

## Rotator Cuff Repair with Ultrasonic Suture Welding Technology

Louis F McIntyre, MD,  
Mirjam Norris, RN, Bruce Weber, PT.

Westchester Orthopedic Associates  
222 Westchester Ave Suite 101  
White Plains, NY 10604  
[www.westchesterorthopedics.com](http://www.westchesterorthopedics.com)  
[lfm@woapc.com](mailto:lfm@woapc.com)

### Abstract

Rotator cuff repair techniques traditionally employ suture fixation of the tendon. The suture is tied by hand or arthroscopic knot pusher to provide secure loops to fix tissue to facilitate healing. A new technology allows the creation of secure loops with ultrasonic energy welding.

This study was conducted to assess the clinical results of rotator cuff repair employing ultrasonic suture welding. Fifty consecutive patients treated by one surgeon were retrospectively evaluated with an average follow-up of 26 months. These patients were then compared to 55 patients treated by the same surgeon with a technique employing standard knot-tying with non-absorbable suture with similar follow-up.

The groups were similar in regards to age, sex, hand dominance and preoperative duration of symptoms. All procedures were performed in a hospital ambulatory surgery center in a lateral decubitus position under a general anesthetic. A glenohumeral arthroscopy and arthroscopic acromioplasty were performed in all cases. The rotator cuff tear was repaired through a mini-open incision. All patients were evaluated by an independent examiner using the UCLA scale.

47 of the 50 suture weld patients were available for evaluation. Pre-op UCLA score averaged 12.5 and post-op 29.8. There were four failures in this group. Two of the patients who failed had a significant post operative traumatic event; a dislocation in one and a car accident in another. The two patients who had additional trauma underwent revision cuff repair. At revision, both patients exhibited suture loops that had pulled through tendon without failure of the weld.

40 of the 55 patients treated with tied sutures were available for evaluation. Pre-op UCLA score averaged 13.2 and post-op 31.6. There was one failure in this group of patients.

An Analysis of Covariance (ANCOVA) of post operative UCLA scores was also not statistically significant.

Suture welding produces secure loops that allow for cuff repair with results similar to traditional knot-tying techniques. Welding technology may facilitate arthroscopic cuff repair by obviating the need to tie arthroscopic knots.

## Introduction

Tissue repair in orthopedic surgery is generally accomplished by utilizing sutures to secure tissue to facilitate repair. The tissues are held together with secure loops of suture while healing takes place. The loops have traditionally been made by tying knots in the sutures. The ability of the knot to secure the loop of suture is vital to successful tissue repair. The knot-suture loop construct must be able to resist the physiologic loads across the repair to maintain the structural integrity of the repair. Knot security is defined as the ability of the knot to resist slippage or breakage as loads are applied across the repair. Loop security is defined as the ability to maintain a tight loop as the knot is tied. Surgical techniques for tissue repair must maximize both knot and loop security to ensure successful repair outcomes.<sup>1,2,3,4,5,6,7,8.</sup>

With the increasing popularity of arthroscopic rotator cuff repair<sup>9,10,11,12,13,14</sup>, knot and loop security have been receiving increased attention. The failure of different suture and knot constructs has been studied and recommendations regarding surgical techniques to prevent failure have been made.<sup>1,2,6,7,8,15.</sup>

A new technology allows for the creation of secure suture loops using ultrasonic suture welding without using knots.<sup>16,17</sup> The technology employs a hand held probe that holds a section of the suture loop in close apposition as tension is placed across the loop. The instrument then converts a piezoelectric force into an ultrasonic frequency that is transmitted to the part of the suture loop in contact with the probe. This area then bonds together as a result of the ultrasonic vibrations producing a secure suture loop (Fig 1).

