

RESEARCH ARTICLE

Preliminary Results of a Consecutive Series of Large & Massive Rotator Cuff Tears Treated with Arthroscopic Rotator Cuff Repairs Augmented with Extracellular Matrix

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Abstract

Background: Recurrence rate of rotator cuff tears is still high despite the improvements of surgical techniques, materials used and a better knowledge of the healing process of the rotator cuff tendons. Large to massive rotator cuff tears are particularly associated with a high failure rate, especially in elderly. Augmentation of rotator cuff repairs with extracellular matrix or synthetic patches has gained popularity in recent years with the aim of reducing failure. The aim of this study was to investigate the outcome of rotator cuff repairs augmented with denatured extracellular matrix in a series of patients who underwent arthroscopic rotator cuff repair for large to massive tears.

Methods: Ten consecutive patients, undergoing arthroscopic rotator cuff repair with extracellular matrix augment for large and massive tears, were prospectively enrolled into this single surgeon study. All repairs were performed arthroscopically with a double row technique augmented with extracellular matrix. Oxford Shoulder Score, Constant Score and pain visual analogue scale (VAS) were used to monitor the shoulder function and outcome pre-operatively and at three, six and 12-month follow-up. Minimum follow up was three months. Mean follow up was 7 months.

Results: Mean Constant score improved from 53 (SD=4) pre-operatively to 75 (SD=11) at final follow up. Mean Oxford score also increased from 30 (SD=8) pre-operatively to 47 (SD=10) at the final follow up. The visual analogue scale (VAS) improved from seven out of 10 (SD=2) preoperatively to 0.6 (SD=0.8) at final follow up. Additionally, there was significant improvement at three months mark in Constant score.

Conclusion: Arthroscopic repair and augmentation of large and massive rotator cuff tears with extracellular matrix patch has good early outcome.

Keywords: Augmentation, Double-row technique, Extracellular matrix, Owl technique, Patch, Rotator cuff repair, Rotator cuff tear, Scaffold, Tendinopathy

Introduction

Rotator cuff tears are very common particularly in elderly population. Although a proportion of these tears are asymptomatic, many patients suffer with pain, reduced function and quality of life and are therefore candidates for surgical repairs. In the last 15 years, advances in surgical techniques and equipment have revolutionized arthroscopic rotator cuff repairs (1,2). Despite these developments, large and massive rotator cuff tear repairs are still associated with a high failure rate ranging from 25% to in excess of 70% in older age group (1,3).

The sites of failure of the rotator cuff repairs are

reported to be at the bone-tendon interface and at the junction suture-tendon (4-6). The biology of the healing process between tendons and bone is complex because it involves healing between two dissimilar tissues and a successful repair is dependent on establishment of collagen fibers continuity between tendon and bone (5).

Additionally, large-massive rotator cuff repairs are often performed in chronic tears of elderly population who often have poor quality tendon and fragile tissue. As a consequence, at the tendon-suture interface there is a higher risk of failure particularly

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in presence of a high tension repair. An optimal repair is one that establishes a fine tuned balance where tension of the repair is spread as uniformly as possible with preserved blood supply to the area (7).

Several different techniques have been used to try to minimize the re-tear rate following rotator cuff (RC) tears. Double row repair is one strategy that has gained huge popularity. There are a number of biomechanical studies that clearly indicate double row repairs are stronger construct with increased load to failure and better restoration of the tendon footprint (7,8). Furthermore, recent radiology studies are indicating that double row technique can reduce the re-tear rate of rotator cuff repairs (RCR) (9). However, despite these biomechanical and radiological studies, there does not appear to be a significant clinical differences in the overall shoulder function when comparing single with double row techniques (10).

Another strategy is addition of platelet rich plasma (PRP) at the time of RCR. Although further research is required on PRP's role for RCR, so far there does not appear to be any convincing evidence for the positive role of PRP in overall outcome of shoulder function nor re-tear rate of rotator cuff tears (RCT) (1,3,11-13).

