

Material Properties of Quill™ SRS Monoderm™ Sizes 0, 2-0 and 3-0

Summary

Using in vitro real-time degradation testing over 28 days at 37 °C, the tensile strength and break strength retention (BSR) of absorbable Monoderm™ (a polyglycolide-poly-e-caprolactone copolymer) bidirectional self-retaining sutures sizes 0, 2-0 and 3-0 were compared to conventional absorbable Monocryl™ (poliglecaprone 25, a copolymer of glycolide and ε-caprolactone) sutures one USP diameter smaller (sizes 2-0, 3-0 and 4-0, respectively). Under the conditions of this study, bidirectional self-retaining sutures were significantly stronger than conventional sutures of one size smaller at each of Days 7, 14 and 21. Of particular interest, at Day 7, percent BSR was between 72% and 74.0% for the Monoderm™ sutures and between 37% and 47% for the Monocryl™ sutures. By Day 28, the strength remaining was zero or minimal for all suture types and sizes. Differences observed in the tensile strengths of the test and control products may in part be accounted for by variances introduced through the use of the two tensile strength test systems: the standard knot pull test for conventional sutures versus the straight pull test for bidirectional self-retaining sutures that by design do not require knot tying.

Introduction

Bi-directional self-retaining sutures (Quill™ SRS, Angiotech, Reading, PA) are a novel technology indicated for use in soft tissue approximation. The tissue retainers (for example, barbs) are arranged around the suture in opposite directions from each side of a short retainer-free segment; a needle is crimped onto each suture end. The suture is available in both absorbable (polydiox-anone, PDO; polyglycolide-poly-e-caprolactone copolymer, Monoderm™) and non-absorbable (polypropylene; nylon) formulations, and in various lengths with various needle types and sizes to facilitate soft tissue approximation. In the case of the Monoderm™ suture, the copolymer degrades in vivo over time by hydrolysis of the ester links in the polymer backbone, until dissolution and absorption by the body occurs.

Compared to traditional sutures, the benefits of the bidirectional self-retaining sutures for soft tissue approximation relate to the ease, speed and economy of suture placement. No suture knot tying is required, and no third hand is needed to follow the suture placement. As a result, suture deployment is faster. Depending on the extent of the soft tissue closure needed, there is the potential for considerable time savings. And, by avoiding the tying of multiple individual suture loops, tension can be more uniformly distributed along the entire length of the closure. These benefits are increasingly being used to advantage for soft tissue approximation in a variety of surgical procedures from urological, gynecological and laparoscopic to plastic and reconstructive applications.

Because the production of barbs on a suture decreases the internal core diameter of the suture, bidirectional self-retaining sutures were designed to be approximately equal in strength to conventional sutures (that is, sutures that are not self-retaining) that were one size smaller. Each of the bidirectional self-retaining suture formulations has been tested with a goal to establishing their material properties relative to conventional sutures. We report the performance of the Monoderm™ bidirectional self-retaining sutures sizes 0, 2-0 and 3-0 compared with conventional Monocryl™ conventional sutures sizes 2-0, 3-0 and 4-0 (Ethicon, Somerville, NJ) respectively in the categories of tensile strength and break strength retention. These properties are of particular interest for absorbable formulations since it is critical that the suture continue to hold the wound together until a desired amount of healing has occurred.

