Suture Properties of Swellable, Absorbable Multifilament Braids

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Statement of Purpose: Results of early and recent preliminary studies on thermoplastic absorbable hydrophilic polyether-esters as melt-processable polymers, well-suited for conversion into multifilament yarn and braids therefrom prompted the pursuit of a focused study on the clinical potential of these braids as hydroswellable sutures.[1-3] This led to the study, subject of this communication, which deals with the successful synthesis and processing of selected types of hydro-swellable polymers into braided multifilament sutures as well as the *in vitro* and *in vivo* evaluation of key suture properties.

Methods: Copolymers in Table I were prepared by end-grafting glycolide and ε-caprolactone (USG 13) or *l*-lactide and glycolide (USLG 1), using polyether diols as initiator as previously described.[1] This yielded two systems having unique hydroswellability and degradation profiles.

Polymers were melt-extruded into multifilament fibers using a ¾" single screw extruder with 5 heating zones and oriented to maximize fiber strength. Fibers were subsequently braided and heat treated to increase stability. Braided sutures were sterilized by ethylene oxide prior to analysis.

Tensile testing was performed using an MTS universal load frame according to USP guidelines. *In Vivo* (*IVV*) breaking strength retention was determined by subcutaneous implantation in Sprague-Dawley rats for clinically relevant durations. Swellability was calculated by placing sutures in 37°C solution for 1 hour and assessing the percent change in diameter.

Results: Polyether contents in the USG 13 and USLG 1 copolymers, as described in Table I, led to hydro-swellable sutures. An added benefit is that the braided sutures "soften" when moistened, improving the perceived feel of the suture by the surgeon.

Table I. Polyether content of copolymers and hydroswellability of their respective braided sutures

Polymer	Polyether content, %	% Diameter change at 1 hour[1]
USG 13	5	12.5
USLG 1	8	6.5

Multifilament braided sutures prepared from USG 13 and USLG 1 polymers exceeding USP guidelines for initial knot strength, as exhibited in Table II. Sutures prepared from USG 13 exhibited strength retention similar to that of Vicryl Rapide®.

Suture from USLG 1 represents a new class of suture due to the extended duration of strength retention. Currently, there is no marketed absorbable suture that retains strength as long as USLG 1 braided suture. Additional data (not shown) indicates USLG 1 retains strength for up to 4 months *in vivo*, indicating its possible use for orthopedic surgery or for difficult/slow healing wounds.

Table II. Properties of braided sutures

Polymer		USG 13	USLG 1
USP Suture Size		3-0	4-0
Diameter, mm		0.33	0.24
Ultimate Load, N	Straight	31.1	22.4
	Knot	23.1	12.2
BSR[1], *IVV*	1 wk	35	-
	2 wk	3	-
	4 wk	-	61
	6 wk	-	54
	8 wk	-	51

[1]*In Vivo* Breaking strength retention, implanted subcutaneously in Sprague-Dawley rats

Conclusions: Braided multifilament sutures exhibited clinically relevant initial strengths and strength loss profiles. USLG 1 holds particular interest due to its unique extended strength retention, for possible use in orthopedic surgery. This would provide one of the few absorbable sutures that are approved for use in orthopedic applications.

References:

1. Shalaby, S.W. et al., U.S. Pat. app. 11/596,545 (2006).
2. Lindsey III, J.M. et al., 8th World Biomater congress, Abs No 1895 (2008).
3. Ingram, D.R. et al., *Trans Soc Biomater*, 31, 533 (2009).

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