Person at Agency: Mark Wilkison

Contact's e-mail address: mark.d.wilkison.civ@mail.mil

Contact's mailing address: 820 Chandler Street
Fort Detrick, MD 21702

Performance Period: 9/29/14 – 9/28/21

Level of Funding: Total Funding

Project Goals: This is a prospective Phase 1/2 clinical trial of an implanted electrical stimulator to improve both continence and voiding in human subjects with chronic spinal cord injury.

Specific Aims/Tasks:

1. To improve continence by electrical stimulation in human subjects with SCI (Stage 1)
2. To improve voiding by electrical stimulation in human subjects with SCI (Stage 2)

PI: Creasey

Role: Principal Investigator

Overlap: None

Pending Support

None

CURRENT / PENDING SUPPORT

Bourbeau, Dennis, PhD

Dr. Bourbeau has a memorandum of understanding between the Cleveland VAMC and MetroHealth Medical Center (MMC), which declares that he spends 60% of his full-time effort on VA time and 40% on MMC time.

CURRENT

Project Title: **Restoration of Bladder and Bowel Function using Electrical Stimulation and Block after Spinal Cord Injury**

Time Commitment: 0.6 calendar months

Supporting Agency: Department of Defense (DoD)

Contact Person at Agency: Mark Wilkison

Contact's e-mail address: mark.d.wilkison.civ@mail.mil

Contact's mailing address: 820 Chandler Street
Fort Detrick, MD 21702

Performance Period: 9/29/14 – 9/28/21

Level of Funding: Total Funding

Project Goals: This is a prospective Phase 1/2 clinical trial of an implanted electrical stimulator to improve both continence and voiding in human subjects with chronic spinal cord injury.

Specific Aims/Tasks:

1. To improve continence by electrical stimulation in human subjects with SCI (Stage 1)
2. To improve voiding by electrical stimulation in human subjects with SCI (Stage 2)

PI: Creasey

Role: Co-Investigator

Overlap: None

Project Title: **Conscious Ambulatory Bladder Monitoring to Understand Neural Control of Lower Urinary Tract Function**

Time Commitment: 1.8 calendar months

Supporting Agency: NIH SPARC

Contact Person at Agency: Tyler Best

Contact's e-mail address: tyler.best@nih.gov

Contact's mailing address: 9000 Rockville Pike
Bethesda, MD 20892

Performance Period: 1/1/17 – 4/30/21

Level of Funding: Total Funding

Project Goals: The objective of this study is to design, prototype, test, and validate a catheter-free, wireless, implantable, rechargeable bladder monitoring device to monitor biomarkers of bladder function for use in research applications.

Specific Aims/Tasks:

1. Design, develop, and validate a wireless, catheter-free sensor of bladder function for use in animal research
2. Design, develop, and validate a wireless sensor of bowel function for use in animal research
3. Design, develop, and validate associated transmission and recharge hardware and software for use with sensor technologies
4. Map patterned sacral root stimulation on to bladder and pelvic floor functions in awake, behaving cats using wireless bladder sensor technology

PI: Bourbeau
Role: Principal Investigator
Overlap: None

Project Title: Ambulatory closed-loop stimulation to inhibit neurogenic bladder overactivity

Time Commitment: 2.4 calendar months
Supporting Agency: Craig H Neilsen Foundation
Contact Person at Agency: Tracey Wheeler

Contact's e-mail address: tracey@chnfoundation.org
Contact's mailing address: 16830 Ventura Blvd, Ste 352
Encino, CA 91436

Performance Period: 2/1/20 – 1/31/23

Level of Funding: Total Funding

Project Goals: The objective of this project is to evaluate the potential feasibility and effectiveness of automated closed-loop genital nerve stimulation to inhibit unwanted bladder contractions using our custom algorithm and a wireless, catheter-free bladder pressure sensor developed with collaborators.

