Clinical Experience with the Rotation Medical Bioinductive Implant for Rotator Cuff Repair with Biological Augmentation

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Introduction

Symptomatic partial thickness rotator cuff tears refractory to conservative management present a treatment dilemma for orthopedic surgeons. A recent systematic literature review has shown that 6.5-34.6% of partial rotator cuff tears progress to full-thickness tears[1]. The current treatment recommendation for partial-thickness rotator cuff tears <50% is debridement with or without acromioplasty and for tears >50% of the tendon substance is rotator cuff repair[1]. Ruotolo et al. showed that a distance of 7mm from the articular margin during arthroscopy represents a 50% tear of the tendon[2]. More specifically, the Ellman classification describes partial rotator cuff tears further (Table 1). Some recommendations include Ellman grade 1 articular or bursal-sided tears, and grade 1 and 2 articular-sided tears, be treated with debridement with or without acromioplasty[4]. Further, grade 2 bursal-sided tears and grade 3 articular or bursal-sided tears be treated with repair, with or without acromioplasty[4]. While these current treatment recommendations have shown good to excellent outcomes, the progression of partial-thickness to full-thickness tears up to 34.6% still exists. Local strain at the site of injury is believed to contribute to impaired healing and tear propagation[5]. Moreover, trans-tendinous and takedown repairs often lead to prolonged recovery and stiffness. Furthermore, none of the above treatments address tissue quality.

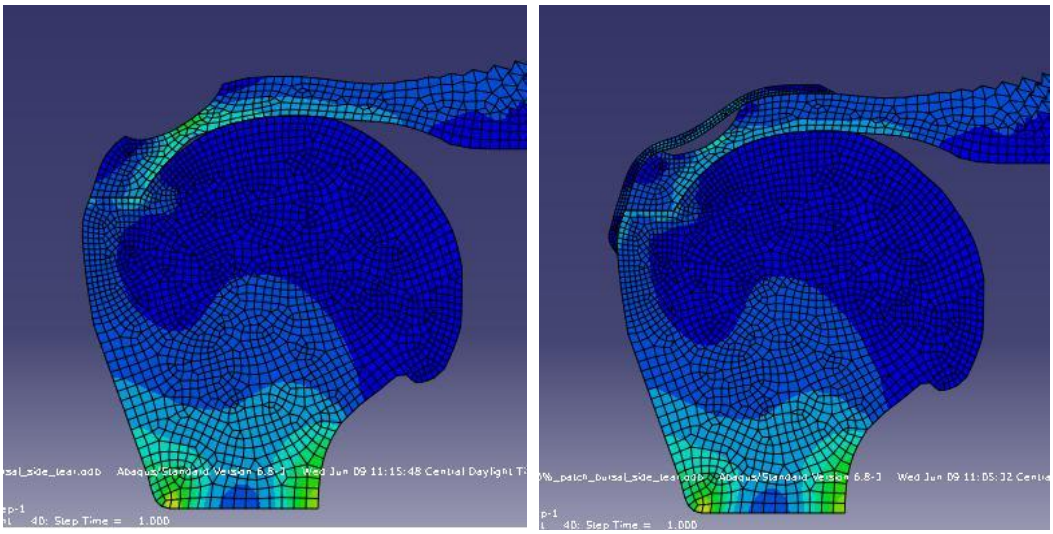
Table 1. Ellman Classification of Partial-Thickness Rotator Cuff Tears

Location	Grade
A: Articular Surface	1: <3mm deep
B: Bursal Surface	2: 3-6mm deep
C: Interstitial	3: >6mm deep

