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TITLE: Regenerative Peripheral Nerve Interfaces for the Treatment of Painful Neuromas in Major Limb Amputees

PRINCIPAL INVESTIGATORS: Dr. Stephen W.P. Kemp

CONTRACTING ORGANIZATION: University of Michigan, Ann Arbor, MI

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14. ABSTRACT

There are currently 1.6 million people in the U.S. living with limb loss. More than 185,000 people undergo amputations in the US alone each year, and the total number of amputees is expected to be nearly 3.6 million people by 2050. Moreover, there have been approximately 1,700 combat service-related amputations between 2001 and 2015 resulting from recent U.S. military operations. Almost one-third of these individuals will form painful neuromas as a result of nerve injury that occurs at the time of amputation. This study investigates the novel use of Regenerative Peripheral Nerve Interfaces (RPNIs) to alleviate neuroma pain. Aim 1 of the study will determine the ability of RPNI surgery to treat existing painful neuromas in major lower limb amputees. Aim 2 of the study will assess the efficacy of RPNI surgery to prevent the formation of painful neuromas in patients undergoing major lower limb amputation. Aim 3 will assess both peripheral and central nervous system changes and responses to RPNI treatment. Peripheral changes will be assessed using MR neurography and DTI. Central brain changes in response to neuroma treatment will be analyzed using fMRI. The outcomes of this study will provide much needed insight into the effectiveness of RPNI surgery to treat the debilitating effects of painful neuromas on lower limb amputees. The results will also direct the future surgical standard of care for these individuals, potentially revolutionizing the standard of care for the millions of amputees

15. SUBJECT TERMS
None listed.

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1. INTRODUCTION

There are currently 1.6 million people in the U.S. living with limb loss. More than 185,000 people undergo amputations in the US alone each year, and the total number of amputees is expected to be nearly 3.6 million people by 2050. Moreover, there have been approximately 1,700 combat service-related amputations between 2001 and 2015 resulting from recent U.S. military operations. Almost one-third of these individuals will form painful neuromas as a result of nerve injury that occurs at the time of amputation. This study investigates the novel use of Regenerative Peripheral Nerve Interfaces (RPNIs) to alleviate neuroma pain. Aim 1 of the study will determine the ability of RPNI surgery to treat existing painful neuromas in major lower limb amputees. Aim 2 of the study will assess the efficacy of RPNI surgery to prevent the formation of painful neuromas in patients undergoing major lower limb amputation. Aim 3 will assess both peripheral and central nervous system changes and responses to RPNI treatment. Peripheral changes will be assessed using MR neurography and DTI. Central brain changes in response to neuroma treatment will be analyzed using fMRI. The outcomes of this study will provide much needed insight into the effectiveness of RPNI surgery to treat the debilitating effects of painful neuromas on lower limb amputees. The results will also direct the future surgical standard of care for these individuals, potentially revolutionizing the standard of care for the millions of persons with amputations.

2. KEYWORDS

Regenerative Peripheral Nerve Interface (RPNI)
Neuroma
Pain
Amputation
Peripheral nerve
MRI
MR Neurography
Neural plasticity

3. ACCOMPLISHMENTS

What were the major goals of the project?

The major goals of this project, as approved in the statement of work, are listed below. Italicized text indicates the status of each of these goals.

Major Task 1: Determine the efficacy of <u>treating</u> existing neuromas by implanting RPNIs

Subtask 1a: Submit documents for University of Michigan review. IRB approved - *100% complete*
Subtask 1b: Submit IRB approval and necessary documents to HRPO. HRPO approved – *100% complete*

Subtask 1c: Determine metrics to assess efficacy of RPNI implantation after neuroma excision and directly post-amputation. *100% complete*
Subtask 1d: Recruitment of study participants via telephone, clinic and pre-op visits. Target enrollment: 60 individuals. *45.00% complete; 33.33% complete when adjusted for patient withdrawal* (See Detailed Explanation of Patient Withdrawals at end of Report)
Subtask 1e: Complete RPNI surgeries including neuroma excision and implantation of RPNIs. *45.00% complete; 33.33% complete when adjusted for patient withdrawal*

Major Task 2: Determine the efficacy of <u>preventing</u> neuroma formation by implanting RPNIs

