

A synthetic reinforcement patch in repair of challenging two-tendon rotator cuff tears

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ABSTRACT

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Conflicts of Interest

None declared

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Background The repair of chronic massive tendon tears may be a challenging procedure, especially with a frayed tendon caused by degeneration. The aim of this case series was to evaluate the outcome of a synthetic patch in the repair of complex rotator cuff tears, with regard to shoulder function, pain relief and quality of life.

Methods A synthetic patch (Artelon® Tissue Reinforcement; Artimplant AB, Västra Frölunda, Sweden) was used in 17 patients with challenging repairs of chronic rotator cuff tears. The outcome of surgical treatment was evaluated after 3, 6 and 12 months by the Constant functional score and the Western Ontario Rotator Cuff (WORC) score.

Results Significantly less pain and improved shoulder function, as evaluated by the Constant score, was seen 1 year after surgery, as well as an increased WORC score as a measure of improved disease-related quality of life. Re-operation was performed in one patient as a result of a re-tear. There were no complications related to the use of the reinforcement patch.

Conclusions This case series showed satisfying results in technically challenging repairs of rotator cuff tears with the use of a synthetic reinforcement patch. Postoperatively, the patients showed less pain and improved shoulder function to the extent to perform better in daily life activities.

INTRODUCTION

Rotator cuff injury affects a diverse group of patients and leads to significant disability with respect to lost time from work and the inability to participate in sports or other activities, thereby affecting the individual's quality of life [1]. Rotator cuff injuries are strongly age correlated [2,3]. The incidence of rotator cuff injuries is therefore expected to grow as the population ages, and with a growing elderly population that is increasingly active and less willing to accept functional limitations. Asymptomatic partial and full thickness rotator cuff tears have been shown to occur in more than 50% of individuals > 60 years old [4]. Studies have revealed that 50% of the individuals with asymptomatic rotator cuff tears became symptomatic over a 5-year period [5].

Besides age, the outcome of surgical repair depends strongly on the size of the rotator cuff tear and on the duration of symptoms [6,7]. The time from injury to surgical repair is crucial because the edges of the tear can retract and degenerate. Also, the involved muscle atrophies with time and irreversible fatty infiltration proceeds [8,9]. Even though surgical techniques for rotator cuff repair have progressed, the repairing of chronic large or massive tendon tears may be a challenging procedure, especially with a frayed, retracted and inelastic tendon caused by chronic degeneration. Apposition of the tendon edges may be possible, although the likelihood of failure is high in tears of degenerative nature [10]. To further improve the results, and in particular to enhance post-operative active motion and strength, the search for improved

rehabilitation protocols and surgical methods is still of great importance in the repair of larger tears [6].

The Artelon® Tissue Reinforcement device (Artimplant AB, Västra Frölunda, Sweden) is intended for use in rotator cuff surgical procedures for reinforcement of soft tissue where weakness exists. The synthetic patch is sutured over torn tissue as a reinforcement of sutures and suture anchors. The aim of this case series was to evaluate the outcome of the use of a synthetic reinforcement patch in the repair of complex rotator cuff tears, with regard to shoulder function, pain relief and quality of life.

MATERIALS AND METHODS

A series of patients with complex rotator cuff tears were treated in the present study. Inclusion criteria were patients with a large or massive rotator cuff tear, diagnosed by magnetic resonance imaging (MRI), and with pain and insufficient muscle function for at least 3 months. The final inclusion was made during surgery and was based on whether poor tissue quality was present (i.e. a thin and macerated tendon tissue) and whether it was even possible to mobilize and repair the tendon. Exclusion criteria were ongoing infection, evidence of significant osteoarthritis or cartilage damage in the shoulder, chronic dislocation and glenohumeral arthropathy. Patients who had an ongoing medication inappropriate for the study, such as systemic corticosteroids or chemotherapeutics, or those who had a major medical condition, were also excluded. None of the patients had undergone previous surgery on the

Table 1 Patient characteristics

		<i>n</i>
Sex	Female/male	12/5
Age (years)	< 55	1
	55 to 64	5
	≥ 65	10
Damaged shoulder	Right/left	6/11
Involvement of dominant hand	Yes/no	8/9
Cause of damage	Trauma/wear	7/8
	Trauma + wear	1
	Unknown	1
Duration of symptoms (months)	< 12	11
	13 to 24	2
	> 24	4

affected shoulder. In total 17 patients (12 females) received an Artelon® Tissue Reinforcement in the repair of a rotator cuff tear between October 2008 and October 2009 (Table 1). One patient had repeat surgery after 8 months, and thus the 1-year follow-up includes 16 patients. The mean age at surgery was 65 years (range 45 years to 76 years). All patients had a full-thickness tear in the supraspinatus, which also involved the infraspinatus tendon (i.e. a two-tendon tear). In two patients, the tear also involved the subscapularis tendon. The tissue quality of the tendons was evaluated during surgery, as well as the size of the rotator cuff tear and the extent of retraction. The dimensions of the tear were measured in the anterior–posterior and medial–lateral planes.

