Suture Properties of Swellable, Absorbable Monofilaments

M. S. Taylor, D. R. Ingram, B. P. Baum, D. E. Linden, †K. J. L. Burg, S. W. Shalaby
Poly-Med, Inc., Anderson, SC
† Department of Bioengineering & Institute for Biological Interfaces of Engineering, Clemson University, Clemson, SC

Statement of Purpose: Interest of our laboratory in amphiphilic absorbable polyether-esters with unique physicochemical properties commenced in the 1990s with the successful development of hydrogel-forming liquids, which led, in part, to the commercialization of an injectable antibiotic, controlled release formulation for treating periodontitis.[1-3] Extension of the amphiphilic polyether-esters technology led to the recent development of hydroswellable melt-processable materials.[4] Preliminary findings on the preparation and properties of monofilament and multifilament yarns and their potential use as absorbable sutures were the subject of recent reports.[5,6] This prompted further exploration of the clinical potential of certain members of the family of hydroswellable polymers as swellable absorbable **monofilament** sutures. This communication deals with the successful synthesis and processing of selected hydroswellable polymers into **monofilament** sutures as well as the *in vitro* and *in vivo* evaluation of key suture properties.

Methods: Copolymers listed in Table I were prepared in one or two steps using polyether diols as initiator, as previously described.[4] The copolymers were designed to have varying levels of hydrophilic polyether-ester segments. Specifically, USG, USD, and USL polymers were prepared by end-grafting glycolide, dioxanone, and *l*-lactide, respectively, on hydrophilic initiators with minor components in each polymer system comprised of caprolactone and trimethylene carbonate. This produced three polymer systems exhibiting unique hydro-swellability, as well as strength retention properties.

Polymers were melt-extruded into monofilament fibers using a ¾ inch single screw extruder (with 4 heating zones) and quenched in a water bath. Subsequently, fibers were oriented to maximize the linear and knot properties and heat treated to increase stability. Sutures were sterilized by ethylene oxide. Tensile testing was performed using an MTS universal load frame according to USP guidelines. *In vivo* (*IVV*) breaking strength retention was determined after subcutaneous implantation in Sprague-Dawley rats for clinically-relevant durations. Swellability was calculated by placing sutures in a 7.2 pH, 100 mM phosphate buffered solution at 37°C for 1 hour and assessing the percent change in diameter.

Results: Increased polyether content results in increased swellability of each polymer system, as noted in Table I. This is more pronounced in the USG series of polymers, as these materials exhibit high levels of swelling with relatively low amounts of the hydrophilic component. USL polymers exhibit less swelling, and the swellability is generally low until a critical value between 20 and 26% polyether content.

Table I. Polyether Content of Polymers and Hydroswellability of Their Respective Fibers

Polymer	Polyether content, %	% Diameter change at 1 hour[1]
USG 10	4	2
USG 11	8	5
USG 3	20 - 21	16
USG 1	27 - 32	59
USD 3	5	3
USD 1	9 - 10	5
USL 11	9	1
USL 5	20 - 21	6
USL 6	26	30

[1]Incubated in 37 °C, 7.2 pH, 100 mM phosphate buffered solution

Table II. Properties of Select Fibers

Polymer		USG 11	USD 1	USL 5
USP Suture Size		2-0	3-0	3-0
Diameter, mm		0.40	0.30	0.31
Ultimate Load, N	Straight	43.5	30.5	25.2
	Knot	25.4	20.1	20.0
BSR[1], *IVV*	1 wk	51.8	-	69[2]
	2 wk	20.2	58.3	56[2]
	4 wk	-	51.8	45.6[2]
	6 wk	-	-	34.8[2]

[1]Breaking strength retention after sub-cutaneous implantation in Sprague-Dawley rats
[2]*In Vitro* results, 37 °C, 7.2 pH, 100 mM phosphate buffered solution

USG 11 exhibited strength retention longer than Chromic Gut and Vicryl® Rapide suture, maintaining 20% of its initial strength after 2 weeks. USD 1 and USL 5 exhibited similar strength retention profiles, both of which are between the strength retentions of Vicryl® and PDSII® sutures. USD 1 has an advantage over USL 5 due to a lower tensile modulus, which indicates it is a more compliant suture (data not shown).

Conclusions: Processed fibers exhibited clinically relevant initial strengths and strength loss profiles, with the unique added benefit of exhibiting swellability. This is a good indication that these sutures hold promise as a new class of sutures, holding particular interest for cardiovascular surgery where a self-sealing suture would provide a layer of protection at the surgical site.

References:

1. Shalaby, S.W., U.S. Patent 5,612,052 (1997).
2. Salz, U., et al., *Trans Soc Biomater*, 24, 294 (2001).
3. Eickholz, P. et al., *J Clin Periodont*, 29, 108 (2002).
4. Shalaby, S.W. et al., U.S. Pat. app. 11/596,545 (2006).
5. Lindsey III, J.M. et al., 8th World Biomaterial Congress, Abstract No 1895 (2008).
6. Ingram, D.E. et al., Trans Soc Biomater, 31, 533 (2009).

Acknowledgement: This work is supported by National Institutes of Health SBIR Phase II Grant No. 2R44 BM 079808-02A2