In Vivo Comparison of Marketed Biologically Augmented Hernia Grafts

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Statement of Purpose: One of the gold standard surgical approaches to repairing abdominal wall hernias is the use of a synthetic graft to bolster the repair. However, synthetic grafts pose challenges because of the propensity for complications such as adhesions to the underlying abdominal viscera. Therefore, next generation synthetic grafts with biologic components have been released to market to reduce the likelihood of post-surgical adhesion formation and other complications. The present study was performed in order to evaluate the *in vivo* biologic responses and tendency for adhesion formation in the following five marketed biologically modified hernia grafts: C-Qur™ Mesh (Atrium Medical Corporation, Hudson, NJ), Parietex™ Optimized Composite Mesh (Covidien, Mansfield, MA), Proceed™ Surgical Mesh (Ethicon Endo-Surgery, Inc., Blue Ash, OH), Ventralight™ ST Mesh (Bard Davol, Inc., Warwick, RI), and Zenapro™ (Cook Medical, Inc., Bloomington, IN).

Methods: All surgical grafts were sourced through their respective manufacturing distributors. Animal surgeries were performed at the University of Notre Dame. A three-week subcutaneous implant model using BALB/c mice was performed to assess the angiogenic and localized tissue remodeling responses of the graft materials, as described by Janis *et al.*[a] Depth of angiogenesis ingrowth was characterized by perfusing fluorescent microspheres (FluoSpheres® 0.2 µm yellow-green fluorescent microspheres, Invitrogen, Eugene, OR) into the mouse vasculature followed by explantation of the test materials and visualization using confocal microscopy. H&E and trichrome-stained tissue sections were visualized using brightfield microscopy to assess tissue reactivity. A three-week full-thickness abdominal wall defect model using Sprague Dawley rats (n=8 animals per material), as described by Suckow *et al.*,[b] was performed to assess the adhesiogenic potential of the graft materials. Non-coated polypropylene mesh (Prolene™ Soft Polypropylene Mesh, Ethicon Endo-Surgery, Inc., Blue Ash, OH) was used as a positive control in the rat model for visceral adhesion formation. Adhesions were scored for extent (0, no adhesions; 1, up to 25% coverage; 2, up to 50% coverage; 3, up to 75% coverage; 4, up to 100% coverage) and tenacity (0, no resistance; 1, mild resistance; 2, moderate resistance; 3, marked resistance; 4, sharp dissection required for adhesion separation from graft). After adhesion scoring, graft materials were explanted from the rats and were assessed histologically.

Results: Parietex, Proceed, Ventralight, and Zenapro each supported robust angiogenic ingrowth (≥ 2.9 mm; no significant difference among the group). In contrast, C-Qur exhibited only minor angiogenic ingrowth (~ 0.4 mm), which was significantly less than the other four materials ($p<0.02$). Histologically, Parietex, Proceed, Ventralight, and Zenapro each showed moderate-to-robust host-derived cellular integration and modest degrees of neo-collagen deposition adjacent to the synthetic fiber structures. Of note, these materials also exhibited varying degrees of inflammatory reactions adjacent to the graft fibers. Proceed and Zenapro showed minor-to-modest tissue reactivity, whereas Ventralight and Parietex exhibited moderate and marked tissue inflammatory responses, respectively. C-Qur demonstrated very minimal signs of any fibrovascular ingrowth. The scoring results for adhesion extent and tenacity in the rat model, represented as the percentage of test devices per scoring group (out of n=8), are summarized in Figures 1 and 2, respectively. The uncoated polypropylene (Prolene) exhibited extensive and tenacious adhesions. The synthetic grafts with biologic components performed similarly with respect to adhesion extent and tenacity.

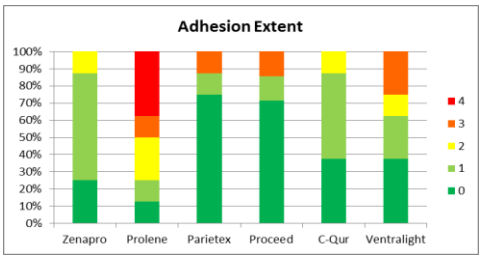

Figure 1. Adhesion extent

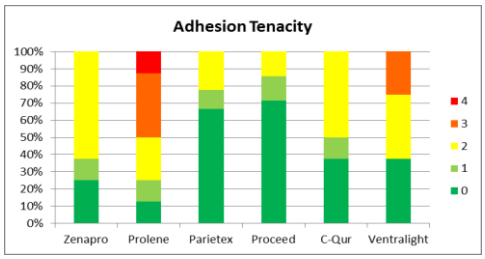

Figure 2. Adhesion tenacity

Conclusions: Parietex, Proceed, Ventralight, and Zenapro each exhibited low-grade adhesiogenesis tendencies and favorable fibrovascular infiltration, with Proceed and Zenapro having the least inflammatory-like tissue reactivity. C-Qur had favorable adhesion scores, but did not support fibrovascular integration with host tissue to the same level as the other materials. In conclusion, newer generation synthetic grafts with biologic components offer improved outcomes relative to non-coated polypropylene when used as bolsters for abdominal hernia repair.

References:

a. Janis AD. J Biomaterials Applications. 2012; 26:1013-1033.
b. Suckow MA. J Biomaterials Applications. 2012; 27:231-237.