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Arthroscopic Rotator Cuff Repair Using the Opus Knotless Suture Anchor Fixation System

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Background: The reported failure rate of arthroscopic rotator cuff repair varies widely. The influence of repair technique on failure rates and functional outcomes after arthroscopic cuff repair remains controversial.

Purpose: To determine the functional outcome of arthroscopic knotless fixation using the Opus AutoCuff device for rotator cuff repair and to compare our results with those reported in the literature.

Study Design: Case series; Level of evidence, 4.

Methods: Fifty-six consecutive patients underwent arthroscopic rotator cuff repair using an Opus AutoCuff device (Arthrocare, Sunnydale, California) with greater than 2 years' follow-up. Subjective and objective clinical examinations were performed to include the University of California at Los Angeles (UCLA) shoulder score, the American Shoulder and Elbow Surgeons (ASES) rating scale, the visual analog scale (VAS), and the Tegner Activity Level scale.

Results: Forty-eight patients were evaluated at a mean follow-up of 26 months (range, 24-35 months). The mean UCLA shoulder score was 33.1 of 35 (SD, 2.89) possible points, and the mean ASES rating scale was 94.2 of 100 (SD, 7.76) compared with a mean preoperative score of 65.7 ($P < .001$). Postoperative UCLA shoulder scores had 42 of 45 (93.3%) patients with good and excellent results. The mean preoperative ASES pain score was 1.3 (SD, 1.0), and the mean postoperative score was 4.4 (SD, 1.0) ($P < .001$). The Tegner Activity Level scores demonstrated restoration of function to preinjury status. There were 3 failures (6.3%), 2 by anchor failure (1 with specific trauma), and 1 by rotator cuff retear, all requiring revision surgery.

Conclusion: Arthroscopic knotless suture fixation with the Opus AutoCuff device results in good to excellent results similar to those reported in the literature with conventional suture anchors.

Keywords: arthroscopic rotator cuff repair; knotless fixation; outcomes; Opus AutoCuff

Rotator cuff tears are a common cause of shoulder pain and dysfunction. Surgical treatment of rotator cuff tears has evolved from an open procedure to a completely arthroscopic repair. Arthroscopic rotator cuff repairs are becoming increasingly popular because of improved instrumentation, less postoperative pain, and earlier functional recovery.^{2,4,6,12,15-17}

Recent studies have shown 90% to 95% good to excellent results in arthroscopic rotator cuff repairs using standard suture anchors and arthroscopic knot-tying

techniques.^{4,12,15-17} Alternative systems that employ knotless fixation are available. Knotless fixation reduces suture material and knots that can be abraded or loosened in the subacromial space and may serve as a source of mechanical symptoms. Knotless systems may also offer the theoretical advantage of reduced operative time because the suture-passing device places a horizontal mattress suture with one pass.

The Opus AutoCuff device (Opus, Arthrocare, Sunnydale, California) and SmartStitch (Arthrocare) use an incline mattress stitch and allow for adjustable knotless suture fixation and restoration of the rotator cuff to the bony footprint. A biomechanical study found the resistance to gapping and the mode of failure for the Opus knotless suture anchor system comparable with conventional titanium anchors, but no clinical outcome studies have been published.³ The purpose of this study was to determine the clinical outcomes of this device compared with those reported in the literature.

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One or more authors has indicated a potential conflict of interest: David R. Diduch is a stockholder of Arthrocare.

MATERIALS AND METHODS

Between April 2005 and May 2006, 70 patients had an arthroscopic rotator cuff repair using the Opus AutoCuff device. Fifty-six patients met the inclusion criteria. Forty-eight patients returned for objective and subjective clinical evaluations. Inclusion criteria included patients having an arthroscopic rotator cuff repair using the Opus knotless anchor system with or without additional side-to-side margin convergence sutures. Patients who had a distal clavicle excision ($n = 10$), biceps tenotomy ($n = 4$), or biceps tenodesis ($n = 2$) at the time of rotator cuff repair were included in the study. Fourteen patients were excluded from the study. Exclusion criteria included workers' compensation patients, open or mini-open procedures, prior surgical repair for a rotator cuff tear, and concomitant rotator cuff and labral repairs.