The persistently high RCR re-tear rates have drawn attention of the investigators into the use of patch augmentation. There are a number of patches in the market including augmentation with cellular components (either allogenic or autogenic), and extracellular matrix (xenograft, allograft, and synthetic). The aim here to decrease re-tear rates by evenly spreading the mechanical load across the repair site and strengthening the repair construct as well as enhancing the biological environment required for healing by providing different growth factors and structural protein (14). There are a number of biomechanical studies that demonstrate a mechanical advantage with augmentation of the graft (15-17). Clinically there are some studies which show

better outcome whereas others which do not (18,19).

The aim of this study was to study the early outcome of arthroscopic rotator cuff repair of large and massive rotator cuff tears performed where the repair was additionally augmented with extracellular matrix augmentation.

Materials and Methods

Ten consecutive patients undergoing arthroscopic rotator cuff repair with extracellular matrix augment for large and massive tears were prospectively enrolled into this single surgeon study. All the patients were assessed pre-operatively in clinic, by the consultant or the upper limb clinical fellow, with shoulder X-rays (antero-posterior, axillary and outlet view) and magnetic resonance imaging (MRI). Oxford Shoulder Score, Constant Score and pain visual analogue scale (VAS) were used to score shoulder function. All were reviewed three weeks post surgery and again at three, six months and 12 months. Oxford Shoulder Score, Constant Score and pain visual analogue scale (VAS) were used to score shoulders function on each occasion except at three weeks post surgery.

Only patients with large or massive repairable rotator cuff tears were included in the study (20,21) [Table 1]. We did not use the augment to bridge the gap in irreparable RCT.

Our exact technique has been previously described (22). All the procedures were performed under general anesthesia (GA) and inter-scalene block. Teicoplanin 400mg and Gentamycin 120mg were given as prophylaxis to all the patients at induction.

With the patient in the lateral position, an arthroscopic diagnostic assessment was performed through a standard posterior port. The size and shape of the tear, the quality of the tendons and the amount of retraction of the cuff was evaluated. At this stage, when necessary, extensive release of adhesions was performed in order to mobilize the rotator cuff.

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> Large (> 3cm) RC tears Massive (i.e. > 2 tendons) RC tears Repairable RC tears Poor tissue quality Patient goals of pain relief and improved shoulder function No evidence of cuff arthropathy No signs of OA of the GHJ Muscular atrophy of Goutallier stage I – III (26) Systemically well 	<ul style="list-style-type: none"> Small (< 1cm) RC tears Medium (1 < 3cm) RC tears Irreparable RC tears Good tissue quality Non achievable patient objectives Evidence of cuff arthropathy OA of the GHJ Muscular atrophy of Goutallier stage IV (27) Active Infections

HH: humeral head; OA: osteoarthritis; GHJ: gleno humeral joint.

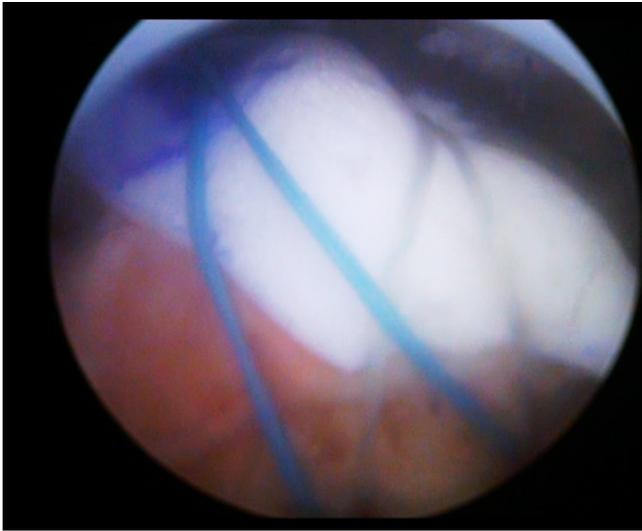


Figure 1. Intraoperative picture of the augmentation patch secured to the RC with a double row repair. Scope is introduced through the lateral port.

In presence of subscapularis tears, arthroscopic subscapularis repair was concomitantly performed. Similarly, in those patient with clinical features of long head of biceps (LHB) pathology and arthroscopic evidence LHB abnormality, either LHB tenotomy or tenodesis was performed. Additionally, arthroscopic sub-acromial decompression was performed in all the patients and acromio-clavicular (ACJ) excision was performed in those with ACJ tenderness.

