Clinical practice differences in Japan and USA when using open surgical grafts

HBD East 2023
December 14th
Ariake Central Tower Hall & Conference

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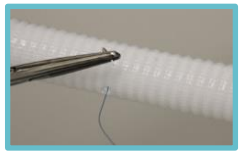
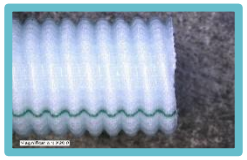
Synthetically Sealed Graft (SSG) – Key Benefits

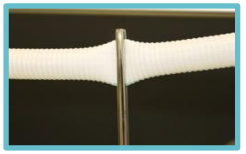


Minimal suture hole bleeding

Zero graft body sweating

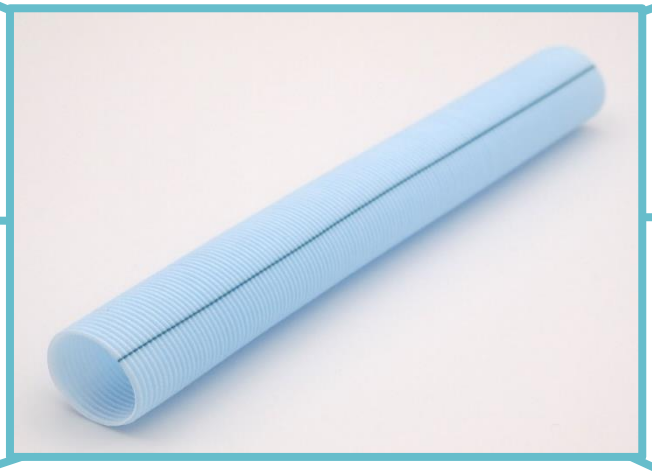


Minimal graft fraying



Robust construction

Electrocautery resistance



No bovine collagen or gelatin
No animal-derived components
Sealant may have infection control benefits

Excellent handling

First new Open Surgical Graft Technology in Decades

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Clinical Practice Similarities

- Same Patient Population
- Same disease states / conditions
- Same technique / procedure
- Same OR support staff
- Same sutures / suturing technique

Therefore…. No additional training required

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Clinical Practice Differences with SSG vs. Tradtional Open Surgical Grafts

- Less Blood Loss
- Fewer Blood Products per Procedure
- Potential for Lower Risk of Infections
- Shorter on Pump and Cross Clamp times
- Shorter Procedure Times Free up Valuable OR space
- Less Traumatic Revisions if Required in the Future

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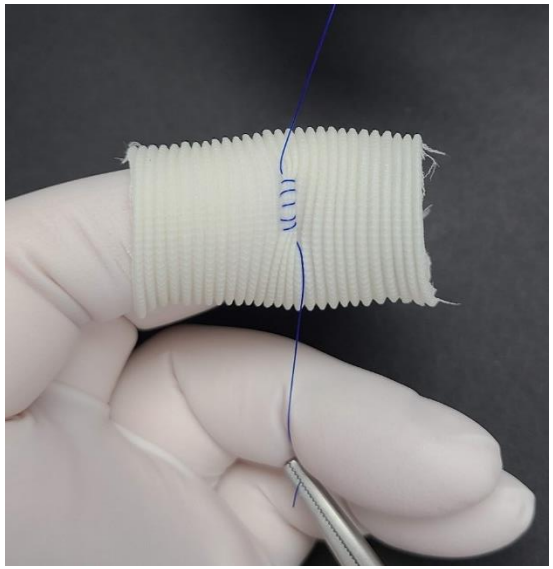
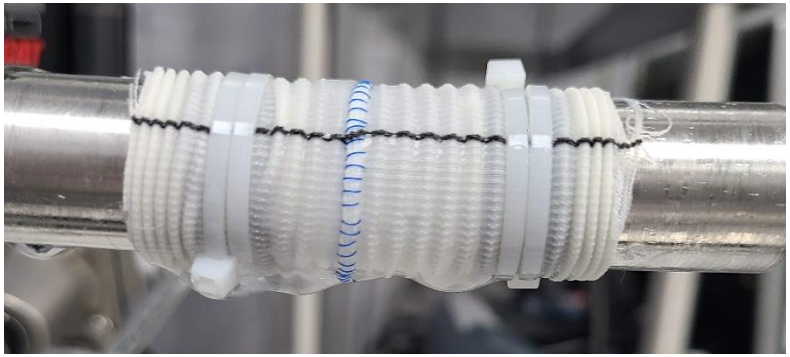
Suture Hole Leak Test Data