Institutional review board approval was obtained, and all patients gave written consent to participate in this clinical trial postoperatively. All repairs were performed by the 2 senior authors. Patients had a minimum of 12 weeks of symptoms with failed nonoperative treatment, to include any or all of oral anti-inflammatory medications, subacromial steroid injections, and physiotherapy. All patients underwent a standard history, physical and radiological examination, and a preoperative magnetic resonance imaging (MRI) arthrogram. Preoperative and postoperative assessments were completed retrospectively for the American Shoulder and Elbow Surgeons (ASES) rating scale and the Tegner Activity Level scale. Postoperative assessments were completed for the visual analog scale (VAS) for shoulder pain and the University of California at Los Angeles (UCLA) shoulder score. Study-specific physical examinations and outcome assessments were performed at the patient's final follow-up visit by independent observers not involved in the index procedure. All patients had postoperative radiographs performed. Patients with failed repairs requiring revision surgery did not have postoperative scores included in the analysis.

Surgical Technique

Rotator cuff tears were classified by size, according to their greatest diameter, as follows: small, <1 cm; medium, 1-3 cm; large, 3-5 cm; and massive, >5 cm, as popularized by DeOrto and Cofield.⁸ L-shaped and U-shaped tears were first repaired using margin convergence of the 2 edges of the cuff before fixation of the cuff to the bone. A no. 2 non-absorbable high-strength suture was used for margin convergence and tied using conventional arthroscopic knots. Repair of the rotator cuff was then performed with the Opus device. The SmartStitch dual-needled automatic suture-passing/receiving device was used to place an incline mattress stitch in the lateral edge of the tendon in a predetermined spot. The 2 free ends were then shuttled out of the anterolateral portal. The anchor site was then created using a trochar lateral to the footprint on the greater tuberosity. The suture ends were then loaded into

the knotless fixation anchor (Opus Magnum anchor, Arthrocare). The anchor inserter was then used to place the suture-loaded anchor into the prepunched hole, and the anchor fins were deployed beneath the cortex using the trigger mechanism on the inserter handle. The Opus Magnum internal mechanism provided cinchable and reversible tension, pulling the cuff flush with the footprint of the greater tuberosity. Once proper suture tension was achieved, the suture lock was engaged to permanently lock the sutures. The inserter was then removed and the sutures trimmed (Figure 1).

Postoperatively a sling was used in all cases. All patients were discharged home from the recovery room with oral analgesics. No patients were readmitted for pain-control issues. Pendulum and elbow range of motion exercises were initiated the day after surgery. All patients were referred for formal physiotherapy beginning 2 weeks after surgery. Active-assisted range of motion was started after 4 weeks, and patients gradually discontinued the sling between 4 and 6 weeks. At 6 to 8 weeks, progressive resistive cuff strengthening began and continued until functional goals were obtained. Heavy manual labor and overhead activities were allowed after restoration of shoulder strength, usually 5 months after surgery.

Pain rating and shoulder function from before and after surgery were compared with a paired-samples *t* test. Strength and stability between operated and nonoperated shoulders at the time of clinical follow-up were compared using independent-samples *t* tests. Differences were considered statistically significant if the *P* value was less than or equal to .05.

RESULTS

Forty-eight patients who had an arthroscopic rotator cuff repair using the Opus AutoCuff device were evaluated at an average follow-up of 26 months (range, 24-35). The average age was 60 years (range, 32-79). Of the 48 patients, there were 25 men and 23 women. There were 2 high-grade partial tears that were completed and repaired, 5 small tears (<1 cm), 25 medium tears (1-3 cm), 15 large tears (3-5 cm), and 1 massive tear (>5 cm). There were 34 crescent-shaped tears, 8 U-shaped tears, and 4 L-shaped tears. All 48 tendons were repaired anatomically, and side-to-side repair was performed as dictated by the geometry of the tear. Margin of convergence sutures were used in 12 repairs: 8 U-shaped and 4 L-shaped tears. One anchor was used in 10 cases, 2 anchors in 23 cases, 3 anchors in 13 cases, 4 anchors in 1 case, and 5 anchors in 1 case (mean, 2.2 anchors).