Specific Aims/Tasks:

1. Develop a system for administering closed-loop GNS
2. Determine the feasibility and efficacy of ambulatory, automated closed-loop GNS in human participants with SCI and NDO

PI: Bourbeau
Role: Principal Investigator
Overlap: None

Project Title: Long Term Genital Nerve Stimulation to Improve Urinary Continence

Time Commitment: 1.2 calendar months
Supporting Agency: Department of Veterans Affairs
Contact Person at Agency: Audrey Kusiak

Contact's e-mail address: audrey.kusiak@va.gov
Contact's mailing address: 810 Vermont Avenue NW
Washington, DC 20420

Performance Period: 1/1/18 – 12/31/20

Level of Funding: Total Funding

Project Goals: The objective of this study is to determine the feasibility and effectiveness of long term chronic take-home neuromodulation using non-invasive surface electrodes to improve bladder control for individuals with neurogenic detrusor overactivity. Results from this work will be used to design an approach for improving colonic motility in humans.

Specific Aims/Tasks:

1. Determine the long-term ability of genital nerve stimulation (GNS) to reduce incontinence and improve quality of life in individuals with SCI.
2. Design and fabricate an improved surface stimulator for effective GNS home use.

PI: Gustafson
Role: Co-Investigator
Overlap: None

Project Title: Afferent Stimulation to Evoke Recto-colonic Reflex for Colonic Motility

Time Commitment: 6.0 calendar months
Supporting Agency: Department of Veterans Affairs

Contact Person at Agency: Audrey Kusiak
Contact's e-mail address: audrey.kusiak@va.gov
Contact's mailing address: 810 Vermont Avenue NW
Washington, DC 20420
Performance Period: 1/1/16 – 12/31/20
Level of Funding: Total Funding
Project Goals: The objective of this study is to test the hypothesis that patterned electrical stimulation to increase colonic motility for individuals with neurogenic bowel dysfunction. If successful, a clinical trial will be conducted to test this approach.
Specific Aims/Tasks: 1. Determine the sensitivity of the recto-colonic reflex to electrical stimulation parameters
2. Determine the effect of electrical stimulation on colonic pressure, motility, and daily defecation in chronic spinalized cats
PI: Bourbeau
Role: Principal Investigator
Overlap: None

Pending Support

Project Title: High frequency sacral root stimulation to improve bladder and bowel emptying following SCI
Time Commitment: 7.2 calendar months
Supporting Agency: Department of Veterans Affairs
Contact Person at Agency: Audrey Kusiak
Contact's e-mail address: audrey.kusiak@va.gov
Contact's mailing address: 810 Vermont Avenue NW
Washington, DC 20420
Performance Period: 12/1/20 – 11/30/22
Level of Funding: Total Funding
Project Goals: The objective of this study is to test the feasibility and potential effectiveness of hundred hertz frequency sacral root stimulation to achieve urethral sphincter inhibition in individuals with neurogenic bladder dysfunction. We hypothesize that while stimulation at lower frequencies will evoke urethral sphincter activity, stimulation at frequencies from 200-600 Hz will reduce urethral sphincter activity.
Specific Aims/Tasks: 1. Determine if 200-600 Hz frequency sacral root stimulation reduces contraction of the urethral sphincter.
2. Determine if bladder emptying can be achieved using 200-600 Hz frequency stimulation.
PI: Bourbeau
Role: Principal Investigator
Overlap: None

CURRENT / PENDING SUPPORT

Singh, Harminder, MD

Current Support

Project Title: **Restoration of Bladder and Bowel Function using Electrical Stimulation and Block after Spinal Cord Injury**

Time Commitment: 0.18 calendar months

Supporting Agency: Department of Defense (DoD)

Contact Person at Agency: Mark Wilkison

Contact's e-mail address: mark.d.wilkison.civ@mail.mil

Contact's mailing address: 820 Chandler Street
Fort Detrick, MD 21702

Performance Period: 9/29/14 – 9/28/21

Level of Funding: Total Funding

Project Goals: This is a prospective Phase 1/2 clinical trial of an implanted electrical stimulator to improve both continence and voiding in human subjects with chronic spinal cord injury.

