



Medical Textiles: Application of an Absorbable Barbed Bi-directional Surgical Suture

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ABSTRACT

Today's medical textile market is producing state-of-the-art polymeric textile implantable devices that are redefining traditional materials and methods of surgery. These sophisticated high-tech polymer materials are engineered for specific uses in surgical and interventional procedures. One of the new biotextile products is an absorbable bi-directional barbed surgical suture that does not require surgical knots for wound closure. This novel idea has the attention of many physicians and surgeons where wound closure or tissue approximation is needed. The barbed suture has the potential to change the way wound closure is perceived in various clinical fields of surgery and veterinary medicine.

KEYWORDS: sutures, medical textiles, biotextiles, barbed suture, surgical suture

Introduction

The medical textile industry has diversified with new materials and innovative designs. Evolving polymer technology has yielded a wide range of applications of implantable medical textile devices or biotextiles. King has defined biotextiles as: "structures composed of textile fibers designed for use in specific biological environments (e.g. surgical implants, biomass reactors), where their performance depends on their interactions with cells and biological fluids as measured in terms of their biocompatibility and biostability"¹. Applications of implantable biotextiles range from polymeric valves through woven or knitted artificial ligaments to polymeric wound closure devices. Examples of implantable biotextiles include

cardiac support devices (Figure 1), vascular prosthesis (artificial arteries), heart valves (Figure 2), and sutures.

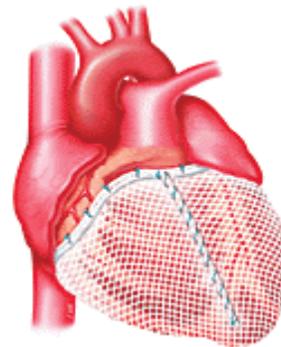


Figure 1. Cardiac support device (Courtesy of Acorn Cardiovascular, Inc)

Sutures are the most common biotextile implantable devices due to their diverse usage in surgical procedures. They are used to achieve wound closure whenever tissue separation has occurred due to an incision, puncture, abrasion, or other injury.

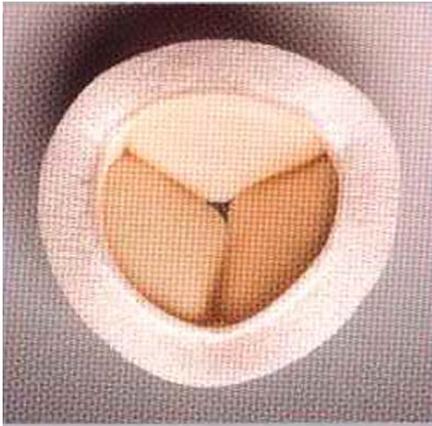


Figure 2. Bioprosthetic aortic valve with knitted polytetrafluoroethylene sewing ring (Courtesy Edwards Lifesciences)

History of Sutures and Wound Closure

The history of wound closure dates back to 5000-3000 B.C., the origins of surgery¹. Early wound closure devices were made of natural materials such as flax, silk, linen strips, and cotton². These natural materials were lubricated in oil and wine prior to application so as to reduce tissue drag and create a cleaner wound closure procedure². Another early form of a wound closure technique involved the use of the mandibles of soldier ants³. With the development of synthetic polymers and fibers, synthetic sutures were introduced into the market. These sutures allow for designers to engineer the polymer configuration, the fiber type and size, and the surface lubricant and/or coating for specific applications. Today, surgical sutures come in many forms: natural, synthetic, nonabsorbable, and absorbable. The application depends on the surgeon's preference as well as the specific site and clinical technique being performed.

Market Size

Surgical sutures serve as a means of wound closure and tissue approximation.

Sutures bring together and maintain the tissue on each side of a wound until the natural healing process has provided a sufficient level of wound strength⁴. While other techniques for wound closure using, for example, clips, staples, or tissue adhesives have been developed in recent years, the suture continues to be the wound closure device of choice for most procedures. This is due to the extensive research and data that has been collected over time describing the exact behavior of suture materials and their tissue reactions *in vivo*. In 1999, there were 41.3 million inpatient and 31.5 outpatient surgeries performed in the United States. During these surgical procedures, sutures were the most common form of wound closure device. This number of interventions produced a market size of \$210 million worth of surgical sutures.