The ASES rating scale reflected considerable improvement in the status of the shoulder when the preoperative scores were compared with the scores at the time of the most recent follow-up. The average total score increased from 65.7 points preoperatively to 94.2 points postoperatively after arthroscopic rotator cuff repair. The improvement compared with the mean preoperative score was

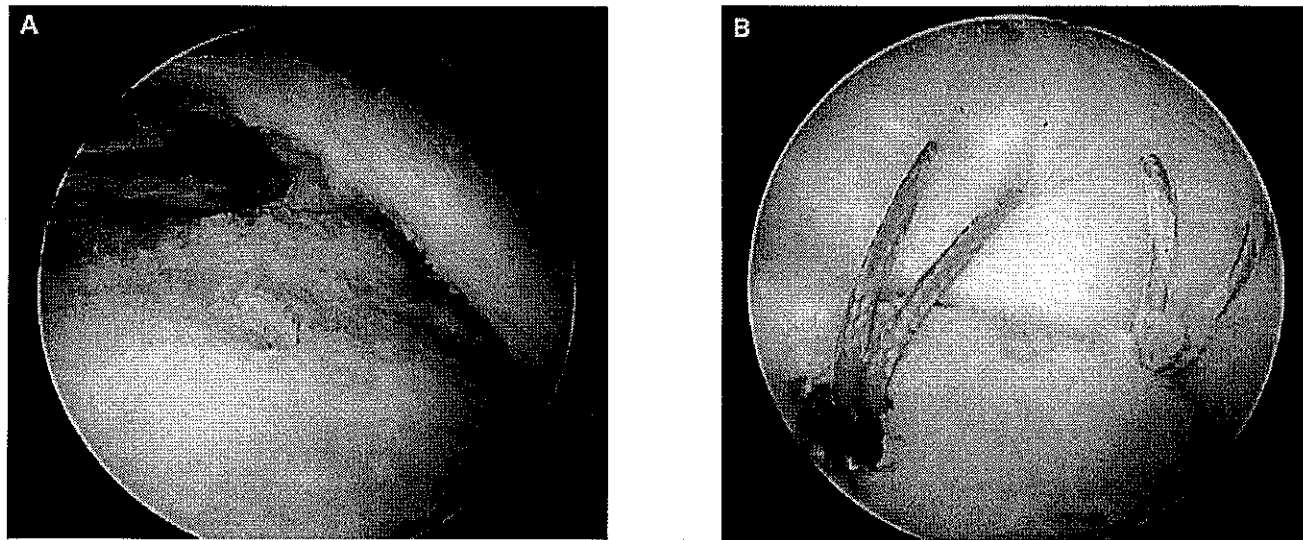


Figure 1. A, the footprint of a medium-sized, crescent-shaped rotator cuff tear is abraded with a mechanical shaver. B, horizontal mattress sutures compress the rotator cuff to the bony footprint with single anchors and knotless fixation.

TABLE 1
Components of the American Shoulder and Elbow Surgeons Rating Scale With Statistical Results

	Preoperative	Postoperative	Operated Side	Nonoperated Side	P Value
Pain rating	1.3 ± 1.0	4.4 ± 1.0			<.001
Shoulder function	30.7 ± 15.3	55.2 ± 6.9			<.001
Strength			19.8 ± 0.7	19.7 ± 1.0	.73
Stability			15 ± 0	15 ± 0	NA

significant ($P < .001$) (Table 1). The function of the shoulder improved according to the scores for all 15 activities of daily living included on the ASES rating scale at most recent follow-up. The mean postoperative UCLA shoulder score was 33.1 of 35 (SD, 2.89) with 25 excellent results, 17 good results (42/45 good and excellent results), and 3 fair results. Postoperative UCLA shoulder scores had 42 of 45 (93.3%) patients with good and excellent results.

The average postoperative active range of motion (ROM) was as follows: 172.2° (SD, 10.1°) of abduction, 175.2° (SD, 6.7°) of flexion, 72.0° (SD, 13.9°) of internal rotation, and 81.6° (SD, 13.9°) of external rotation. The contralateral shoulder ROM was as follows: 175.2° (SD, 7.9°) of abduction, 176.8° (SD, 5.1) of flexion, 76.8° (SD, 14.8°) of internal rotation, and 84.6° (SD, 14.9°) of external rotation.