Specific Aims/Tasks:

1. To improve continence by electrical stimulation in human subjects with SCI (Stage 1)
2. To improve voiding by electrical stimulation in human subjects with SCI (Stage 2)

PI: Creasey

Role: Co - Investigator

Overlap: None

Pending Support

None

Restoration of Bladder and Bowel Function using Electrical Stimulation and Block after Spinal Cord Injury W81XWH-14-2-0132



PI: Graham Creasey, MD

Org: Palo Alto Veterans Institute for Research

Award Amount: \$998,463

Study/Product Aim(s)

- To improve continence by electrical stimulation in human subjects with SCI
- To improve voiding by electrical stimulation in human subjects with SCI

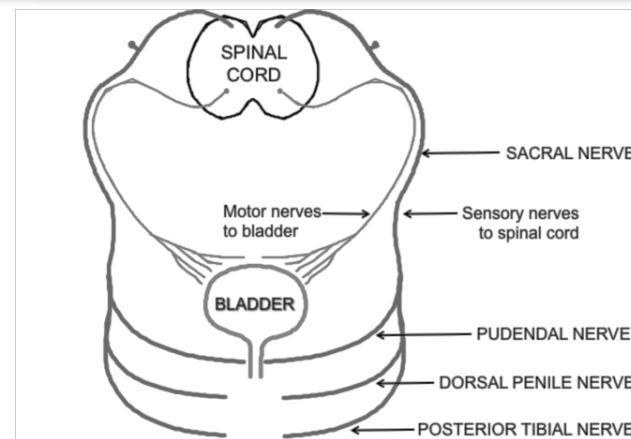
Approach

The purpose of this study is to improve both continence and voiding of urine by electrical stimulation of nerves in patients with spinal cord injury. Electrical stimulation of the sacral nerves or roots has been used before to produce bladder contraction and improve voiding, but it has usually been combined with cutting of sacral sensory nerves to reduce reflex contraction of the bladder and sphincter. However, cutting the nerves has many undesirable side effects. A new protocol of electrical stimulation of nerves using a surgically implanted system without cutting nerves will now be tested for its ability to:

- Inhibit reflex contraction of the bladder and improve continence;
- Block reflex contraction of the sphincter and improve voiding.

Timeline and Cost

Activities	FY	15	16	17	18	19	20
Obtain & maintain regulatory approvals							
Stage 1: Recruitment, Surgery, Evaluation							
Stage 2: Recruitment, Surgery, Evaluation							
Expansion of trial to non-veteran sites							
Estimated Budget (\$K)		\$126	\$333	\$245	\$121	\$171	\$



Animal research studies have shown that stimulating sensory nerves can inhibit bladder contraction and high frequency stimulation of motor nerves can block action potential propagation and prevent unwanted external urethral sphincter contraction in order to produce bladder emptying. The effect of stimulation is easily reversible.

Goals/Milestones

FY15 Goal – Initial Participant Recruitment, Screening & Evaluation

- Assemble regulatory documents and research protocol
- Coordinate study staff for clinical trial
- Recruitment and screening of first participants
- Obtain FDA approval for Stage 1

FY16 Goals – Further Participant Recruitment, Surgery and Evaluation

- Continue with Recruitment and screening
- Evaluate patients in Urodynamic laboratory

FY17 Goal – Participant Evaluation

- Expand recruitment to non-veterans
- Evaluate continence and voiding in urodynamic laboratory

FY18 Goal – Further Participant Recruitment, Surgery and Evaluation

- Obtain FDA approval for non-veteran clinical trial sites

FY19 Goal: Expansion of trial to non-veteran sites

- Implant non-veteran

FY20 Goal: Implant further non-veteran subjects

- Evaluation and follow-up
- Additional site and recruitment

Budget Expenditure to Date

Projected Expenditure: \$998,463

Actual Expenditure: \$959,194

Updated: (10/27/2020)