Experimental Design

- A suture was sewn around each sample to mimic an end-to-end anastomosis
  - Average of 108 holes/sample
- 3 different sutures/needle sizes were used
  - 3-0, 4-0, & 5-0
- The grafts were then pressurized to 120 mm Hg for 1 minute with blood analog
  - 60/40 water/glycerol
- The leakage was captured and measured





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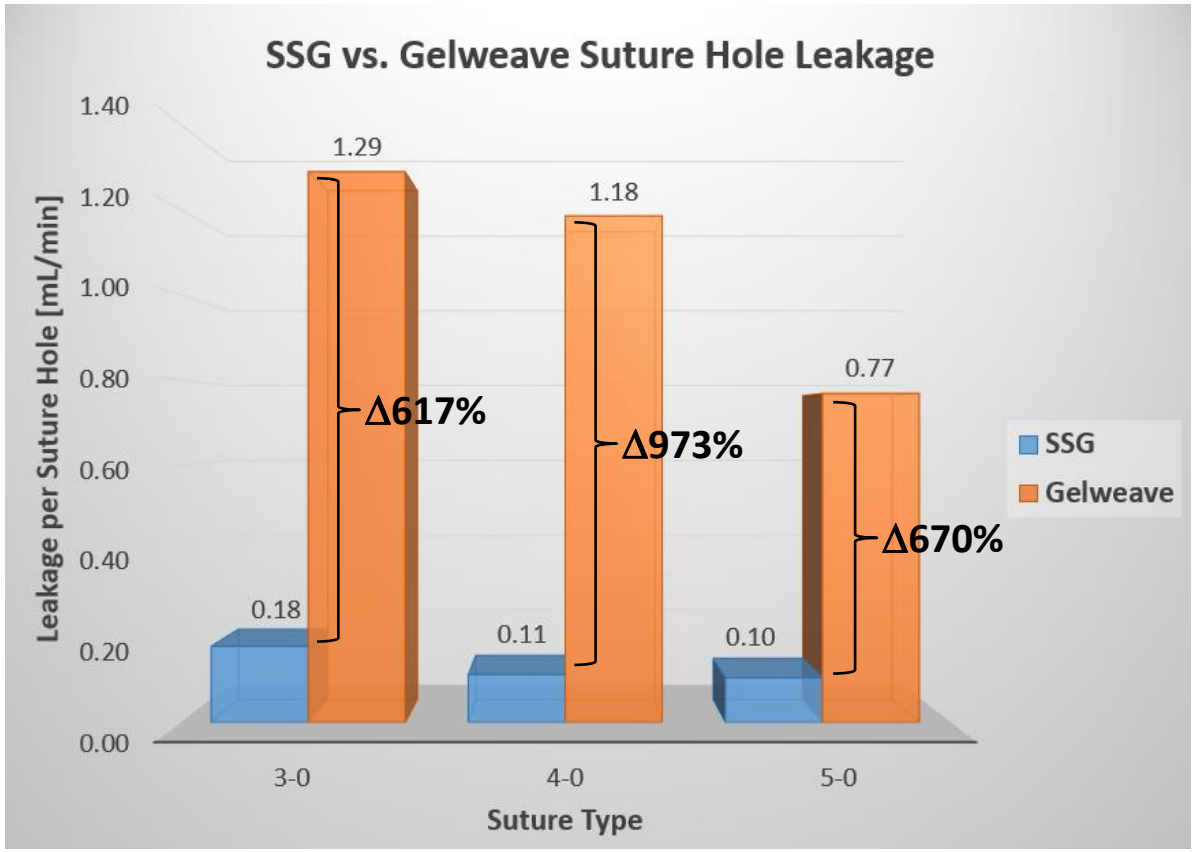
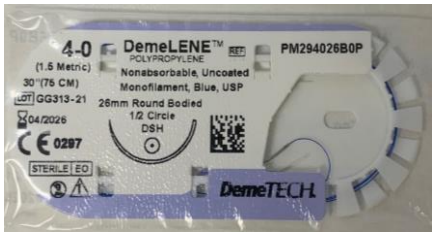
Results





