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ORIGINAL ARTICLE

Synthetic patch rotator cuff repair: a 10-year follow-up

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ABSTRACT

Background The present study aimed to determine the long-term outcome as a result of the use of synthetic patches as tendon substitutes to bridge massive irreparable rotator cuff defects.

Methods All patients who previously had a rotator cuff repair with a synthetic patch (2-mm Gore DUALMESH ePTFE patch; Gore, Flagstaff, AZ, USA; or a 2.87-mm Bard PTFE Felt pledgets; CR Bard, Warwick, RI, USA) were followed-up at a minimum of 8.5 years postoperatively. Assessment of shoulder pain, function, range of motion, strength and imaging was performed.

Results Six patients had an interpositional repair with a synthetic patch. One patient had died. In the remaining five patients, the mean tear size at repair was 27 cm^2. At 9.7 years postoperatively, all the patches remained *in situ* and no patient required further surgery. The repair was intact in four out of five patients. Patients had improved external rotation and abduction compared to before surgery ($p < 0.02$).

Conclusions We describe the long-term outcomes of patients who had undergone synthetic patch rotator cuff repair for an irreparable rotator cuff tear. At 9.7 years postoperatively, patients reported less severe and more infrequent pain, as well as greater overall shoulder function, compared to before surgery. Patients also had increased passive external rotation and abduction. All the patches remain *in situ* and there have been no further operations on these shoulders.

INTRODUCTION

The shoulder joint is reliant on the proper functioning of the muscles and tendons of the rotator cuff. Tears of the rotator cuff are very common and the current practice is to repair them surgically when symptomatic. Despite recent advances in technique, re-tears are not uncommon, with re-tear rates of between 20% and 90% [1–4]. This is especially true for larger and more chronic tears [5,6]. In many cases, the torn tendon cannot be repaired back to the humeral footprint and, in these instances, the tears are often considered irreparable.

Several different materials and techniques have been investigated as possible solutions to these irreparable rotator cuff tears. Allografts, autografts, xenografts and tendon transfers have been used as tendon substitutes; however, they have yielded mixed results, frequently with high failure rates and/or compatibility issues [7–15]. Synthetic materials have also been proposed. Two short-term (44 months and 43 months) studies have demonstrated improvements in overall shoulder scores in 27 and 41 patients after a rotator cuff repair with a synthetic patch [16,17]. Animal trials have also demonstrated tissue in-growth into synthetic materials [18–19].

Despite this, other synthetic grafts have not fared well in humans over the long term. For example, in anterior cruciate ligament reconstructions with expanded polytetrafluoroethylene (ePTFE) and polyethylene terephthalate, there has been documentation of osteolysis, device failure and osteoarthritis [20–23]. There is currently no long-term (> 3.5 years) data regarding the use of synthetic patches as tendon substitutes in otherwise irreparable rotator cuff tears. Specifically, no study has monitored the progression of pain, function, range of motion and strength over time. No imaging studies have investigated the appearance and integrity of these repairs beyond 3.5 years.

The present study aimed to investigate the long-term viability of patients who had undergone synthetic patch repair that was conducted by the senior investigator (GACM) approximately 10 years ago. Investigations were made into pain, function, strength, range of motion and repair integrity.

We hypothesized that an interpositonal synthetic patch would act as a tendon substitute in an otherwise irreparable rotator cuff defect, and would lead to improved patient outcomes over the long term.

MATERIALS AND METHODS

This retrospective study was approved by the (blinded for review purposes) Service's Human Research Ethics Committee – Central Network. All patients provided their written informed consent.

Recruitment and eligibility

All written operative reports of the senior investigator (GACM) were analyzed for the period between 1996 and 2005. Patients were recruited if they had a rotator cuff repair with a synthetic patch ['PTFE' (2.87-mm PTFE Felt; CR Bard, Warwick, RI, USA) or 'Gore-Tex' (2-mm Gore-Tex ePTFE; Gore, Flagstaff, AZ)] during this time. There were no other exclusion criteria.