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Methods

In vitro hydrolysis testing of Monoderm™ bidirectional self-retaining sutures and of Monocryl™ conventional sutures was performed at 37°C. Sutures from each group and suture size were either set aside for baseline testing (Day 0) or were placed in test tubes of phosphate buffered saline and set in the water bath at 37°C. Samples from each group were removed from the water bath at Days 7, 14, 21 and 28 for tensile strength testing. An attempt was made to collect 10 samples per test group; however, at longer degradation times (21 and 28 days) the tensile strength of the sutures was too low to perform the test successfully. Samples were evaluated using the Instron® Tensile/Compression Test System to examine tensile strength using load cells and grips appropriated for the size of suture being tested. A knot pull tensile test, where tension is applied at either ends of a suture in which a single knot has been tied in the middle, was performed for all conventional Monocryl™ sutures; this is currently the standard test for conventional sutures in the U.S. Since bidirectional self-retaining sutures do not require the tying of a knot, a straight pull tensile strength test was used as a more appropriate alternative for the Monoderm™ sutures. Each suture was placed between the two grips and the suture was made taut. In the case of conventional sutures, samples were placed with the knot approximately midway between the clamps. The System was activated and the load at peak was measured; means and standard deviations were calculated for each suture type and size at each termination interval. In addition, the percent break strength retention (%BSR), which is a function of the tensile strength retained by the suture over time, was calculated as:

$$\%BSR = \frac{\text{mean load at peak at time interval}}{\text{mean load at peak at time zero}} \times 100$$

Results

Table 1. In vitro tensile strength and break strength retention at 37°C

	Quill™ SRS Monoderm™ 0 Straight Pull		Monocryl™ 2-0 Knot Pull	
	Load at Peak (kgf)	% BSR	Load at Peak (kgf)	%BSR
	mean ± SD	mean ± SD	mean ± SD	mean ± SD
Day 0	4.636 ± 0.240	100.0 ± 7.32	4.509 ± 0.322	100.0 ± 10.10
Day 7	3.432 ± 0.100	74.0 ± 4.40	1.662 ± 0.155	36.9 ± 4.33
Day 14	2.003 ± 0.142	43.0 ± 3.79	0.367 ± 0.067	8.1 ± 1.60
Day 21	0.886 ± 0.137	19.1 ± 3.12	0.000 ± 0.000	0.0 ± 0.00
Day 28	0.000 ± 0.000	0.0 ± 0.00	0.000 ± 0.000	0.0 ± 0.00
	Quill™ SRS Monoderm™ 2-0 Straight Pull		Monocryl™ 3-0 Knot Pull	
	Load at Peak (kgf)	% BSR	Load at Peak (kgf)	%BSR
	mean ± SD	mean ± SD	mean ± SD	mean ± SD
Day 0	2.897 ± 0.146	100.0 ± 7.13	2.657 ± 0.268	100.0 ± 14.26
Day 7	2.088 ± 0.103	72.1 ± 5.08	1.101 ± 0.065	41.4 ± 4.84
Day 14	0.922 ± 0.074	31.8 ± 3.02	0.286 ± 0.050	10.8 ± 2.17
Day 21	0.335 ± 0.054	11.6 ± 1.95	0.000 ± 0.000	0.0 ± 0.00
Day 28	0.077 ± 0.017	2.7 ± 0.60	0.000 ± 0.000	0.0 ± 0.00
	Quill™ SRS Monoderm™ 3-0 Straight Pull		Monocryl™ 4-0 Knot Pull	
	Load at Peak (kgf)	% BSR	Load at Peak (kgf)	%BSR
	mean ± SD	mean ± SD	mean ± SD	mean ± SD
Day 0	1.783 ± 0.076	100.0 ± 6.03	1.511 ± 0.131	100.0 ± 12.26
Day 7	1.278 ± 0.054	71.7 ± 4.30	0.712 ± 0.044	47.1 ± 5.02
Day 14	0.586 ± 0.054	32.9 ± 3.34	0.316 ± 0.085	20.9 ± 5.91
Day 21	0.218 ± 0.038	12.2 ± 2.19	0.052 ± 0.024	3.4 ± 1.62
Day 28	0.000 ± 0.000	0.0 ± 0.00	0.000 ± 0.000	0.0 ± 0.00