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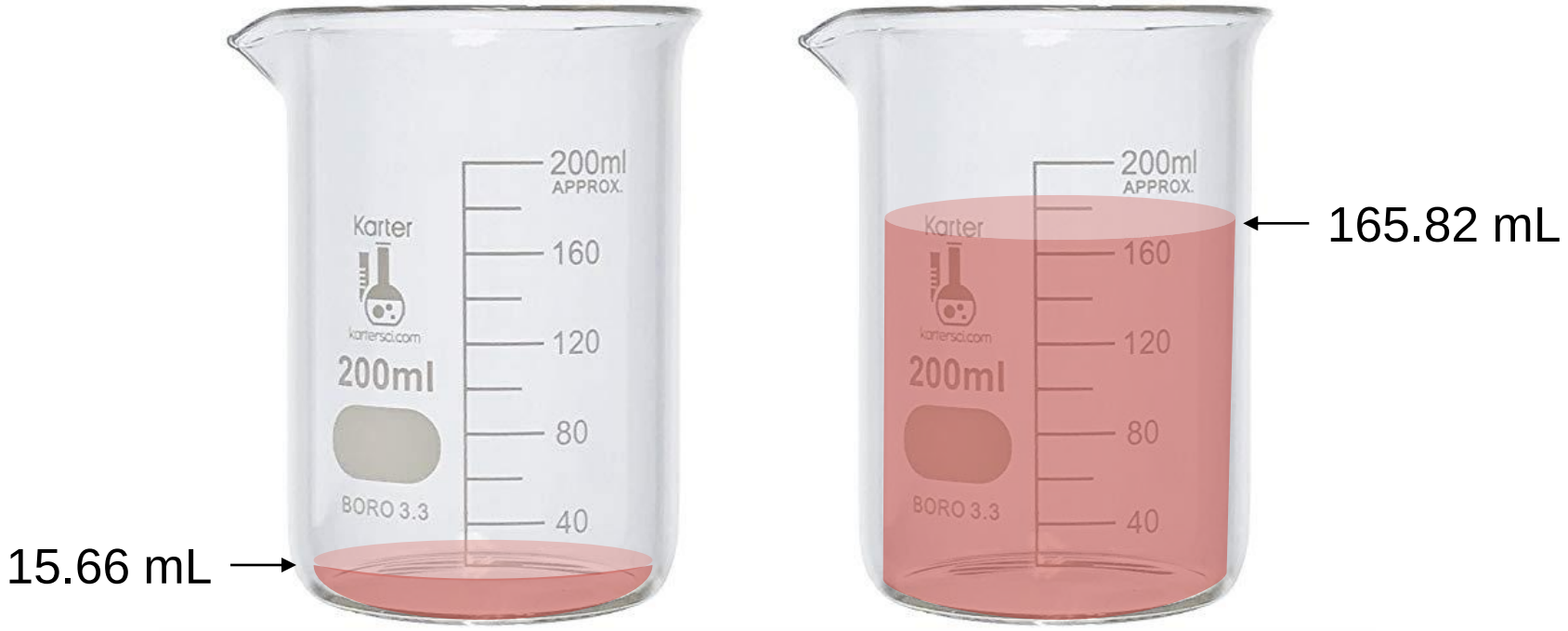
Conclusion

- If a typical anastomosis requires **20 suture holes** with a **4-0** suture and takes **7 minutes** to reach hemostasis…



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Impact of Reduced Blood Loss

- Patient benefits
  - Typical risks of bleeding during surgery can include complications associated with a higher risk of infection, ischemic events attributable to hypo-perfusion (e.g., myocardial infarction, acute kidney injury), in-hospital mortality, and transfusion-related adverse events. Bleeding can lead to cardiac tamponade, shock, dilutional coagulopathy and impaired hemostasis.
- Hospital benefits
  - Shorter time to hemostasis may lead to more cases performed per year
  - Shorter time to patient discharge, i.e. less DRG used on follow up care
  - Reduced cost / usage of blood products and surgical adhesives
- Economics of blood products and surgical adhesives
  - See U of FLA analysis

