Effect of Coating on the Performance of a New Absorbable Composite Mesh for Hernia Repair

Peniston, S.J.[1], Taylor, M.S.[1], Shalaby, W.S.W.[2], Corbett, J.T.[1], and Shalaby, S.W.[1]
[1]Poly-Med, Inc., Anderson, South Carolina
[2]St. Francis Hospital, Wilmington, Delaware

Statement of Purpose: Knitted meshes, mostly made of non-absorbable polypropylene and polyethylene terephthalate, are widely used in repairing hernial defects in spite of a number of undesirable clinical outcomes. These include the inability to (1) transfer gradually the holding load to healing tissue to assist wound healing; (2) prevent or minimize adhesion formation due to the mesh surface inertness; and (3) prevent or minimize the likelihood of extrusion and infection.[1,2] This led to a number of unsuccessful attempts to use absorbable meshes because of their transient nature. This was attributed to the relatively brief breaking strength retention (BSR) profile of these compared to the wound strength regain profile. Subsequently, the concept of using composite meshes having two yarns displaying fast and slow BSR profiles was evoked.[3,4] Further experience in our laboratory relative to the clinical advantage of coating braided multifilament sutues, raised the question of how might an absorbable coating effect *in vitro* and *in vivo* performance of composite meshes. And this provided the incentive to pursue the study, subject of this communication.

Methods:

• **Polymer and Mesh Preparation** – A polyaxial segmented copolyester, MG9, was prepared by end grafting a polyaxial poly(trimethylene carbonate) with glycolide and caprolactone. MG9 was melt extruded under typical conditions into a 20-filament yarn. SMC7 was polymerized by end grafting linear poly(trimethylene carbonate) with l-lactide and trimethylene carbonate. MG9 was used as a fast-degrading multifilament yarn and SMC7 as a slow-degrading component. Mesh construction was based on warp knitting the two yarns using an 18 gauge raschel knitting machine followed by a heat setting process. Mesh construction from the two yarns is initially interdependent and will transition to exhibit independent, functional mechanical properties for the slow-degrading component. Coating made of a polyaxial caprolactone copolymer was prepared as described earlier[5] and applied by dip coating from an acetone solution.

• **Evaluation of *In Vitro* Mesh Properties** – *In vitro* conditioned burst strength retention [BSR = (max. strength at time point / initial max. strength)*100] was conducted using a MTS MiniBionix Universal Tester (model 858) equipped with a scaled-down burst test apparatus, proportioned to that detailed in ASTM D3787-01, that accepted 3cm x 3cm test meshes. Samples were conditioned using a 0.1M solution of 7.2pH buffered sodium phosphate and incubated at 37°C under constant orbital-agitation. Samples were removed at 1, 3, and 6 week time points to determine the maximum burst strength.

• **Evaluation of *In Vivo* Mesh Properties** – *In vivo* evaluation was completed using Sprague-Dawley rats by folding a 6cm x 6cm mesh and placing it into a dorsal, subcutaneous pocket. Coated and uncoated meshes were sterilized using a low-temperature ethylene oxide cycle. Mechanical properties were obtained as described for *in vitro* evaluation.

Results: Data in Table I describe the initial and *in vitro* conditioned mesh maximum burst strength. Data suggests that the application of the polyaxial caprolactone copolymer improves the *in vitro* conditioned BSR.

Table II contains information on the maximum burst strength profile of coated and uncoated mesh to the *in vivo* environment. Beyond 3 weeks *in vivo* coated meshes show improved BSR when compared to uncoated meshes under the same conditions.

Table I. *In Vitro* Conditioned BSR for Coated and Uncoated Composite Mesh

In vitro Duration (Weeks)	Uncoated Mesh		Coated Mesh (10% Add-on)	
	BSR (%)	Maximum Burst Strength (N)	BSR (%)	Maximum Burst Strength (N)
0	--	164	--	147
1	62	102	72	106
3	54	88	67	98
6	50	82	69	102

Table II. *In Vivo* BSR for Coated and Uncoated Composite Mesh

In vivo Duration (Weeks)	Uncoated Mesh		Coated Mesh (10% Add-on)	
	BSR (%)	Maximum Burst Strength (N)	BSR (%)	Maximum Burst Strength (N)
0	--	179	--	156
1	88	157	81	126
3	58	103	78	122
6	58	104	78	121

Conclusions: Available results indicate that coating the composite meshes with an absorbable polymer does improve their key clinically relevant *in vitro* and *in vivo* properties.

References:

[1]Klosterhalfen B. et al., *Langenbecks Arch. Chir.*, 382, 87 (1997).
[2]Amid, P.K., *Hernia*, 1, 15 (1997).
[3]Shalaby, S.W. et al., U.S. Pat. Appl. 11/879,357 (2007).
[4]Shalaby, S.W. et al., U.S. Pat. Appl. 11/866,370 (2007).
[5]Shalaby, S.W. et al., U.S. Pat. # 6,462,169 (2002).