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AWARD NUMBER:

W81XWH-13-2-0014

TITLE: Joint Global War on Terror (GWOT) Vascular Injury Study 2

PRINCIPAL INVESTIGATOR: MAJ Zachary Arthurs, MD

CONTRACTING ORGANIZATION: The Geneva Foundation,
Tacoma, WA 98402

REPORT DATE:

February 2016

TYPE OF REPORT:

Annual

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

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) February 2016		2. REPORT TYPE Annual Technical Report		3. DATES COVERED (From - To) 1 Feb 2015 - 31 Jan 2016	
4. TITLE AND SUBTITLE Joint GLOBAL WAR ON TERROR (GWOT) VASCULAR INJURY STUDY 2				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-13-2-0014	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Zachary M. Arthurs, MD, Chief of Vascular Surgery MAJ, US Army zachary.m.arthurs.mil@mail.mil				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Geneva Foundation 917 Pacific Ave, Suite 600 Tacoma, WA 98402				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The objective of the proposed study is to initiate a large scale investigation of patient based outcomes following extremity vascular injury in the wars in Afghanistan and Iraq. This study proposes to link acute injury and clinical management information from the Joint Theater Trauma Registry (JTTR) to authentic patient-based outcomes years following injury. In this effort, the study aims to provide novel information on amputation and return to duty rates as well as to characterize the relationship between eventual quality of limb and psychological recovery or well-being.					
15. SUBJECT TERMS extremity vascular injury, extremity, vascular injury, vascular trauma, vascular injury management, survey, OIF, OEF, Iraq, Afghanistan, Iraq, deployment, training					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER 8	19a. NAME OF RESPONSIBLE PERSON
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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1. INTRODUCTION:

The objective of the proposed study is to initiate a large scale investigation of patient based outcomes following extremity vascular injury in the wars in Afghanistan and Iraq. This study proposes to link acute injury and clinical management information from the Joint Theater Trauma Registry (JTTR) to authentic patient-based outcomes years following injury. In this effort, the study aims to provide novel information on amputation and return to duty rates as well as to characterize the relationship between eventual quality of limb and psychological recovery or well-being. Finally, this program aims to characterize and compare the physical and emotional burden in large cohorts of US service personnel having had successful limb salvage or amputation in the years following extremity vascular injury. An updated vascular study is needed to evaluate long-term outcomes and lifelong follow-up of the injured Service Member with vascular injury.

2. KEYWORDS: extremity vascular injury, extremity, vascular injury, vascular trauma, vascular injury management, survey, OIF, OEF, Iraq, Afghanistan, Iraq, deployment, training

3. ACCOMPLISHMENTS:

What were the major goals of the project?

- **Study Phase I (Acute and Mid-Term Data Collection):**
 - Several databases, including the JTTR, WISPR, PASBA, JPTA, AHLTA, DEERS, etc., will be searched to identify Service Members who incurred vascular injury in theater.
 - To augment data on acute injury characteristics and management strategies, a retrospective review of the medical records of those in the cohort will be performed.
- **Study Phase II (Patient Based Outcomes):**
 - Service Members identified via the database established in Phase I will be contacted to obtain status information to include the most recent date of vascular follow-up.
- **Study Phase III (Analysis):**
 - Information from Phase I and Phase II will be analyzed to provide comprehensive descriptive information on the patient cohort pertaining to demographics, injury information and management strategies.

What was accomplished under these goals?

Project was awarded on February 2013. Study Phase I of the project is underway and we have developed the surveillance program design and identified Service Members who incurred vascular injury. Two research nurse coordinators, one research fellow, one technical writer and one biostatistician have been hired in support of the award. The GWOT 2 Wartime Vascular Injury Study is an ongoing effort, therefore, the number injured continues to grow contingent upon additional potential subjects that are added to the database from yearly queries derived from the Department of Defense Trauma Registry (DoDTR). The Principal investigator, Col Todd Rasmussen, changed duty stations and he is now at Fort Detrick in Combat Casualty Care.