Cost of Blood Products and Surgical Adhesives

Less time to hemostasis = potentially ↓ OR costs, ↑ cases per OR

Average Cost: Chronic & Acute vs. Subacute/Chronic vs. Acute/Hyperacute/Acute on Chronic

	Cyroprecipitate	Platelets	Red Blood Cells	Fresh Frozen Plasma	Crossmatch	Other	Blood Products (B-G)	Blood Products Only (B-E)	Surgical Adhesives	Clotting Factors	Grand Total: Blood Products + Surgical Adhesives + Clotting Factors
Chronic & Acute	$2,269.83	$1,477.97	$1,251.59	$57.74	$372.46	$52.84	$5,274.25	$5,057.12	$1,048.43		**$6,530.47**
Subacute/Chronic	$2,353.89	$1,532.71	$1,297.95	$59.87	$384.90	$54.81	$5,357.39	$5,244.42	$1,069.69		**$6,687.55**
Acute/Hyperacute/Acute on Chronic	$2,278.96	$1,488.60	$1,253.49	$55.86	$372.23	$53.22	$5,292.70	$5,076.92	$1,050.58		**$6,552.56**

Average Cost: TEVAR Subacute/Chronic vs. TEVAR Acute/Hyperacute/Acute on Chronic

	Cyroprecipitate	Platelets	Red Blood Cells	Fresh Frozen Plasma	Crossmatch	Other	Blood Products (B-G)	Blood Products Only (B-E)	Surgical Adhesives	Clotting Factors	Grand Total: Blood Products + Surgical Adhesives + Clotting Factors
Subacute/Chronic	$2,648.38	$1,570.59	$1,177.63	$25.72	$345.77	$47.55	$5,412.51	$5,422.33	$1,062.43		**$6,795.30**
Acute/Hyperacute/Acute on Chronic	$2,301.29	$1,501.50	$1,262.78	$54.93	$368.80	$54.01	$5,330.58	$5,120.50	$1,047.67		**$6,590.59**

Average Cost: TEVAR vs. Non TEVAR for Chronic and Acute Dissections

	Cyroprecipitate	Platelets	Red Blood Cells	Fresh Frozen Plasma	Crossmatch	Other	Blood Products (B-G)	Blood Products Only (B-E)	Surgical Adhesives	Clotting Factors	Grand Total: Blood Products + Surgical Adhesives + Clotting Factors
Chronic and Acute w TEVAR	$2,301.29	$1,501.50	$1,262.78	$54.93	$368.80	$54.01	$5,330.58	$5,120.50	$1,047.67		**$6,590.59**
Chronic and Acute w/o TEVAR	$2,371.55	$1,530.65	$1,285.92	$61.23	$381.11	$55.57	$5,246.37	$5,249.35	$1,062.15		**$6,552.49**

* NOTE – Clotting Factors are a significant cost to any procedure when used

Source: University of Florida, 2023

Synthetically Sealed Graft – Infection Control

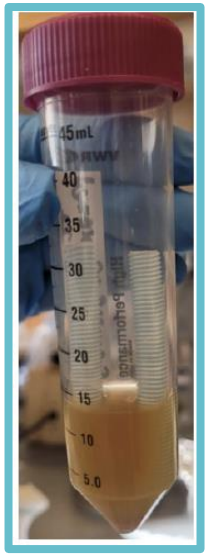
Infection Control – Initial Testing

Evaluation of the Anti-biofilm Property of Diaxamed Synthetically Sealed Grafts

The purpose of the study is to evaluate the anti-biofilm formation properties of Diaxamed Grafts and their ability to prevent bacterial migration from the outer surface to the inner surface of the grafts

Anti-biofilm Property of SSG

1. Diaxamed and the competitor's grafts of a diameter of 6 mm were evaluated in this study
2. Individual grafts submerged in sterile 50 mL conical tubes containing 10 mL of growth media containing 1,000 CFU/mL overnight culture of *Staph. aureus*
3. At 24 hours post-incubation at 37°C, the bacterial culture in the sample reservoir was discarded, and the grafts were rinsed 3 times with 10 mL of phosphate-buffered saline (PBS) and gently mixed to remove any unbound cells
4. Bacteria biofilm on the outer surface of the washed grafts was recovered by adding 10 mL of PBS into the conical tubes and sonicated in an ultrasound water bath for 15 minutes, then enumerated
5. The experiment was conducted in triplicates independently, and the number of bacteria recorded



