60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

PROTOCOL #: FDG20170026A **DATE:** 4 June 2018

PROTOCOL TITLE: Comparison of Open Arterial Revascularization Using Expandable PTFE Stent Grafts vs Sewn PTFE Interposition Bypass in an Infected Field Porcine (*Sus scrofa*) Model.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Maj Anders Davidson

DEPARTMENT: SGSC **PHONE #:** 507-828-8804

INITIAL APPROVAL DATE: 20 July 2017 **LAST TRIENNIAL REVISION DATE:** N/A

FUNDING SOURCE: SG

1. RECORD OF ANIMAL USAGE:

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	15	15	15

2. PROTOCOL TYPE / CHARACTERISTICS: (Check all applicable terms in **EACH** column)

___ Training: Live Animal	___Medical Readiness	___Prolonged Restraint
___ Training: non-Live Animal	___Health Promotion	___Multiple Survival Surgery
_X_ Research: Survival (chronic)	___Prevention	___Behavioral Study
___ Research: non-Survival (acute)	___Utilization Mgt.	___Adjuvant Use
___ Other ( )	___Other (Treatment)	___Biohazard

3. PROTOCOL PAIN CATEGORY (USDA): (Check applicable) ___C _X_ D ___E

4. PROTOCOL STATUS:

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

_X_ Completed, all approved procedures/animal uses have been completed

5. Previous Amendments:
List all amendments made to the protocol. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
1	5 Oct 17	Personnel

6. FUNDING STATUS: Funding allocated: $15,225 Funds remaining: $0.00

7. PROTOCOL PERSONNEL CHANGES:

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? _X_ Yes ___No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

None

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

NAME	PROTOCOL FUNCTION	DATE OF DELETION
Maj Robert Faulconer	AI	5 October 2017

8. PROBLEMS / ADVERSE EVENTS: Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

Animal 2028: Unanticipated illness leading to early termination of the study term on post implant day 6. A retained laparotomy sponge was found in the abdomen upon necropsy, and it was defined as the cause of the illness. The animal was excluded from the final data analysis. The IACUC was notified via SABR report, and process improvement was implemented to prevent future adverse events.

9. REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No.

10. PUBLICATIONS / PRESENTATIONS: (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

1. UCD Resident Research day breakout poster presentation. 2018

2. 60 MDG Research Symposium Poster Presentation. 2018. Excellence in Research Poster Presentation Award.

3. Manuscript in progress. Journal of Trauma.

11. PROTOCOL OBJECTIVES: (Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?)

The protocol objectives were met, and the findings may affect future management of vascular injuries.

12. PROTOCOL OUTCOME SUMMARY: Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

See Attachment 1.

ANDERS J. DAVIDSON, Maj, USAF, MC 2 Jul 2018 **(Date)**

ANDREW M. WISHY, Capt, USAF, MC 29Jun2018 **(Date)**

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

Attachment 1
Defense Technical Information Center (DTIC) Abstract Submission

Objectives:
Autologous reconstruction for vascular injuries in a contaminated field requires time, technique, and appropriately sized conduit. Expandable polytetrafluoroethylene (ePTFE) grafts are often used. Direct-site endovascular repair (DSER) with ePTFE stent grafts may offer an expeditious alternative to sewn graft in this setting. We hypothesized that DSER would demonstrate less device failure and less morbidity when compared to ePTFE interposition bypass.

Methods:
Bilateral iliac arteries were transected in Fourteen Yorkshire-cross swine One randomly assigned artery received sewn ePTFE bypass while the other was treated with DSER followed by contamination with Methicillin-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa.* Device failure was assessed with ultrasound and angiography on day 7 and 21 respectively. Physiologic measurements and arterial samples were obtained at the terminal procedure.

Results:
No devices failed at day 7. DSER had less failure at day 21 (0/14 vs. 9/14, p=<0.001). DSER was faster (24±6 min vs. 62±17 min, p=<0.001). No difference was seen in gross infection (10/14 vs. 7/14, p=0.440) and flow rates at baseline, placement, or harvest (p=0.921, 0.252, 0.321).

Conclusion:
DSER demonstrated superior efficacy, faster placement, and similar infection rates when compared to ePTFE bypass for open arterial revascularization in an infected field. DSER may improve outcomes as a bridge to definitive repair.

Grant:
Dr. Davidson received support for this project from the National Center for Advancing Translational Sciences, National Institutes of Health, through grant number UL1 TR001860.