Subtask 2a: Submit documents for University of Michigan review. IRB approved - *100% complete*
Subtask 2b: Submit IRB approval and necessary documents to HRPO. HRPO approved – *100% complete*
Subtask 2c: Determine metrics to assess efficacy of RPNI implantation after neuroma excision and directly post-amputation. *100% complete*
Subtask 2d: Recruitment of study participants via telephone, clinic and pre-op visits. Target enrollment: 160 individuals. *43.33% complete; 37.50% complete when adjusted for patient withdrawal*
Subtask 2e: (i) Complete RPNI surgery at the time of amputation. *45% complete; 41.25% complete when adjusted for patient withdrawal*
(ii) Control surgery. *41.25% complete; 37.50% complete when adjusted for patient withdrawal.*

Major Task 3: Assess effects of RPNI surgery on treatment of painful neuromas using MR Imaging

Subtask 3a: Recruitment of subjects via telephone, clinic, and pre-op visits. Target enrollment: 40 individuals, 20 individuals from Aim 1, and 20 healthy controls. *12.5% complete*
Subtask 3b: MR evaluation for candidates of neuroma treatment. *10% complete*
Subtask 3c: MR evaluation for healthy control group. *15% complete*

<u>Milestones:</u>

Milestone #1: We obtained both IRB and HRPO approval for this study. 100% complete
Milestone #2: Program for data management is in place. We are currently using the REDCaP system. *100% complete*
Milestone #3: RPNIs implanted in 10 Aim 1 participants in year 1, 25 participants in year 2, and 25 participants in year 3. *33.33% complete*
Milestone #4: RPNIs implanted in 10 Aim 2 participants in year 1, 35 in year 2, and 35 in year 3. *41.25% complete*
Milestone #5: Deliver summary of clinical patient outcomes when performing RPNI surgery to treat or prevent painful neuroma formation. *Currently Assessing.*

Milestone #6: Initial data descriptors from MR studies on density of myelinated fibers, number of motor and sensory fascicles, mapping of painful stimuli in the brain, and peripheral nerve regeneration in the RPNI construct group. *Currently Assessing.*
Milestone #7: Deliver summary of patient outcomes correlating quantified MR data on RPNI patients. *Currently Assessing.*

What was accomplished under these goals?

(1) Major activities:

Recruitment: We have been actively recruiting through patient clinic visits, referrals, and pre-operative visits. We have also successfully added the VA as a site to our study. We have obtained the necessary HRPO approval, and all of our Research Assistants have passed all required VA training. We are confident that we will begin to recruit patients from this site in the near future. In total, we have currently enrolled 85 subjects (Aim 1=20; Aim 2=60; Aim 3=5). The first patients have finished their one-year follow-up, and have therefore completed the study. We are still actively recruiting additional subjects to all three Aims.

Data Collection/Analysis: All participants have completed their pain questionnaire surveys at the appropriate testing times. All patients are serially evaluated for a one year time period. See detailed Data Management Statistics at the end of report.

(2) Specific objectives:

Our initial objectives of obtaining IRB and HRPO approval have been met (both at the University of Michigan University Hospital and the Ann Arbor VA). We have also validated all of our pain questionnaires. We are actively working on finishing each specific objective for each participant.

(3) Significant results:

We have begun to assess our early timepoint data, and had several conference presentations accepted to this year's American Society for Peripheral Nerve Conference in January, 2021 (see Publication and Conference Presentation section).

(4) Other achievement:

NA to our study.

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

Our new resident working on the project, Dr. Nishant Kumar, has had the opportunity to train and learn from our Radiology colleagues on how to conduct MRI imaging, MR neurrography, and patient data analysis.

How were the results disseminated to communities of interest?

Peer-reviewed Publications:

1. Kubiak CA, Kemp SWP, Cederna PS, Kung TA. Prophylactic regenerative peripheral nerve interfaces (RPNIs) to prevent postamputation pain. *Plastic and Reconstructive Surgery*, 144(3), 421e-430e, 2019.

Conference Presentations:

