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

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/// 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.

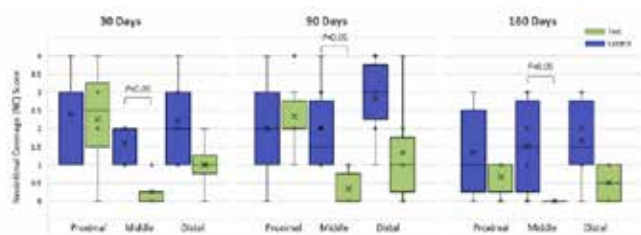
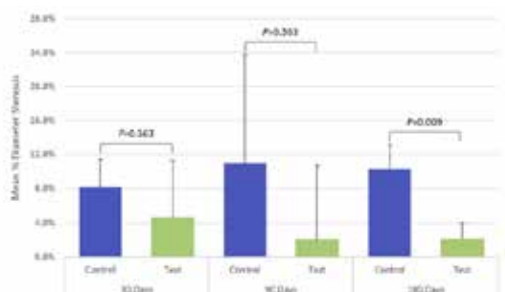
Test Groups	Merit WRAPSODY™	Control Group
	Endoprosthesis	Leading Covered Stent

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 ($P > .05$).



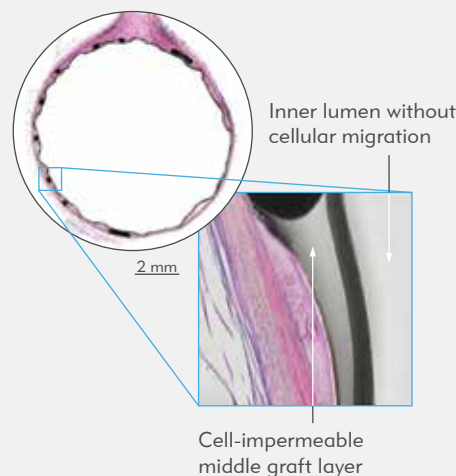
When present, test and control devices exhibited no neointimal detachment from the graft surface. Except for the migrated test device, no thrombus was observed. Transgraft cellular migration was absent in test devices but present in control devices with tissue accumulation around the stent struts.

/// CONCLUSIONS

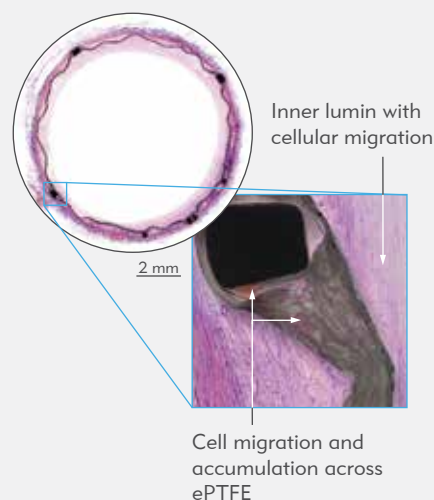
Test and control devices demonstrated excellent patency in an ovine model. Compared to the control, test devices exhibited significantly lower %DS values at 180 days and significantly lower mid-device NC scores at 30, 90, and 180 days.

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

Merit WRAPSODY



Leading Covered Stent



REFERENCE 1. Dolmarch, 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.

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