Diaxamed SSG

Competitor

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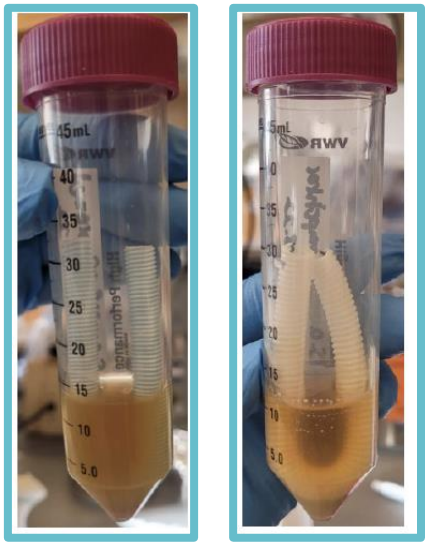
Bacteria Migration Prevention Property of SSG

1. Bacteria, if any, that managed to migrate from the outer surface of the grafts to the inner surface of the grafts were enumerated by adding 4 mL of PBS into individual grafts and sonicated in an ultrasound water bath for 15 minutes, then enumerated

2. The experiment was conducted in triplicates independently, and **the results indicated that no bacteria were able to migrate through the Diaxamed grafts**, i.e., no bacteria were recovered from the inside of the Diaxamed grafts



Diaxamed SSG **Competitor**

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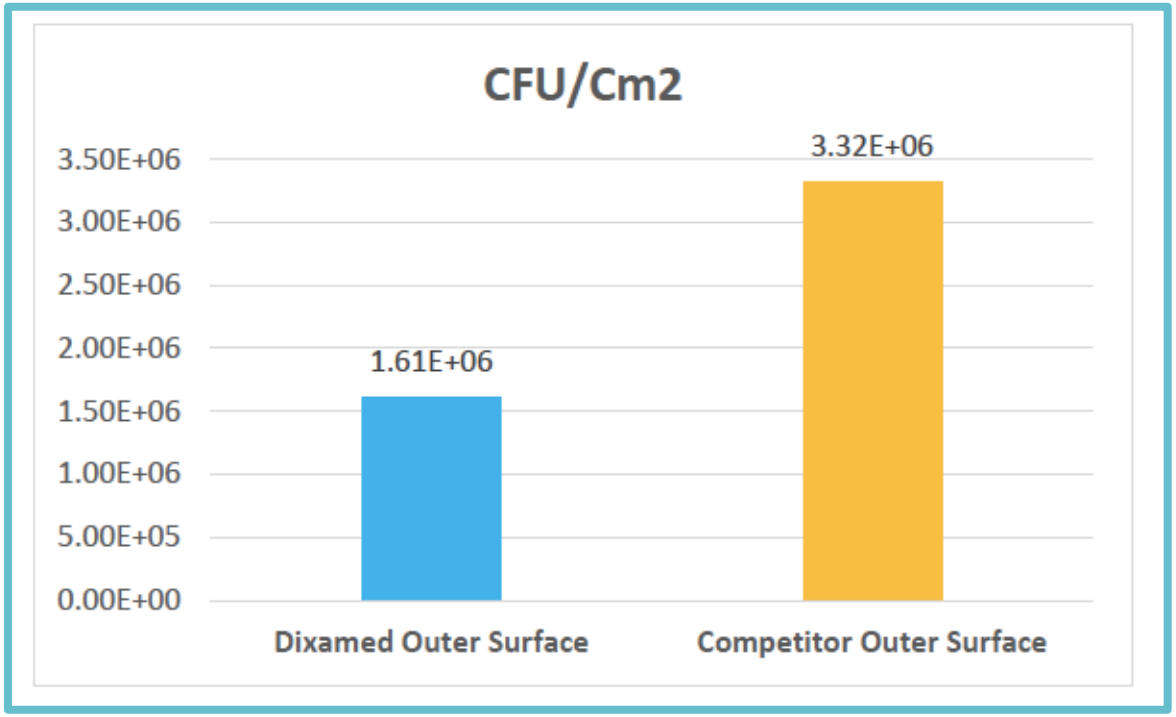
Anti-biofilm Testing Results