The investigation plan and informed consent documents were reviewed by the Union Pines Surgery Center. All patients provided their informed consent before participating.

Surgical technique

All patients underwent open repair according to the technique described by Neer [11]. An anterior acromioplasty was performed and, with the hypertrophic bursa excised, the cuff was evaluated and mobilized both on the intra-articular side, as well as the bursal side. Adhesions and contractures were released if necessary. If the tendons could be approximated together and attached to the footprint, even if the quality of the tendons was very poor or if tension at the footprint was tenuous, then the reinforcement patch

was utilized. Most repairs began posterior to anterior with margin convergence and side to side, gradually closing the large defect. The sutures of the primary repair edges were inverted to avoid prominent knots causing a bulging of the patch.

The footprint was prepared by making a small trough in the greater tuberosity by debriding the bony surface of the greater tuberosity to create a small bleeding surface. Drill holes were made and interosseous tunnels were created (i.e. as many as were deemed necessary for the repair). Three non-absorbable sutures were put through each of the interosseous tunnels. In this way, there were multiple sutures not only to repair the tendon to the bone, but also for later application of the synthetic patch, creating a ‘tethering’ effect and reinforcement of the footprint repair.

Once the cuff repair was completed, application of the patch began, starting with sutures on the posterior side. The patch was cut and shaped to fit over the repair, allowing at least a 5-mm overlap onto what was felt to be decent tendon tissue. The edges were rounded to make smooth corners. Usually, a simple stitch on the back side was made because it was technically difficult to get any other stitch on that very far back side. Alternate vertical mattress stitches were made going from medial to lateral and then lateral to medial, aiming to keep the patch taut to the cuff below. This tended to press the patch tightly to the bursal side of the tendon and tended to prevent overpulling the patch more to one side or the other. If further reinforcement was needed, it was still possible to place sutures in between the non-absorbable stitches. The excess patch was trimmed so that its border was over and on top of the footprint, but yet proximal to the inferior lower interosseous sutures. This allowed some of the previously placed interosseous sutures to pass not only through the tendon, but also through the patch. Then, as the suture was tied down, the suture lying on top of the patch kept the patch firmly down to the cuff (Fig. 1).

The arm was thereafter taken through range of motion with internal and external rotation to determine the tightness. The gained information was used as a guide to the postoperative rehabilitation protocol. A blunt instrument was used to simply test the construct to ensure that it was tight and that it appeared to be very snug to the actual cuff repair. The deltoid split, subcutaneous tissue and skin were closed in a standardized way. Mean surgery time was 103 minutes (range 82 minutes to 133 minutes). The patients received one dose of prophylactic antibiotics.

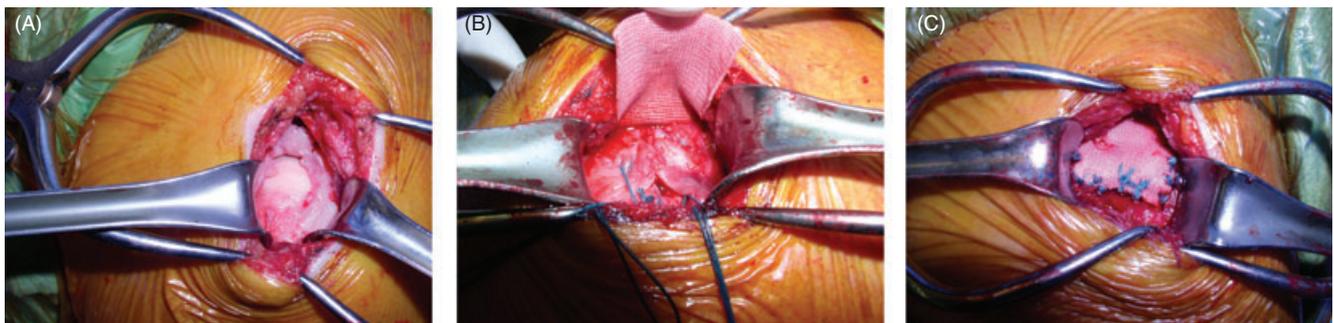


Fig. 1 (A) Intra-operative view of a complex tear before the commencement of the repair. (B) The application of a synthetic reinforcement patch has begun. (C) The repair is completed.