All the rotator cuff repairs were performed by the same surgeon (AN). A double row technique was used. A cannula was positioned in the lateral portal (Passport 10mm x 4/5cm - Anthrex, Naple, FL). One or two medial row anchors (Helicoil 5.5 PK, Smith & Nephews) were used depending on the dimensions of the tear. There were four or eight passes into the tendon (four with one medial row anchor and eight with two medial row anchors) as in a knotted mattress technique. Following this the repair was augmented using extra-cellular matrix (ECM) (Arthrex DX, Naples, FL) using the "Owl" technique as previously described.

The suture limbs of the medial row anchors were passed through holes of the augment which was then inserted into the subacromial space. The augment was then stabilized by inserting two lateral anchors (Swivelock 5.5 biocomposite - Arthrex, Naples, FL) with the medial row suture limbs (similar to "transosseous equivalent" with the exceptions of medial anchor suture limbs going over the augment before being inserted laterally with the lateral row anchors) [Figure 1].

Shoulders were immobilized in a *shoulder abduction wedge* at the end of the procedure and patients were

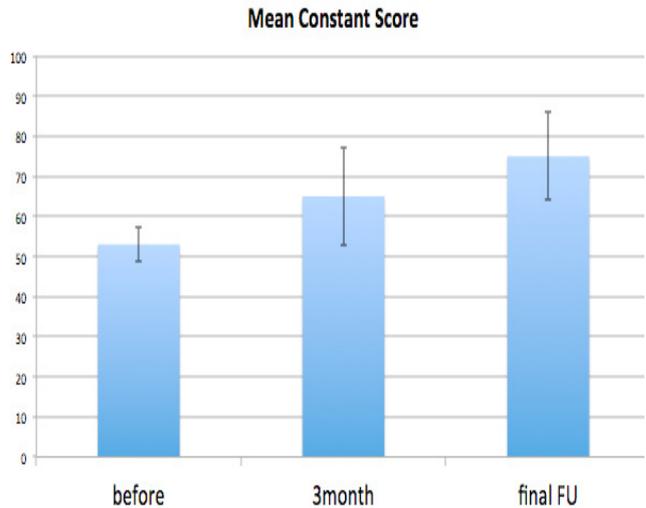


Figure 2. Constant shoulder score pre-surgery, at 3 months post surgery and at 6 months post surgery.

instructed to wear this for six weeks. Physiotherapy as per large-massive rotator cuff repair protocols is organized before discharge.

Differences between Constant and Oxford scores as well as visual analogue scores and abduction range recorded preoperatively and postoperatively were evaluated by use of Mann Whitney U test.

Results

The mean age of the patients was 74 (range, 65-82). There were six females and four males. Minimum follow up was three months with an average follow up period of seven months (range 3-12 months) [Table 2].

Five patients underwent concomitant ACJ excision whereas LHB tenotomy was performed in three patients. Concomitant subscapularis repair was also performed in two of the patients. Five patients had large supraspinatus tears and five had massive tears. The tear also involved the infraspinatus in 4 patients. We did not have any infections.

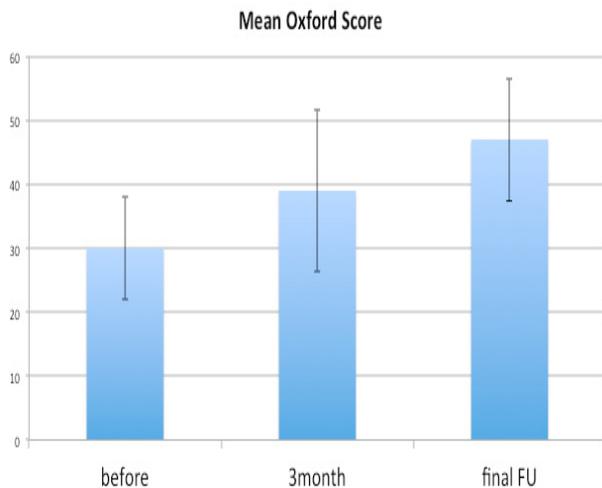
Mean Constant score improved from 53 (SD=4) pre-operatively to 75 (SD=11) at final follow up ($P<0.05$). Mean Constant score at the three months mark (mean=65, SD=12) was also significantly improved compared to pre-op score ($P<0.05$) [Table 2, Figure 2].