MAJ Zachary Arthurs was selected to be the incoming PI of this effort by Col Rasmussen and has taken leadership of the protocol. HRPO approval was obtained September 9, 2014. Currently, 4,193 potential subjects have been identified with 3,725 records verified. Of those records, 1,574 did not meet criteria for inclusion, 1,418 were successfully contacted by the

research staff and 686 consented to be included in the survey. From the consented subgroup, 518 health surveys and 380 vascular surveys have been returned. For the 2015 reporting year, 524 new patients were added to the database however, many are not meeting the inclusion criteria. 226 contact attempts were made for the new inclusions with 14 surveys returned. During IRB protocol review delays, the research staff reviewed all past records for quality control purposes and found updated contact information for 55 existing records. New attempts were made to contact the 55 patients with updated contact information resulting in 6 completed surveys. Also during this reporting period, Attempts were made to scan and enter in data from the Vietnam Vascular Registry. 167 records were manually scanned from the VVR files. On the regulatory side, Annual Continuing Review was completed and conditionally approved on 1 Jul 2015. After stipulations were met, full approval was received on 15 Jul 2015. After extended work, IRB approved Amendment 30 in July, 2015. A minor amendment 31, primarily for staffing changes, was approved in January, 2016. GWOT2 was approved for a no cost extension of the project until 31JAN, 2017 in January of 2016.

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

The GWOT2 Project continues to provide professional development opportunities for its research staff as well new research opportunities for surgical residents focusing on vascular research at SAMMC/USAISR.

How were the results disseminated to communities of interest?

We aimed at disseminating and promoting the GWOT 2 Wartime Vascular Injury Study to the research community through national civilian and military academic conferences/or meetings. Details are included in Section 6 of report. Additionally, once we complete manuscripts, these will be submitted to peer-reviewed journals for publishing.

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

While the rate of wartime injuries has declined, they unfortunately continue to occur. The team plans to continue to identify new vascular injury candidates for inclusion within the study. Future plans also include ongoing continuous review of Wartime Vascular Injury Database for QC, new contact information and record identification and to amplify recruitment and return of surveys for improved data. While an attempt was made to scan and include records from the Vietnam Vascular Database into the study, the scope of such an endeavor was deemed beyond the means of the current study. While an initial attempt at collaboration between the Veterans Affairs Health System and the USAISR to amplify recruitment and return of surveys for data collection via data sharing was not successful due to IRB concerns, an agreement between the the two interested parties is again being explored. Current vascular research residents are examining popliteal vein data from the database for a possible, future paper.

4. IMPACT:

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

Vascular injury represents a common cause of morbidity and mortality in not only wartime but also the civilian trauma sector in the US. Historically advances in the management of civilian disease and injury have resulted from wartime experience in the areas of burn care, resuscitation, infectious diseases and vascular surgery. What is learned from the mid and long-term follow up provided by this study will undoubtedly impact the management of age-related vascular disease in the United States. Additionally the management of vascular injury in the civilian setting stands to benefit from the activities of this study. Given the minimal published data on host national vascular injuries, any information in this arena would be of potential benefit to developing

proven management strategies. Lastly understanding of vascular injury including limb ischemia and reperfusion is relevant to other vascular distributions including the coronary and cerebrovascular circulations which are also prone to ischemic insult.

For the first time, this study proposes a mixed methods approach to link data from the time of injury, the subsequent medical record, and real time patient-based outcomes assessment years after injury. In this context, the proposed study encompasses the entire timeline from point of battlefield injury to eventual perceived physical and psychological recovery. Findings from this study stand to characterize the physical and psychological impact of extremity vascular injury and guide military providers, patients and their families as they cope with recovery from extremity injury. Finally, in characterizing the relationship between the SMFSA and the SF-36 surveys, this study promises to provide novel insight in to a long suspected, but never quantified, relationship between quality of limb and quality of life; a finding that would impact the management of military and civilian extremity injury worldwide.

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

- Technology support staffing vacancies at the USISR resulted in delays updating and/or accessing the GWOT2 database. Temporary workarounds have been utilized while awaiting new staff hires to be completed.
- Significant delays were incurred waiting for protocol approval involving the VA /USAISR data sharing collaboration. Ultimately, the collaboration was removed from the protocol to facilitate approval from IRB allowing continuation of the project. Continued legal opinion is being sought to determine if a future collaboration is possible.

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

To date 31 amendments and 35 protocol versions have been submitted and approved by Brooke Army Medical Center IRB. Most recently amendment #31 was submitted to add and remove personnel due to staffing changes. This amendment was approved in January, 2016. The protocol was also approved by the MPMC HRPO office in January 2016.