The procedure resulted in a significant reduction in pain. The ASES rating scale reflected a preoperative pain level average of 1.3 with a level of 1 indicative of marked pain. The average postoperative pain level was 4.3 with a level of 5 indicative of no pain. The improvement compared with the mean preoperative scores was significant ($P < .001$) (Table 1). In addition, the VAS mean postoperative pain score was 1.4. The Tegner Activity Level scale averages were approximately equal before and after surgery (4.6 vs 4.3, respectively). This scoring system indicates that patients were able to return to the same

activity level they were involved in before injuring their rotator cuff.

There were no intraoperative or perioperative complications. No patient had any wound infections or drainage from the wound. No patient needed manipulation for postoperative stiffness. There were a total of 3 failures (6.3%). None of the 3 failures had margin of convergence sutures incorporated into the repair. Postoperative radiographs were routinely performed on all patients. Two patients failed because of displaced anchors, which were detected radiographically. One of the failures due to displaced anchors had associated trauma, a fall from standing height directly onto the affected shoulder less than 2 weeks after surgery. He had increased pain associated with weakness on clinical examination. The second failure due to anchor displacement was in an older female patient with poor bone quality. She reported sudden pain and weakness 8 weeks after her index procedure. Standard radiographs confirmed the anchor pullout. One patient had failed results due to a rotator cuff retear, which was detected via a computed tomography (CT) arthrogram that was obtained when his strength failed to improve by 3 months after surgery despite extensive therapy. All patients with failed results underwent an uneventful revision surgery and were doing well at their most recent follow-up.

DISCUSSION

Encouraging results, technical advances, and increased demand among patients for minimally invasive surgical procedures with reduced morbidity and faster recovery have contributed to the increased popularity of arthroscopic rotator cuff repair. Over the past 20 years, operative repair of rotator cuff tears has evolved from an open procedure to a completely arthroscopic procedure. Authors in recent studies of arthroscopic rotator cuff repair report good and excellent results in 90% to 95% of cases.^{4,11,12,15-17} This study is unique among arthroscopic rotator cuff studies because it is the first to report results using a knotless suture anchor system, the Opus AutoCuff device.

In an effort to maximize tendon-to-bone surface contact and mechanical strength, double-row fixation methods with suture anchors have been employed, adding to the complexity of the repair, as well as the number of anchors and sutures. A clinical improvement in outcomes over a single-row repair has been difficult to measure and a matter of debate, but the increased surface area of tendon contact has been embraced as desirable. The Opus AutoCuff system with the SmartStitch suture-passing device is a relatively simple rotator cuff repair system without a difficult learning curve. The suture passer uses an incline mattress stitch that has the ability to compress a large portion of the rotator cuff to the bony footprint with a single anchor and knotless fixation. The anchor inserter also allows gradual adjustment of tension on the sutures.

The use of knotless fixation for rotator cuff repair may raise concern regarding the biomechanical properties of these anchors. In a recent study that performed biomechanical testing on a number of suture anchors in porcine femora, the Opus Magnum anchor was found to have pull-out strengths with cyclic loading comparable with conventional screw-in anchors.¹ While failure can occur at the anchor, the tendon, or the suture, in that study, the weakest point of a repair was found to be the suture-tendon interface with the suture cutting through the tissue rather than suture anchor failure. Another recent biomechanical study found the resistance to gapping and the mode of failure for the Opus knotless suture anchor system comparable with the performance of a conventional titanium anchor system.³ Despite these biomechanical trials, there have been no published clinical outcomes studies to assess the efficacy of this device in patients.

With the exception of 3 patients with failed repairs, all patients demonstrated clinically improved outcome measures. The ASES rating scale reflected significant improvement in the status of the shoulder when the preoperative scores were compared with the scores at the time of the most recent follow-up. The average total score increased from 65.7 points preoperatively to 94.2 points postoperatively ($P < .0001$). The function of the shoulder improved according to the scores for all 15 activities of daily living included on the ASES rating scale at most recent follow-up. The average pain score on the ASES rating scale improved from 1.3 to 4.3 ($P < .0001$). In addition, the VAS average evaluating postoperative pain

was 1.4. The average ROM was essentially normal in comparison to the contralateral shoulder.