Similarly mean Oxford score also increased from 30 (SD=8) pre-operatively to 47 (SD=10) at the final follow up ($P<0.05$). Although there was also an increase in Oxford score at three months (mean=38.7, SD=12.7), this improvement was not significant ($P>0.05$) [Table 2, Figure 3].

The visual analogue scale (VAS) improved from seven out of 10 (SD=2) preoperatively to 0.6 (SD=0.8) at final

Table 2. Follow up scores at the final visit

Patient Number	Follow Up Period	Pre-Op Oxford Scores	Final Follow up Oxford Scores	Pre-Op Constant Scores	Final Follow up Constant Scores
1	12 months	19	42	50	59
2	12 months	35	55	51	80
3	6 months	17	63	57	78
4	6 months	35	48	57	88
5	6 months	34	48	51	73
6	6 months	34	48	55	89
7	6 months	35	41	54	56
8	6 months	18	31	57	70
9	3 months	35	58	44	76
10	3 months	33	39	55	80

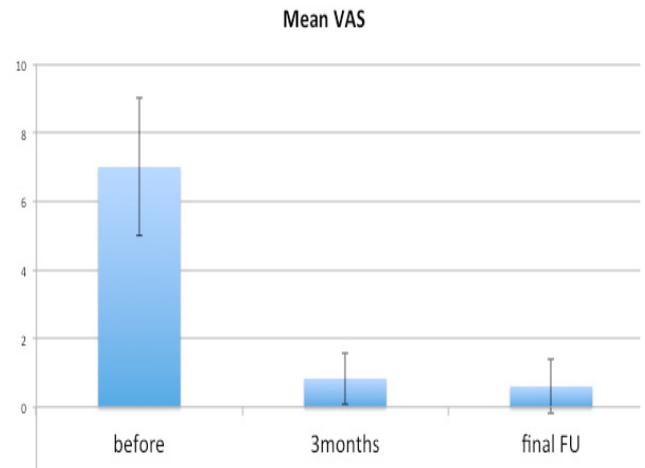
**Figure 3. Oxford shoulder score pre-surgery, at 3 months post surgery and at 6 months post surgery.**

follow up ($P<0.05$). Mean VAS at three months mark (mean=0.83, SD=0.8) was also significantly improved compared to pre-op score ($P<0.05$) [Figure 4].

Mean abduction also improved from 93 (SD=27) pre-operatively to 153 (SD=24) at the final follow up ($P<0.05$). Mean abduction at the three months mark (141, SD=31) was also significantly improved compared to pre-op score ($P<0.05$) [Figure 5].

Discussion

Despite the huge advances in arthroscopic techniques

**Figure 4. Visual analogue scores (VAS) pre-surgery, at 3 months post surgery and at 6 months post surgery.**

and instrumentation, re-tears following arthroscopic repairs are common and in elderly population with cuff repairs for massive and large tears can be in excess of 70% (23). This is a comparable re-tear rate to that reported by Zumstein et al (57%), Miller et al (41%), Kim et al (42.4%), and Park et al (25%) (24-27). It is therefore not surprising that in recent years there has been a focus of attention into ways of reducing this significant re-tear rate.