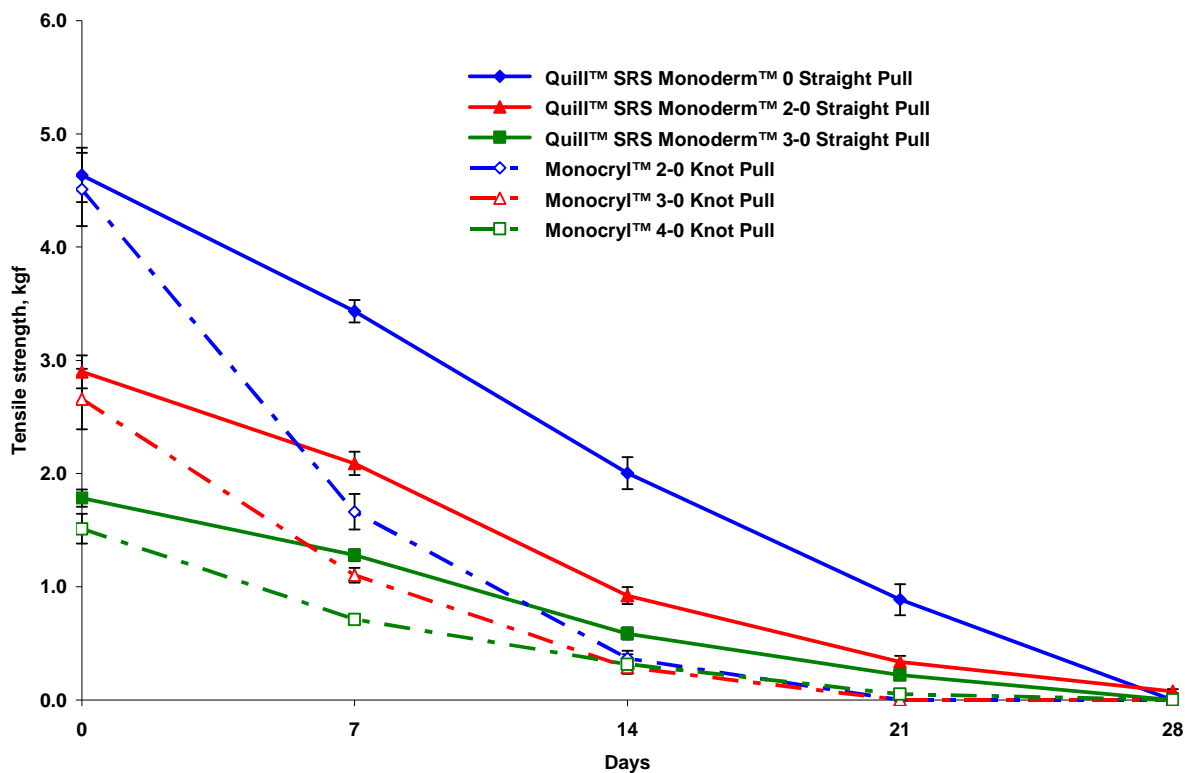
kgf=kilogram force; BSR=break strength retention

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Based on a two-way ANOVA followed by Bonferroni's post-hoc, the self-retaining Monoderm™ suture size 0 was significantly stronger than the conventional Monocryl™ suture size 2-0 at each of Days 7, 14 and 21. Similarly, the self-retaining Monoderm™ suture sizes 2-0 and 3-0 were significantly stronger than the conventional Monocryl™ suture size 3-0 and 4-0 respectively at each of these days. By Day 28, the strength remaining was zero or minimal for all suture types and sizes. Differences in the tensile strengths of the bidirectional self-retaining sutures and their controls may in part be accounted for by variances introduced through the use of the two test systems. It is well-recognized that a knot weakens a suture such that a knot pull tensile test produces lower break strength values than a straight pull tensile test performed on a suture of the same size and formulation. If the bidirectional self-retaining suture was indeed equivalent in strength to a conventional suture one size smaller, it might be expected – as was observed – that a straight pull tensile strength test performed on the bidirectional self-retaining suture would yield higher tensile strengths than a knot pull tensile strength test performed on a conventional suture one size smaller.

