

Material Properties of the Absorbable Quill™ SRS PDO Sizes 3-0 and 4-0

Summary

Using in vitro real-time degradation testing over 56 days at 37 °C, the tensile strength and break strength retention (BSR) of absorbable polydioxanone (PDO) bidirectional self-retaining sutures sizes 3-0 and 4-0 were compared to that of conventional absorbable PDO sutures one USP diameter smaller (sizes 4-0 and 5-0, respectively). Under the conditions of this study, PDO bidirectional self-retaining sutures were shown to be greater in strength than conventional sutures of one size smaller at all time points. 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 (polydioxanone, PDO; a polyglycolide-poly-ε-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 PDO suture, the material 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 tissue retainers 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 lacking tissue retainers) 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 PDO bidirectional self-retaining sutures sizes 3-0 and 4-0 compared with conventional PDO sutures sizes 4-0 and 5-0 (PDS™ II, Ethicon, Somerville, NJ) respectively in the categories of tensile strength and break strength retention. These properties are of particular interest for absorbable formulations such as PDO since it is critical that the suture continue to hold the wound together until a desired amount of healing has occurred.

Methods

In vitro hydrolysis testing of Quill™ SRS PDO self-retaining sutures sizes 3-0 and 4-0, and of PDS™ II sutures sizes 4-0 and 5-0, was performed at 37 °C. 10 sutures from each group were set aside for baseline testing (Day 0). Forty sutures from each group were placed in test tubes of phosphate buffered solution and placed in the water bath at 37 °C. Ten samples from each group were removed from the hydrolysis bath at each time point (Days 14, 28, 42 and 56). Samples were evaluated using the Instron® Tensile/Compression Test System to examine tensile strength using load cells and grips appropriate 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 PDO sutures; this

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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 self-retaining PDO 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 (kgf) 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 follows:

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

Results

In these in vitro tests, both the Quill™ SRS PDO 3-0 and 4-0 retained 90% or more of their original strength out to Day 42, with a significant decrease only at Day 56 (Table 1, Figures 1 and 2). By Day 28, the PDS™ II 4-0 retained only 56% of its original strength and the PDS™ II 5-0 retained only 59%.

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

	Quill™ SRS PDO 3-0 straight pull		PDS™ II 4-0 knot pull	
	Load at Peak (kgf)	% BSR	Load at Peak (kgf)	% BSR
	mean ± SD	mean ± SD	mean ± SD	mean ± SD
Day 0, Baseline	1.89 ± 0.10	100.0 ± 7.8	1.35 ± 0.06	100.0 ± 6.1
Day 14	1.83 ± 0.11	96.8 ± 7.9	0.92 ± 0.08	68.1 ± 6.8
Day 28	1.88 ± 0.13	99.3 ± 8.9	0.75 ± 0.09	55.8 ± 7.0
Day 42	1.80 ± 0.10	94.9 ± 7.4	0.39 ± 0.16	28.7 ± 11.8
Day 56	1.17 ± 0.08	61.8 ± 5.5	0.23 ± 0.07	17.2 ± 5.5
	Quill™ SRS PDO 4-0 straight pull		PDS™ II 5-0 knot pull	
	Load at Peak (kgf)	% BSR	Load at Peak (kgf)	% BSR
	mean ± SD	mean ± SD	mean ± SD	mean ± SD
Day 0, Baseline	1.28 ± 0.03	100.0 ± 3.2	0.86 ± 0.05	100.0 ± 8.5
Day 14	1.20 ± 0.09	93.8 ± 7.3	0.70 ± 0.03	81.0 ± 5.7
Day 28	1.15 ± 0.11	90.3 ± 8.6	0.51 ± 0.03	59.0 ± 4.9
Day 42	1.15 ± 0.12	90.2 ± 9.5	0.57 ± 0.02	66.2 ± 4.8
Day 56	0.79 ± 0.09	62.0 ± 7.2	0.31 ± 0.06	35.5 ± 7.7

kgf=kilogram force; BSR=break strength retention

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 that a straight pull tensile strength test performed on the bidirectional self-retaining suture yields higher tensile strengths than a knot pull tensile strength test performed on a conventional suture one size smaller.