Augment patches have acquired popularity in the last 10 years as yet another strategy to optimize

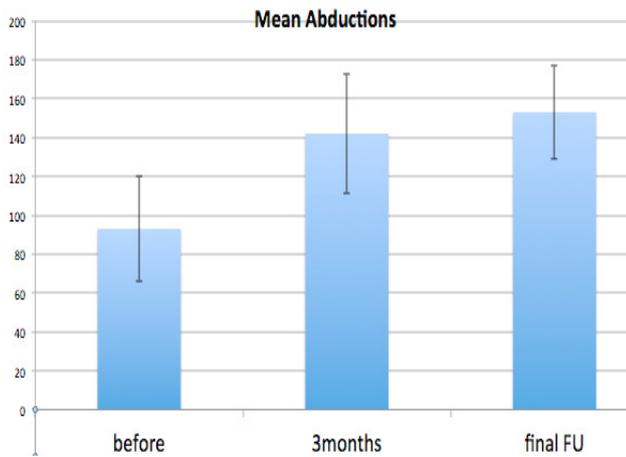


Figure 5. Mean abduction pre-surgery, at 3 months post surgery and at 6 months post surgery.

healing and reduce re-tear rates. The increased load to failure of a rotator cuff repair augmented with a patch is demonstrated by a biomechanical cadaveric study of Shea et al. (15). Non augmented RCR had a rate failure of 33%, while all the augmented repairs remained intact with the loading cyclic protocol. It is also reported that the gap at the interface tendon-bone is decreased by 40% when an augmentation is performed. As most of the rotator cuff repair failures occur in the interface tendon-bone, an increased contact at this level can make the difference in the natural history of the repair (4,20).

Recent literature reports suggest that good outcomes and reduced re-tear rates may be achieved when augmentation patches are utilised. Wong et al. (2010) published a study using graftjacket allograft a-cellular human dermal matrix to repair large to massive RCT, reporting good results at two-year follow-up (18). Similarly, Barber et al. reported encouraging results using acellular human dermal matrix graft (28). Intact repairs were found in 85% of the augmented group and 40% of the non augmented group (gadolinium-enhanced MRI at 14 months). The shoulder functions were also better in the augmented group, at 2-year follow-up (28).

In 2013, Gupta AK. et al. used a porcine xenograft to repair large to massive RCT. They reported that the overall shoulder function improved (two-year follow-up) and 73% of the patients had a fully intact tendon-graft reconstruction showed by the shoulder ultrasound (US), performed two years post-operatively; 22% had a partially intact reconstruction, 5% (1 patient) had a complete tear at the graft-bone interface caused by suture anchor pullout as a result of a fall (29). The same year, an Italian group published good long term results using a porcine dermal collagen repair patch. Better

shoulder outcome achieved and no re-tears observed at two and half years follow-up (30).

A poly-l-lactic acid synthetic patch was used as a reinforcement device by Proctor et al. In their study, 83% of patients at 12 months after surgery and 78% of patients at 42 months after surgery had an intact RC with substantial functional improvement of the shoulder function (31).

In another study, polypropylene patch augmentation was demonstrated to significantly improve the 36-month outcome in terms of function, strength, and re-tear rate if compared with a control group of patients who had a simple RCR and a third group who had the RC repaired with a collagen patch. The group treated with a collagen patch had a higher re-tear rate if compared with the other two groups (19).

Our data also provides evidence for positive short-term outcome following arthroscopic RC repair with extracellular matrix augmentation for large and massive RC tears. There were significant improvements in shoulder function outcome scores, visual analogue scores and abduction at the final follow up (minimum follow up was three months and average follow up was over seven months). It is also interesting to note that there were also significant improvements in Constant scores, visual analogue scores and shoulder abduction at the three months mark. Although Oxford shoulder score also improved at three months, this improvement was not significant at $P < 0.05$ level. This is in contrast to Hughes et al study where there was only a significant improvement in Constant scores at the six months mark and not the three months with arthroscopic cuff repair without augmentation (25). The improved function and pain observed with our patients at the three months mark may be due to the augment reducing the tension of the repair in the early rehabilitation phase and therefore minimizing pain and optimizing the healing environment.