Anti-biofilm Property of Diaxamed Synthetically Sealed Grafts



The bacteria recovered from the outer surface of the competitor's grafts are 3.32 x 106 CFU/Cm2
The bacteria recovered from the outer surface of the Diaxamed's grafts are 1.61 x 106 CFU/Cm2, which is
SSG has 52% less bacteria on the outer surface compared to Gelweave

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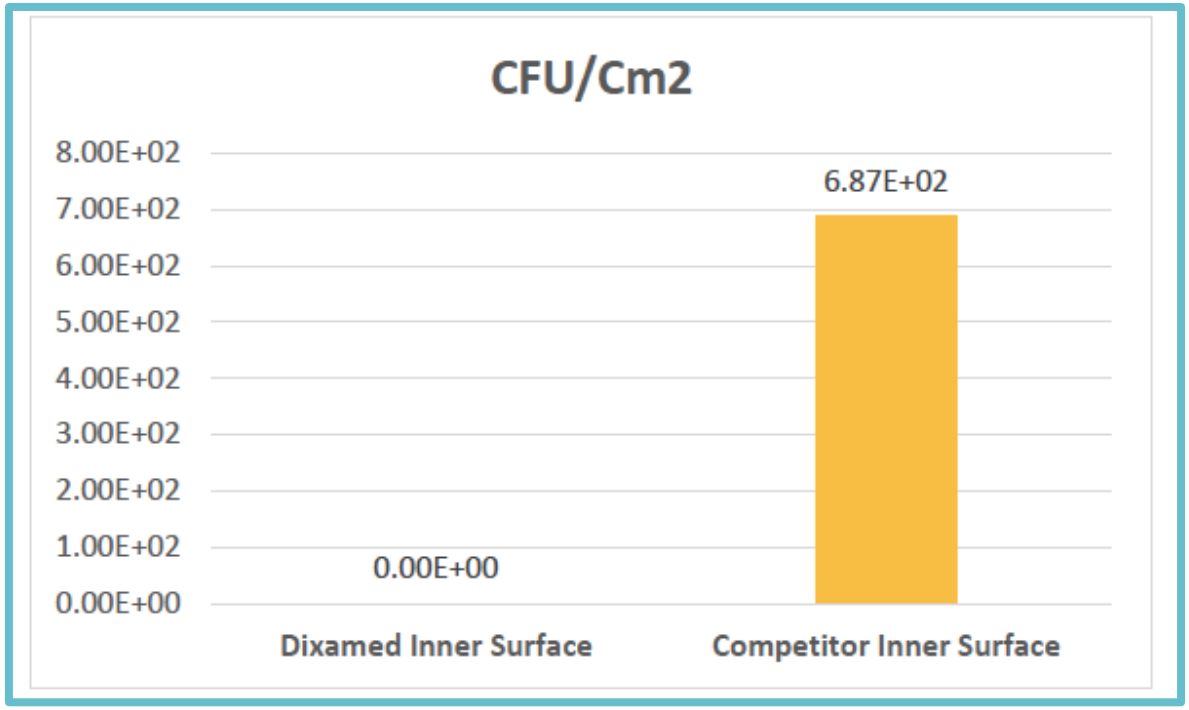
Bacterial Migration Prevention Results

Bacterial Migration Prevention Property of Diaxamed Synthetically Sealed Grafts



The bacteria recovered from the inner surface of the competitor's grafts are 6.87 x 102 CFU/Cm2.

No bacteria were recovered from the inner surface of the Diaxamed's grafts, which indicates that the Diaxamed Synthetically Sealed Grafts were able to prevent the migration of bacteria from the outer surface to the inner surface

