

AWARD NUMBER: CDMRPL-16-0-DM167033

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

PRINCIPAL INVESTIGATOR: LTC Leon Nesti MD PhD

RECIPIENT: Henry M. Jackson Foundation for the Advancement of Military Medicine Inc.

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**14. ABSTRACT**

The current award is to carry out 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

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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:** Peripheral Nerve Injury, Database, Data Repository, Nerve, enrollment, targeted patient, prospective, retrospective, database development, hosting network, data housing, logistical process, collections, analysis

## 3. OVERALL PROJECT SUMMARY:

With the switch to SAMMC as the lead site for the project, all regulatory documents were submitted and approved by the IRBs at SAMMC and WRNMMC as well as HRPO.

Major Task 3 is ongoing with the help of a database manager at SAMMC. Data collection commenced in summer of 2017. Retrospective and prospective analysis of patients were analyzed. To date: San Antonio has 120 patients in the database Walter Reed 250 patients.

Major Task 2 and 4 only require the final host environment. Host environment has an estimated completion time in the first quarter of 2021.

## 4. KEY RESEARCH ACCOMPLISHMENTS

To date, 448 patients have been identified and added to the database, 419 retrospective and 29 prospective. Additionally, biological sample acquisition and analysis are still ongoing.

To date, the data obtained from the enrolled patients in the study produced one publication in addition to five additional abstracts that were submitted to four journals.

The clinical database developer has created an advanced database to perform multiple complex algorithms. The only thing pending database completion is confirming the host environment.

## 5. CONCLUSION:

Although we had a delayed in year two due to the extensive delay in obtaining IRB approval at WRNMMC, tremendous strides were made in year 3 with no deviation from the original proposal or SOW. The most recent delay is with the database host

environment, and COVID-19 issue. All the sites facilities were shut down and are now slowly opening up at a limited capacity for activities. With additional year of project extension, we will be able to mitigate the delay and complete the project successfully.

Almost 500 patients have been identified to be in the study and added to the database. The clinical database developer has created an advanced database to perform multiple complex algorithms and the plan is in motion to host the database on the USUHS network. The plan is still to integrate the database with MOTION database.

Biological sample collection is planned for current and future patients to expand capabilities and assist with algorithm development.

## 6. PUBLICATIONS, ABSTRACTS, 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

**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*

Medical Center.

Presentations: Nothing to report

**7. INVENTIONS, PATENTS AND LICENSES:**

Nothing to report

**8. REPORTABLE OUTCOMES**

Nothing to report

**9. OTHER ACHIEVEMENTS:**

Nothing to report

**10. REFERENCES:**

SUR-90-4220 References

1. Cross, J.D., Ficke, J.R., Hsu, J.R., Masini, B.D. and Wenke, J.C. (2011). Battlefield orthopaedic injuries cause the majority of long-term disabilities. *The Journal of the American Academy of Orthopaedic Surgeons* 19 Suppl 1, S1-7..
2. Campbell, William W. (2008). Evaluation and Management of Peripheral Nerve Injury. *Clinical Neurophysiology*. **119**: 9. 1951 – 1965.
3. Daneyemez, M., Solmaz, I., Izci, Y. (2005). "Prognostic Factors for the Surgical Management of Peripheral Nerve Lesions." *Tohoku Journal of Experimental Medicine* **205**: 269-275.
4. Defense, U. D. o. (2007). "Casualty Reports:."
5. Diao, E., Vannuyen, T. (2000). "Techniques for primary nerve repair." *Hand Clin* **16**(1): 53-66, viii.
6. Gordon, T., Sulaiman, O., Boyd, J.G. (2003). "Experimental strategies to promote functional recovery after peripheral nerve injuries." *Journal of Peripheral Nerve System* **8**(4): 236-250.

7. Gousheh, J. (1995). "The treatment of War Injuries of the Brachial Plexus." The Journal of Hand Surgery **20A**(3 ): S68-S76.
8. Hartmann, E. J. (2006). "Neurology in Operation Iraqi Freedom: Risk Factors for referral, clinical presentations and incidence of disease." Journal of the Neurological Sciences **241**: 83-90.
9. Kim, D. H., Murovic, Judith A., Kim, Yong-Yeon, Kline, David G. (2006). "Surgical treatment and outcomes in 15 patients with anterior interosseous nerve entrapments and injuries." Journal of Neurosurgery **104**: 757-765.
10. Kim, D. H., Murovic, Judith A., Tiel, Robert L., Kline, David G. (2004). "Mechanisms of Injury in operative brachial plexus lesions." Neurosurgery Focus **16**(5): 1-8.
11. Kim, D. H., Murovic, Judith A., Tiel, Robert L., Kline, David G. (2004). "Penetrating injuries due to gunshot wounds involving the brachial plexus." Neurosurgery Focus **16**(5): 1-6
12. Koehler, P. J., Lanska, Douglas J. (2004). "Mitchell's Influence on European Studies of Peripheral Nerve Injuries During World War I." Journal of the History of the Neurosciences **13**(4): 326-335.
13. MacKinnon, S. E., Doolabh, V.B., Novak, C.B., Trulock, E.P. (2001). "Clinical outcome following nerve allograft transplantation." Plastic Reconstruction Surgery **107**(6): 1419-1429.
14. Roganovic, Z., Petkovic S. (2004). "Missile severances of the radial nerve. Results of 131 repairs." Acta Neurochir **146**: 1185-1192.
15. Shin, Alexander Y.. (2014). "Peripheral Nerve Injuries: Advancing the Field Through Research, Collaboration, and Education". J Hand Surg Am. **39**: Oct: 2052 – 2058.
16. Spinner, R. J., Kline, D.G. (2000). "Surgery for peripheral nerve and brachial plexus injuries or other nerve lesions." Muscle Nerve. **23**(5): 680-695.
17. Rich, Norman M. and Hughes, Carl W.. (1969). Vietnam Vascular Registry: A preliminary report. Surgery. **65**(1): 218 – 226.
18. "US Army Medical Department." Brooke Army Medical Center. N.p., 20 June 2016. Web.
19. Vrebalov-Cindro, V. (1999). "Peripheral Nerve War Injuries." Military Medicine **164**(5): 351-352.
20. Weber, R. V., MacKinnon, S.E. (2005). "Bridging the neural gap." Clinical Plastic Surgery **32**(4): 605-16, viii.

#### **11. APPENDICES:**

None

#### **12. TRAINING OR FELLOWSHIP AWARDS:**

None

#### **13. COLLABORATIVE AWARDS:**

None



# 14. QUADCHART:

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

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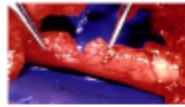


PI: LTC Leon Nesti MD PhD      Org: WRNMMC      Award Amount: \$851K (d + id)

**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



Data Repository



**Timeline and Cost**

CR-PNI Chart Review		Years 1-2				Years 3-4			
Summary Gantt Chart		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
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								█

V14 Updated: July 30, 2020

**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 Goals**
- Complete Data Entry and Analysis
- CY 19 and 20**
- Continue analysis, data housing close out
- Comments/Challenges/Issues/Concerns:** Major Task 1, 2 and 3 completed at SAMMC and WRNMMC
- Budget Expenditure to Date**
- Projected Expenditure: \$ 851K
- Actual Expenditure: \$ 840.1K