

Histological Evaluation of Abdominal Wall Defect Repair with a Novel Warp-Knit Mesh

G.T. Hilas, S.J. Peniston, J.T. Corbett
Poly-Med, Inc. Anderson, SC 29625

Statement of Purpose: Hernia repair is one of the most frequently performed surgical operations in the US with approximately 800,000 procedures performed annually.¹ This is primarily due to the relatively high lifetime risk of inguinal hernia development: 27% in men and 3% in women.² The vast majority of these repairs employ a “tension-free” repair technique which involves the use of synthetic surgical meshes. Although these procedures appear to have reduced the frequency of recurrence, they have led to the introduction of several long-term complications. These include chronic pain, increased abdominal wall stiffness, fibrosis, visceral adhesions, and mesh contraction.³ The present study examines the *in-vivo* performance of a novel warp-knit mesh construct that exhibits early mesh stability and long-term extensibility with compliance similar to the native abdominal wall.

Methods: Polymer and Mesh Preparation – A fiber-forming copolyester, S-7 (Osteoprene®), was prepared for use as a fully-absorbable long-lasting mesh fiber component. It consisted of an L-lactide (LL)/trimethylene carbonate (TMC) copolyester and was synthesized using procedures described by Shalaby.⁴ A fiber-forming polyaxial segmented copolyester, S-9, was prepared by end grafting a polyaxial poly(TMC) with glycolide and caprolactone as described by Shalaby for use as a fast-degrading mesh component.⁵ S-7 and S-9 were melt extruded under typical conditions into a 43 and 10 filament yarn, respectively. Mesh construction was based on warp knitting the two yarns using an 18 gauge raschel knitting machine followed by a heat setting process.⁶ This unique co-knit construction results in a mesh having initial mechanical stability but long-term extensibility with compliance similar to the abdominal wall. In addition, a coating made of a polyaxial high caprolactone copolymer was prepared as described earlier⁵ and applied to a grouping of the mesh by dip coating from an acetone solution as a possible drug carrier.

Surgical Procedure and Histological Evaluation – A total of 14 Sprague-Dawley male rats were used for this study with implantation durations of 6 and 9 weeks. Surgery for all animals involved a laparotomy followed by en bloc removal of a section of the abdominal wall to create a 2 X 3cm full-thickness defect site that was ~1.5cm distal to the xiphoid. This defect site was then repaired using a 3 X 4cm warp-knit mesh (WM) as an abdominal wall replacement in an on-lay position that was sutured around the periphery of the created defect with 5-O Prolene™. At the end of each implantation period, the meshes were explanted and fixed in 10% formaldehyde. A small section of the center portion of each mesh was then removed, embedded in paraffin, and sectioned for histological preparation using hematoxylin and eosin (H&E) and Masson’s Trichrome (MT). Granuloma thickness measurements were obtained using a microscope (Leica DME), digital camera (Moticam 2300), and Motic Images Plus 2.0 ML software.

Results: Microscopic examination of H&E stained tissue slides showed a marked foreign body reaction to both uncoated and coated WM at 6 and 9 week time points. Examination of granuloma thickness measurements shows that coated WM had significantly larger granuloma thickness measurements than uncoated WM both at 6 and 9 week implantation times (p -value < 0.05).

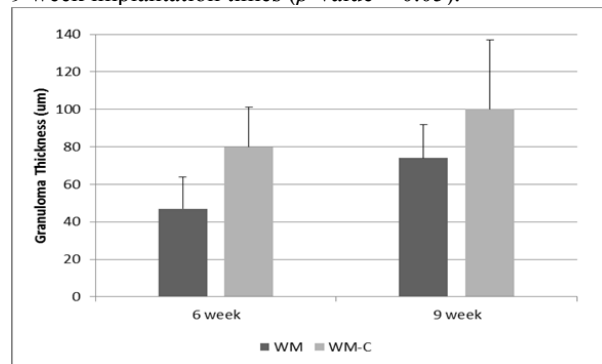


Figure 1. Granuloma thickness of uncoated (WM) and coated (WM-C) warp knit mesh. Coated mesh had significantly thicker granulomas than uncoated mesh at both time points examined (p -value < 0.05).

Examination of collagen deposition in and around the wound site showed complete collagen encapsulation of the mesh fiber bundles (Figure 2). In addition, slides stained with MT reveal a thick bundle of highly oriented collagen forming over the mesh material for both mesh types tested at 6 and 9 week implantation periods.

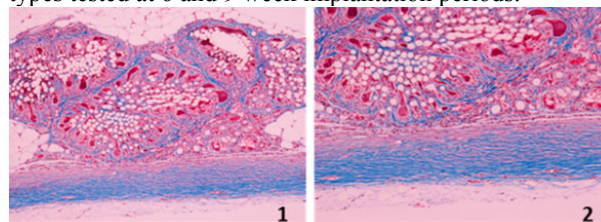


Figure 2. Representative histological sample at a 9-week implantation time stained with Masson’s Trichrome at (1) 70X magnification and (2) 100X magnification.

Conclusions: The results indicate that a high caprolactone based mesh coating elicits an increased foreign body reaction. In addition, the high degree of collagen orientation seen at the wound site may be in response to the biomechanical properties of the studied warp-knit mesh construction. Specifically, a mesh that displays early stability and long-term extensibility may result in the formation of functional tissue that could reduce the likelihood of hernia recurrence.

References:

1. Rutkow, I.M. *Surg Clin North Am.* **83**(5), 1045 (2003).
2. Jenkins, J.T., et al. *BMJ.* **336**, 7638 (2008).
3. Amid, P.K., et al. *J Am Coll Surg.* **205**, 381 (2007).
4. Shalaby, S.W., U.S. Patent 6,342,065 (2002).
5. Shalaby, S.W., U.S. Patent 6,462,169 (2002).
6. Shalaby, S.W., et al., U.S. Pat. 11/879,357 (2007).