6. PRODUCTS:

- **Publications, conference papers, and presentations**
 - Mid-term, amputation free survival and patient based outcomes following wartime vascular injury-The American Association for the Surgery of Trauma 18-21 September 2014, podium presentation
 - REBOA-Clinical Use and Update for Vascular Wartime Injuries-Trauma Rounds and Symposium at the Aberdeen Royal Infirmary, 7 November 2013
 - Use of the Short Musculoskeletal Function Assessment for Assessing Limb-Specific Outcomes Following Extremity Vascular Injuries-Society for Military Vascular Surgery and Peripheral Vascular Surgery Society, 30 January 2014, podium presentation
 - Mental health co-morbidities of service members with extremity vascular injuries acquired in Iraq and Afghanistan, Society for Trauma Nurse, 2-4 April 2014, poster presentation
 - Vascular discharge education and follow-up care subsequent to wartime vascular trauma; Presented in San Antonio, TX, May 2014
- **Journal publications.**
Nothing to Report
- **Books or other non-periodical, one-time publications.**
Nothing to Report
- **Other publications, conference papers, and presentations.**
Nothing to Report
- **Website(s) or other Internet site(s)**
Nothing to Report
- **Inventions, patent applications, and/or licenses**
Nothing to Report
- **Other Products**
Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Col Todd E. Rasmussen, MD, FACS
Project Role:	PI
Nearest person month worked:	2
Contribution to Project:	Col Todd E. Rasmussen is the former PI of the award.

Name:	MAJ Zachary M. Arthurs, MD
Project Role:	PI
Nearest person month worked:	14
Contribution to Project:	MAJ Zachary M. Arthurs is the current PI of the award

Name:	Thomas Evans
Project Role:	Research Nurse
Nearest person month worked:	24
Contribution to Project:	Mr. Evans assisted in developing the surveillance program design and continues to identify Service Members who incurred vascular injury. Mr. Evans also worked as lead on the VVR data scanning project.
Name:	Joe Holguin
Project Role:	Research Nurse Coordinator
Nearest person month worked:	11
Contribution to Project:	Mr. Holguin assisted in developing the surveillance program design and identified Service Members who incurred vascular injury
Name:	Shawn Dalle Lucca
Project Role:	Technical Writer
Nearest person month worked:	9
Contribution to Project:	Ms. Dalle Lucca provided technical writing expertise to GWOT Wartime Vascular Injury staff.
Name:	Kira Long, MD
Project Role:	Research Fellow
Nearest person month worked:	8
Contribution to Project:	Dr. Kira Long assisted in developing the surveillance program design and identified Service Members who incurred vascular injury. She has left the study.
Name:	Andrea Russell
Project Role:	Research Nurse
Nearest person month worked:	24
Contribution to Project:	Ms. Andrea Russell assisted in developing the surveillance program design and continues to identify Service Members who incurred vascular injury for inclusion in the study. Ms. Russell also oversees all regulatory records and submissions.
Funding Support:	USAISR, Research Directorate
Name:	Lee Ann Zarzabal
Project Role:	Biostatistician
Nearest person month worked:	1

Contribution to Project:	Ms. Zarzabal provided biostatistician and data analysis expertise to GWOT Wartime Vascular Injury staff
Name:	Diane Miller
Project Role:	Research Nurse
Nearest person month worked:	6
Contribution to Project:	Diane Miller assisted in developing the surveillance program design and identified Service Members who incurred vascular injury. She departed to join another research study.
Name:	Irma McNamee
Project Role:	Research Nurse
Nearest person month worked:	24
Contribution to Project:	Irma McNamee assisted in developing the surveillance program design and continues to identify Service Members who incurred vascular injury for inclusion in the study.
Name:	Julie Cutright
Project Role:	Research Nurse Coordinator
Nearest person month worked:	6
Contribution to Project:	Assisted in reviewing Service Member records for inclusion in the 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?

The first Principal investigator, Col Todd Rasmussen, changed duty stations and he is now at Fort Detrick in Combat Casualty Care. MAJ Zachary Arthurs was selected to be the incoming PI of this effort by Col Rasmussen and took leadership of the protocol and award. sAdditionally, Maj Brandon Propper will assist MAJ Zachary Arthurs to lead the program. Both are vascular surgeons at SAMMC. Geneva sent a request for PI change from Col Todd Rasmussen to MAJ Zachary Arthurs to sponsor on 20 Feb 2014. Dr. Rose Ramos and COL Lorne Blackbourne are no longer working in support of this award. MAJ Zachary Arthurs assumed the role of PI on XXX Date after award PI change approval. MAJ Zachary Arthurs continues to be the PI for the award.

What other organizations were involved as partners?