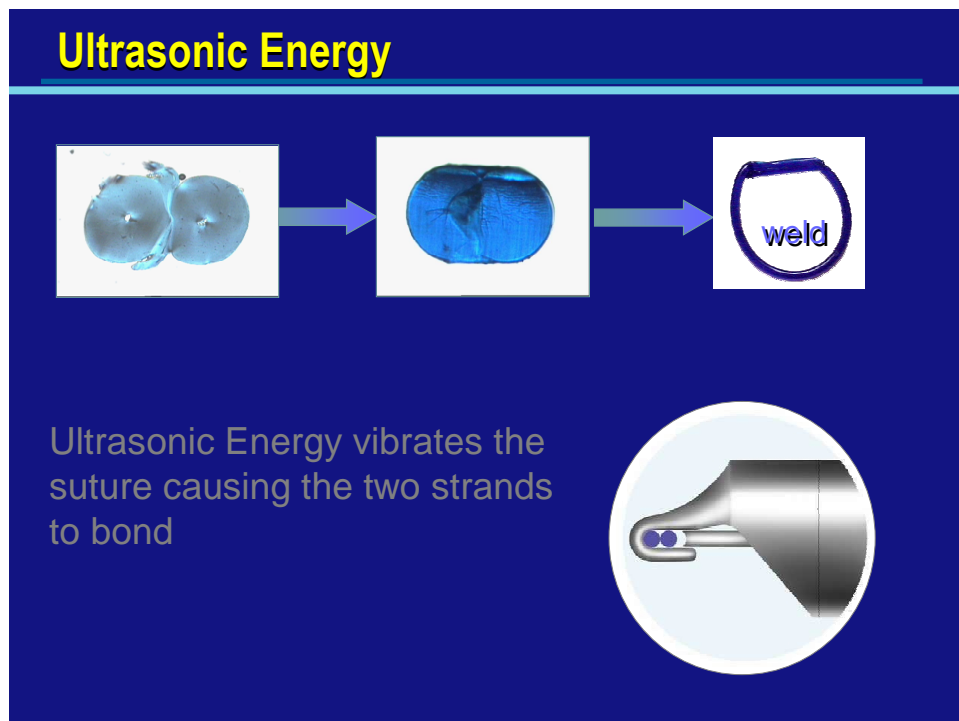


Fig 1  
Ultrasonic Suture Welding

Laboratory studies comparing suture loops created with knots and welds have shown that the welded loops compare favorably to hand and arthroscopic knot types in both single load to failure and cyclic load failure modes.<sup>16,17</sup> Figure 2 compares the elongation of welded loops created with #2 polypropylene and nylon to knot-tied loops created with #2 polyester braided suture with both hand and arthroscopic knot types in cyclic load testing. Figure 3 documents the ultimate load to failure of welded polypropylene suture loops to hand tied braided polyester loops.

