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Barbed, Bi-directional Surgical Sutures

Jeffrey C. Leung, Ph.D. and Gregory L. Ruff, M.D.
Quill Medical, Inc., Research Triangle Park, NC, USA
Martin W. King, Ph.D. and Philip P. Dattilo, Jr.
College of Textiles, North Carolina State University, Raleigh, NC, USA

ABSTRACT

Surgical sutures are the most frequently used biomaterial for wound closure and tissue approximation. However, they rely on the surgeon's ability to tie secured knots, which is a challenging and time consuming process. Improper tying and handling can result in knot breakage or slippage, and potentially wound dehiscence. Further, the knot impedes wound healing, constricts blood flow, distorts tissue, and increases scar formation. To alleviate these problems, attempts have been made to design self-anchoring sutures. Recently, a novel knotless suture has been developed (Figure 1) in which bi-directional barbs are introduced into an absorbable monofilament suture using micro-machining techniques.

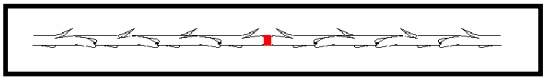


Fig. 1 - Magnified mid-section of barbed suture

This paper describes the analytical characterization of the barb geometry, and the biomechanical performance of the suture, including *in vitro* and *in vivo* wound closure testing. The former employs specialized microscopy and image analysis techniques. The latter entails tensile strength testing and apposition of tissues with a variety of stitch techniques, in comparison to commercially available sutures. These results will form the basis for further research into barb/tissue interactions and optimization of barb geometry for specific surgical applications.

INTRODUCTION

Surgical Repair and Conventional Sutures

Each year in the U.S., some 50 million open surgical procedures are performed. This number is expected to grow to 63 million by the year 2005 (1). These procedures have one common challenge and that is the need to connect tissue. Typically, tissue connection involves closing a wound or incision across various levels of muscle, fascia, fat, or skin. Natural fibers such as cotton, silk and surgical gut were predominantly used until the development of synthetic polymers for suture use. These new polymers comprise a range of improved performance characteristics and absorption profiles.

To close a wound, sutures must be knotted. Suture failure occurs most frequently at the knot since local stresses weaken the fiber. Therefore, the US Pharmacopeia (USP) specifies minimum knot-pull tensile strength requirements for sutures. Tying knots requires time and extensive training. Because of the manner in which they are placed, conventional sutures are prone to various complications due to the presence of knots and excessive wound tension. Potential problems include:

a) Knot breakage and slippage –The more slippery the suture material, the more likely a given knot will slip (2, 3). This may lead to knot failure. Knots may also fail from improper tying or from damage caused by improper handling with surgical tools.

b) Suture extrusion or 'spitting' – A suture knot left below the skin, due to its bulk, may erupt through the wound causing infection, inflammation, and patient discomfort (4, 5). The rate of suture 'spitting' may be as high as 5%.

c) Infection – The interstices within a suture knot, as well as the many spaces and pores between the filaments of a braided suture, have been shown to offer a haven for bacteria (2).

d) Dehiscence – Wound failure at the closure site of tightly approximated wounds is primarily due to tissue pull-through. Up to 88% of suture loops in disrupted wounds may be found intact at the time of disruption (6).

e) Reduced Breaking strength and inflammation – Excessive tension has been shown to reduce wound strength by as much as 77% (7, 8, 9). Histologically, wounds closed under tension demonstrate a neutrophilic inflammatory cell infiltrate and increased tissue myeloperoxidase activity (9).

f) Ischemia and scarring – Overly taut sutures can produce pressure necrosis (10). With microangiographic examination, tightly tied sutures caused avascularity in the tissue within and around the suture loops (11). In addition to compromising wound strength, the resultant microinfarction leads to increased scarring.