Surgical technique

A description of the open technique used for the synthetic patch repairs is provided below. After an interscalene block, each patient

was placed in the beach chair position and the shoulder prepped and draped. A 5-cm transverse skin incision was made parallel to and 1-cm distal to the lateral border of the acromion, and centred over its anterior edge. The skin edges were held with a Gelpi self-retaining retractor. The deltoid was detached from the anterior edge of the acromion using a cautery and then split laterally in line with its fibres for 4 cm, and retracted with a Gelpi retractor. An anterior acromioplasty was performed with an oscillating saw and then the subacromial bursa removed to reveal the torn supraspinatus (and infraspinatus). The synthetic material, 2-mm Gore-Tex ePTFE (Gore) or 2.87-mm PTFE Felt (CR Bard), was cut to a sufficiently large size to fill the defect. Vertical mattress sutures (#2 ethibond; Ethicon, Inc., Somerville, NJ, USA) were passed through the lateral edge of the torn tendon and then through the patch. The patch was secured to the tendon using two half-hitches and three alternating half-hitches to lock the knot.

Mitek RC Quickanchors (Mitek Surgical Products, Norwood, MA, USA) loaded with #2 ethibond sutures were placed in the greater tuberosity just lateral to the supraspinatus landing site. Sutures from the anchor were passed through the lateral edge of the patch in a horizontal mattress configuration. The anterior deltoid was reattached to the anterior edge of the acromion with #2 ethibond sutures and the skin was closed.

Patients were rehabilitated in the same manner as a normal rotator cuff repair. Their arm was placed in a sling for a period of 6 weeks. They were initially started on pendulum exercises. At 2 weeks postoperatively, patients were introduced to passive flexion and extension range of motion exercises. At the 6-week postoperative visit, active range of motion and simple isometric strengthening exercises were initiated. Finally, at 3-month follow-up, patients proceeded to free overhead activities and lifting 5 kg or more.

Outcome measures

Shoulder pain and function, range of motion and strength measurements were collected for each patient. Data were analyzed against the same measurements taken pre-operatively and during postoperative follow-ups at 1 week, 6 weeks, 12 weeks, 6 months and 18 months, as well as between 8.5 years and 11.5 years after surgery.

Patient-determined outcomes. Each patient completed a standardized validated patient-determined outcome questionnaire based on the Shoulder Rating Questionnaire [24] (Table 1). Each outcome was graded between 0 and 4 for statistical analysis.

Examiner-determined outcomes. Passive range of motion (abduction, forward flexion, internal and external rotation) was determined by visual inspection as described previously [25]. Strength data (internal and external rotation, supraspinatus, adduction and lift-off) were collected using a hand-held dynamometer (HFG-110; Transducer Techniques, Temecula, CA, USA) as described previously [26]. Patients were encouraged to exercise their full force against the dynamometer for 3 seconds. Each measurement was taken three times and the mean was calculated.

Table 1 Patient-determined outcomes (based on the Shoulder Rating Questionnaire) [24]

1. How often is your shoulder . . . : (always, daily, weekly monthly, never)
(a) Painful during activity?
(b) Painful when you sleep?
2. What is the level of your shoulder pain: (very severe, severe, moderate, mild, none)
(a) When you are resting?
(b) With activities above your head?
(c) When you sleep?
3. How 'stiff' is your shoulder? (very, quite, moderate, a little, not at all)
4. How much difficulty do you have: (very severe, severe, moderate, mild, none)
(a) When reaching behind your back?
(b) With activities above your head?
5. How is your shoulder overall? (very bad, bad, poor, fair, good)

Imaging assessment. Ultrasound investigations were performed using a General Electric Logiq E9 (GE Corporation, Sydney, NSW, Australia) with a 6-MHz and 15-MHz linear transducer, by an experienced sonographer (Lisa Hackett), in five out of five patients. The ultrasound technique is described elsewhere [27]. Coronal X-rays were taken in four of the five patients using a Hologic Insight Fluoroscan (Hologic, Inc., Bedford MA, USA).

Statistical analysis

Outcomes in the present study are reported as the mean ± SEM. Nonparametric patient-determined data were compared using Wilcoxon signed rank tests. Range of motion and strength data were compared using paired Student's *t*-tests. $p < 0.05$ was considered statistically significant.

