



IMPROVEMENTS IN THE CUFF AND GRAFT INTERFACE WITH A TOTAL ARTIFICIAL HEART



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OBJECTIVE

To evaluate design improvements of the inflow cuff-port and outflow graft-port interface of a BiVACOR Total Artificial Heart (TAH) on pannus formation.

BACKGROUND

Congestive Heart Failure (CHF) is a highly prevalent diagnosis within the United States, impacting 6.2 million individuals alone¹. The Total Artificial Heart (TAH) is seen as a stage-D intervention per AHA guidelines with utilization as both terminal therapy & bridging to transplant treatment options.

Previous research with the Jarvik TAH showed that Biomer had the lowest rate of pannus formation at 17%², our study with Corriente (Bos taurus) calves delves into new innovations within cuff precision manufacturing with data suggesting a near absent level of pannus growth in subjects.

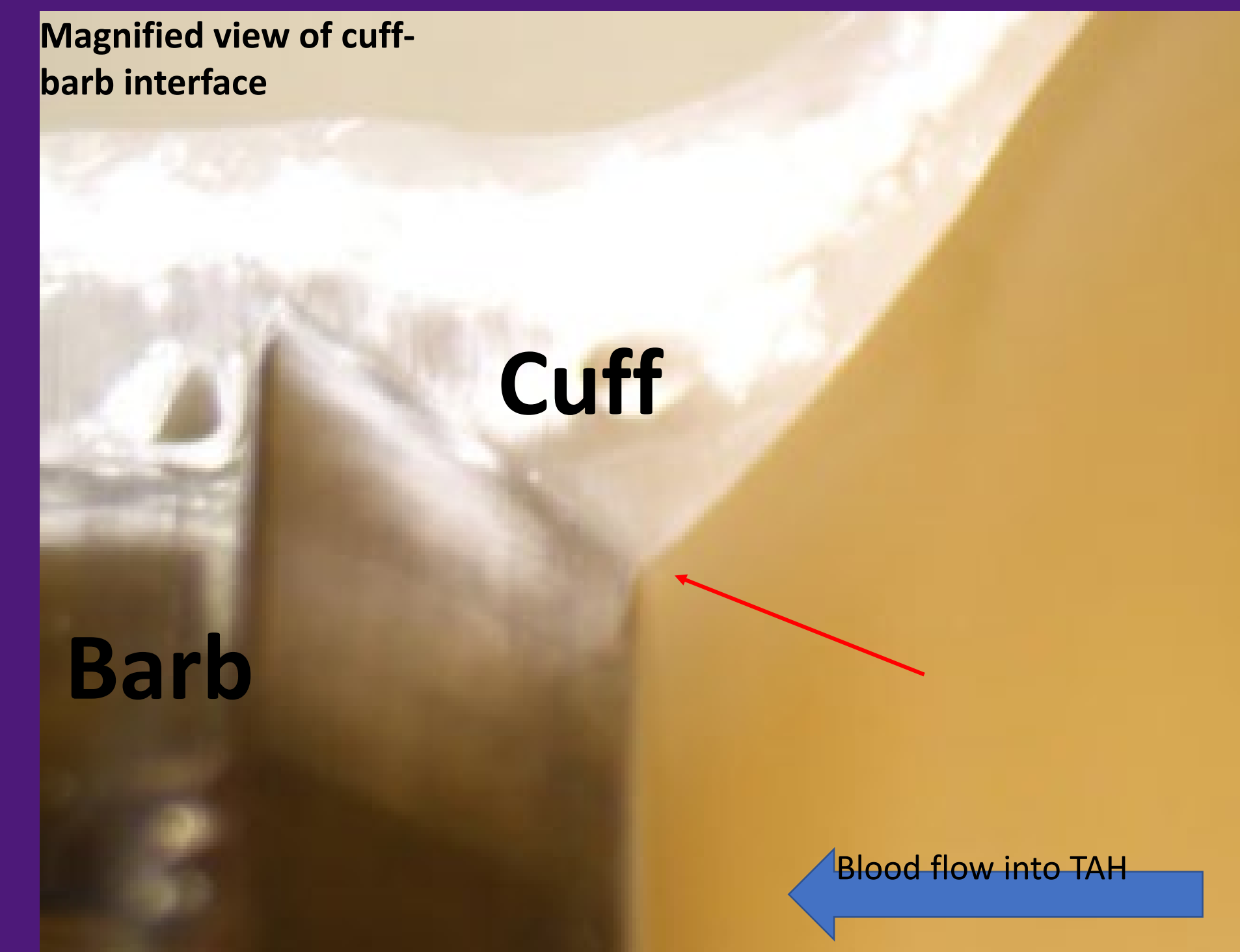
This project utilized the BiVACOR TAH in vivo animal studies as well as a Syncardia database evaluation via the FDA MAUDE portal which revealed that out of 3027 reported Syncardia TAH cases, there were 2 reported deaths, 2 reported injuries, and 4 malfunctions that did not have any impacts on patient health.

