CHAPTER 15

SOFT TISSUE REPAIR USING THE AXYA KNOTLESS FIXATION SYSTEM

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CONCEPTS

Soft Tissue Repair

The objective in any soft tissue repair is to reapproximate lacerated or torn tissue through the distribution of tension force across the repair site. Proper alignment of injured tissue margins will allow for disrupted collagen bundles to be reestablished and ensure that a smooth gliding surface is produced.[1]

The success of tissue repair is influenced by several factors: The type of repair, the properties of the suture material, such as tensile strength and coating material, the tension required to create a tight loop and knot, the number of sutures and knots, knot configuration, and the skill of the surgeon all combine to determine the outcome. Given that the strength of the repair is highly dependent on the tying of suture, this area is widely considered the "weak link" in the repair process and is often an early failure point as a result of suture breakage or knot slippage.[1-5]

Sutures and Surgical Knots

Hand-tied sutures produce multiple, bulky knot bundles that can lead to tissue impingement, adhesions, and foreign body tissue reaction.[1,2,5] Knot failure, either through slippage of the knot or breakage of the suture itself, creates gapping in the repair site, which can progress to a biologic failure to heal, and require surgical revision. Increasing the number of knot throws in an attempt to strengthen the overall holding capacity of the suture loop can adversely affect healing, given that the volume of the knot has been shown to be directly proportional to the degree of inflammatory reaction in the soft tissue surrounding that knot.[1] Loop security, or the capacity to maintain a tight loop while the knot is being tied, is dependent upon the skill of the surgeon and made significantly more difficult to achieve in arthroscopic and laproscopic procedures.

Mechanical stress on the suture itself can also reduce its ability to maintain closure of the repair site. Knot security, which is the ability of the knot to resist slippage or breakage, is lessened with repeatedly applied forces.[5] It has been reported that during the first 6 weeks following rotator cuff surgery that soft tissue repairs are subjected to 2,000 cycles of loading.[1] Cyclic loading causes suture fatigue whereby the mechanical properties are weakened, inducing the suture to undergo plastic deformation. This can result in unraveling, knot failure, and suture loop elongation. Clearly, a knot-suture construct that could be reliably reproduced to resist physically induced mechanical forces, while providing a low profile suture loop with structural integrity, would be a welcome advancement in surgical soft tissue repairs.

AXYA KNOTLESS FIXATION SYSTEM

General Information

Axya Medical has introduced an innovative suturing technique that eliminates the suture knot. Instead, an ultra-secure suture loop is produced in less than one second through ultrasonic welding. This revolutionary process allows surgeons to create suture repairs that are consistently reproducible and mechanically superior compared to hand-tied knots. It can be used to repair soft tissue to soft tissue and soft tissue to bone (via anchors) in arthroscopic, laproscopic, and open surgical procedures where conventional sutures or staples are appropriate.

The Axya system employs a patented technology that uses a proprietary welding process. Electricity is converted into ultrasonic energy through a transducer, which in turn actuates an ultrasonic horn. As a result, the ultrasonic horn vibrates and the energy is transferred to the material opposing the horn.[3] Using only 70 kHz of ultrasonic vibration, sufficient localized heating is produced to fuse the polymers of the suture strands without inducing thermal damage to the surrounding tissues.[4] The result is a secure welded

suture loop with no profile and no large knot bundle. Given that no knot is created, there is no knot slippage or knot bundle impingement, and no subsequent inflammatory reaction or tissue gapping.

Tissue repair begins in the traditional fashion by passing a loaded suture needle though the injured tissue margins. The suture strand ends are then crossed over one another and captured in parallel alignment by articulating jaws at the end of the welding handpiece. The nested suture strands can then be tensioned to close the repair and the suture loop welded. No loss of tension across the repair site occurs because loop security is maintained by the welding sleeve during the fusion process. The ultrasonic energy required to fuse the suture is localized within the welding sleeve tip, thus preventing burn injury to the repaired tissue. Furthermore, it has been demonstrated that the energy needed to cut or ablate soft tissue is several orders of magnitude greater than the power required to safely weld suture.[3]

The knotless fixation system offers surgeons a highly effective way to reapproximate tissues with the appropriate amount of tension to maintain loop security. It simplifies and reduces the steps to accomplish tissue repair and eliminates the challenge of knot tying encountered in arthroscopic and laproscopic procedures by allowing the suture loop to be secured in one pass.

Components

The Axya system consists of a control unit, a fixation handpiece, the welding sleeve, Axya specific monofilament suture, a protective sheath, and sterilization tray. The control unit houses all the electronics that generate the ultrasonic energy. Embedded software runs continuous self-tests and safety checks and requires no input or adjustments by the user. It is lightweight, fits most operating room carts or stands, and has a low profile, which allows for stacking.

The fixation handpiece connects to the control unit and contains the ultrasound transducer that converts electrical energy into ultrasonic motion that is transmitted down the ultrasonic horn. All controls for attaching and releasing the welding sleeve, positioning the suture, and initiating welding are located on the handpiece and can be activated using one hand. Cleats are located on opposite sides of the handpiece to secure the suture strands and maintain tension during welding. The handpiece and attached connection cord are a sealed unit that can be soaked, cleaned, and autoclaved for repeated use on multiple patients.