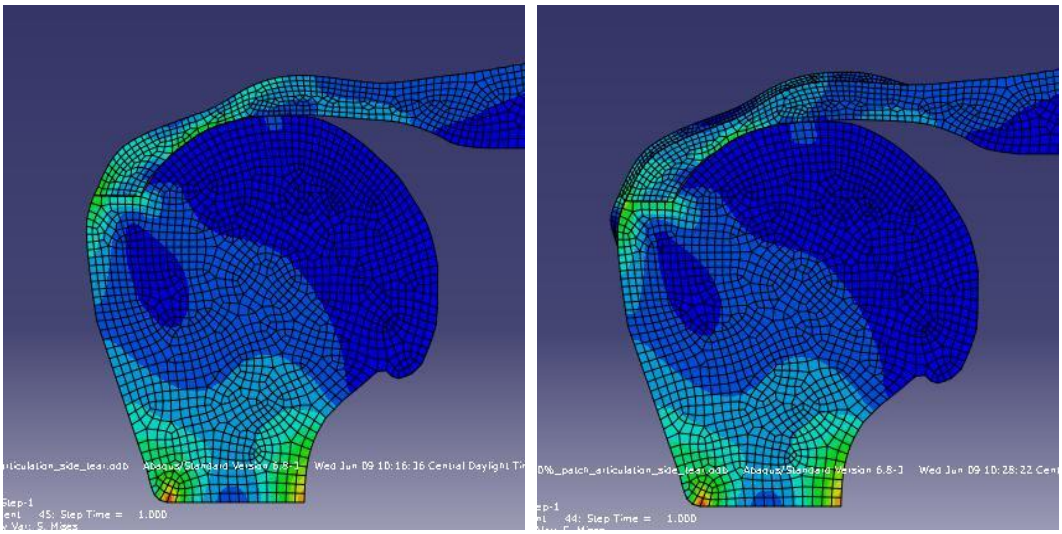
Ellman H: Diagnosis and treatment of incomplete rotator cuff tears. *Clin Orthop* 1990;254:64-74

A novel highly porous, high purity, bioinductive implant made with reconstituted collagen fibers obtained from bovine Achilles tendon has been developed by Rotation Medical (Plymouth, MN) for the treatment of partial thickness rotator cuff tears and rotator cuff repairs via biological augmentation. Initially, a finite element analysis was performed and revealed a decrease in peak strain at the injury site. For articular-sided tears, the decrease was 40% and for bursal-sided tears, the decrease was 47%[6]. It was hypothesized that inducing a new layer of tendon-like tissue that shares the load with the underlying tendon will result in a decrease in peak strain at the site of the tear and create an environment more conducive for healing. An animal model utilizing sheep revealed induction of new tissue and functional remodeling of the induced tissue, with the implant being completely absorbed by 26 weeks, and continued remodeling and stability of the new tissue out to 52 weeks[7]. There was no inflammatory response observed in the sheep study at any time period of evaluation. These early preclinical studies prompted a clinical trial of 39 total patients (33 treatment and 6 controls) in Australia (Drs. Sonnabend, Bokor,

Cass, and Young). This study revealed a 100% incorporation of the implant with a mean bursal-sided tendon thickness increase of 2.4mm and substantial to complete filling in of partial-thickness tear defects.



Bursal surface tear-- 47% reduction in peak strain.



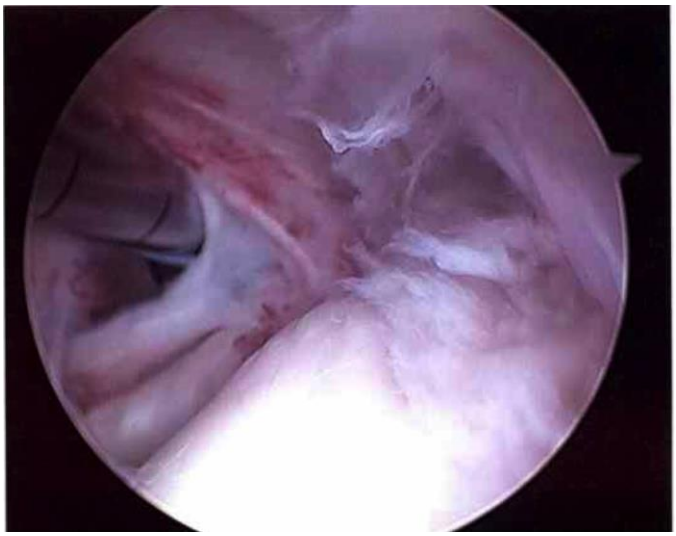
Articular surface tear-- 40% reduction in peak strain.

Dr. Chen, Material and Structural Testing Core, Mayo Clinic, Rochester, MN

Because of this new innovation, we believe that the Rotation Medical (Plymouth, MN) implant will allow orthopedic surgeons a novel and excellent option to treat symptomatic partial thickness rotator cuff tears and biologically augment rotator cuff repairs with poor tissue quality. It will allow patients a shortened rehabilitation time with a quicker return to work. The novel processing technique will significantly reduce the possibility of hypersensitivity reactions.