1. Kemp SWP, Kubiak CA, Cederna PS, Kung TA. Regenerative peripheral nerve interfaces for both treatment and prophylactic prevention of postamputation neuroma pain. 2018 Military Health System Research Symposium (MHSRS), Kissimmee, FL, Aug.20-23, 2018.
2. Kung TA, Kubiak CA, **Kemp SWP**, Cederna PS. Regenerative Peripheral Nerve Interfaces for the Prevention of Postamputation Pain. Oral Presentation at the 10th Annual European Plastic Surgery Research Council. Hamburg, Germany, August 23-25, 2018. **2nd PLACE OVERALL PAPER.**
3. Kung TA, Kubiak CA, Kemp SWP, Cederna PS. Regenerative Peripheral Nerve Interfaces for the Prevention of Postamputation Pain. 64th Plastic Surgery Research Council, Baltimore, MD, May 2-5, 2019.
4. Kubiak CA, Hamill, JB, Kim HH, Roth RS, Cederna PS, **Kemp SWP**, Cederna PS, Geisser ME, Kung TA. Accuracy of patient medication reporting using the Neuropathic Pain Medication Log. American Society for Peripheral Nerve Annual Meeting, January 15-22, 2021.
5. Kumar NG, Kubiak CA, Hamill JB, Kim HM, Kemp SWP, Tinney MJ, Roth RS, Cederna PS, Geisser ME, Kung TA. Preliminary results of a clinical trial to determine the efficacy of Regenerative Peripheral Nerve Interfaces for post-amputation pain after lower limb amputations. American Society for Peripheral Nerve Annual Meeting, January 15-22, 2021.
6. Kubiak CA, Hamill JB, Kim HH, Roth RS, Cederna PS, Kemp SWP, Geisser ME, Kung TA. Neuropathic Pain Adversely Impacts Quality of Life in Patients with Lower Extremity Amputations. American Society for Peripheral Nerve Annual Meeting, January 15-22, 2021.

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

Impact of COVID-19: Similar to other institutions across the world, all clinical research was suspended for months at The University of Michigan in response to the worldwide COVID-19 epidemic. During this time, we were unfortunately severely limited in what we could accomplish, as we were not allowed to recruit new patients into our study at either The University of Michigan or the Ann Arbor VA site.

Once these restrictions are lifted, we will continue to recruit subjects into all 3 Aims of our study. We are confident that the inclusion of the Ann Arbor VA will lead to a dramatic increase in patients enrolled in the study. We will also continue data collection and

analysis. We also plan to submit abstracts to several conferences to disseminate our study findings once they become available. In addition to the annual CDMRP conference, we also plan to present our findings at The American Society for Peripheral Nerve and the Plastic Surgery Research Council.

4. IMPACT

This was the third calendar year of our experimental studies. We are satisfied with patient recruitment thus far in Aim 2, and hope to increase enrollment substantially in both Aims 1 and 3 during the next calendar year. While initial results seem promising, it is still too early to ascertain the true impact of this work. Further to the previous section, we were severely impaired from conducting research this calendar year due to the COVID-19 health crisis. We are hopeful that things will resume to normal once the pandemic has been brought under control.

What was the impact on the development of the principal discipline(s) of the project?
Nothing to report

What was the impact on other disciplines?
Nothing to report

What was the impact on technology transfer?
Nothing to report

What was the impact on society beyond science and technology?
Nothing to report

5. CHANGES/PROBLEMS

Changes in approach and reasons for change
Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them
Our recruitment to Aims 1 and 3 have been slower than anticipated. We hope that this will increase next year with the inclusion of the Ann Arbor VA as a site for this study.

Changes that had a significant impact on expenditures
Nothing to report

Significant changes in use or care of human subjects
Nothing to report

Significant changes in use or care of vertebrate animals
Not applicable to our study

Significant changes in use of biohazards and/or select agents
Nothing to report

6. PRODUCTS

Publications, conference papers, and presentations

Peer-reviewed Publications:

1. Kubiak CA, Kemp SWP, Cederna PS, Kung TA. Prophylactic regenerative peripheral nerve interfaces (RPNIs) to prevent postamputation pain. *Plastic and Reconstructive Surgery*, 144(3), 421e-430e, 2019.

Conference Presentations:

1. Kemp SWP, Kubiak CA, Cederna PS, Kung TA. Regenerative peripheral nerve interfaces for both treatment and prophylactic prevention of postamputation neuroma pain. 2018 Military Health System Research Symposium (MHSRS), Kissimmee, FL, Aug.20-23, 2018.
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Journal publications
See previous section for reference.