Ellman et al⁹ defined a score of 34 to 35 points according to the UCLA shoulder score as excellent, a score of 29 to 33 as good, and a score of less than 29 as fair or poor. In the present study, the average UCLA shoulder score was 33.1 (SD, 2.89). Forty-two of 45 (93.3%) shoulders had a good ($n = 17$) or excellent ($n = 25$) result, and only 3 had a fair result (6.7%).

Arthroscopic rotator cuff repair can now achieve outcomes that compare favorably to the results of open repair. There are only a few studies that report the results of arthroscopic rotator cuff repair with 2-year follow-up using UCLA shoulder score-type rating systems. Gartsman et al¹² reported 83.6% satisfactory and 16.4% unsatisfactory results in his case series of 73 patients. Tauro¹⁶ reported 92.5% excellent and good results and 7.5% poor and fair results in 53 patients. Burkhart et al⁴ reported 95% good to excellent results in a series of 53 patients including all tear sizes. These results were all obtained using a standard knot-tying conventional suture anchor and are similar to those achieved with open techniques. In a review of over 60 publications, Cofield⁵ found that for open rotator cuff repair, the overall results averaged 87% for pain relief and 77% for patient satisfaction. The level of improvement of various parameters described in the present study suggests that Opus knotless arthroscopic rotator cuff repair produces at least equivalent results to those reported in the literature for arthroscopic and open rotator cuff repair.

Potential weaknesses of this study include the retrospective study design, which can add to the number of patients that may be lost to follow-up. These patients lost to follow-up may have had retears of their rotator cuff, which would have affected our failure rate. Another weakness is our lack of preoperative UCLA, VAS, and ROM values. All tear sizes were included, even 2 partial tears that were completed and then repaired, which may have improved the results. There were no irreparable rotator cuff tears found intraoperatively. Irreparable rotator cuff repairs were determined preoperatively and were not included in the study. The determination of reparability remains a difficult clinical decision to make, and exclusion may have falsely improved our outcomes. From this study, the treating surgeon determined irreparability before any attempt at surgery based on degree of rotator cuff atrophy and fibrosis by MRI, proximal humeral head migration on radiographs, secondary glenohumeral arthritic changes, and findings of rotator cuff arthropathy.¹³ The degree of cuff retraction is a relative issue that can often be addressed through mobilization and margin convergence, especially when adequate rotator cuff tissue can be seen anteriorly and posteriorly on sagittal MRI views.⁷ Another weakness is the lack of postoperative imaging to evaluate cuff integrity. It has been reported that many patients achieve good results despite ultrasound or MRI showing a failure of healing of the rotator cuff repair.¹⁰ Lastly, the follow-up period is relatively short. There is evidence in the literature that maximum improvement after rotator cuff repair occurs during the first postoperative year^{11,14}; however, with the recent advent of arthroscopic techniques, it

remains to be seen what happens to these rotator cuff repairs with longer follow-up. To further evaluate this, longer term studies need to be completed.

The results document the success of knotless suture anchor fixation using the Opus AutoCuff device for arthroscopic rotator cuff repairs. This method of repair provides results comparable with those previously reported for arthroscopic and open rotator cuff repairs. In a review of the literature, it is believed this is the first reported outcome study for a knotless fixation system for rotator cuff repair. Potential advantages of the Opus knotless repair system include less suture material in the subacromial space, fewer steps for suture passage, more efficient suture management, the possible reduced operative time and soft tissue distention, the ability to adjust tension on the repair, and a mattress incline stitch configuration that allows compression of the cuff against the bony footprint. Potential disadvantages include cost, implant size, and the possible failure of the anchor to deploy. The Opus anchor costs roughly twice that of a standard absorbable anchor; however, a double-row repair is not necessary with this technique. The Opus anchor once deployed has a larger diameter, which can be a problem if revision surgery is necessary. In addition, it is made of metal, and postoperative MRI may be difficult to interpret, in which case a CT arthrogram may be obtained to evaluate the integrity of the rotator cuff repair. Failure of the anchor to deploy is a theoretical disadvantage, but this did not occur in any of the 48 patients who underwent rotator cuff repair in this case series. Arthroscopic knotless suture fixation with this device results in good to excellent results similar to those reported in the literature with conventional suture anchors.

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