Case Descriptions

Case 1: A 58 year-old right hand dominant female clerical worker presented to the office complaining of right shoulder pain after tripping over her dog and sustaining a right shoulder injury in April 2014. Her initial visual analog scale (VAS) for pain was 9 out of 10. The patient's pain was refractory to physical therapy, anti-inflammatory medications and multiple corticosteroid injections over a period of 6 months. At that time, an MRI revealed severe tendinosis and partial-thickness tearing involving the anterior aspect of the infraspinatus and articular side of the supraspinatus. She was then offered arthroscopic surgery and she agreed to proceed. Intra-operatively, the patient was found to have a high-grade partial-thickness, articular-sided supraspinatus tear (Ellman Grade 3) with 50% of the tuberosity exposed. She was also found to have a Type II SLAP tear and a biceps tenotomy was performed. A thorough subacromial decompression with acromioplasty of a Type II acromion was completed followed by biological augmentation of the rotator cuff with a 20x25-mm Rotation Medical collagen implant. Post-operatively, she began utilizing a CPM immediately and the sling was discontinued at 14 days. The patient started physical therapy approximately 1 week post-operatively with forward flexion and abduction initially limited from 0-90 degrees for the first 4 weeks to prevent impingement of the implant. She was also restricted with no combined abduction and external rotation or resistance exercises for 6 weeks. She progressed well with physical therapy and returned to work approximately 5 weeks post-operatively with a VAS score of 2 out of 10. At her most recent 3-month post-operative follow-up, her VAS was 0 with full range of motion and strength. She was no longer requiring pain or anti-inflammatory medications.

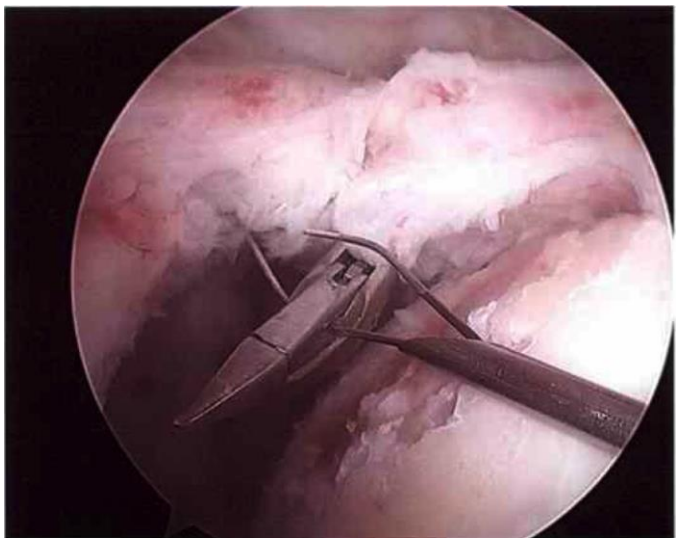


Case 1. The arthroscopic image reveals an Ellman Grade III partial thickness articular-sided tear with approximately 50% of the tuberosity exposed.

