

AWARD NUMBER: CDMRPL-16-0-DM167033

TITLE: Establishment of Peripheral Nerve Injury Data Repository to Monitor and Support Population Health Decisions

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Fort Detrick, Maryland 21702-5012

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13. SUPPLEMENTARY NOTES

None

14. ABSTRACT

The award is to be carried out in an Ambispective (prospective and retrospective) epidemiologic chart reviews of patients who were referred to San Antonio Military Medical Center (SAMMC) and Walter Reed National Military Medical Center (WRNMMC) for Peripheral Nerve Injury (PNI) treatment. A database, the Peripheral Nerve Injury Database (PNIDB), will be established to catalog and describe the characteristics, mechanisms, management, and outcomes of PNIs using both retrospective chart review and prospective patient enrollment. Collected data will be utilized to: 1. Describe the outcomes of various PNI and 2. Suggest outcomes that support population health decisions for patients with PNIs. These outcomes could be used in future study to further characterize PNIs and delineate which management techniques have the best outcome for any PNI, leading to an improved standard of care and patient quality of life. Follow-up data collection will accurately document PNI recovery outcomes. This prospective data will aid healthcare professionals to accurately evaluate the time course of a patient's recovery and the efficacy of treatment decisions. Data collected will include combat related and non-combat related PNIs to fully characterize all forms of PNI.

15. SUBJECT TERMS

Peripheral Nerve Injury, Database, Data Repository, Nerve

16. SECURITY CLASSIFICATION OF:

a. REPORT
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b. ABSTRACT
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c. THIS PAGE
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17. LIMITATION OF ABSTRACT

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1. INTRODUCTION:

The purpose of this study is to catalog and describe the characteristics, mechanisms, management, and outcomes of PNIs using both retrospective chart review and prospective patient enrollment. Collected data will be utilized to 1) describe the outcomes of various PNI and 2) suggest outcomes that support population health decisions for patients with PNIs. These outcomes could be used in future study to further characterize PNIs and delineate which management techniques have the best outcome for any PNI, leading to an improved standard of care and patient quality of life. Follow-up data collection will accurately document PNI recovery outcomes. This prospective data will aid healthcare professionals to accurately evaluate the time course of a patient's recovery and the efficacy of treatment decisions.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

: Peripheral Nerve Injury, Database, Data Repository, Nerve, Data Collection, Retrospective and Prospective

3. ACCOMPLISHMENTS: The PI is reminded that the recipient organization is required to obtain prior written approval from the

What were the major goals of the project?

1. Retrospective review of Peripheral Nerve Injuries Sustained by the US Military personnel and to complete the Protocol
2. Recruit up to 100 Study Subjects for the Prospective arm of the study
3. Identify up to 300 Study Subjects for the Retrospective arm of the study
4. Execute a Data Sharing Agreement with BAMC as applicable in accordance with the Protocol
5. Develop PNIDB and assist with its maintenance
6. Collected data on injury type, including mechanism, severity, treatment and outcomes.
7. Created database to include combat related and non-combat related PNI, fully characterize all forms of PNI.

What was accomplished under these goals?

Prospectively and retrospectively recruited and added patients with peripheral nerve injuries to the study's dataset.

Recruiting of patients with peripheral nerve injuries completed. Data collected include combat related and non-combat related PNIs to fully characterize all forms of PNI. Collected data supposedly will aid healthcare professionals to accurately evaluate the time course of a patient's recovery and the efficacy of treatment decisions.

- 448 total patients enrolled in the study
- Sample acquisition and analysis are ongoing
- Database built for the clinical archival and statistical analyses of raw data
- Data Housing, using Redcap at USUHS

Five abstracts submitted and one published to date

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

The database created will provide a source of reference for future students regarding Peripheral Nerve Injuries-PNI

How were the results disseminated to communities of interest?

Result of this research effort, as evidenced in the products section of this report, varies in mode of dissemination: research using RED Cap database at USUHS, the listed publications and journals.