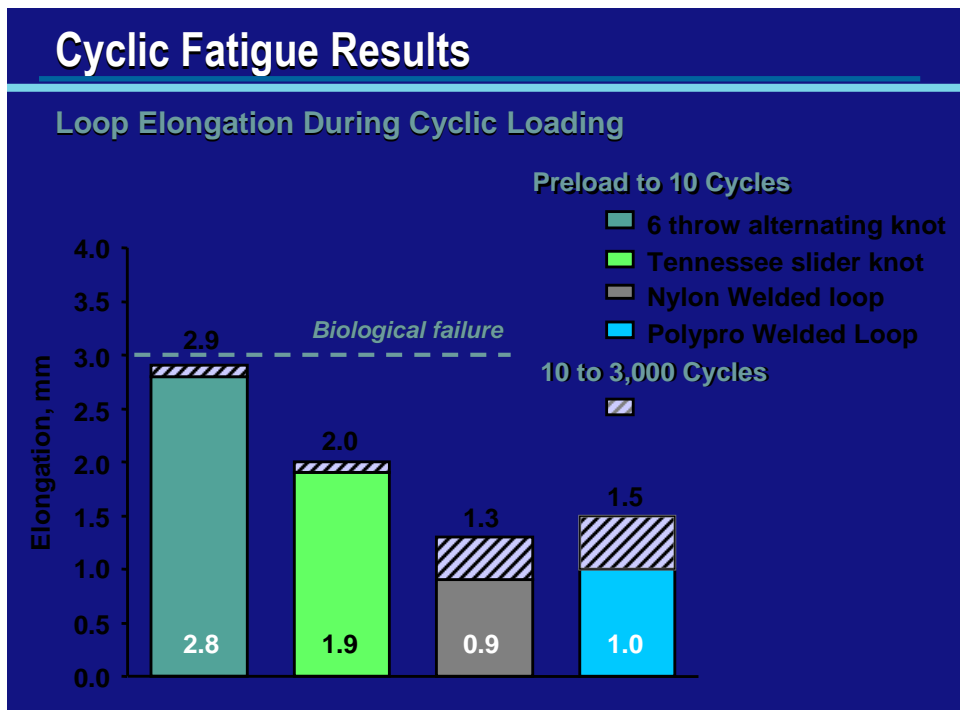


Fig 2  
Cyclic Elongation of Suture Loop Constructs

## Welding vs. Hand Tied Knots<sup>2</sup>

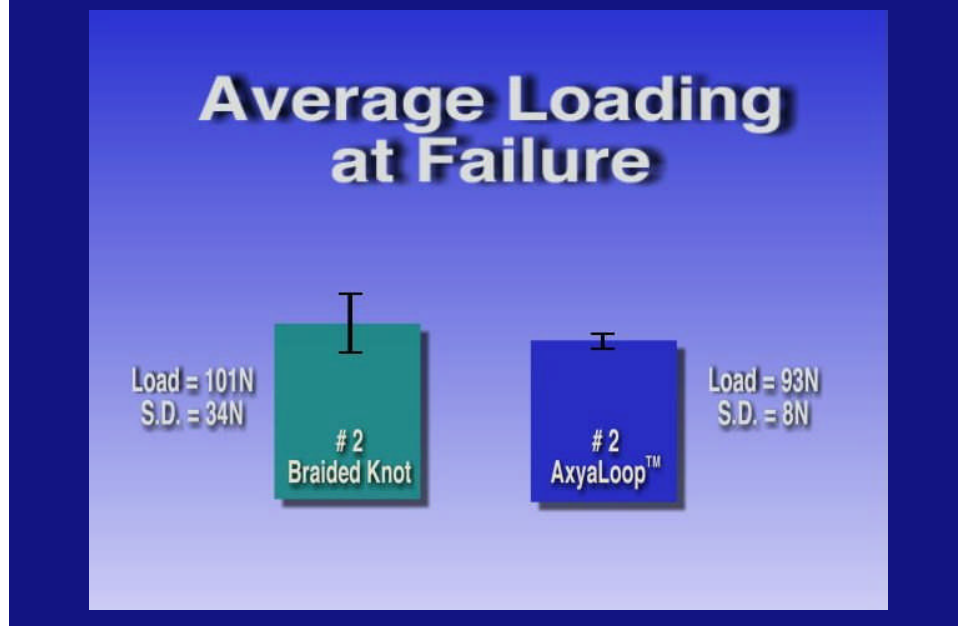


Fig 3  
Comparison of Load to Failure

This study was undertaken to assess the clinical efficacy of rotator cuff repair utilizing ultrasonic suture welding and to compare the results to a similar group of repairs performed with a standard knot tying technique.

### Materials and Methods

The study group consists of 50 consecutive patients who underwent rotator cuff repair by the same surgeon with ultrasonic suture welding. There were 29 men and 21 woman with an average age of 55.7 years ( range 37-78). The right side was repaired in 30 and the left in 20 with the dominant side being affected in 31 of the 50. Pre-operative symptoms averaged 9.9 months ( range 1-36). Twenty four had acute symptoms after trauma. Five patients in this group had had a previous cuff repair that had failed.