Competing Technologies in Wound Closure Market

Other related devices in the wound closure market are broadly categorized as follows:

a) Staples and ligating clips – Although these can be placed with greater ease and speed, the surgeon has less feel of the pressure generated within the tissue. They are limited in the range of use and cannot replace conventional sutures in many instances.

b) Closure strips – They are used only topically. Though uses are limited due to inadequate holding strength, these non-invasive strips have high product acceptance.

c) Tissue adhesives and sealants – Dermabond™ is an example of a surface skin glue based on cyanoacrylate chemistry. Though it provides satisfactory cosmetic results, it is only indicated for uses comparable to that of a 5-0 suture (a relatively small size). Fibrin sealants are biocompatible for internal use but have many processing challenges and are of insufficient strength for most surgical needs (12).

d) Suture Tying Aids – Several devices, e.g. *Suture Assistant*™ and *Quick Stitch*,™ have been developed to facilitate suture knot tying. To eliminate the knot entirely, Axya has developed an ultrasonic system for welding suture ends together. These devices are limited by cost and extensive training requirements.

Clearly, all of the above commercial products have their own limitations and cannot totally overcome the complications and problems associated with suture knots. Thus, conventional sutures continue to dominate the tissue connection market with nearly 350 million uses each year in the U.S. alone (1).

Barbed Sutures

Several self-anchoring suture concepts, particularly barbed, one-way sutures have been disclosed in U.S. Patents (13-15). Sutures with barbs in only one direction appear limited

by their need to be anchored on one end. This compromises potential time savings and is unsuitable for many surgical applications. Because of these limitations, and probable manufacturing constraints, usage of these has rarely been reported (16).

Recently, a novel knotless suture has been developed (Figure 1) in which bi-directional barbs have been introduced into an absorbable monofilament suture using micro-machining techniques (17, 18). Some performance findings related to this suture has been reported previously (19, 20, 21), including strength and histopathology evaluations (20). The goal of this study was to analytically characterize the barb geometry, to evaluate the biomechanical properties of the suture, and to test its wound closure efficacy in vitro and in vivo.

MATERIALS AND METHODS

Barbed Suture

While a range of suture materials, sizes, lengths, and barb geometry designs have been investigated, this paper only focuses on test results related to the suture described below.

A bi-directional barbed suture was fabricated from a monofilament fiber made of polydioxanone (PDO). The suture is 7" long and 0.45 mm in diameter (size '0' per USP). The middle 3" of the suture contains 78 barbs that are escarped into the fiber. The barbs are positioned in a spiral pattern around the circumference of the monofilament. They are divided into two equal groups that face each other in opposing directions from the suture midpoint. Extending beyond the barbed sections are unbarbed sections of the monofilament that are each 2" long. Depending on the stitch technique, a straight or curved needle can be attached to either end of these sections.

Characterization of Barb Geometry

The barb geometry of size '0' barbed polydioxanone (PDO) suture was characterized using an Optem Zoom 100 custom microscope with a CCD video camera with both ring and back lighting. Dimensions of the barbs – cut angle, θ, and the depth of cut, D_c (see Figure 2) – were measured from ten calibrated images and the averages were reported. This enabled the length of cut, L_c, to be calculated using the following formula:

$$L_c = \frac{D_c}{\sin(180 - \theta)}$$

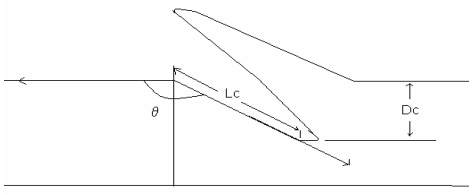


Fig. 2 – Geometry of individual barb

Fig. 3 – Twisted suture with barbs aligned

In addition, the spirality angle was observed and measured from the magnified images. The suture specimen was then mounted in a twisting device with one end clamped in a fixed position. Twist was imparted by rotating the other end of the specimen until the barbs

were aligned (Figure 3) and the spirality angle was zero. Then the longitudinal distance between cuts, P, was measured.

