Composite Mesh Incorporating Biointegrative Reticulated Elastomeric Matrix for Hernia Repair

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Introduction: The combination of surgical meshes and tension-free repair methods substantially reduced historical recurrence rates for hernia repair. However, the early heavy weight meshes resulted in complications such as loss of tissue wall compliance, shrinkage and scarring of surrounding tissues leading to infection pain and discomfort [1,2] usually observed over longer time periods. The use of light weight large pore meshes have alleviated some of the shortcomings but have not eliminated fibrotic scarring reaction leading to sub-optimal clinical outcomes. A biostable and biointegrative scaffold in the form of 3-D flexible polymeric matrix[3] that supports vascularized tissue ingrowth, an uninterrupted contiguous void volume for tissue re-modeling and a demonstrated potential to prevent device encapsulation or fibrous capsule formation represents a promising solution owing to it's superior biointegration and a more optimal biocompatibility to the host tissue.

This purpose of this study was to investigate whether a composite mesh consisting of two outside layers of biostable and biointegrative polymer matrix[3], that acts as a scaffold for superior biointegration, reinforced with a lightweight polypropylene mesh sandwiched between the two layers for mechanical strength would provide improved outcomes in a partial thickness abdominal wall defect in a rat model.

Materials and Methods: REVIVE™ Surgical Mesh (Fig.1) is a composite structure consisting of a knitted polypropylene (PP) mesh sandwiched between two layers of flexible biodurable, crosslinked, reticulated elastomeric polycarbonate-polyurethane-urea (RPCPU) matrix comprising of an interconnected 3-D network of cells and pores. The RPCPU matrix is biostable resisting hydrolytic, enzymatic and oxidative degradations. The high void (> 95 %) reticulated morphology of the RPCPU is designed to facilitate cellular proliferation and tissue ingrowth throughout the scaffold leading to improved bio-integration with host tissue. Bio-integration is further assisted by a more structurally compatible interface presented by low elasticity flexible matrix in contrast to the underlying stiffer PP mesh. A low level of cross-linked silicone adhesive is used to adhere the flexible RPCPU matrix to PP mesh to form a soft and conformable composite structure that enables delivery, positioning and fixation without significant manipulation in both open and laproscopic procedures. The composite mesh has a thickness of ~ 2 mm and is available in various sizes. REVIVE™ surgical mesh was characterized for its functional performance parameters.

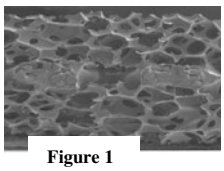

Figure 1

A partial thickness rat abdominal wall model was used as the experimental system. Sprague-Dawley rats weighing 300-500g were subjected to incision and partial thickness 1.0 cm x 1.0 cm resection of the abdominal wall leaving intact the peritoneum and the transversalis fascia. The defect was repaired with test articles of matching dimensions using 4-0 Prolene™ for fixation to the abdominal wall. The skin was closed using 4-0 Vicry™. The animals were sacrificed at various time points up to 26 weeks with 4 animals per time point. Histomorphologic response of the tissue was conducted for vascularization, connective tissue formation, and presence of multinucleate giant cells (MNGC). Device shrinkage was measured at 26 week.

Results and Discussion The average device properties: suture retention strength of 27±4 Newton (N), mesh break strength of 216±25 N, mesh stiffness of 0.32±0.05 N, ball burst strength of 352±51 N. These values are equivalent to commercial surgical meshes undergoing similar testing and it's indicative of high mechanical strength. High Darcy permeability of 262±65 similar to that of native RPCPU is an indicator of extensive inter-connectivity of the device demonstrating that the device fabrication did not reduce the matrix's potential for tissue ingrowth.

Gross examination of the explanted test articles consistently showed a smooth connective tissue surface across the device with no visible signs of device degradation or adjacent tissue necrosis at any time points. Test samples showed a low shrinkage of 15.0±0.8%.

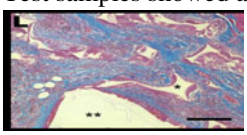

Figure 2

Histological evaluation showed formation of connective tissue, and vascularization after 1 week, which progressed during successive time periods with increasing cellular infiltrate into the RPCPU, increased total connective tissue surrounding the device, and progressive maturation and good integration into the host tissue. Complete cellular infiltration throughout the device, which can be directly attributable to the interconnected and easily accessible network of cells and pores, was observed even at early time-points. It was accompanied by strong angiogenic response and the deposition of extracellular matrix but no fibrotic scarring. The device elicited a mild and typical foreign body response that was limited to a thin area directly associated with the polymer scaffold.

Conclusions: The REVIVE™ surgical mesh showed low shrinkage, complete cellular infiltration, connective tissue formation with maturation and mild foreign body response leading to good integration to surrounding host in a rat partial thickness abdominal wall model.

References:

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3.Datta A. WBC (Amsterdam) 2008; Abstract 702