RESULTS

Over the 10-year period, the senior investigator (GACM) performed six of rotator cuff repairs (four right, two left) with a synthetic patch, and the patch was used to bridge the defect of an otherwise irreparable rotator cuff tear. Five of the original six patients were followed up at a mean of 9.7 years postoperatively (SEM 1.4 years; range: 8.5 years to 11.8 years). The remaining one patient had died. For two of the five patients, the patch repair was performed as a revision surgery for a previously repaired tendon. The mean age of the patients at the time of follow-up was 70 years (SEM: 11 years; range: 57 years to 84 years). One patient had a superficial subcutaneous infection after the surgery. This was remedied by irrigation and debridement, and there was no communication with the underlying joint. No patient has had a re-repair of his or her rotator cuff tendon or any further surgery on their affected shoulder.

Table 2 Comparison of pre-operative range of motion measurements with 9.7 years (mean) postoperatively

Passive range of motion	Pre-operative (°) (mean ± SEM)	9.7 years postoperatively (°) (mean ± SEM)	*p*-value
Forward flexion	132 ± 22	176 ± 2	0.09
Abduction	131 ± 14	176 ± 2	0.02
External rotation	35 ± 6	70 ± 9	0.007
Internal rotation	L1 (two vertebral levels)	T12 (two vertebral levels)	0.93

Table 3 Comparison of pre-operative strength measurements with 9.7 years (mean) postoperatively

Shoulder strength	Pre-operative (N) (mean ± SEM)	9.7 years postoperatively (N) (mean ± SEM)	*p*-value
Internal rotation	74 ± 23	103 ± 23	0.11
External rotation	56 ± 19	69 ± 6	0.42
Supraspinatus	54 ± 29	44 ± 15	0.81
Lift-off	40 ± 10	70 ± 20	0.07
Adduction	75 ± 24	109 ± 14	0.15

Patient information

1. 60-year-old female, 4 cm × 6 cm tear, ePTFE (Gore-Tex) patch
2. 78-year-old male, 8 cm × 10 cm tear, PTFE (Bard Felt) patch
3. 57-year-old male, 3 cm × 3 cm tear, ePTFE (Gore-Tex) patch
4. 71-year-old male, 3 cm × 5 cm tear, ePTFE (Gore-Tex) patch
5. 83-year-old female, 4 cm × 2 cm tear, PTFE (Bard Felt) patch

Patient-determined outcomes

The most notable improvements were in patient-ranked level of pain with overhead activity, frequency of pain with activity and during sleep, and overall shoulder function. On average, patients ranked their pain with overhead activity and the frequency of pain with activity pre-operatively as being between severe and very severe, and occurring between daily and always. At a mean of 9.7 years postoperatively, patient-ranked pain with overhead activities was ranked as mild – none, and the frequency of pain with activities was between monthly and never. The frequency of patient-ranked pain with sleep diminished from between always and daily to between monthly and never. This was mirrored by patient-ranked overall shoulder function, which improved from between bad and poor, to between fair and good.

There were less marked improvements in the level of pain with rest and sleep, shoulder stiffness, and difficulty with overhead and behind the back activities.

Examiner-determined outcomes

Passive range of motion. Abduction (131° ± 14° to 176° ± 2°; $p = 0.02$) and external rotation (35° ± 6° to 70° ± 9°; $p = 0.007$) range of motion improved between pre-operatively and the 9.7-year (mean) postoperative follow-up (Table 2). An increase in forward flexion (132° ± 22° to 176° ± 2°) and internal rotation (L1 ± 2 vertebral levels to T12 ± 2 vertebral levels) did improve between these time points but did not reach statistically significance.

Strength. Pre-operative strength data was unavailable for two of the five patients. There were no significant differences in all shoulder strength (internal rotation, external rotation, supraspinatus, lift-off and adduction) between the pre-operative data and 9.7-year postoperative measurements (Table 3).

Imaging studies

At 9.7 years postoperatively, the patch material was identified by ultrasound in all patients. The repair was intact in four out of five patients. The patch to humerus interface was visualized in all five patients. The patch to tendon interface was visualized in four out of five patients. The tendon to patch interface could not be visualized in one patient. The patch was identified as an echogenic band. X-ray images were taken in four out of five patients. Proximal humeral head migration was noted in one out of the four patients. The same patient demonstrated moderately severe osteoarthritis of the glenohumeral joint and a lack of tendon-to-patch integrity on ultrasound.