The welding sleeve attaches to the handpiece by sliding over the ultrasound horn. At the tip of the sleeve, articulating anvils can be opened and closed to capture the suture strand ends. The device is fabricated with a high degree of precision and provides an accurate space for location and proper alignment of the suture ends. The tip of the ultrasound horn is then in direct contact with the suture and the energy it transmits is contained within the space created by the anvils. Both the welding sleeve and Axya specific suture are provided in single patient use sterile packages. When the system is not in use, a protective sheath is placed over the ultrasound horn on the handpiece to avoid damaging the horn tip during sterilization and storage.

Step-By-Step Procedure

A suture needle loaded with Axya provided suture is passed through the tissues or bone anchors. The suture strand ends are crossed in opposing directions and held taut with one hand. With the free hand, the jaws at the end of the sleeve tip are opened and advanced over the parallel strands. Once the jaws have been closed and the suture strands captured, verify that the strands can move freely through the jaws. One end of the suture is secured to one of the cleats on the side of the handpiece. The entire unit is then advanced until the sleeve tip is flat across the soft tissue. Use the free suture end to tighten the loop until the tissues are re-approximated in the desired position with the appropriate amount of tension and secure it to the opposite cleat. Sliding a switch on the handpiece exposes the button to initiate welding. This is depressed until a buzzer on the control unit stops (<1s). The suture strands can then be uncleated from the handpiece. Opening the jaws will release the now secure suture loop and the strand ends can be trimmed. When performing arthroscopic or laproscopic surgery, the same procedure steps are accomplished through a cannula.

LITERATURE REVIEW

Fatigue Properties

Apreleva[1] compared the cyclic fatigue and load to failure properties of welded monofilament Axyaloop suture to hand-knotted braided FiberWire and

Ethibond. Two knot-types were used for the hand-tied sutures; a 6 throw alternating post knot and a Tennessee slider knot followed by a 5 throw alternating post knot. Samples were cyclically tensioned between 10N-30N at 1Hz for 3000 cycles. The majority of suture loop elongation occurred after 10 cycles in all samples. No statistical difference in mean cycles to failure between welded and hand-tied suture was observed. Similarly, all samples had comparable values for ultimate failure load, demonstrating equal tensile strengths. However, the average elongation for welded sutures (1mm) was significantly smaller than both FiberWire and Ethibond (both 4 mm). This was attributed to a high variation in knot strength, which led to increased knot slippage. This study indicates that the Axya welded suture demonstrates greater loop security and knot strength than hand-tied sutures.

Tensile Testing in Ligament Repair

Hertzog[2] compared the tensile load required for failure of a native (uninjured) ligament, a repaired ligament, and an Axya welded suture loop secured to a bone anchor. Results indicated 17N were needed to rupture ligaments, whereas the welded suture loops failed at 76N. The study concludes that the weakest link in ligament repair is the attachment site of the ligament to suture and that Axya welded suture provides ample strength required for ligament repair.

Welded Versus. Hand-Tied Suture In Rotator Cuff Repair

McIntyre[5] assessed the clinical efficacy of rotator cuff repair using Axya welded suture as compared to standard knot-tying techniques. Patients underwent similar surgical procedures using mini-open repair. Results showed no statistical difference postperatively in UCLA scores between welded and hand-tied procedures, which demonstrates the applicability of the Axya welded suture technique in rotator cuff repair.

Histological Comparison of Welded and Knotted Sutures

Connolly[3] conducted a two-part study to examine the safety of using welded suture in animal models as compared with hand-tied knots. The first part was an acute study to determine the effect of the ultrasonic welding process on rabbit colon tissue. Tissues repaired with Axya welded sutures were compared with those sutured with Prolene and Maxon. Results showed no histologic pathology associated with welding. However, significant mechanical disruption was observed in tissues with hand-tied sutures. The second part was a chronic study to compare skin repair using Axya welded suture and hand-tied Dermalon. Both suture lines were intact after one week with no demonstration of infection or wound dehiscence. Interestingly, the hand-tied suture repair line showed more evidence of swelling and redness. Furthermore, 6 out of 8 hand-tied sutures had loosened or been removed as compared to 1 out 8 welded sutures. The authors concluded that the ultrasonic welding process does not create pathologic histological changes and presents no significant risk to underlying tissue. In addition, suture welding may create less inflammatory reaction and mechanical damage than hand-tied knots.

SUMMARY

Techniques for the surgical repair of soft tissue must provide optimal knot and loop security to ensure positive results. Suture loops welded using the Axya knotless fixation system can be consistently and reliably reproduced. Welded sutures exhibit small variation in ultimate load failure and significantly less loop elongation as compared with traditional hand-tied knots. They offer a no profile suture loop with good tensile performance and no capacity for knot slippage. Welded suture loops have the strength required for ligament and tendon repair. The advantages gained by using a suturing process that eliminates knot bundles and knot impingement can improve the outcomes in surgical ligament and tendon repairs. The use of ultrasonic energy to weld suture presents no risk of thermal injury to soft tissues and creates less mechanical damage as compared with hand-tied knots. The application of the Axya knotless fixation system in podiatric surgery can be used in retrocalcaneal exosectomy, Achilles tendon repair (both open and arthroscopic), capsule closure in bunion surgery and primary soft tissue repairs.

REFERENCES

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