Organization Name: USAF 59MDW/ST Chief Scientist's Office

Location of Organization: 2200 Bergquist Dr. Ste 1.
JBSA Lackland AFB, TX 78236

Partner's contribution to the project

- Facilities-project staff use the partner's facilities for project activities

Organization Name: United States Institute of Surgical Research

Location of Organization: 3698 Chambers Pass
JBSA Fort Sam Houston, Tx 78234-6315

Partner's contribution to the project

- Facilities-project staff use the partner's facilities for project activities
- Collaboration-Support for Ms. Andrea Russell's time in support of award.

Joint GWOT Vascular Initiative 2

12339071 / Forward Surgical/Intensive Critical Care
W81XWH-13-2-0014



PI: MAJ Zachary Arthurs, MD

Org: SAMMC / USAISR / The Geneva Foundation

Award Amount: \$2.16m

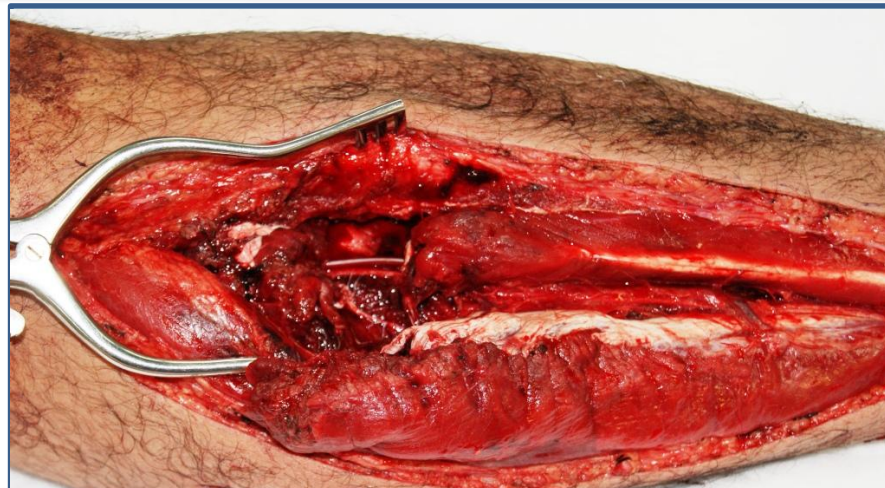
Study Aims

The objective of the proposed study is to initiate a large scale investigation of patient based outcomes following extremity vascular injury in the wars in Afghanistan and Iraq. In this effort, the study aims to provide novel information on amputation and return to duty rates as well as to characterize the relationship between eventual quality of limb and psychological recovery or well-being.

Approach

This study proposes to link acute injury and clinical management information from the Joint Theater Trauma Registry (JTTR) to authentic patient-based outcomes years following injury.

- **Objective 1:** Generate first patient-based outcomes data related to surgical intervention of vascular traumatic injuries for planning and programming.
- **Objective 2:** Translate criteria and strategies for selective vascular repair at key points in the joint theater trauma system.
- **Objective 3:** Identify additional factors influencing secondary amputation



Accomplishment: Patient identification and database expansion continues as new data is obtained.

Timeline and Cost

ACTIVITIES	CY14	CY15	CY16
Develop Surveillance Program Design			
Obtain IRB Approval and Hire Staff			
Enroll Patients and Complete Data Collection			
Conduct Data Analysis and Develop Strategies			
Disseminate Study Findings Through Peer-Reviewed Presentations and Publications			
Estimated Total Budget (\$2.16M)	\$701K	\$719K	\$740K

Updated: (21MAR2016)

Goals/Milestones

CY14 Goals – Design and Implement Study

- ☒ Develop Surveillance Program
- ☒ Obtain IRB Approval and Hire Required Staff

CY15 Goal – Continue to Expand Data Collection Efforts

- ☒ Implement Enrolment Plan
- ☒ Add Additional Staff as Required
- ☒ Adjust and modify Protocol as needed to improve enrollment success rates.

CY16 Goals – **Complete Data Collection and Analyze**

- ☐ Complete Data Collection
- ☐ Conduct Data Analysis and Develop Strategies
- ☐ Disseminate Study Findings Through Peer-Reviewed Presentations and Publications

Comments/Challenges/Issues/Concerns

- To increase our enrollment rates, we are seeking out alternate ways to improve contact information for potential enrollees. We are also reviewing existing records for updated contact information.

Budget Expenditure to Date

Projected Expenditure: \$1,42M

Actual Expenditure: \$1.33M