The postoperative regimen was immobilization of the arm in a sling for 6 weeks. The patient was initially advised to start with elbow range of motion exercises, as well as Codman's pendulum and passive external rotation with a stick. These exercises were extended to include passive forward elevation and passive internal rotation. At 6 weeks, the sling was removed and the patient was encouraged to use the arm, although only at waist level. Formal cuff strengthening was delayed until 12 weeks postoperatively.

Clinical evaluation

The pre- and postoperative examinations included both subjective and objective tests, and were performed before surgical treatment and after 3, 6 and 12 months. The function of the shoulder was assessed by the Constant–Murley functional assessment of the shoulder (primary outcome measure). The subjective parameters in this questionnaire assess the degree of pain (15 points) and the ability to perform the normal tasks of daily living (20 points). The objective parameters assess active range of motion (40 points) and strength (25 points). The total maximum score is 100 points [12]. Patients who were unable to achieve the test position of 90° of shoulder abduction in assessment of strength were assigned a strength score equal to zero [13]. The evaluation of the surgical treatment also included the Western Ontario Rotator Cuff (WORC) score, including 21 items with a visual analogue scale representing five domains of disease-specific quality of life questions [14,15]. The scores for each domain were transformed to 0% to 100%. The Short Form 36 (SF-36) health survey (version 2) was used as a general measure of health-related quality of life [16]. The questionnaire consists of 36 items divided into eight subscales measuring physical and mental components. The scores for each subscale range from 0 (poor) to 100 (good). The treating doctor's satisfaction with the patient's progress/outcome was graded as non-acceptable, acceptable, good or excellent. Any events during the course of the study were recorded, regardless of whether they were related to the arm/shoulder or not.

Radiographs were taken pre-operatively to provide information on the position of the proximal humerus in relation to the glenoid and to exclude other pathology, such as osteoarthritis. MRI was performed pre-operatively to assess the size of the rotator cuff tear, and postoperatively to evaluate the status of the rotator cuff. The degree of muscle atrophy was estimated pre- and postoperatively by an independent radiologist.

Statistical analysis

Descriptive data and analyses comparing pre- and postoperative results include 13 patients because pre-operative data are not available for four patients. Changes over time were analyzed with the Wilcoxon signed rank test. Mean differences at 12 months are given with 95% confidence intervals (CI). All significance tests were two-tailed and conducted at the 5% significance level.

RESULTS

The evaluation of the rotator cuff tendon during surgery revealed poor tissue quality. The mean (SD; range) maximum tear diameter was 30 mm (5 mm; 23 mm to 43 mm). The amount of retraction was 29 mm (7 mm; 18 mm to 43 mm).

Significantly less pain and improved shoulder function, as evaluated by the Constant score, was seen 1 year after surgery ($p = 0.002$, 95% CI for total score = 42 to 59; Table 2), as well as an increased WORC score as a measure of improved disease-related quality of life ($p = 0.002$, 95% CI for total score = 44 to 66; Table 2). Pain decreased soon after surgery. The recovery in daily activities and range of motion continued during the 1-year follow-up (Fig. 2). Before treatment, 11 of 13 patients with available pre-operative scores reported disturbed sleep during the night because of the shoulder, when answering the Constant questions dealing with daily activities. The other two patients reported occasional sleep disturbances. At 1-year follow-up, only one of 16 patients experienced disturbed sleep during the night

Table 2 The pre- and postoperative Constant and Western Ontario Rotator Cuff (WORC) scores

