AWARD NUMBER: W81XWH-20-1-0652

TITLE: Can Preoperative Skin Perfusion Predict Wound Healing Complications in High-Risk Peri-Articular Tibial Fracture Fixation

PRINCIPAL INVESTIGATOR: Raymond Pensy, MD

CONTRACTING ORGANIZATION: University of Maryland, Baltimore

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Fort Detrick, Maryland 21702-5012

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Can Preoperative Skin Perfusion Predict Wound Healing Complications in High-Risk Peri-Articular Tibial Fracture Fixation

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5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
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12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This prospective single group observational study will enroll 160 patients with closed peri-articular tibial fractures that require surgical fixation from three trauma centers in the United States. Following informed consent, eligible patients will undergo LA-ICGA perfusion measurements of their injured limb at their index surgery as well as their delayed open definitive surgery (if required). The perfusion will be standardized relative to the capillary ICG concentration as measured by a pulse dye densitometer. Patients will be assessed at regular clinical follow-up visits for 90 days after definitive fixation and monitored for the primary outcome of wound complications.

15. SUBJECT TERMS

NONE LISTED

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
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1. **INTRODUCTION:** Using a commercially available LA-ICGA system to objectively measure soft-tissue perfusion, our proposed research continues the work from our pilot studies. The current study will establish the relationship between preoperative soft tissue perfusion and postoperative wound complications for periarticular tibia fractures. Additionally, the study will quantify the magnitude of perfusion recovery from the time of injury to definitive fixation when a delayed fixation strategy is selected.

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

    - **IRB –** Internal Review Board
    - **HRPO –** Human Research Protections Office
    - **DoD –** United states Department of Defense
    - **UMD –** University of Maryland, Baltimore
    - **DHMC** – Dartmouth Hitchcock Medical Center
    - **UC Irvine** – University of California, Irvine medical center
    - **LA-ICGA** – Laser Assisted Iodocyanine Green Angiography

3. **ACCOMPLISHMENTS:**

    - **What were the major goals of the project?**
        - Draft, edit and submit protocol to Maryland IRB
        - Submit protocol to HRPO
        - Draft and edit case report forms (CRFs)
        - Build digital database for CRFs using University of Maryland's Redcap

- Establish sub contracts between University of Maryland, Baltimore, Dartmouth-Hitchcock Medical Center, and University of California Irvine
- Site Training
- Enrollment: 160 patients (across all sites)
- Subject Follow-up
- Site monitoring and data validation
- Data cleaning and analysis
- Manuscript preparation and other knowledge translation activities

- **What was accomplished under these goals?**
  - DoD approval has been obtained for University of Maryland, Baltimore and DHMC.
  - Protocol Version 1 has been approved by the University of Maryland IRB.
  - Case review forms have been approved by the University of Maryland IRB. A redcap database has been built.
  - Subcontracts have been drafted for DHMC and UC Irvine, to be executed following approval and finalization.
  - DHMC has been approved as a participating site by the University of Maryland IRB. A reliance agreement between DHMC and UMB has been fully executed. This process is still under way with UC Irvine.
  - DHMC has submitted protocol version 1 and other supporting documents to their local IRB for review and approval.
- **What opportunities for training and professional development has the project provided?**
  - Nothing to Report.
- **How were the results disseminated to communities of interest?**
  - Nothing to Report.
- **What do you plan to do during the next reporting period to accomplish the goals?**
  - By the next reporting time-point we expect:
    - All participating sites will have approval from their local IRBs and HRPO.
    - Subcontracts and reliance agreements for all participating sites will be fully executed.
    - All sites will have been trained on study procedures and granted access to the Redcap database.
    - All sites will have begun actively enrolling and following up with patients.
  - UMD will remain in regular contact with participating sites to ensure these goals are accomplished in a timely and efficient manner.

4. **IMPACT:**

   - **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?**
     - It is anticipated that this study will determine if LA-ICGA is useful prognostic tool that surgeons can use to objectively guide their surgical decision making, specifically relating to the use of delayed fixation and optimal timing of definitive open fixation. The overarching goal is to minimize infection while safely expediting patient recovery and rehabilitation.

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**
     - Nothing to Report

6. **PRODUCTS:**

   - **Publications, conference papers, and presentations**
     Nothing to Report.
     - **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
   - **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**

   - **What individuals have worked on the project?**

Name:	Dr. Leah Ida Gitajn
Project Role:	Co-Investigator
Contribution to Project:	Dr. Gitajn is prepared to contribute to the study once the IRB and subcontract approvals are in order.
Funding Support:	n/a

Name:	Dr. John Scolaro
Project Role:	Co-Investigator
Contribution to Project:	Dr. Scolaro is prepared to contribute to the study once the sub contracts, reliance agreements, and IRB/HRPO approvals are in order
Funding Support:	n/a

   - **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.
     - Partner sites are academic medical institutions. At this time, these two centers have agreed to support the trial by enrolling and following a share of study participants, however, they are not able to begin study procedures until local IRB, UMD IRB and HRPO approvals have been granted.
       - **Organization Name:** University of California at Irvine Medical Center; Dartmouth-Hitchcock Medical Center
       - **Location of Organization:** Orange, California; Lebanon, New Hampshire
       - **Partner's contribution to the projec**t
         - **Collaboration**

8. **SPECIAL REPORTING REQUIREMENTS**

   - **QUAD CHARTS:** Has been updated and submitted with attachments

9. **APPENDICES:** Nothing to Report