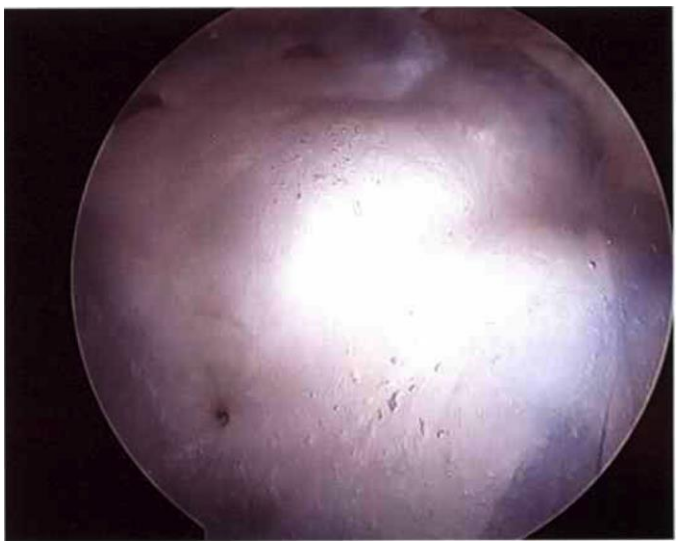
Case 2: A 46 year-old right hand dominant male construction worker presented to the office complaining of right shoulder pain and weakness. His initial VAS score was 8 out of 10. The patient's symptomatology was refractory to physical therapy and multiple corticosteroid injections over a treatment course of approximately 10 months. An MRI of the right shoulder revealed distal supraspinatus tendinosis with high-grade partial-thickness tearing of the bursal surface as well as tendinosis of the infraspinatus and subscapularis. There was also acromioclavicular joint arthrosis with impingement along the myotendinous junction of the supraspinatus. He was then offered arthroscopic surgery and he agreed to proceed. Intra-operatively, the patient was found to have high-grade partial-thickness tearing along the bursal side of the supraspinatus measuring 3-6mm deep (Ellman Grade 2) in certain areas as well as a Type II SLAP tear. The patient also had tearing of the long head of the biceps tendon, therefore, the biceps tendon was cut arthroscopically and an open subpectoralis biceps tenodesis was performed after completion of the arthroscopic portion of the procedure. A thorough subacromial decompression with acromioplasty of a Type II acromion was completed followed by rotator cuff repair with biological augmentation with a 20x25-mm Rotation Medical collagen implant. A distal clavicle excision was also performed. The patient underwent a similar post-operative rehabilitation protocol as the patient in case 1 with early shoulder range of motion; however, he was kept in the sling for 4 weeks to protect the biceps tenodesis. The abduction pillow was removed at 2 weeks. At 6 weeks, his VAS pain score was rated at 4 out of 10. The patient progressed well with physical therapy and returned to work in construction at 3 months with his pain resolved and strength restored. His 3-month VAS pain score was rated at 0 out of 10.

Case 3: A 46 year-old right hand dominant female custodian presented to the office complaining of right shoulder pain and weakness. She originally injured her shoulder on September 22, 2013 when she heard a "pop" while lifting heavy garbage. An outside orthopedic surgeon performed an arthroscopic rotator cuff repair on February 8, 2014. Six weeks later, she ruptured her proximal biceps, which was later repaired by the previous surgeon. She had persistent pain and difficulties with activities of daily living. Her initial VAS score was 7-8 out of 10. Imaging studies revealed a retracted tear of the supraspinatus and infraspinatus, chronic SLAP tear, glenohumeral chondromalacia, and a high-riding humeral head. A long discussion was had with the patient regarding her treatment options. It was discussed with her that she will likely need an arthroplasty procedure for her glenohumeral chondromalacia and high-riding humeral head, however, because of her young age and activity level, she was offered a two-stage procedure. The goal of the first stage was to repair and reconstruct her rotator cuff followed by an arthroplasty procedure. She agreed to proceed with a two-stage procedure. Intra-operatively, she had Grade 4 chondromalacia of the glenohumeral joint, absent biceps, and a retracted tear of the supraspinatus and infraspinatus. The patient underwent an arthroscopic rotator cuff repair with biological augmentation using the Rotation Medical collagen implant, capsular release, glenohumeral chondroplasty, labral debridement, and glenoid microfracture. The patient followed

a standard rotator cuff repair protocol and was maintained in a sling for 6 weeks post-operatively with Codman's exercises and biceps isometrics started at 1 week. The sling was discontinued at approximately 6 weeks post-operatively with the initiation of active range of motion. She was then gradually progressed from active range of motion to strengthening. At her 3-month post-operative visit, she was doing well, however, still complaining of pain from her glenohumeral arthritis with a VAS score of 7 out of 10. She did continue with therapy and restored her full rotator cuff strength by month 4. At this point, she will be proceeding with the second stage in the form of an arthroplasty procedure. Her VAS score at last follow-up visit was a 4 out of 10 related to her glenohumeral arthritis.