The patients were all treated in a hospital ambulatory surgery unit and underwent an exam under anesthesia and diagnostic arthroscopy in the lateral decubitus position. All had an arthroscopic acromioplasty. Four patients had a biceps tenodesis and one had debridement of glenohumeral arthritis. One patient had excision of a type IV SLAP lesion and two had excision of calcifying tendinitis. One patient had adhesive capsulitis treated with arthroscopic capsular release. The patients all had a rotator cuff repair through a mini-open incision. Number 2 polypropylene was used to fix the tendon and then welded with an AXYA (AXYA Shoulder Fixation System, AXYA Medical, Beverly, MA.)

probe to create secure suture loops. Twenty nine of the patients had an interval component to their tear and 43 had suture anchors placed to fix tendon to bone. The comparison group contained 55 consecutive patients treated by the same surgeon with rotator cuff repair using braided polyester suture and hand tied knots. There were 38 men and 17 woman with an average age of 54.7 (range 17-78). The right side was repaired in 33 and the left in 22 with the dominant side being affected 36 of the 55. Pre-operative symptoms averaged 10.4 months (range 1-36). Twenty five had acute symptoms after trauma. Five patients in this group had a previous cuff repair that had failed. These patients underwent a similar operative scenario with the exception that they were fixed with number 1 braided polyester suture with hand tied knots through a mini-open incision. 32 of the patients had an interval component to their tear and 46 had suture anchors placed to fix tendon to bone. All the patients were treated with sling immobilization for three weeks with the initiation of a passive range of motion program beginning approximately one week after surgery. Active range commenced six weeks post op.

## **Results**

All patients available were evaluated in the office setting by independent examiners and rated with the UCLA scoring system. Analysis of the results was retrospective. There were 47 of 50 patients in the suture weld group available for evaluation with an average follow up of 26 months ( range 18-33). Forty of the 55 comparison group were available for evaluation with an average follow up of 28 months ( range 19-39 ). There were no infections and no neurovascular or suture anchor complications in any of the patients.

Pre-op UCLA score for the suture weld group was 12.5 improving to 29.8 postoperatively. There were 13 (26%) excellent, 24 (48%) good, 6 (12%) fair and four (8%) poor results in this group according to the scale. The pre-op score for the comparison group averaged 13.2 and improved to 31.6 with 17 (30.9%) excellent, 18 (32.7%) good, 4 (7.3%) fair and 1 (1.8%) poor result.

Statistical analysis of the results showed that both groups experienced significant improvement in their scores. Post operative scores for the two groups did not differ significantly according to ANCOVA analysis.

## **Discussion**

This study represents the first report of the clinical results of tissue repair utilizing ultrasonic suture welding. The study group of consecutive patients treated by one surgeon demonstrates the applicability of the technology for all rotator cuff repair situations but suffers from retrospective analysis and an absence of an evaluation of the structural integrity of the repairs produced by suture welding. This latter weakness is shared by many studies in the orthopedic literature concerned with evaluating rotator cuff repair.<sup>9,10,11,12,13,14</sup> The comparison group is remarkably similar to the study group in demographics and pathology but suffers from a follow up rate of only 73%. Both groups of patients represent a spectrum of shoulder pathology and as such may not be comparable to previous studies.

There were 6 patients with fair results. All experienced improvement in their pain scores and were satisfied with their result but fell into the fair category because of motion and strength deficits. Five of the six had pathology in addition to their rotator cuff tear. All declined further treatment for their shoulders.

There were four patients with poor results. Of these four, one patient had had a previous failed repair, one was involved in a workman's compensation case and two had massive retracted tears. Two had contrast enhanced MRI scans which indicated recurrent tearing of the cuff and were indicated for revision repair but as of this writing have not had surgery.

Two patients had additional post operative trauma; one from a dislocation three months post repair and another from a car accident 8 months post repair. Both these patients had contrast enhanced MRI scans that documented recurrent tears. These two patients underwent revision repair.