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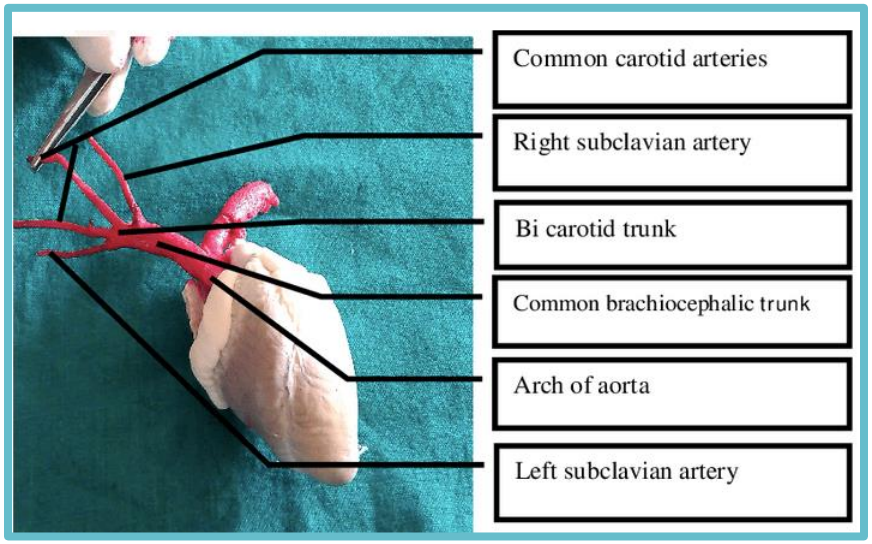
A Preclinical Study for the Chronic Evaluation of a New Thoracic Graft in the Sheep Model 180 day results

Synthetically Sealed Graft – GLP Study Design

- Sheep aortic model
- Sheep 1-3 years / 75kg-95kg
- End to end anastomosis
- 12x test (SSG, woven conduit)
- 5x control (Gelweave, woven conduit)
- GLP Site – University of Minnesota



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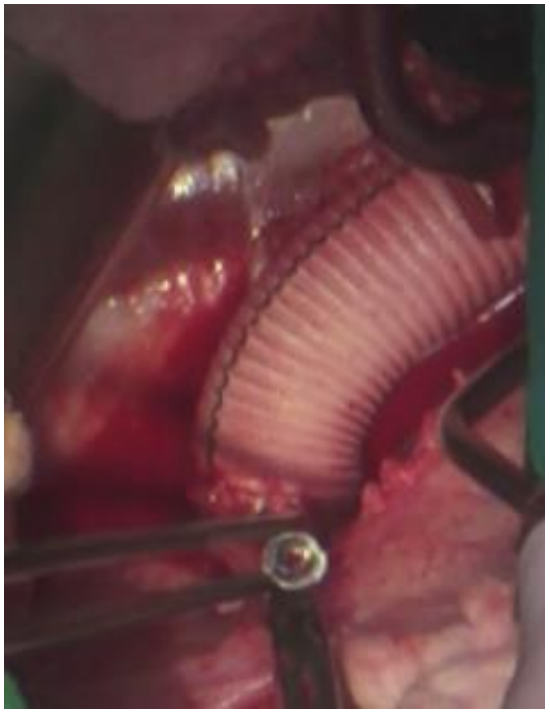
Identification Information for all 180-day samples

University of Minnesota ID	CVP Accession Number	Target Tissue	Type of Graft Implanted	Time Point/ Control (C) or Test (T)
DTG-1	DXM23-009	Aortic Graft	Gelweave 18mm	180 Day (Control)
DTG-2	DXM23-010	Aortic Graft	Gelweave 18mm	180 Day (Control)
DTG-3	DXM23-011	Aortic Graft	SSG 16mm	180 Day (Test)
DTG-4	DXM23-012	Aortic Graft	SSG 20mm	180 Day (Test)
DTG-6	DXM23-013	Aortic Graft	Gelweave 18mm	180 Day (Control)
DTG-7	DXM23-014	Aortic Graft	SSG 20mm	180 Day (Test)
DTG-8	DXM23-015	Aortic Graft	SSG 20mm	180 Day (Test)
DTG-9	DXM23-016	Aortic Graft	SSG 20mm	180 Day (Test)
DTG-10	DXM23-008	Aortic Graft	SSG 20mm	*150 Day (Test)
DTG-11	DXM23-017	Aortic Graft	SSG 20mm	180 Day (Test)
DTG-13	DXM23-018	Aortic Graft	SSG 20mm	180 Day (Test)

* Cause of early death is not device related, final determination of cause to be made however suspected to be confirmed adrenal disorder.