Books or other non-periodical, one-time publications
Nothing to report

Website(s) or other Internet site(s)
Nothing to report
Technologies or techniques
Nothing to report

Inventions, patent applications, and/or licenses
Nothing to report

Other products
Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name:	Stephen Kemp, Ph.D.
Project Role:	Principal Investigator
Researcher Identifier:	
Nearest person month worked:	12
Contribution to project:	Dr. Kemp has completed all of the HRPO requirements, trained students, has been actively involved in data collection and analysis
Funding Support	

Name:	Theodore Kung, M.D.
Project Role:	Principal Investigator
Researcher Identifier:	
Nearest person month worked:	12
Contribution to project:	Dr. Kung has completed all IRB submissions and amendments. He has performed surgery on participants. He has been actively involved in data collection and analysis
Funding Support	

Name:	Paul Cederna, M.D.
Project Role:	Co-Investigator
Researcher Identifier:	
Nearest person month worked:	1
Contribution to project:	Dr. Cederna provides insight into research design and analysis. He also performs RPNI surgery.
Funding Support	

Name:	Carrie Kubiak, M.D.
Project Role:	Post-doctoral Fellow
Researcher Identifier:	

Nearest person month worked:	6
Contribution to project:	Dr. Kubiak is instrumental in designing the patient drug logs, recruiting patients, entering patient data
Funding Support	

Name:	Jenni Hamill
Project Role:	Research Co-ordinator
Researcher Identifier:	
Nearest person month worked:	6
Contribution to project:	Established REDCaP computer based system for online patient questionnaires, high level regulatory support, database management
Funding Support	
Name:	Kelsey White
Project Role:	Research Co-ordinator
Researcher Identifier:	
Nearest person month worked:	6
Contribution to project:	Provided regulatory support, patient follow-ups, administrative duties
Funding Support	

Name:	David Brown, M.D.
Project Role:	Research Staff
Researcher Identifier:	
Nearest person month worked:	1
Contribution to project:	Patient recruitment and performs RPNI surgeries
Funding Support	

Name:	Chandu Vemuri, M.D.
Project Role:	Research Collaborator
Researcher Identifier:	
Nearest person month worked:	1
Contribution to project:	Attending surgeon in vascular surgery. Dr. Vemuri's patients will serve as control patients for Aim 2.
Funding Support	

Name:	Michael Geisser, M.D.
Project Role:	Co-Investigator
Researcher Identifier:	
Nearest person month worked:	3

Contribution to project:	Involved in design and selection of pain questionnaires. IRB support.
Funding Support	

Name:	Jon Jacobson, M.D.
Project Role:	Co-Investigator
Researcher Identifier:	
Nearest person month worked:	1
Contribution to project:	Dr. Jacobson provides ultrasounds and subsequent analysis.
Funding Support	

Name:	Yoav Morag, M.D.
Project Role:	Co-Investigator
Researcher Identifier:	
Nearest person month worked:	1
Contribution to project:	Dr. Morag provides ultrasounds and subsequent analysis
Funding Support	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
Nothing to report

What other organizations were involved as partners?
Nothing to report

8. SPECIAL REQUIREMENTS
Our quad chart is attached
9. APPENDICES

Detailed Explanation of Patient Withdrawals from the Study.

Aim 1:

1. Patient Identifier:1015
Enrollment Status: Withdrawn by Patient Request
Consent Date: Enrolled in Arm 1 (Chronic Pain RPNI) 8/12/2019
Study Group: RPNI Intervention

2. Patient Identifier: 1007
Enrollment Status: Withdrawn by PI
Consent Date: Enrolled in Aim 1 (Chronic Pain RPNI) 11/1/2018
Study Group: RPNI Intervention

3. Patient Identifier: 1010
Enrollment Status: Withdrawn by PI
Consent Date: Enrolled in Aim 1 (Chronic Pain RPNI) 12/14/2018
Study Group: RPNI Intervention

4. Patient Identifier: 1016
Enrollment Status: Withdrawn by PI
Consent Date: Enrolled in Arm 1 & 3 3/10/2020
Study Group: RPNI Intervention

5. Patient Identifier: 1011
Enrollment Status: Withdrawn by PI
Consent Date: Enrolled in Aim 1 Ineligible 2/21/2019
Study Group: RPNI Intervention

6. Patient Identifier: 1012
Enrollment Status: Withdrawn by PI
Consent Date: Ineligible 2/21/2019
Study Group: RPNI Intervention

7. Patient Identifier: 2010
Enrollment Status: Withdrawn by PI
Consent Date: Ineligible 11/1/2018

Aim 2:

1. Patient Identifier: 2050
Enrollment Status: Withdrawn by Patient Request
Consent Date: Enrolled in Aim 2 (Primary Amputations) 6/20/2019
Study Group: Control - no RPNI

2. Patient Identifier: 2084
Enrollment Status: Withdrawn by Patient Request
Consent Date: Enrolled in Aim 2 (Primary Amputations) 12/13/2019
Study Group: Control - no RPNI

