

Barbed, Bi-directional Surgical Sutures: *In Vivo* Strength and Histopathology Evaluations

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INTRODUCTION

A barbed, bi-directional surgical suture, which can approximate tissue without the need to tie knots, has been developed recently.¹ This novel self-anchoring suture, fabricated from polydioxanone (PDO), features barbs that are escaped into the monofilament fiber in a spiral configuration, and are divided into two groups that face each other in opposing directions from the suture midpoint. Advantages include simpler and faster suture placement without complications associated with conventional suture knots such as slippage, extrusion or 'spitting,' and tissue distortion.²



Magnified mid-section of barbed suture

The *in vivo* wound closure efficacy of the barbed, bi-directional suture in various tissues has been successfully demonstrated in a canine model.¹ The goal of this study was to evaluate over time the *in vivo* suture tensile strength and barb holding strength, as well as histologic changes.

MATERIALS AND METHODS

Barbed Suture: The bi-directional barbed PDO suture is 7" long and 0.018" in diameter (size 0), and contains 78 barbs in the middle 3".

***In Vivo* Suture Tensile Strength:** Barbed PDO sutures were implanted into the subcutis layer of eight New Zealand White rabbits, via a large bore catheter. A total of at least four sutures, placed parallel to the dorsal midline, were implanted in each rabbit. At 2, 4, 6, and 8 weeks postoperatively, two animals were sacrificed respectively and the corresponding sutures retrieved for tensile strength testing. They were compared to the suture tensile strength before implantation (week 0).

***In Vivo* Barb Holding Strength:** At pre-determined, randomized locations in the dorsal aspect of four dogs, the barbed PDO suture was placed into the dermal layer of the skin with a straight needle, burying at least 3 cm of the barbed section. The other half of the suture remained out of the skin and was protected with gauze and adhesive tape. For each dog, 6 sutures were implanted at day 0, 7, 14, 21, and 28, respectively, resulting in implantation times of equivalent durations. Immediately after implantation on day 28, all animals were sacrificed. The segment of the skin and deep subcutaneous tissue containing the suture was excised, clamped and fastened onto a Digital Force Gauge (Chatillon DFIS2) or a NorMark Weigh-in Electronic Digital Scale (Model 15). The free suture end was secured by a knot to a stainless steel suture that was attached to a Syringe Pump (KD Scientific Model 220), set to pull at 2.9 cm/min. The barb holding strength was determined as the peak force recorded by pulling the suture from the tissue.

Histopathology Evaluations:

1) **Canine Dermis.** Selected suture sites (2-4 for each time period) from the barb holding strength experiment above were harvested for histopathology. These were compared to similar sites implanted with commercial PDO monofilament sutures (3-0 PDS II) in the same animals, at equivalent time intervals. Histopathological evaluation was modeled after a scoring protocol devised by Scott et al.³ Specifically, each slide (stained with hematoxylin and eosin) was examined and a score of 0 (no significant findings), 0.5 (rare or very slight), 1 (slight), 2 (moderate), or 3 (marked) was assigned to each of the following parameters—polymorphonuclear leukocytes, lymphocytes, eosinophils, plasma cells, mast cells, macrophages, giant cells, granulation tissue, fibrosis, hemorrhage, necrosis, degeneration, foreign debris, and relative size of involved area. Thus the maximum score for a single implantation site was 42.

2) **Rabbit Muscle.** Barbed PDO sutures and control plastics (polyethylene) were implanted into the paravertebral muscle of six New Zealand White rabbits, on opposite sides of the spine. The barbed PDO suture measured 2cm and the plastic piece 1mm x 10mm. Three animals were maintained for 8 weeks and the other three 26 weeks. At sacrifice, 3 suture and 3 control sites of each animal were processed for histopathological evaluation. Scoring was similar to above but without the granulation tissue parameter (the maximum score for a single implantation site was 39).

RESULTS AND DISCUSSION

***In Vivo* Suture Tensile Strength:** At each *in vivo* duration in the subcutis layer of a rabbit, the average tensile strength was calculated using at least 5 retrieved sutures.[†] As seen in Fig. 1, the barbed PDO suture lost approximately 20% of its initial tensile strength at both weeks 2 and 4. The loss was 58% at week 6. At week 8, sutures were fragmented at the implant site and were too fragile to be excised intact.

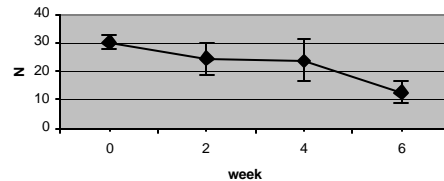


Fig. 1

***In Vivo* Barb Holding Strength:** The average barb holding strength was calculated using at least 12 readings at each time point.[†] After 7, 14, 21, and 28 days in the dermal layer of the skin, the barbed PDO suture exhibited 69%, 58%, 67%, and 50%, respectively, of the initial holding strength (day 0). (Fig. 2)

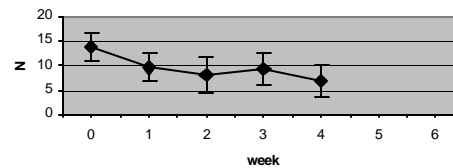


Fig. 2

Histopathology Evaluations: 1) **Canine Dermis.** Fig 3 illustrates the average scores for the implantation sites of control PDS II and barbed PDO sutures at different time intervals.

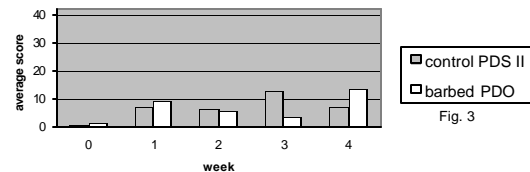


Fig. 3

2) **Rabbit Muscle.** The average scores for the implantation sites of control plastic and barbed PDO suture are illustrated in Fig. 4.

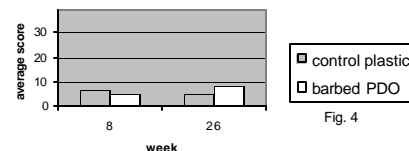


Fig. 4

CONCLUSIONS

In vivo models demonstrate that barbed PDO sutures exhibit sufficient suture tensile and barb holding strength in the initial 4-week period, which includes the critical wound healing phase. Additionally, histologic evaluations indicate that tissue reactions, including any extraneous responses, are similarly mild for both the barbed and conventional sutures.

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] DuBois JJ. A technique for subcutaneous knot inversion following running subcuticular closures. *Mil Med* 157(5): 255, 1992. [3] Scott DW, Miller WH, Griffin CE. *Small Animal Dermatology*, WB Saunders Company, Philadelphia, 1995, 5th Ed, p 55-174.

[†]Not all sutures were retrieved for testing.