The patient with the dislocation initially had a Type IV SLAP lesion and 2.5cm interval tear. At the initial surgery, she had an excision of the SLAP tear and a repair of the interval with 3 stitches. At revision, she was noted to have a Bankart lesion and recurrent interval tear. One of the previous three stitches was visible in the medial portion of the repair that remained intact (Fig 4). An additional intact suture loop was noted floating free in the subacromial bursa. (Fig 5). This loop was a more lateral stitch that probably pulled out of the tendon prior to or at the time of the dislocation. The patient was rated at excellent after revision.

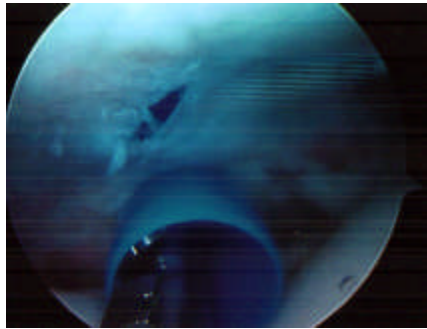


Fig 4  
Suture Loop with Healing



Fig 5  
Free Suture Loop

The patient involved with the car accident initially had a 3 cm crescent tear repaired with two suture anchors and four stitches. At revision, there was a suture visible from the glenohumeral side of the joint at the posterior aspect of the tear. (Fig 6). Inspection from the bursal side showed that the cuff was only partially healed and that the tendon had pulled away from the suture. The suture loop, however, was still intact and connected to the suture anchor. (Fig 7) The patient was rated as good after revision.

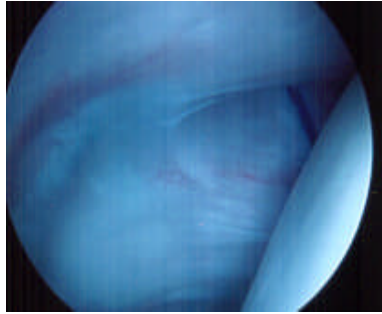


Fig 6  
Partial Healing of Cuff

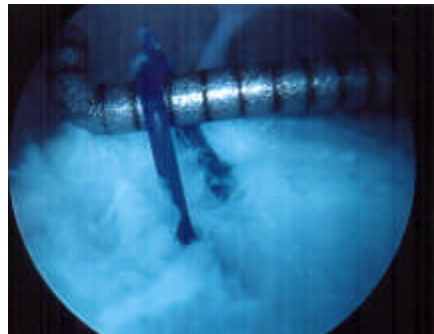


Fig 7  
Intact Suture Loop at Site of Partial Healing

The existence of intact loops in these two patients demonstrates that the suture welds were able to resist physiologic loads placed across the shoulders during rehabilitation and healing. The mode of failure in these two patients was biologic; the suture loops pulled through the substance of the rotator cuff. This is similar to failure modes seen in laboratory studies of suture loops created with braided polyester stitches and hand tied knots subjected to cyclic loading forces.<sup>4,5</sup> Suture loops loaded to failure tend to fail with knot slippage or suture breakage.<sup>3</sup> Since both patients experienced additional trauma after considerable healing had taken place ( three and eight months), it is difficult to draw conclusions concerning the exact reason for failure. The presence of the intact loops,

however, offers some evidence that the results of laboratory testing of the weld strengths can be extrapolated to the clinical setting.

This study was conducted to assess the clinical efficacy of suture weld technology in rotator cuff repair. A mini-open approach was used to enable a comparison with a previous group of consecutive patients treated with a similar technique. Future study will document the use of this technology in consecutive patients with an arthroscopic technique. Arthroscopic cuff repair is technically demanding and requires skill in properly identifying cuff tear morphology, passing stitches and creating secure suture loops with a knot pusher. Use of suture welding obviates the need to tie arthroscopic knots and may simplify arthroscopic tissue repairs.

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