Monofilament Sutures of Copolyesters with Minimized Hydrolytic Instability – A Preliminary Report

S.W. Shalaby, M.S. Taylor, K.A. Carpenter, and J.T. Corbett
Poly-Med, Inc., Anderson, South Carolina, USA

Introduction—Monofilament Sutures have long been sought as a preferred alternative to braided sutures to circumvent some drawbacks in braided suture, which include capillarity, tendency to harbour micro-organisms, tissue drag, and poor knot tie-down[1]. However, to compete with the excellent engineering compliance of braids, monofilament must have lower modulus. For this, a number of sutures have been developed and commercialized, such as PDS® and Maxon®. Presently, Vicryl® has been recognized as the major braided suture, with the absorption and strength retention profiles that have yet to be matched by commercial monofilaments, and this provided an incentive to pursue the study subject of this report, which deals with the development of a high-compliance monofilament suture with comparable strength retention profile to that of Vicryl® using one of earlier patented compositions[2].

Materials and Methods

• **Polymer and Suture Preparation—**A number of glycolide/TMC-based, segmented copolymers were prepared using polyalkylene succinate glycols as initiators and characterized as described earlier (TGS)[2]. A summary of key properties of typical polymers is provided in Table I. The polymers were melt-spun into monofilament using a single screw ¾" extruder equipped with a melt-pump and a 60-mil die. For orientation, a series of godets and hot shoes were used to achieve the desired diameter and strength. The material was then thermally stabilized by a series of annealing and relaxation steps. Physical properties of typical suture sizes based on selected TGS copolymers comprised of about 65% glycolide are also summarized in Table I.

• **Suture Sterilization—**All sutures used were packaged under nitrogen in a hermetically sealed foil package with a Tyvek™ header. The sutures were sterilized with moist ethylene oxide (EtO) for 16 hours at 40˚C.

• **Evaluation of *In Vitro* and *In Vivo* Suture Properties**—The percent *in vitro* breaking strength retention (% BSR) was evaluated by determining the breaking strength of the sutures after incubation in a phosphate buffer at 37°C and 7.4 pH for predetermined periods of time. The *in vivo* BSR was determined on retrieved suture strands that had been implanted subcutaneously in rats for predetermined periods of time according to the animal protocol described in a previous report[3]. The linear breaking strength of suture specimens was determined using an MTS Synergie tester, model 200. This data, along with a comparison to Vicryl® braided suture, are summarized in Table II.

Results and Discussion— The data in Table I illustrate (1) the ability of converting high molecular, crystalline, segmented polymer into exceptionally low modulus (compliant) monofilament sutures with clinically acceptable breaking strength; (2) the tensile strength is higher in the small size sutures as compared to the larger sizes, while also exhibiting a higher percent elongation.

Table I. Properties of Two Typical Polymers and Corresponding TGS Monofilament Sutures

Suture		A1	A2	B
Polymer Properties	T_m, °C	220		222
	ΔH, J/g	50		57
	I.V.[b], dL/g	1.64		1.37
Tensile Properties	Diam., mm	0.24	0.45	0.30
	Max. Load, N	20	53	28
	Knot Load, N	18	45	28
	Tensile Strength, kpsi	63	52	56
	Modulus, kpsi	26	28	29
	Elong,%	96	90	97

[a]At 20˚C/min heat rate [b]I.V. = Inherent Viscosity

Table II data indicate the similarities in strength retention profile of TGS monofilaments and Vicryl® braided sutures. For both the Vicryl® and suture B, *In Vivo* data shows a slower loss in strength than the *In Vitro* data.

Table II. *In Vitro* and *In Vivo* Evaluation of Vicryl® and Typical TGS Monofilament Sutures

Suture	Initial		*In Vitro* BSR[a], weeks		*In Vivo* BSR[a], weeks			
	Diam, mm	Load, N	2	3	2	3	4	5
Vicryl 4/0	0.22	30	-	-	75[b]	50[b]	-	-
Vicryl 2/0	0.36	69	70	17	73	61	-	-
A1	0.24	20	76	16	-	-	-	-
A2	0.45	53	65	7	-	-	-	-
B	0.30	28	80	25	83	68	33	11

[a]Based on the suture maximum load [b]Published data[1]

Conclusion—EtO sterilized TGS monofilament sutures tested in animals retain sufficient fractions of their initial strength to allow their clinical application in many surgical procedures. Preliminary results outlined above demonstrate the potential of TGS as a compliant monofilament with comparable or superior strength retention to Vicryl® braid.

References

1. Shalaby, S.W. and Johnson RA, Chap. 1. Biomedical Polymers. Hanser NY (1994).
2. Shalaby, S.W., U.S. Patent No. 6,255,208 (2001).
3. Anneaux, B.L. et al., *Trans Soc. Biomater*, 24, 157 (2001).