Suture Tensile Strength Measurement

Suture tensile strength measurement was performed using a Test Resources Universal Tester, Model 200Q (Eden Prairie, MN, USA). Barbed sutures were held by two serrated jaws padded with cork gasket materials, whereas regular sutures were held by two capstan roller grips. The length of the suture specimen between the two grips was 5" (which in case of barbed sutures, contained all barbed sections). The specimen was pulled at a rate of 10 in/min until breakage occurred. The peak load was recorded as the straight-pull tensile strength. The average reading of at least 10 measurements was reported.

***In Vitro* Tendon Repair**

Cadaveric porcine digital flexors, 0.7 cm in diameter, were transversely cut and repaired with one of the following methods: 1) traditional Kessler method (Figure 4) using 4-0 Ethibond polyester sutures (Ethicon); 2) 'switchback' method (Figure 5) with barbed '0' PDO sutures; or 3) 'finger-trap' method (Figure 6) with barbed '0' PDO sutures. Each method employed five tendon specimens.

Strength measurement of the repaired tendon specimens was performed. Each specimen was mounted between two serrated jaws on a Test Resources Universal Tester, Model 200Q. The distance between the upper and lower jaws was set to 2" and a pre-loaded of 1.5 N was applied. Each specimen was stretched to failure at a rate of 1 in/min. The force at which the tendon ends were separated by a mean of 2 mm was also recorded. The test data were captured by the WinCom software provided by Test Resources. They were further exported to Excel for analysis.

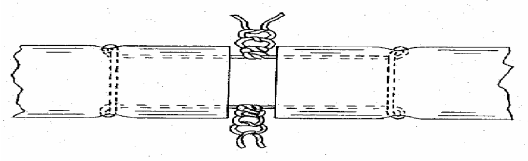


Fig. 4 – Kessler method (side view)

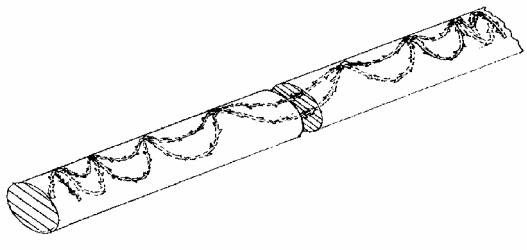


Fig. 5 – "Switchback" method

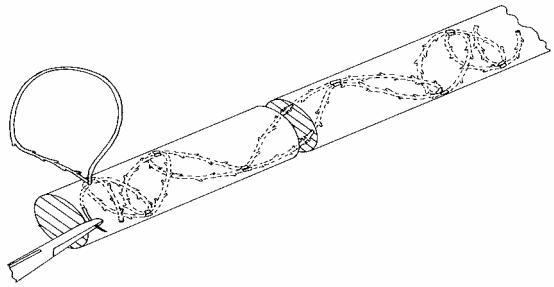
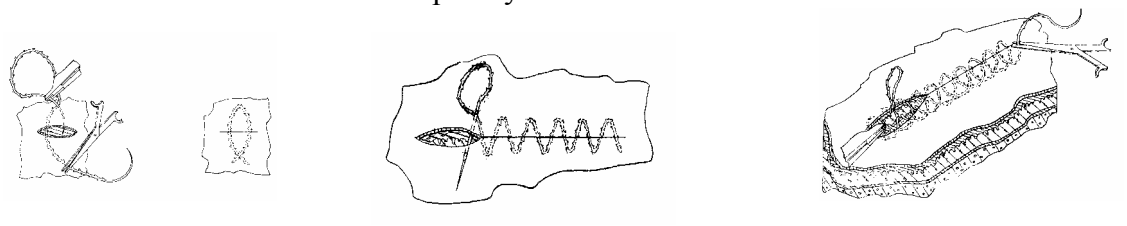


Fig. 6 – "Finger-trap" method

In Vivo Wound Closure Study

Three Mongrel dogs, each about 14 kg, were used. Each animal had seven incisions made at the thorax (twice), thigh (twice), flank, and abdominal midline and paramedian sites. The length of the incisions ranged from ½" to 4" and the depth of the incisions ranged from the dermis to muscular level. The incisions were closed with barbed sutures (PDO '0') and conventional sutures (2-0 silk, 2-0 nylon, and 3-0 PDS II) according to a premeditated randomized scheme. Three stitch methods—alpha, zigzag, and coil (Figure 7)—were used with barbed sutures. All animals were monitored daily for 14 days. At necropsy, the incisions were evaluated macroscopically.