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

Nothing to Report

4. IMPACT:

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

The data that will evolve from the statistical analyses will support health and treatment decisions of patients with peripheral nerve injuries. These outcomes could be used in future study to further characterize PNIs and delineate which management techniques have the best outcome for any PNI, leading to an improved standard of care and patient quality of life

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

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

Nothing to Report

Changes that had a significant impact on expenditures

Nothing to Report

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.

Nothing to Report

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

1. Wade SM, Nesti LJ, Wind GG, Howard RT, Souza JM. The Inverted Free Functioning Gracilis Muscle Transfer For Restoration of Elbow Flexion Following Delayed Presentation or Failed Primary Nerve Reconstruction of Upper Trunk Injuries. **Tech Hand Up Extrem Surg**. 2019 Jul 23. doi: 10.1097/BTH.0000000000000258. PMID: 31343593

2. Sean M. Wade, DesRaj M. Clark, Matthew E. Miller, Jason M. Souza, Leon J. Nesti, Scott M. Tintle. Preserved Sensation of the Palmar Radial Hand by the Superficial Branch of the Radial Nerve Following Median Nerve Laceration **J Hand Surg GO**
Publication stage: In Press Corrected Proof Published online: September 23, 2019

Books or other non-periodical, one-time publications.

Other publications, conference papers, and presentations.

Publications

1. Dunn JC, Goddard R, Eckhoff MD, Waterman BR, Nesti LJ, Kilcoyne KG. Retrospective, nonrandomized analysis of subcutaneous anterior transposition versus in situ decompression of the ulnar nerve of military service members. **J Shoulder Elbow Surg.** 2019 Apr;28(4):751-756. doi: 10.1016/j.jse.2018.12.005. PMID: 30885312
2. Dunn JC, Gonzalez GA, Fernandez I, Orr JD, Polfer EM, Nesti LJ. Supercharge End-to-Side Nerve Transfer: Systematic Review. **Hand** (N Y). 2019 Mar 29:1558944719836213. doi: 10.1177/1558944719836213. [Epub ahead of print] PMID: 30924361
3. Dunn JC, Polmear MM, Nesti LJ. Dispelling the Myth of Work-Related de Quervain's Tenosynovitis. **J Wrist Surg.** 2019 Apr;8(2):90-92. doi: 10.1055/s-0039-1677741. Epub 2019 Jan 29. PMID: 30941245
4. Safa B, Shores JT, Ingari JV, Weber RV, Cho M, Zoldos J, Niaccaras TR, Nesti LJ, Thayer WP, Buncke GM. Recovery of Motor Function after Mixed and Motor Nerve Repair with Processed Nerve Allograft. **Plast Reconstr Surg Glob Open.** 2019 Mar 13;7(3):e2163. doi: 10.1097/GOX.0000000000002163. eCollection 2019 Mar. PMID: 31044125
5. Wade SM, Nesti LJ, Wind GG, Howard RT, Souza JM. The Inverted Free Functioning Gracilis Muscle Transfer For Restoration of Elbow Flexion Following Delayed Presentation or Failed Primary Nerve Reconstruction of Upper Trunk Injuries. **Tech Hand Up Extrem Surg.** 2019 Jul 23. doi: 10.1097/BTH.0000000000000258. PMID: 31343593
6. Jones PE, Meyer RM, Faillace WJ, Landau ME, Smith JK, McKay PL, Nesti LJ. Combat Injury of the Sciatic Nerve - An Institutional Experience. **Mil Med.** 2018 Sep 1;183(9-10):e434-e441. doi: 10.1093/milmed/usy030. Erratum in: *Mil Med.* 2018 Sep 1;183(9-10):246. PMID: 29590419
7. Sean M. Wade, DesRaj M. Clark, Matthew E. Miller, Jason M. Souza, Leon J. Nesti, Scott M. Tintle. Preserved Sensation of the Palmar Radial Hand by the Superficial Branch of the Radial Nerve Following Median Nerve Laceration **J Hand Surg GO** Publication stage: In Press Corrected Proof Published online: September 23, 2019