DISCUSSION

The present study investigated the long-term viability of using synthetic materials to bridge defects in irreparable supraspinatus rotator cuff tears. At 9.7 years, patients had less severe pain with overhead activities, had less frequent pain with activities and during sleep, and had greater overall shoulder function compared to pre-operative measurements. Improvements in passive range of motion were observed for external rotation and abduction between pre-operatively and 9.7 years postoperatively.

Several other methods have been proposed as treatments for irreparable rotator cuff tears, each with varied success. Moore et al. investigated 28 patients who underwent a cadaveric tendon allograft reconstruction of an irreparable rotator cuff tear at a mean of 31 months postoperatively [13]. It was found that, despite outcome satisfaction in 23 of 28 patients, all 15 patients who had magnetic resonance imaging performed at that follow-up demonstrated complete failure of their repaired construct [13]. Extracellular matrices are another form of biological material used with mixed outcomes. Within our institution, four of 25 patients who underwent a rotator cuff repair with a porcine small intestinal submucosa implant developed an overt inflammatory reaction at a mean of 13 days postoperatively [11]. At 2 years postoperatively, patients with the xenograft had less strength, more impingement and a slower resolution of pain during activities compared to a control group [11]. Iannotti et al. compared the outcomes of repairing large or massive rotator cuff tears using porcine small intestinal submucosa augmentation (15 patients) with repairs that used no augmentation (15 patients) [15]. Four out of 15 patients

with augmentation demonstrated healing at 1 year postoperatively compared to nine of 15 who had no augmentation [15].

As far as we are aware, the present study is the longest retrospective investigation of patients who had undergone a rotator cuff repair with any type of interpositional material. Two previous short-term (43 months and 44 months) studies have investigated the outcomes of rotator cuff repairs with synthetic patches [16,17]. Hirooka et al. reviewed 27 patients at a mean of 44 months after a rotator cuff repair using Gore-Tex material to either bridge a defect or to augment a tendon repair [16]. The overall Japanese Orthopaedic Association score in their patients improved (from 58 points to 86 points; $p < 0.0001$). Pain scores improved most dramatically (from 9 points to 28 points; $p < 0.0001$). Within the present study, the level of pain with overhead activities went from between very severe and severe pre-operatively, to between mild and none after 9.7 years. The frequency of pain with activity and during sleep improved from between daily and always, to between monthly and never.

The results of the present study have been of sufficient merit such that we now use an arthroscopic version of this technique [28] for all irreparable rotator cuff tears providing that there is a good tendon edge to sew into and no arthropathy. A biomechanical study that we have performed in an ovine model suggests that tendon – ePTFE patch – bone repair provides more footprint contact pressure and fails at a much higher load than a tendon to bone repair [29]. A short-term (6 months) investigation within our institution compared the outcomes of arthroscopic repairs of massive rotator cuff tears using direct tendon to bone repairs (21 patients) with repairs that used a synthetic patch to bridge the tendon defect (eight using a multiple mattress suture repair technique [28] and eight using a newer weave method of patch-tendon attachment). At 6 months postoperatively, over 50% (11 out of 21) of patients who underwent a direct tendon to bone repair had a re-tear on imaging compared to 0% (0 out of 16) of patients whose repair was performed using a synthetic patch. Six months after surgery, the patch repair group (weave method) had better shoulder strength in abduction of the scapular plane and external rotation compared to the direct tendon to bone repair group [30].

A major limitation of the present study is the small sample size. A larger sample size would have provided us with a clearer understanding of the long-term outcomes, as well as whether or not some of the trends seen were indeed significant. The study design is a single cohort study and there is no group to compare our results with. A control group would have allowed us to determine whether the outcomes documented were a direct result of the patch repair, or the result of another factor such as the natural history of the disease process.

CONCLUSIONS

We have described the long-term (mean 9.7 years) outcomes of patients who had undergone a synthetic patch rotator cuff repair for an irreparable rotator cuff tear. At 9.7 years postoperatively, patients reported less severe and more infrequent pain, and greater overall shoulder function, compared to pre-operative measurements. Patients also had increased external rotation and abduction range of motion. All the patches remain *in situ* and there have been no further operations on these shoulders. The outcomes demonstrated in the present study suggest that this technique (or an arthroscopic version of it) may be a surgical option for the management of an otherwise irreparable rotator cuff tear.

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