Performance Enhancement of a Knotless Suture via Barb Geometry Modifications

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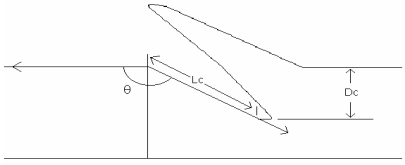
INTRODUCTION

Bi-directional barbed sutures have been previously shown to effectively close wounds without the need for knots in an *in vivo* canine study.[1,2] This novel material, which elicits similarly mild tissue reaction as its conventional predicate,[3] was found to be superior in minimizing incisional gap formation in two repair models.[2,4] Although barbed sutures, by eliminating bulky suture knots, allow the surgeon to choose larger suture diameters, previous studies compared barbed sutures to conventional sutures of one or more sizes smaller, in order to match the straight-pull tensile strength of the former and the knot-pull tensile strength of the latter.[1] The goal of this study was to increase the tensile strength of barbed sutures via changes in barb geometry while maintaining or improving their tissue holding capacity.

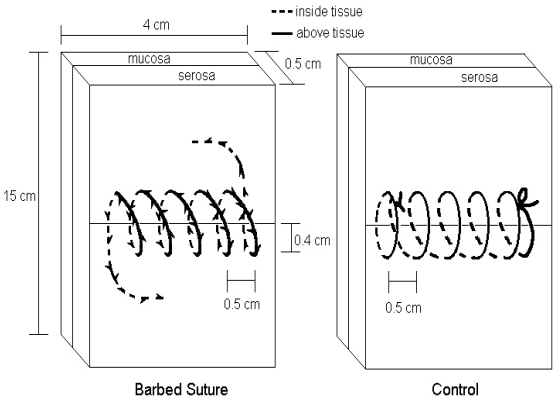
MATERIALS AND METHODS

Barbed Sutures: Two different barb geometry designs (A & B) of a bi-directional barbed suture were fabricated from polydioxanone (PDO), size 0. Each suture was 7" long and contained 78 barbs, equally divided into two opposing segments, in the middle 3". The average straight-pull tensile strength of each design was measured using ten samples.[1,2]

Barb Geometry Measurement: Using an Optem Zoom microscope with an attached video camera, the barb geometries were characterized by four different parameters as previously reported: cut angle (θ), cut depth (D_c), calculated cut length (L_c), and the distance between cuts.[2,4]



Tissue Holding Performance Evaluation: A full-thickness, 3-cm incision was created in the distal jejunum of a cadaveric pig perpendicular to its length. (The jejunal segment measured about 10 cm in outer circumference and 5 mm in thickness.) The wound was closed with either a barbed suture (2 designs) or control PDS II, all of size 0, using a running "over-and-over" technique. Suture strands engaged but did not perforate the mucosal layer. A knot (5 throws) anchored each end of the control suture, whereas the barbed suture was finished with a J-shaped bite through adjacent tissue. Bite size (4 mm), distance between bites (5 mm), and number of crosses (11) were equivalent in all suture types.



Each wound was excised so that it was centered on a 4 cm x 15 cm piece of tissue. Wound edges were cut such that only the sutures held the two halves together. Ten sutured tissue specimens of each suture type were tested on a Test Resources Universal Tester, model 200Q, with a 250 lb. load cell, a 5 cm gauge length, and a crosshead speed of 5 cm/min. Each specimen was stretched to failure and the maximum load was recorded.

RESULTS AND DISCUSSION

The straight-pull tensile strengths and barb geometries of the barbed sutures were determined to be as follows:

Parameters	Design A	Design B
Tensile strength (lb.)	7.12 ± 0.25	9.89 ± 0.34
Cut angle, θ (º)	152.3 ± 0.8	162.2 ± 2.2
Cut depth, D_c (mm)	0.25 ± 0.01	0.12 ± 0.02
Cut length, L_c (mm)	0.54 ± 0.02	0.38 ± 0.04
Distance b/w cuts (mm)	0.82 ± 0.01	0.91 ± 0.04

The average peak forces required to separate the pig intestinal wounds are shown below:

Sutures, size 0	Tissue Holding Capacity (lb.)
Barbed PDO, A	7.64 ± 1.39
Barbed PDO, B	8.40 ± 1.83
Control PDS II	6.61 ± 2.02

Judging by the US Pharmacopeia (USP) minimum knot-pull tensile strength requirement of size 0 absorbable sutures, 8.60 lb., the tensile strength of barbed PDO design A (similar to the first prototype whose results were reported previously[1,2,3]) appears inferior. However, its wound holding capacity compares favorably to that of the same-size control in the pig intestinal model (p=0.19). Further, design B, with a modified barb geometry, not only exceeds the USP requirement but also demonstrates a trend towards higher mechanical performance than the conventional suture (p=0.06).

CONCLUSIONS

The results of this study indicate that: 1) a barbed suture can perform equivalently to its same-size conventional counterpart even with a lower tensile strength; and 2) a barbed suture can exhibit equal or better biomechanical performance, when fabricated with specific barb geometry parameters, than a knotted predicate suture in both tensile strength and wound holding capacity.

References [1] Leung JC, Ruff GL, Megaro, MA. Barbed, bi-directional medical sutures: biomechanical properties and wound closure efficacy study. 2002 Society for Biomaterials 28th Annual Meeting Transactions, #724. [2] Leung JC, Ruff GL, King MW, Dattilo PP. Barbed, bi-directional surgical sutures. *MEDTEX03, International Conference & Exhibition on Healthcare & Medical Textiles, Conference Proceedings, 2003, Bolton, UK.* [3] Leung JC, Pritt S. Barbed, bi-directional surgical sutures: *In vivo* strength and histopathology evaluations. 2003 Society for Biomaterials 29th Annual Meeting Transactions, #100. [4] Dattilo PP, King MW, Leung JC. Tissue holding performance of knotless absorbable sutures. 2003 Society for Biomaterials 29th Annual Meeting Transactions, #101.