alpha zigzag coil

Fig. 7 – Stitch methods with barbed sutures

RESULTS AND DISCUSSION

Barb Geometry

Various barbed suture geometries were precisely measured using a specialized microscope and image analysis system. The ranges of the measured dimensions for the left and right directional barbs are shown in Table I.

Cut angle, θ	152 – 172 ^{o}
Cut depth, Dc	0.08 - 0.23 mm
Cut length, Lc	0.34 - 0.59 mm
Distance between cuts, P	0.88 - 0.98 mm
Spirality angle	11 – 22^{o}

Table I – Barb geometry measurements

For each suture geometry design, statistical analysis was performed on the data using a t-test with $\alpha < 0.05$. No significant differences were found between measured dimensions for the left and right directional barbs. Our results suggest that the geometry of the cuts in opposing directions is equivalent to each other. These data will now be used to develop and validate a mathematical model to predict the mechanical properties of barbed sutures, and to optimize specific design parameters for specific surgical applications. Some preliminary findings have been reported (21).

Suture Tensile Strength

Escarpment of barbs into a size '0' PDO monofilament, depending on the geometry design, reduced the straight-pull tensile strength approximately 45-60%, from 17.72 lb to 7.0-10.0

lb (Table II). This compares favorably with a conventional suture of equivalent size when the USP minimum knot-pull strength is taken into account. Even the weakest barbed suture of the range, with the smallest "effective" diameter, compares well with conventional 2-0 or 3-0 sutures. Since knot size and bulk frequently limit the maximum suture diameter chosen by the surgeon, barbed sutures should allow them to choose larger suture diameters when desired.

Suture	Straight-pull (lb.)	USP Knot-pull (lb.)	Barbed, Straight-pull (lb.)
PDO '0'	17.72	8.60	7.0 – 10.0
PDO 2-0	11.86	5.91	NA
PDO 3-0	8.82	3.90	NA

Table II – Tensile strength comparison of barbed vs. conventional sutures

The results of the *in vitro* and *in vivo* studies below were generated with a size '0' barbed PDO suture whose average tensile strength was 7.03 lb.

In Vitro Tendon Repair

For the repaired tendon specimens, the ultimate breaking strengths as well as the forces required to induce a 2 mm gap were determined. Typical load vs. time graphs for the three repair methods—Kessler, 'finger-trap,' and 'switchback'—are plotted in Figure 8.