3. Patient Identifier: 2099
Enrollment Status: Withdrawn by Patient Request
Consent Date: Enrolled in Aim 2 (Primary Amputations) 8/20/2020
Study Group: RPNI Intervention

4. Patient Identifier: 2014
Enrollment Status: Withdrawn by PI
Consent Date: Ineligible Aim 2 11/9/2018
Study Group: Control - no RPNI

5. Patient Identifier: 2017
Enrollment Status: Withdrawn by PI
Consent Date: Ineligible Aim 2 11/16/2018
Study Group: Control - no RPNI

6. Patient Identifier: 2020
Enrollment Status: Withdrawn by PI
Consent Date: Ineligible Aim 2 12/3/2018
Study Group: Control - no RPNI

7. Patient Identifier: 2026
Enrollment Status: Withdrawn by PI
Consent Date: Enrolled in Arm 2 (Primary Amputations) 2/27/2019
Study Group: RPNI Intervention

8. Patient Identifier: 2071
Enrollment Status: Withdrawn by PI
Consent Date: Enrolled in Arm 2 (Primary Amputations) 10/3/2019
Study Group: Control - no RPNI

Enrollment**	**10/2/2020**	**7/8/2020**	**6/1/2020**	4/23/2020	3/18/2020	1/16/2020	10/14/2019	7/8/2019	4/11/2019	4/4/2019	3/18/2019	Withdrawn
Arm 1	20(7)	18(7)	18 (6)	18 (6)	18 (6)	13	13	10	10	10	10	6
Arm 2 RPNI	33(3)	31 (2)	31(2)	30(1)	29(1)	25	23	18	16	16	12	1
Arm 2 Controls	27(6)	26(6)	26 (7)	26 (7)	24 (7)	24	20	17	12	10	8	7
Arm 3 RPNI*	2	2	2	2	2	1	1	1	0	0	0	0
Arm 3 Controls	3	3	3	3	3	3	3	3	1	1	1	0
Total Enrolled	85	81	81	80	77	66	60	49	39	37	31	14

*also counted as Arm 1

** Includes withdrawn pts - see ( )

By Visit Q'naire Completion **	**10/2/2020**	**7/8/2020**	**6/1/2020**	**4/23/2020**	3/18/2020	1/16/2020	10/14/2019	7/8/2019	4/11/2019	4/4/2019	3/18/2019
Preop	67/67 (100%)	59/59 (100%)	56/56 (100%)	55/55 (100%)	56/56 (100%)	46/46 (100%)	42/42 (100%)	36/36 (100%)	29/30 (97%)	28/29 (97%)	21/22 (95%)
1-Week	56/63 (89%)	49/58 (84%)	47/55 (85%)	47/55 (85%)	46/54 (85%)	38/46 (83%)	36/42 (86%)	29/36 (81%)	23/27 (85%)	22/26 (85%)	18/22 (82%)
4-Month	51/61 (84%)	47/56 (84%)	42/50 (85%)	37/45 (82%)	36/44 (82%)	31/39 (79%)	24/31 (77%)	15/19 (79%)	12/17 (71%)	12/17 (71%)	10/14 (71%)
12-Month	26/40 (65%)	20/31 (65%)	17/24 (71%)	17/22(77%)	15/17 (88%)	11/13 (85%)	7/9 (78%)	3/5 (60%)	3/4 (75%)	3/4 (75%)	3/4 (75%)

By Visit Ultrasound Completion**					3/18/2020	1/16/2020	10/14/2019	7/8/2019	4/11/2019	4/4/2019	3/18/2019
Preop	7/13 (54%)	5/9 (56%)	5/9 (56%)	5/9 (56%)	6/10 (60%)	4/6 (67%)	5/7 (71%)	5/7 (71%)	4/6 (67%)	4/6 (67%)	4/6 (67%)
4-Month	26/61 (43%)	26/50 (52%)		25/44 (57%)	26/44 (59%)	24/40 (60%)	19/32(59%)	13/20 (65%)	10/16 (63%)	8/14 (57%)	8/12 (67%)
12-Month	14/44 (32%)	12/30 (40%)		14/24 (58%)	15/23 (65%)	9/14 (64%)	5/8 (63%)	3/6 (50%)	2/4 (50%)	2/4 (50%)	2/4 (50%)

**excludes withdrawn pts.

Declined	21
Ineligible	18
Not Approached	11