There are a number of limitations with our study. First of all, the number of patients is small and we have a short follow up period. Secondly, this is not a randomized controlled study therefore it may be the case that if we have compared the series to a group patients having rotator cuff repairs without augmentation, there may have not been a difference between the two groups and the patients with RC repair without augmentation may have done as well as those with augmentation. Thirdly, we did not perform imaging in all the patients post surgery to confirm that the rotator cuff has indeed healed without any evidence of re-tears. Nevertheless, we feel that our series demonstrate that good outcomes may be achieved following arthroscopic RC repair with augmentation and highlight the need for randomized controlled studies with long term follow ups to investigate whether this good outcome is better than that observed with RCR without augmentation. Our series also suggest that cuff repairs with augmentation may lead to significant function improvement as early as three months post repair which has not been the case with previous literature on standard

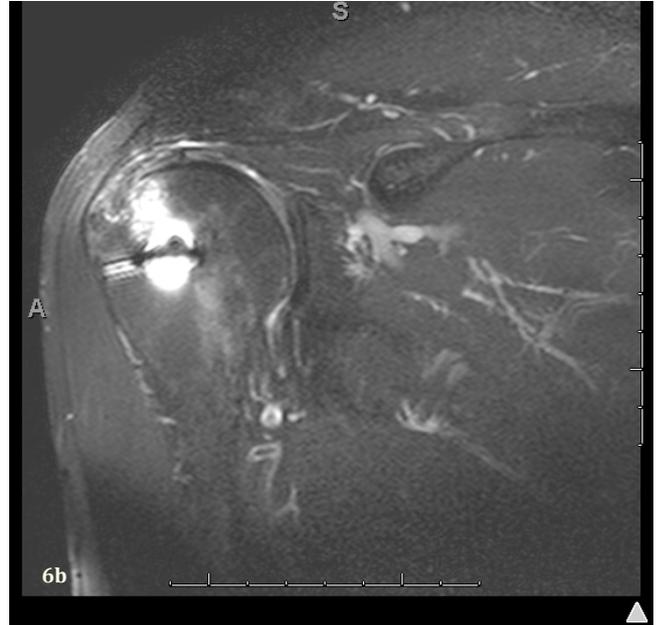
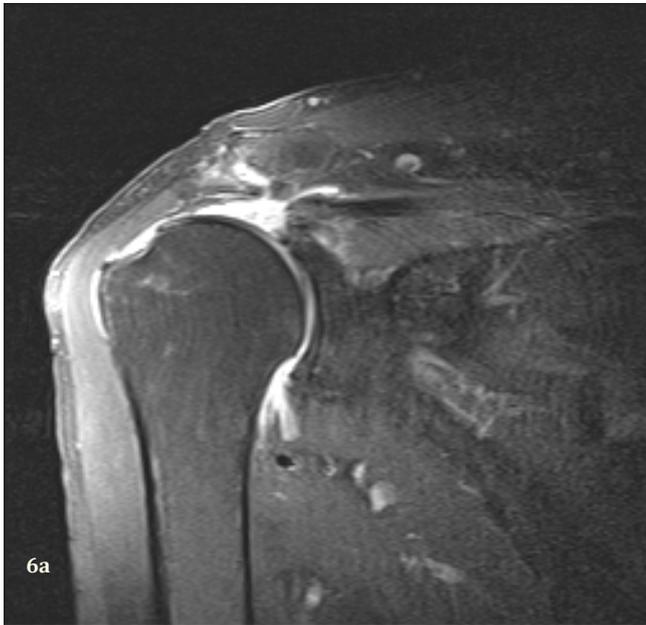


Figure 6. MRI of tear pre-op (6a) and one year post op (6b) in the same patient.

RC repair. We did not do any magnetic resonance imaging (MRI) in our patient before the 12 months mark as we felt it was important to wait at least for a year before any meaningful conclusions could be drawn as to whether the RC has healed on the MRI images. We did do MRI imaging in two patients who had past one year mark and the repair was intact in both patients [Figure 6a, b].

Biomechanically, augmentation of the RCR makes sense (15-17). Furthermore, it might optimize the healing environment by distributing the load and reducing the tendon repair tension in the early rehabilitation period. There may also be some additional biological advantages too when augmenting the repair with extracellular augment. Clinically, our series suggest that good short term outcomes may be observed with RC repair and augmentation. Augmentation, therefore may prove to be the tool to decrease the re-tear rates in large and massive tears in elderly.

Arthroscopic repair and augmentation of large and massive rotator cuff tears with extracellular matrix

patch has good early outcome.

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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