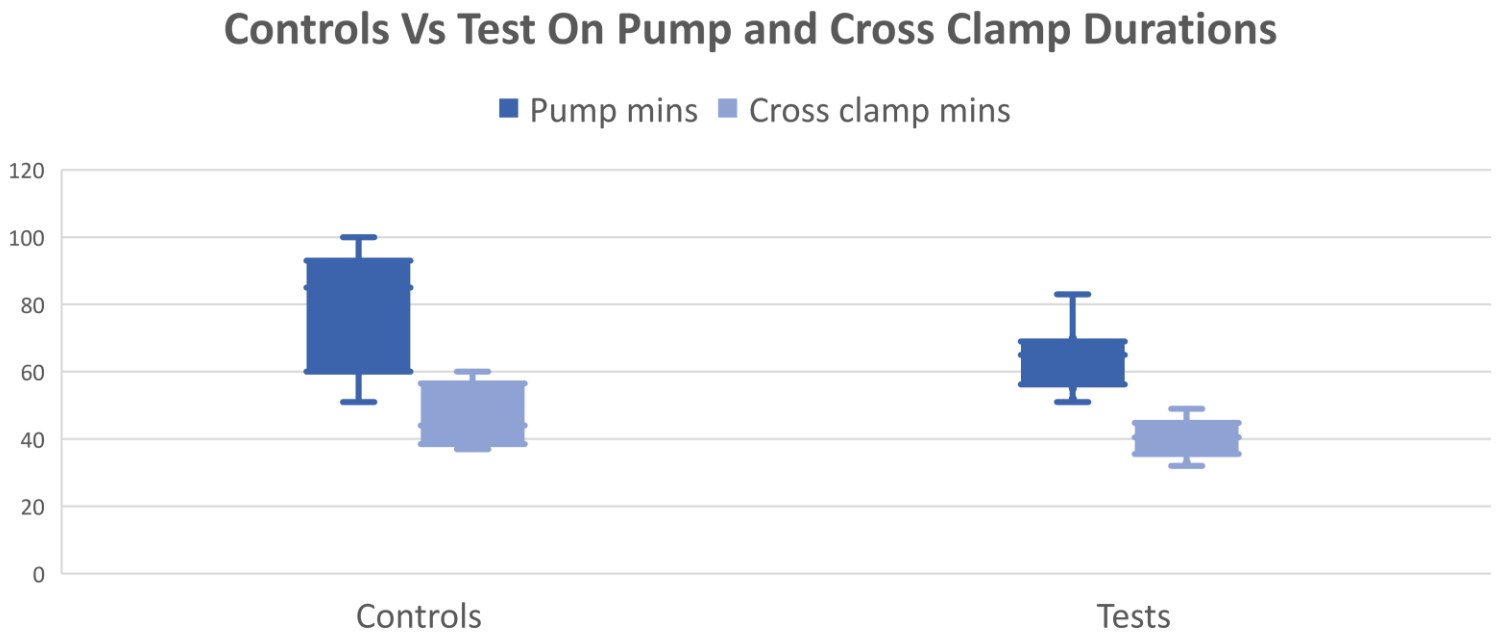
In Situ Graft Images - At Implantation

SSG- No graft Blushing, entirely blood tight



Gelweave - Graft Blushing

Summary of On Pump and Cross Clamp Time all implants



Category	# of implants	Average Cross clamp time (minutes)	Average On Pump time (minutes)
Control (Gelweave)	5	46.8	78.32
Test (SSG)	12	40.17	63.92
% Time Difference	-	16.5% Increase	22.5% Increase

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Along with Clinical and Economic benefits, Future benefits for Doctors in both Japan and USA

- “Nice , not as stiff as expected , easy to cut and size, like the orientation line along the graft “
- “No dulling of the needle. Usually by second anastomosis, the drag on the needle is much greater. This is not the case with the SSG.”
- “When suturing and you release the needle to grab it from the other side, it does not move or fall out. Gives you the ability to have a consistent and effortless cadence.”
- “Saturability and handling very nice”
- “Nice, easy to cut, sew and handle in the surgical field”
- “Graft appeared hemostatic instantly when clamps were removed”

Implantation Notes on Diaxamed SSG During GLP Study

Thank You!

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