METHODS

We implanted 5 Corriente calves with BiVACOR TAHs and observed them for a period of 30 days. During this time multiple variables were monitored in addition to coagulation parameters. Upon subject euthanasia at 30D post-implantation, necropsy was performed & pannus development evaluated congruent with initial TAH Jarvik study².

Improvements in inflow & outflow graft-port interface significantly reduced pannus & thrombus formation in chronic animal implants treated with limited to no anticoagulation.

Pannus grade	Area Reduction (%)	Lumen Size	Pannus Shelf Size
0- Absent	0%	2.4 cm	0
1- Mild	<25%	2.0-2.4 cm	<2mm
2- Moderate	25-50%	1.6-2.0 cm	2-4mm
3- Severe	50-75%	1.2-1.6 cm	4-6mm
4- Extreme	>75%	<1.2 cm	>6mm



Subject	Pannus grade R-Inflow	Pannus grade L-Inflow	Pannus grade R-outflow	Pannus grade L-Outflow	Pannus risk level
B-2064‡	1	1	1	2	Mild-moderate
B-2070†	0	0	0	0	Absent
B-2067*	0	0	1	1	Mild
B-2079*	0	0	0	1	Mild
B-2080*	0	0	0	0	Absent

‡: POD 01 & onward 100-600u heparin/hr
POD 03-08 Warfarin titrated to INR 1.8±0.9

†: POD 22 & onward, 500u heparin/hr

*: no anticoagulation therapy utilized

RESULTS

Necropsy showed mild to absent pannus growth in four of five subjects. Initial subject, B-2064, had moderate growth at the outflow graft due to improper graft attachment that following subjects did not experience.

These findings represent a continued demonstration regarding excellent subject tolerance of the cuff, graft, and TAH. Low pannus development is seen despite minimal to non-existent anticoagulation therapy. Modifications made in cuff geometry & manufacturing precision enabled elimination of possible step-off (red arrow) that would otherwise cause current eddies to form.

Cuff design utilized a blood-contacting layer of bio-span as to minimize risk of activating coagulation factors, along with utilizing velour mesh on external aspect of cuff to provide structural reinforcement. This technique allowed for a combination of flexibility & elasticity that enabled surgeons to pull the cuff over the TAH barb while ensuring that there would be no step-off post-implantation once materials were at body temperature. Feedback from surgeons that performed implantation demonstrated ease of cuff placement onto TAH barb.

FUTURE DIRECTIONS

Ramifications for this data could lead to increased adoption of the TAH as a terminal therapy for CHF patients once human trials commence.

Other next steps include further efforts in evaluating anticoagulation needs, activity tolerance, and individual appropriateness for implantation.

Our next step directly involves plans for submitting to the FDA for approval to initiate human trials.

ACKNOWLEDGEMENTS

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CITATIONS

1. Virani SS, Alonso A, Benjamin EJ. Heart Disease and Stroke Statistics—2020 Update: A Report From the American Heart Association. AHA Journal. January 29, 2020. Accessed March 2, 2023. <https://www.ahajournals.org/doi/10.1161/CIR.0000000000000757>.
2. Jarvik RK, Kessler TR, McGill LD, Olsen DB, DeVries WC, Deneris J, Blaylock JT, Kolff WJ. Determinants of pannus formation in long-surviving artificial heart valves, and its prevention. Trans Am Soc Artif Intern Organs. 1981;27:90-6. PMID: 7331167.



Subject B-2064 left side outflow cuff

Subject B-2070 right side inflow cuff

Subject B-2067 right side inflow cuff