	Pre-treatment, <i>n</i> = 13;	1 year, <i>n</i> = 12;	Change 0 year to 1 year, <i>n</i> = 12;	
	Mean (SD), range	Mean (SD), range*	Mean (SD), range	<i>p</i>
Constant (points)				
Pain	4.5 (2.9), 0 to 10	11.6 (3.3), 5 to 15	7.1 (3.4), 3 to 12	0.002
Daily activities	6.5 (2.3), 2 to 11	17.5 (2.5), 13 to 20	11.0 (2.5), 7 to 15	0.002
Range of motion	6.2 (5.1), 0 to 16	32.0 (5.9), 18 to 38	26.2 (7.7), 16 to 36	0.002
Strength	0	6.0 (7.5), 0 to 25	6.0 (7.5), 0 to 25	0.005
Total score	17.1 (6.4), 5 to 27	67.1 (11.6), 43 to 88	50.3 (13.2), 35 to 77	0.002
WORC (%)				
Physical symptoms	41 (20), 12 to 78	88 (12), 61 to 100	49 (21), 15 to 77	0.002
Sports/recreation	28 (19), 6 to 68	80 (22), 37 to 100	54 (24), 13 to 86	0.002
Work	22 (16), 1 to 46	81 (16), 44 to 99	61 (20), 33 to 95	0.002
Lifestyle	30 (24), 0 to 69	89 (11), 70 to 98	62 (18), 30 to 96	0.002
Emotions	48 (35), 0 to 96	94 (8), 76 to 100	50 (33), 2 to 100	0.002
Total	34 (18), 8 to 61	86 (12), 61 to 99	55 (17), 31 to 87	0.002

*One patient was re-operated after 8 months.

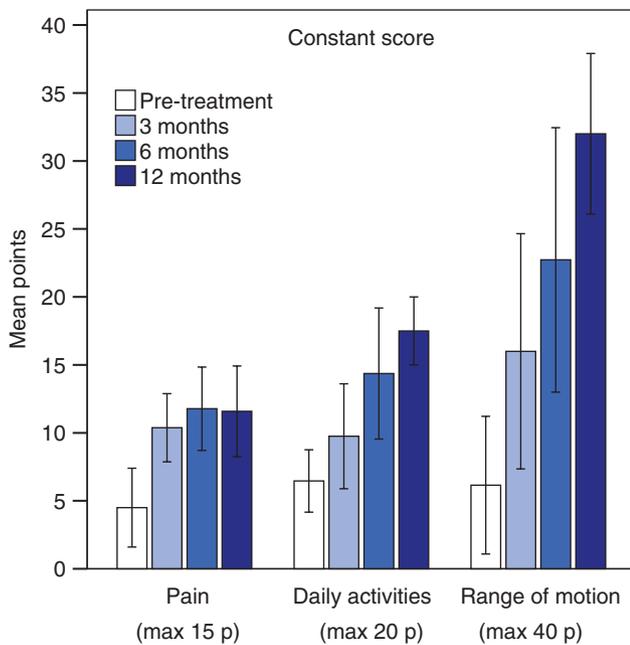


Fig. 2 The bars illustrate the score change in the Constant subscales during follow-up. Strength was not evaluated at the 3- and 6-month follow-ups because the exercise with the measurement was too soon after surgery and is therefore not shown. Bars show the mean (SD).

because of the shoulder. Seven patients experienced occasional sleep disturbances.

The evaluation of health-related quality of life using the SF-36 score showed a positive change after 1 year in the physical components of the score, including bodily pain. The treating doctor's satisfaction with a patient's progress/outcome was assessed as good or excellent in 13 of 16 patients at the 1-year visit. The outcome of treatment was assessed as acceptable in two patients and non-acceptable in one patient. Initially, this latter patient showed good results but fell after a stroke, sustaining a hip fracture and injuring the shoulder. Except for this patient with an injured shoulder, MRI evaluation showed two further patients with an unhealed tendon tear but, in these cases, the clinical outcome was assessed as good or excellent after 1 year. In six patients, the tear appeared to be closed, although the MRI signal was not conclusive and the tendon did not appear to have fully regained its thickness, indicating a remaining defect. The degree of muscle atrophy was unchanged after 1 year.

Re-operation was performed in one patient as a result of a re-tear, which occurred during the strengthening phase 8 months after the first surgery. The re-tear was much smaller than the original tear and a patch was not necessary for the second surgical repair. The patient had a most satisfactory recovery. In one patient, a superficial infection was seen after 2 months, probably caused by an infected hair follicle. This was resolved with simple cleansing. Another patient developed a subcutaneous abscess, also after 2 months, which did not penetrate through the deltoid fascia. It was treated by surgical debridement and wound care and the patient recovered uneventfully.

DISCUSSION

Surgical repair of rotator cuff tears intends to improve the function of the shoulder. However, chronic degenerative changes, especially with tendon retraction and shrinkage, make the repairs complex and technically challenging. The healing of the repair is also associated with the patient's age and the size of the tendon tear. This has led to the development of different approaches with the use of patches for augmentation aiming to improve the outcome of these rotator cuff tendon repairs.