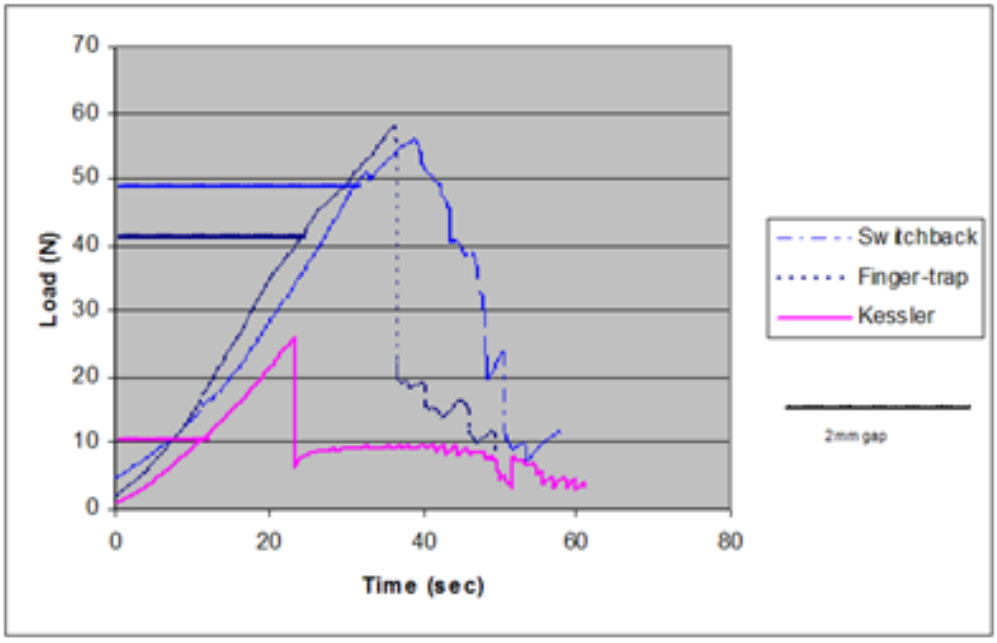


Fig. 8 – Comparison of three tendon repair methods

The commonly used Kessler method involves the placement of intricate stitch patterns to complete the tendon connection with one or two knots (22, 23). The suture knot may be placed on the outside surface of the repaired tendon where it could snag the surrounding tendon sheath and limit motion. If tied between the two ends of the tendon (as in this study), it presents a barrier between tendon sections that must appose in order to effectively

heal. Furthermore the strength of the healed tendon is compromised by a gap between the ends. Kessler-type repairs resulted in a 2 mm gap (10 N) at less than half of the breaking strength (26 N).

The 'finger-trap' and 'switchback' stitch methods deployed with barbed sutures, on the other hand, not only had better holding power but also resisted gap formation. Particularly in the latter method, the force (49 N) required to induce a 2 mm gap was almost the ultimate breaking strength (56 N) of the repaired tendon! Smaller barbed sutures are expected to exhibit similar sustaining characteristics albeit perhaps at lower load values. These results suggest that the barbed sutures may significantly improve tendon repair by eliminating suture knots and minimizing disruption of the wound margin.

In Vivo Wound Closure Study

Wounds closed with size '0' barbed PDO sutures fared well compared to 2-0 and 3-0 control sutures. In various tissues, incision sizes and locations on the dogs, all incisions apposed with the barbed sutures stayed closed and appeared to heal normally throughout the observation period (14 days). No dehiscence occurred.

During the clinical observation period, three out of the six topical skin sites closed with nylon sutures experienced partial or complete suture loss, apparently due to the dogs' self-mutilation (Table III). These were treated with triple antibiotic ointment and healed secondarily without further incident. At necropsy, a small suture abscess was found in a ventral midline incision closed with barbed suture. This occurred in an animal which chewed out control skin sutures from the adjacent paramedian location, perhaps colonizing the barbed suture site with oral flora.

Suture Type	Tissue Layer	No. of Sites	Complications (No.)
Barbed Suture	Dermis	13	Suture abscess (1)
	Subcutaneum	6	0
	Muscle/fascia	5	0
Conventional	Dermis	8	Suture loss, dehiscence (3)
	Subcutaneum	6	0
	Muscle/fascia	1	0

Table III – *In vivo* performance of barbed and conventional sutures

CONCLUSIONS

A novel, self-anchoring suture, consisting of bi-directional barbs formed on a conventional monofilament suture, has been developed and its efficacy successfully demonstrated in two surgical repair models. The barb geometry of this new suture has also been characterized, to facilitate research into optimization of design parameters for specific surgical applications.

The biomechanical performance of the barbed sutures was assessed in an *in vitro* tendon repair model and demonstrated superior wound retention when compared with a conventional suture. The effectiveness of the barbed suture in closing wounds was further manifested in an *in vivo* canine study wherein incisions in the dermis, subcutaneum, and

muscle were successfully apposed and appeared to heal normally. The likelihood of improved therapeutic outcomes and cosmesis due to obviation of suture knots no doubt merits further investigation and longer term studies. Our findings suggest that a barbed, bi-directional suture may provide significantly improved strength and tissue repair in comparison to currently available sutures.

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