With 72 to 74% break strength remaining at 7 days, these in vitro data for self-retaining Monoderm™ sutures sizes 0, 2-0 and 3-0 were not dissimilar from what has been observed in vivo. As printed in the instructions for use, self-retaining Monoderm™ sutures in vivo retain approximately 62% of their original strength 7 days post-implantation. Accordingly, this product is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate; it is contraindicated where extended approximation of tissue under stress is required.¹

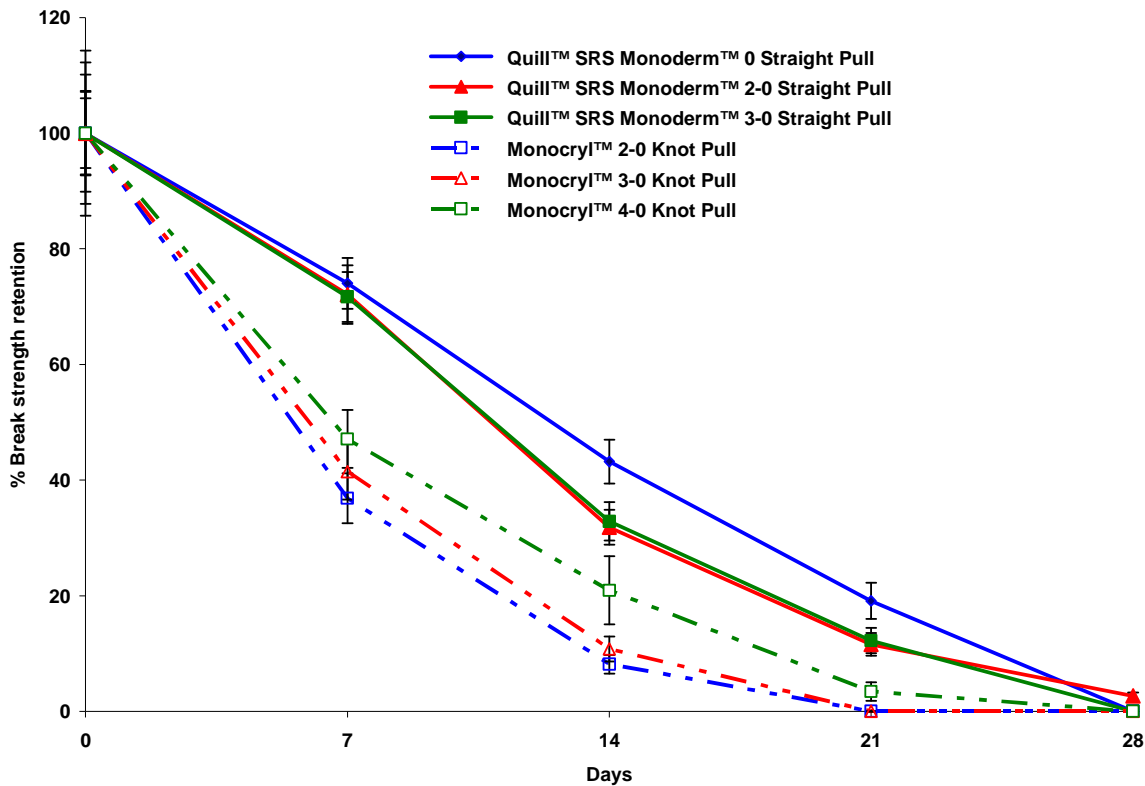
Figure 1. In vitro tensile strength at 37°C



¹ See the instructions for use supplied with Quill™ SRS Monoderm™ for complete information on indications, contraindications, warnings, precautions and adverse reactions.

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Figure 2. In vitro break strength retention at 37°C



Conclusion

Under the conditions of this study, Quill™ SRS Monoderm™ sutures were stronger than conventional sutures of one size smaller at each of Days 7, 14 and 21; by Day 28, the strength remaining was zero or minimal for all suture types and sizes.

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