The results of this case series of primary rotator cuff tendon repairs with the use of a synthetic reinforcement patch showed significantly less pain and improved shoulder function 1 year after surgery as evaluated by the Constant score. The significant increase in the WORC score indicated an improved disease-related quality of life. This series of patients was even more challenging with multiple pathological situations involving the rotator cuff tear, and also 10 of the 17 patients were aged 65 years or older. Some of the retracted tendon edges were very smooth and rounded off, with this representing a more chronic situation and concomitant low vascularity. Others were frayed and macerated. In these patients, it may be difficult to hold the tendon edges together, even though the tendon edges could be apposed in this case series. All patients had a full-thickness tear of the supraspinatus with involvement also of the infraspinatus. Two patients had a three-tendon tear. It has been shown that the involvement of two or more tendons, as well as size and age, is related to a higher re-tear rate [10,17,18].

MRI evaluations showed that the healing of the tendon repair was not successful in three patients. One of these showed good results initially but then had a stroke, causing a fall onto the shoulder. The other two patients, however, still showed good function in daily life activities and the outcome of the treatment was assessed as good or excellent. This could be a result of good decompression and optimal postoperative rehabilitation, although it could also be that the reinforcement patch had a 'tethering' effect (i.e. had a support function). This latter suggestion is an assumption but, to some extent, is based on the impression from the MRI image. Other studies comparing anatomic and clinical results after rotator cuff repair have reported that incomplete healing on MRI does not exclude positive functional results [19–21]. Of interest, in the study by Nho et al, all intact rotator cuff tendons at 1 year remained intact at 2 years [22].

There were no complications related to the use of a synthetic reinforcement patch. Re-operation was performed in one patient as a result of a recurrent tear 8 months after initial surgery. The re-tear, however, appeared to be easier to repair compared to the primary tear, and the impression was that the patch had given support and allowed most healing during the initial phase. At this time point, the amount of graft appeared to be unaltered, as expected as a result of the degradation time of the material. Three patients in this case series had surgery for other medical issues during the follow-up period, unrelated to the treated shoulder, but which had a negative effect on the rehabilitation and training. These patients also showed low Constant and WORC scores.

The device used in the present study acts as reinforcement of the primary suture repair. It is made of Artelon[®], which is a polycaprolactone-based polyurethaneurea with slow degradation [23]. The predictable degradation of the mechanical properties

of Artelon® is important in the function of giving reinforcement to the suture repair during the healing phase, as well as in the later phase of the tendon tissue remodelling process. The material has shown good biocompatibility in soft and hard tissue in animal studies and in clinical use [24–26]. There are yet few studies on the use of a synthetic patch [27,28]. A different kind of synthetic material was used in a case series of patients with small and medium tendon tears indicating promising results, with one re-tear in 10 patients [27]. Devices to augment rotator cuff tendon repairs may also be of biological origin (i.e. derived from extracellular matrix of tissue from different species) [29]. These may be allografts from processed human dermal tissue, or xenografts derived for example from porcine dermal collagen or porcine small intestine submucosa (SIS). Case series with these latter patches of SIS have shown a high proportion of patients with an inflammatory reaction [30,31] and the American Academy of Orthopedic Surgeons (AAOS) does not recommend its use [32]. Studies on patches of processed human dermal tissue have, however, shown more positive results [33,34]. A randomized controlled study showed significantly more intact repairs after a mean follow-up time of 24 months, as determined by gadolinium-enhanced MRI, in a group with augmented repairs ($n = 22$) compared to a group with non-augmented repairs ($n = 20$) [34]. Adverse events included three and nine rotator cuff re-tears, respectively.

Even though only a few studies are available, and most of them comprise retrospective case series, there are indications that reinforcement patches may be a useful option for managing difficult rotator cuff situations. The present results are obtained from a case series and additional prospective investigations are needed to further evaluate the value of reinforcement, as well as to evaluate treatment procedures, such as the protocol for postoperative management. In these patients with complex repairs, isometric exercises were not started until 12 weeks postoperatively, which can be compared to 8 weeks to 10 weeks for more routine rotator cuff repairs at the clinic. Another limitation of the present study was the follow-up time. One year is sufficient for evaluation of the outcome of treatment with regard to improvement in shoulder function in daily activities. However, patients will most likely need more time for maximum recovery of strength [35].

In conclusion, the present case series showed satisfying results in these technically challenging repairs of rotator cuff tears. In patients with thin and macerated tendon tissue, holding the repaired tendon together is difficult and tenuous at best. Postoperatively, the patients showed less pain and improved shoulder function with respect to performing better in daily life activities. It is important to understand that, in these complex repairs, we did not expect 100% pain relief or 100% functional use, range of motion or strength but, an improvement in the patient's condition.

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