



Understand. Innovate. Deliver.™

/// Evaluation of a Novel Spun Polytetrafluoroethylene Stent Graft in an Ovine External Iliac Artery Model¹

Bart L. Dolmatch, MD, John W. Hall, BS, Wayne L. Mower, BS, and Serge D. Rousselle, DVM, ACVP

/// PURPOSE

To evaluate the patency, cellular response, and thrombogenicity of a novel vascular stent graft.

/// MATERIALS AND METHODS

Test stent grafts, incorporating luminal spun polytetrafluoroethylene and a nonpermeable fluoropolymer layer, and control stent grafts, constructed of permeable expanded polytetrafluoroethylene, were implanted in the external iliac arteries of 14 adult sheep with a median weight of 73.4 kg ranging from 60.6–86.8 kg for 30 (n = 4), 90 (n = 4), and 180 (n = 6) days. Angiographic patency and percent diameter stenosis (%DS) were assessed at termination. Excised stent grafts were fixed and stained for histopathologic analysis, including neointimal coverage (NC) assessment.

Animal Model Adult Sheep (n=14)

Target Vessel External Iliac Arteries

Stent graft assignment was designed to achieve a balanced number of test and control devices in each in-life group.

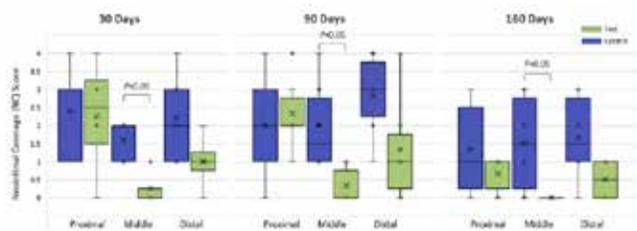
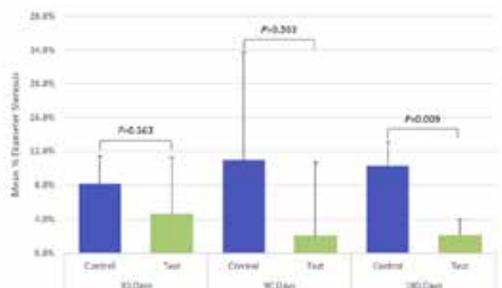
| Test Groups | Merit WRAPSODY™ | Control Group |
|--------------------|------------------------|-----------------------|
| | Endoprosthesis | Leading Covered Stent |

Angiographic patency, %DS, histopathologic NC assessment

| | |
|-------------------|----------------|
| End Points | 30 days (n=4) |
| | 90 days (n=4) |
| | 180 days (n=6) |

/// RESULTS

Test and control device migration occurred in 1 animal, resulting in test device thrombosis. Both devices were excluded from analysis. Mean %DS in test and control implants was 4.6% and 8.2% ($P = .563$), 2.0% and 10.9% ($P = .363$), and 2.1% and 10.3% ($P = .009$) at 30, 90, and 180 days, respectively. Median NC scores at 30, 90, and 180 days were significantly lower in middle test device sections ($P < .05$). Proximal and distal test and control sections exhibited similar median NC scores at all time periods ($P > .05$).



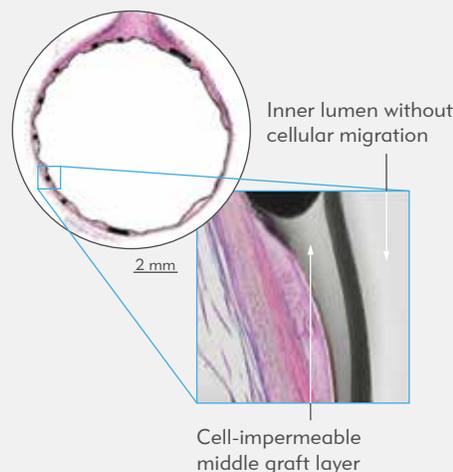
When present, test and control devices exhibited no neointimal detachment from the graft surface. Except for the migrated test device, no thrombus was observed. Transgraft cellular migration was absent in test devices but present in control devices with tissue accumulation around the stent struts.

/// CONCLUSIONS

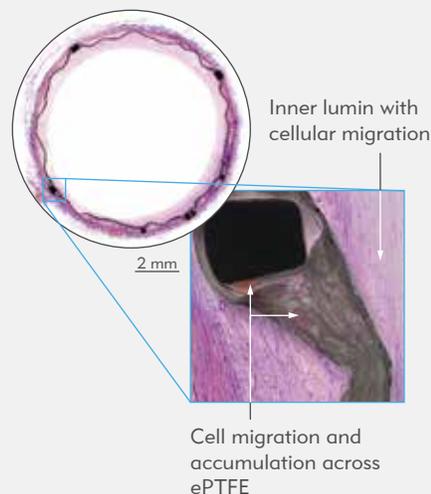
Test and control devices demonstrated excellent patency in an ovine model. Compared to the control, test devices exhibited significantly lower %DS values at 180 days and significantly lower mid-device NC scores at 30, 90, and 180 days.

Cross-Sectional Histology Images: Left External Iliac, Animal, 180 days¹

Merit WRAPSODY



Leading Covered Stent



REFERENCE 1. Dolmatch, Bart L., John W. Hall, Wayne L. Mower, and Serge D. Rousselle. 2020. "Evaluation of a Novel Spun Polytetrafluoroethylene Stent Graft in an Ovine External Iliac Artery Model." *Journal of Vascular and Interventional Radiology* 31: 494–502. <https://doi.org/10.1016/j.jvir.2019.07.036>.

Any conflicts of interest of the respective authors are disclosed in the subject publication.

This product is intended for sale and/or use only in the European Union, for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis outflow circuit of an arteriovenous (AV) fistula or AV graft. This product is not approved, cleared or available for sale or use in the United States, and may not be approved, cleared or available for sale or use in other countries. Before using any product, refer to the Instructions for Use (IFU) for indications, contraindications, warnings, precautions, and directions for use.



Understand. Innovate. Deliver.™

merit.com

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
1.801.253.1600
1.800.35.MERIT

Merit Medical Europe, Middle
East, & Africa (EMEA)
Amerikalaan 42, 6199 AE
Maastricht-Airport
The Netherlands
+31 43 358 82 22

Merit Medical Ireland Ltd.
Parkmore Business Park West
Galway, Ireland
+353 (0) 91 703 733