Today's Sutures

Today's suturing techniques are responsible for two main adverse effects. Sutures require knots so as to ensure optimal tissue closure strength. The goal of wound closure is to bring the edges of the wound together not only with sufficient strength to prevent dehiscence, but also with a minimal residual tension and compression of the tissue. First, the knot tying process leads to residual forces and distortion of the tissue that can cause impaired blood perfusion through the capillaries and can compromise the healing process. The body's natural reaction to foreign materials causes the second adverse effect. Once implanted, sutures provoke a significant inflammatory response, particularly at the knot site, because the knot represents a major mass of foreign material that is concentrated in a small volume⁵. This has led to a continuing debate among surgeons as to how many throws should be incorporated into a surgical knot so as to maximize strength and minimize the tissue reaction.

In 1967 A.R. McKenzie published an article about an experimental multiple barbed suture. He stated that during insertion the barbed suture minimized tissue

damage, which led to milder foreign-body reaction⁶. His study showed that barbed nylon sutures could be used successfully in flexor tendon repair⁶. However, the nylon barbed sutures had to be removed after a four week period, which led to additional late surgical trauma.

Absorbable Bi-directional Barbed Suture

In 1992, Dr. Gregory Ruff of Duke University Medical Center started working on an idea of a barbed suture for cosmetic applications. Dr. Ruff took the idea of a barbed suture and applied it to an absorbable suture material made of polydioxanone. His work is defined in US Patents 5,342,376⁷ and 6,241,747 B1⁸. The advantage of using an absorbable polymer suture is that it does not need to be removed and it does not require knots to make it secure. The knotless design has significant potential in reducing scar tissue due to the absence of a significant foreign- body reaction caused by knots. The barbed configuration anchors the suture into the tissue and provides adequate tissue adhesion while the wound heals under minimum residual tension and pressure.

The success of this novel wound closure device requires the suture geometry to be well characterized and monitored during manufacture for two reasons: quality control (measuring uniformity of the barb geometry) and the need to determine the effect of tissue holding capacity and the barb geometry. Quill Medical, Inc. currently produces this barbed monofilament suture from polydioxanone in size 0, (size 0 has a diameter of 0.30 to 0.39 mm), while other sizes are under development (Figure 3).

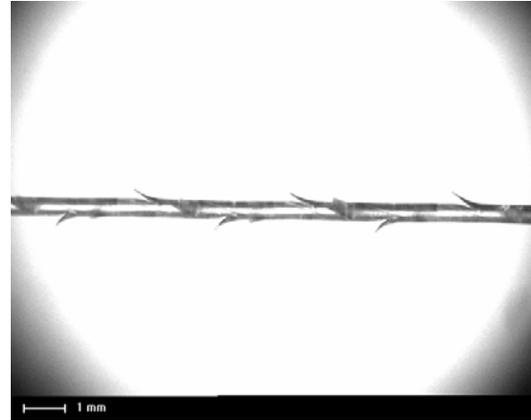


Figure 3. Barbed polydioxanone suture (Source: Dattilo, P. Absorbable Bi-directional Barbed Suture. MS Thesis. North Carolina State University. 2002.)

The monofilament sutures contain up to 78 barbs manufactured in a spiral pattern around the circumference of the suture. The barbs are divided into two groups facing each other in opposing directions around the mid-point (Figure 4). The two sets of barbs divide the suture into two sections, right and left.



Figure 4. Bi-directional barbed suture showing midpoint (Courtesy of Quill Medical, Inc.)

Using image analysis techniques, the geometry of the barbs has been characterized by defining the cut angle (θ), depth of cut (D_c), length of cut (L_c), the distance between cuts, and the number of cuts per unit length (Figure 5).

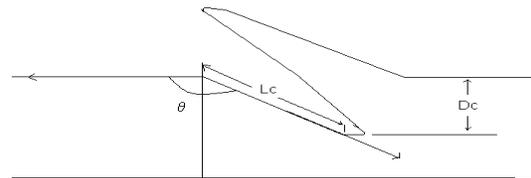


Figure 5. Geometry of individual barb (Source: Dattilo, P. Absorbable Bi-directional Barbed Suture. MS Thesis. North Carolina State University. 2002.)