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Figure 1. In vitro tensile strength at 37°C

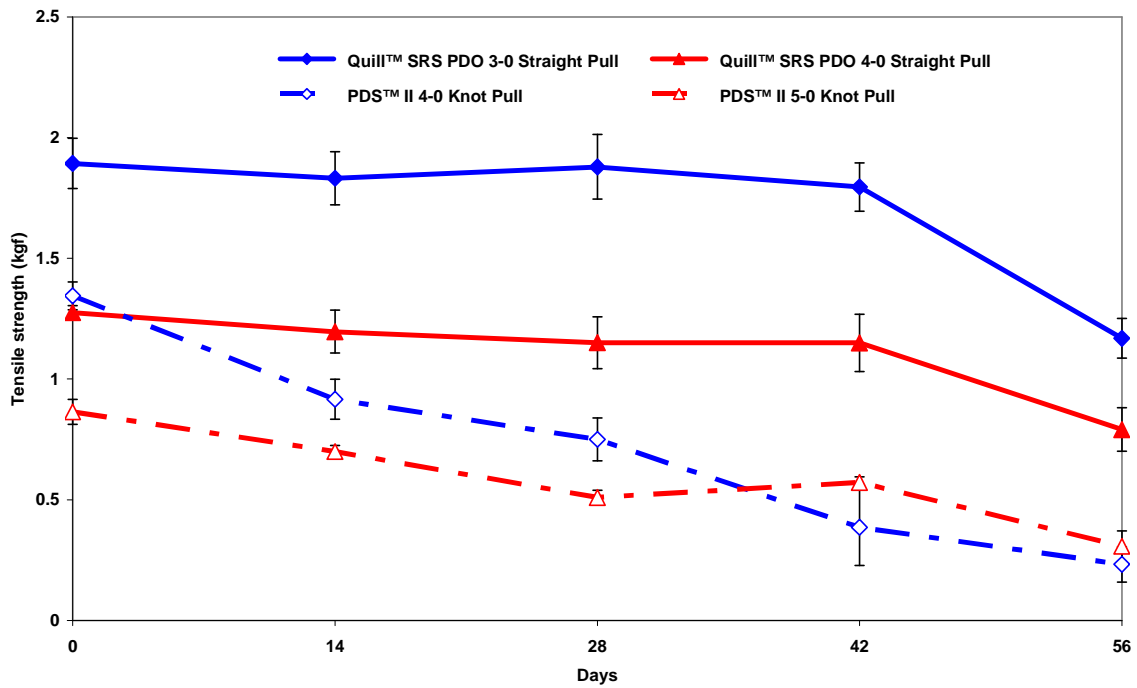
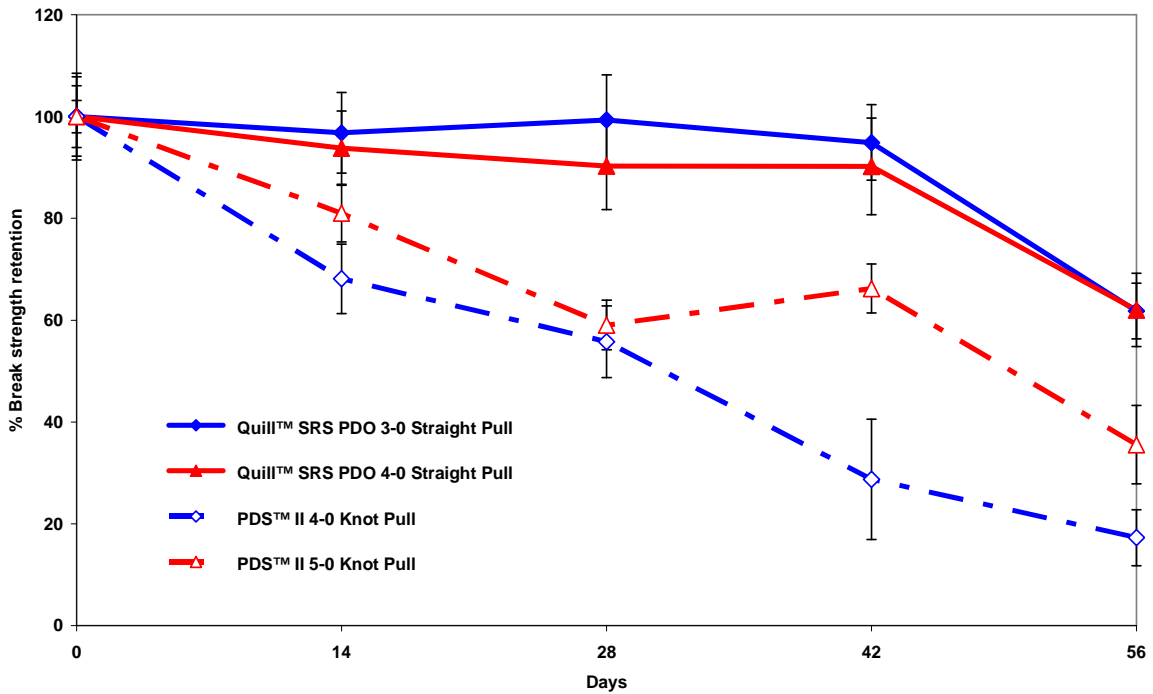


Figure 2. In vitro break strength retention at 37°C



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Conclusion

Under the conditions of this study, Quill™ SRS PDO bidirectional self-retaining sutures were shown to be greater in strength than conventional PDO sutures of one size smaller at all time points.

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