Bicomponent Selectively-Absorbable Hernia Mesh for Improved Wound Healing

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Statement of Purpose: In the western world, mesh hernioplasty is a common general surgical procedure.[1] Despite the frequency of this procedure, the incidence of recurrence and patient complications remains high. As a result, a mesh with improved biocompatibility is still an unmet need for hernia repair. The wound healing process is dynamic with overlapping phases that each has different biomechanical needs. A mesh which modulates biomechanics to overlap the temporal phases of the wound healing process by providing structural stability to the developing extracellular matrix and facilitating mechanical stimulation to remodeling collagen may be required to improve mesh biocompatibility. As such, a novel bicomponent selectively absorbable mesh (SAM) was developed.[2] Specifically, a SAM which temporally modulates its physicomechanical properties and will (1) possess short-term structural stiffness to facilitate tissue stability during the development of wound strength; (2) gradually transfer the perceived mechanical loads as the wound is building mechanical integrity; (3) provide force-extension properties similar to the abdominal wall and load sharing by the remodeling mesh/tissue complex.

Methods:

• **Polymer and Mesh Preparation:** A polyaxial segmented copolyester, P17, was prepared by end grafting a polyaxial poly(trimethylene carbonate) with glycolide and l-Lactide. Ground polymer was melt extruded under typical conditions into a 10-filament yarn. Ultra high molecular weight polyethylene (UHMWPE) yarn of 55 dtex was procured. P17 was used as a fast-degrading multifilament yarn and UHMWPE as the non-absorbable component of the SAM. Mesh construction was based on warp knitting the two yarns using an 18 gauge raschel knitting machine into an interdependent construction.

• **Evaluation of *In Vitro* Mesh Properties:** *In vitro* conditioned burst testing was conducted using a MTS MiniBionix Universal Tester (model 858) equipped with a burst test apparatus as detailed in ASTM D3787-01. Samples were conditioned using a 0.1M solution of buffered sodium phosphate at a 7.2pH in 50mL tubes. Tubes were placed in racks and incubated at 37°C under constant orbital-agitation. Samples were removed at 1, 2, 3, 4, and 9 weeks and burst tested to determine the maximum burst strength and the extension at 16N/cm.

• **Determination of Mesh Physical Properties:** To determine the relative weight ratio of P17 and UHMWPE, samples were incubated at 50ºC for approximately 10 days until the P17 component was significantly hydrolyzed using 12pH buffered sodium phosphate. Subsequently, the original and final mass was compared to obtain the weight ratio. The determination of mesh area weight followed option C in ASTM D3776-07. Porosity measurements were obtained using a digital image of the mesh and high-contrast colorizing of the pores followed by software (Motic ML 2.0) determination of the color covered area.

Results: Data in Table I indicates that the percentage of P17 by weight was significant resulting in an extremely low amount of long-term foreign body from the permanent mesh.

Data in Table II indicates that although a significant reduction in area weight is realized following the degradation of P17, minimal reduction in burst strength was realized through 9 weeks. Furthermore, clinically-relevant strengths are obtained.[3] In addition, data indicates that mesh stiffness is maintained up to 2 weeks, a load transition period is realized between 2 and 3 weeks, and after 3 weeks the mesh shows long-term extensional characteristics similar to those of the abdominal wall.[4] As such, logic suggests that the high compliance of the SAM long-term will facilitate load sharing by the remodeling mesh/tissue complex.

Table I. Component Weight Ratio and Initial Physical Properties of the SAM

Composition by Weight (%)		Area Weight (g/m^2)	Porosity (%)
P17	UHMWPE		
70	30	80	35

Table II. *In Vitro* Conditioned Strength and Extension Properties of the SAM

In vitro Duration (Weeks)	Maximum Burst Strength (N)	Extension at 16N/cm (%)
0	551	8.6
1	545	9.0
2	490	11.6
3	489	23.2
4	501	24.4
9	510	25.5

Conclusions: Available results demonstrate the ability to construct a SAM which can temporally modulate mesh biomechanics. The observed transition in biomechanics may augment the natural healing process and improve the clinical outcome of mesh hernioplasty.

References:

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