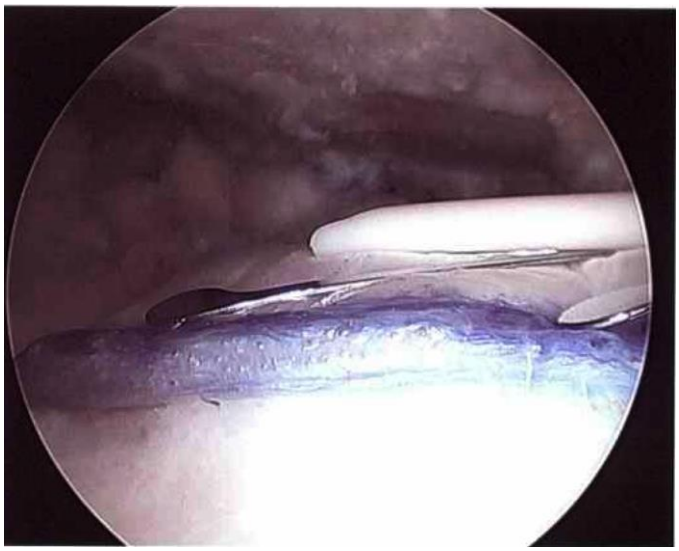
Case 3. Large, retracted tear with glenohumeral chondromalacia.



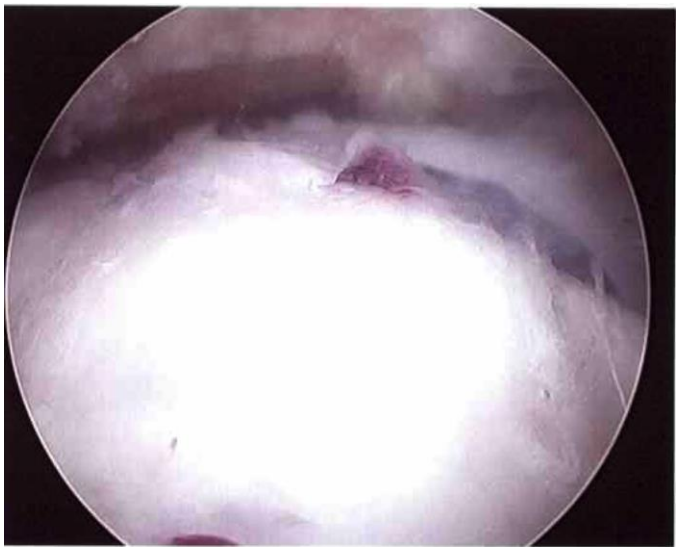
Case 3. Implant secured in place with PLA/PEEK staples.

Surgical Procedure

All 3 patients underwent a rotator cuff procedure with biological augmentation using the Rotation Medical collagen implant. The first 2 cases utilized a 20x25-mm implant while the third case utilized a 25x30-mm implant. Retractable spinal needle markers are first placed during the intra-articular portion of the arthroscopic procedure to mark the anterior edge of the supraspinatus for later appropriate positioning. Following this, the subacromial portion of the procedure is then performed including subacromial decompression with acromioplasty and distal clavicle resection as indicated. It is very important to localize the appropriate position and trajectory of the lateral portal for adequate deployment of the implant prior to making the portal. This portal tends to be significantly lower than the standard lateral portal and is coplane with the tuberosity. For case number 3, a rotator cuff repair was first performed with marginal convergence and a triple-loaded anchor prior to placement of the collagen implant. After all subacromial work is completed satisfactorily, the appropriately sized implant is selected and deployed into the subacromial space via the previously mentioned lateral portal appropriately positioned according to the previously placed markers. The implant is positioned utilizing a proprietary deployment device. Polylactic acid (PLA) soft tissue staples (~5-8) are then placed through the implant and into the tendon below around the perimeter of the implant. After the implant is adequately secured, 2-3 poly-ether-ether-ketone (PEEK) bone staples are placed through the implant and into the tuberosity to complete fixation of the implant. The implant is then checked to ensure appropriate implant security via the PLA and PEEK staples.



Arthroscopic image demonstrating deployment of the implant.



Arthroscopic image demonstrating final product after placement of PLA/PEEK staples. The implant is well secured.