Publications In Progress

1. Managing Complex Peripheral Nerve Injuries within the Military Health System: A Multi-Disciplinary Approach for Treatment, Education, and Research at Walter Reed National Military: Military Medicine
2. Nerve Reconstruction Using Processed Nerve Allograft in the U.S. Military: The Journal of Bone & Joint Surgery
3. Functional Outcome Following Peripheral Nerve Repair Using Processed Nerve Allograft in the U.S. Military: The Journal of Bone & Joint Surgery
4. Combat-Sustained Peripheral Nerve Injuries in the US Military: Journal of Hand Surgery

Website(s) or other Internet site(s)

None

• **Technologies or techniques**

None

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

None

- **Other Products**

Database in USUHS, using RED Cap

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Leon Nesti

Project Role: PI

Nearest person month worked: 6.0

Contribution to Project: Project leadership, Overall design and conduct of the study-no change

Name: Mickey Cho

Project Role: co- PI

Nearest person month worked: 6.0

Contribution to Project: Project leadership (SAMMC site) supervision and conduct of study at site-no change

Name: Jonathan Henry

Project Role: Study Coordinator

Nearest person month worked: 36

Contribution to Project: Managed/ compile updated enrollment and follow up of study subjects

Name: Elizabeth Salazar

Project Role: Clinical Coordinator, SAMMC

Nearest person month worked: 36

Contribution to Project: project lead site enrollment and master protocol amendment at SAMMC.

Name: Jody Richardson

Project Role: Clinical Nurse Manager

Nearest person month worked: 24

Contribution to project: Trained on protocol. Continued project planning and organization. Submitted approval memos and documentation to WRNMMC IRB. Developed training tool to facilitate data entry by research assistants.

Name: Dennis Taylor

Project Role: PM

Nearest person month worked: 24

Contribution to Project: Managed project team meetings and budget, compile updated enrollment and follow up of study

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?

None

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

Establishment of Peripheral Nerve Injury Data Repository to Monitor and Support Population Health Decisions

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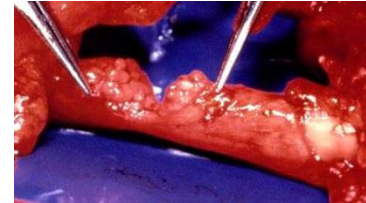


PI: LTC Leon Nesti MD PhD Org: WRNMMC Award Amount: \$851K

Approach: We propose to carry out epidemiologic chart reviews of approximately 400 patients with combat related peripheral nerve injuries who were referred to WRNMMC and SAMMC for tertiary care. A data registry will be established evaluate clinical management and support health decisions.

Specific Aim 1. Establish a database that characterizes PNI epidemiology, causes, diagnostic techniques, treatment options, and common treatment outcomes. Data will be gathered through retrospective chart review.

Specific Aim 2. Evaluate resulting data to correlate clinical history, management and outcomes to provide recommendations for clinical care that will improve optimal outcomes for PNI patients.



Health



Timeline and Cost

CR-PNI Chart Review		Year 1				Years 2-5			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Summary Gantt Chart									
Major Task 1	Start-up, IRB, HRPO	█	█	█	█				
Major Task 2	Develop & Test Database			█	█				
Major Task 3	Data Entry & Validation				█	█	█	█	
Major Task 4	Data Analysis					█	█	█	
Major Task 5	Publication, Closeout								█

Goals/Milestones

CY16 Goals

- Start IRB and HRPO Approval
- Submit Full IRB Application
- Development of fields and coding

CY17 Goals

- Receive HRPO Approval
- Begin Chart Review and Data Entry
- Begin Analysis

CY18-21 Goals

- Complete Data Entry and Analysis
- Continue analysis and close out

Comments/Challenges/Issues/Concerns: Major Task 1, 2 and 3 completed at SAMMC and WRNMMC

Budget Expenditure to Date:

Actual Expenditure: \$ 849,623.01

Updated: Sept. 16, 2021