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

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20150010A **DATE:** 14 March 2016

PROTOCOL TITLE: "Pilot comparisons of temporary open revascularization using stent grafts vs. standard shunts in a sheep (*Ovis aries*) model."

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Lt Col James Sampson

DEPARTMENT: HLVC **PHONE #:** 423-5215

INITIAL APPROVAL DATE: 19 March 2015 **LAST TRIENNIAL REVISION DATE:** N/A

FUNDING SOURCE:

1. **RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Ovis aries	**12**	**3**	**3**

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
___ Research: Survival (chronic)	___ Prevention	___ Behavioral Study
_X_ 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

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

___ 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	16 April 2015	Personnel
2	15 May 2015	Personnel
3	18 June 2015	Procedures

6. **FUNDING STATUS:** Funding allocated: $15,625.00 Funds remaining: $ 0

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)

Dr. Anders Davidson (PI) ,Yes, Dr. Sarah Ashley Ferencz (AI), Yes

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

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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.

Early graft failure was identified during model development. This did not appear to cause any unanticipated animal distress.

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?

More suitable experimental model has been identified.

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).

None.

11. **Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?**

The protocol advanced our experience and understanding with models of vascular injury, promoting our ability to more effectively and efficiently study this significant component of wartime injury.

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.)

Objectives: Pilot study and development of an experimental model to test and compare the performance of endovascular stent-graft as an arterial shunt.

Methods: Developed a model of vascular shunting in an Ovine model. Develop methods of observing and measuring the performance of these vascular shunts.

Results: Exposure and placement of vascular stent-grafts and shunts into the common carotid artery was feasible. Stent-graft and shunt performance could be observed through pressure monitoring, duplex and contrast angiography. Consistently observed low resistance flow patterns, the highly mobile nature of the area and early graft failure during model development raised the question of the appropriateness of this anatomic region for testing of stent-graft/shunts to be used to treat peripheral vascular injury.

Conclusion: Study of endovascular stent-grafts for use as a vascular shunt is feasible. Graft performance may be measured through pressure monitoring, duplex, and angiography. Use in the carotid artery may confound results and limit relevance to proposed use in the management of peripheral vascular injury.

(PI / TC Signature) (Date) 7 Apr 16

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

Attachment 1
Defense Technical Information Center (DTIC) Abstract Submission
This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

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Conclusion: Study of endovascular stent-grafts for use as a vascular shunt is feasible. Graft performance may be measured through pressure monitoring, duplex, and angiography. Use in the carotid artery may confound results and limit relevance to proposed use in the management of peripheral vascular injury.

Grant Number:_____
From:_____
****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**