The length of the cut is a calculated value using the following formula:

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

These values are measured, recorded, and analyzed statistically on a routine basis. No significant differences have been found between the left and right sections of the barbed sutures, indicating that the barbs are deployed using a controlled, uniform and mirrored geometry.

Applications of Barbed Sutures

These bi-directional barbed absorbable sutures can be used in a range of different surgical procedures. The suture can be used in dermal tissue approximation, internal wound closure, and tendon repair. These diverse applications of the suture will allow the product to generate a range of market opportunities.

Dermal tissue approximation currently uses a variety of wound closure techniques including tissue adhesives. A major issue in dermal wound closure is the cosmetic results of tissue approximation. The use of polydioxanone and the barbed configuration allows the suture to be completely sub-dermal, meaning there will be no visible signs of a wound closure device during and after healing (Figure 6).

The barbed configuration does not require surgical knots for adequate tissue strength. A knotless configuration greatly reduces the amount of scar tissue that is created during healing *in vivo*.

Internal wound closure yields the best results when using an absorbable material. Using nonabsorbable wound closure material requires removal of the device after the wound has healed. This can lead to additional visits to the physician or surgeon and the use of more invasive surgical procedures.

The fact that polydioxanone is absorbable makes it an ideal candidate for internal wound closure. Current sutures require the tying of surgical knots.

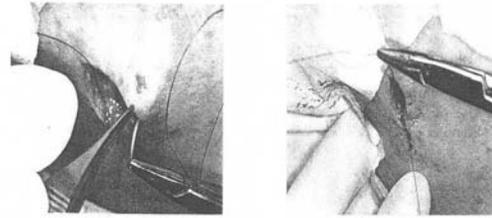


Figure 6. Sub-dermal suture (Source: Sadick NS, D'Amelio DL, Weinstein C. The modified buried vertical mattress suture. A new technique of buried absorbable wound closure associated with excellent cosmesis for wounds under tension. *J Dermatol Surg Oncol.* 1994 Nov;20(11):735-9.)

The throws of these knots are often pushed through a transdermal cannula, which can be tedious and difficult for the surgeon as well as resulting in inferior knot performance⁹. The knotless barbed suture can also be applied through a cannula and, without the need for tedious knot throwing and pushing, it is likely to reduce surgery time and create a more consistent method for tissue approximation.

McKenzie's article describes the use of a nylon barbed suture for repair of the long flexor tendon of the hand⁶ (Figure 7).

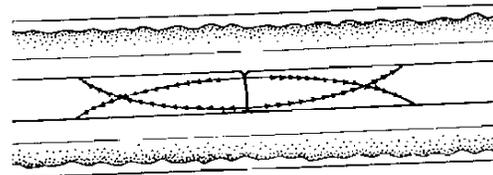


Figure 7. Barbed suture in tendon repair application (Source: McKenzie, A.R. An experimental multiple barbed suture for the long flexor tendons of the palm and fingers. Preliminary report. *JBone Joint Surg Br.* 1967 Aug;49(3):440-7.)

The knotless designed suture increases the flexibility and longitudinal movement of the tendon that would normally be limited by the presence of knots. The polymer suture can be engineered to maintain the required strength for the duration of the complete healing process. In addition, the absorbable barbed suture does not require removal after the repair is healed, thus reducing the number of visits to the surgeon as well as

the trauma associated with a follow-up intervention.

Future Trends

Future experimentation, design, and engineering will lead to better understanding of the characteristics of the barbed suture. The initial product has given positive data when compared to current sutures that require knots. Experiments are currently being performed that test the tissue holding capacity of the sutured wound under stress. The use of micro-electronic mechanical systems (MEMS) is being considered to better understand the reaction between tissue and the individual barbs. Future design applications will look at how different barb geometries affect the performance of the suture and its ability to hold different types of tissue. Also micro-machining technologies are being evaluated to ensure the optimum control over the different manufacturing processes.

Because the bi-directional barbed suture reduces problems that are associated with current sutures on the market, it is believed that this novel product will have a significant impact on the future wound closure industry. This century's new textile products will continue to expand the traditional thinking about sutures and wound closure devices.

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