Results and Conclusion

The Rotation Medical highly porous, high purity collagen implant is used for biological augmentation of partial-thickness and repaired full-thickness rotator cuff tears. Its use is intended to share load with the underlying tendon in order to decrease peak strains at the tear site, thereby creating an environment more conducive for healing. Previous attempts at rotator cuff augmentation with xenografts have been suboptimal. Recent studies by Iannotti et al. and Walton et al. revealed less favorable outcomes in terms of pain and function and hypersensitivity rates between 20-30% in studies comparing primary tendon to bone repair versus repair with xenograft augmentation[8,9]. These studies, however, utilized non-cross-linked, porcine small intestine submucosal xenografts as compared to highly-purified, highly-oriented, and highly-porous bovine type I collagen fibers as used by Rotation Medical. At present, no hypersensitivity reactions have been seen with the Rotation Medical implant. All 3 patients in the study had increased function and decreased pain scores at 3-month post-operative follow-up. All of the patients' wounds are well-healed and there have not been any signs of hypersensitivity reaction to date. The patient in case #3 is still having pain related to her glenohumeral arthritis, but is overall very satisfied with the procedure in terms of pain and function and her rotator cuff function is restored.

One of the advantages of the Rotation Medical implant is decreased rehabilitation time and sling use. Those patients that undergo biological augmentation for a partial-thickness rotator cuff tear are treated the same as patients who have undergone an arthroscopic subacromial decompression without rotator cuff repair. The sling is discontinued in approximately 1-2 weeks and the

patient is graduated from passive to active-assisted to active range of motion until there is no limitation in range of motion or use of the extremity at six weeks. Forward flexion and abduction is initially limited from 0-90 degrees for the first 4 weeks and no combined abduction and external rotation or resistance exercises for 6 weeks. However, the rehabilitation program will have to be altered for concomitant procedures performed. In case 2, rehabilitation was limited by the biceps tenodesis and in case 3, the patient followed standard post-operative rotator cuff repair protocol. A second advantage was that the instrumentation was easy and efficient to use. Implantation did not add a significant amount of time to the surgical procedure. In fact, the Rotation Medical (Plymouth, MN) was actually quicker than a traditional repair.

To date, outcomes with regard to restoration of function and pain relief with the Rotation Medical Bioinductive Implant have been excellent. No hypersensitivity reactions have been encountered thus far. Further studies need to be completed in order to further elucidate the benefits of this procedure as well as the potential for adverse outcomes (e.g., hypersensitivity reactions) but presently this appears to be an excellent option for partial-thickness rotator cuff tears or rotator cuff tears with poor tissue quality.

References:

1. Strauss EJ, Salata MJ, Kercher J, Barker JU, McGill K, Bach BR Jr, Romeo AA, Verma NN. *Arthroscopy* 2011;27(4):568-80.
2. Ruotolo C, Fow JE, Nottage WM. The supraspinatus footprint: An anatomic study of the supraspinatus insertion. *Arthroscopy* 2004;20:246-249.
3. Ellman H. Diagnosis and treatment of incomplete rotator cuff tears. *Clin Orthop* 1990;254:64-74.
4. Wolff AB, Sethi P, Sutton KM, Covey AS, Magit DP, Medvecky M. *J Am Acad Orthop Surg*. 2006 Dec;14(13):715-25.
5. Sano H, Wakabayashi I, Itoi E. Stress distribution in the supraspinatus tendon with partial-thickness tears: an analysis using a two-dimensional, finite element model. *J Shoulder Elbow Surg* 2006 Jan-Feb;15(1):100-5.
6. Dr. Chen, Material and Structural Testing Core, Mayo Clinic, Rochester, MN.
7. Van Kampen C, Arnoczky S, Parks P, Hackett E, Ruehlman D, Turner A, Schlegel T. Tissue-engineered augmentation of a rotator cuff tendon using a reconstituted collagen scaffold: A histological evaluation in sheep. *Muscles Ligaments Tendons J*. 2013 Aug 11;3(3):229-35.
8. Iannotti JP, Codsi MJ, Kwon YW, Derwin K, Ciccone J, Brems JJ. Porcine small intestine submucosa augmentation of surgical repair of chronic two-tendon rotator cuff tears: A randomized, controlled trial. *J Bone Joint Surg Am* 2006;88(6):1238-1244.
9. Walton JR, Bowman NK, Khatib Y, Linklater J, Murrell GA. Restore orthobiologic implant: Not recommended for augmentation of rotator cuff repairs. *J Bone Joint Surg Am* 2007;89(4):786-791.