## Antimicrobial Effectiveness of a Triclosan Coated Warp-Knit Mesh

G.T. Hilas, K.A. Nichter, S.J. Peniston, S.D. Nagatomi

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.<sup>1</sup> This is primarily due to the relatively high lifetime risk of inguinal hernia development: 27% in men and 3% in women.<sup>2</sup> 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, **infection** and mesh contraction.<sup>3-4</sup> To address the issue of increased infection rate, the addition of an antimicrobial to a multifilament surgical mesh is very desirable. The present study examines bacterial inhibition performance of a novel warp-knit mesh construct that is coated with an antibacterial loaded fully-absorbable polymer.

## 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.<sup>5</sup> 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 fiber component.<sup>6</sup> 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.<sup>7</sup> The fully absorbable coating polymer was made of a high caprolactone polyaxial copolymer as described earlier.<sup>6</sup>

Mesh Coating – The coating polymer was dissolved in a solution of acetone containing 5 wt.% triclosan. Meshes were immersed in the coating solution for  $\sim 10$  seconds and hung in a laminar-flow hood to dry. To pull off any remaining solvent, coated mesh was placed under reduced vacuum for a period of at least 24 hours. Samples were ethylene oxide sterilized using a low temperature cycle (40°C) prior to testing.

Zone-of-Inhibition Testing – First, Staphylococcus aureus was thawed in tryptic soy broth and cultured at  $30^{\circ}$ C. The culture was then streaked to a 0.5 McFarland Standard onto a Tryptic soy agar plate to form a confluent lawn. Mesh was cut into 1 X 1cm pieces using a sterile scalpel and placed onto each individual streaked bacterial agar plate. A total of three samples were tested. The plates were allowed to incubate for 24 hours after which the zones of inhibition were measured using a small metric scale. Once the zones were recorded for Day 1, new agar plates were streaked as before and the mesh sample was transferred from the first plate to the new plate. As before, the plates were allowed to incubate for 24 hours and zones of inhibition were measured. This process was repeated for a total of 14 days. In addition, discs loaded with gentamicin and tetracycline were used as positive controls on each bacterial agar plate.

**Results:** As shown in Figure 1 below, mesh coated with a triclosan loaded absorbable polymer maintained zones of inhibition comparable to positive controls (Day 1) throughout the 14-day testing period. Zones of inhibition remained above 25 mm at each time point tested while positive controls have exhausted their drug loading after five days.



**Figure 1.** Zones of inhibition of a triclosan loaded warp-knit mesh for use in hernia repair. The target microbe was *S. aureus*. Antibiotic control consisted of gentamycin and tetracycline loaded discs.

**Conclusions:** Rates of infection are clinically higher in multifilament meshes due to the increased surface area offered for microbial attachment. Therefore, the successful addition of an antimicrobial to a multifilament surgical mesh is very desirable. We have shown here that a triclosan loaded absorbable coating may be used to inhibit the bacterial growth of a warp-knit surgical mesh for a period of at least 14 days. Further testing is required using an *in-vivo* model for infection to assess the clinical significance of the applied coating.

## **References:**

- 1. Rutkow, I.M. Surg Clin North Am. <u>83</u>(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).
- Klinge, U., et al. J Biomed Mater Res. <u>63</u>(6), 765 (2002).
- 5. Shalaby, S.W., U.S. Patent 6,342,065 (2002).
- 6. Shalaby, S.W., U.S. Patent 6,462,169 (2002).
- 7. Shalaby, S.W., et al., U.S. Pat. 11/879,357 (2007).