Treatment of massive rotator-cuff tears with a polyester ligament (Dacron) augmentation

CLINICAL OUTCOME

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We describe the clinical outcome of a technique of surgical augmentation of chronic massive tears of the rotator cuff using a polyester ligament (Dacron) in 21 symptomatic patients (14 men, seven women) with a mean age of 66.5 years (55.0 to 85.0). All patients had MRI and arthroscopic evidence of chronic massive tears. The clinical outcome was assessed using the Constant and Murley and patient satisfaction scores at a mean follow-up of 36 months (30 to 46).

The polyester ligament (500 mm × 10 mm) was passed into the joint via the portal of Neviaser, medial to the tear through healthy cuff. The two ends of the ligament holding the cuff were passed through tunnels made in the proximal humerus at the footprint of the insertion of the cuff. The ligament was tied with a triple knot over the humeral cortex.

All the patients remained free from pain ($p < 0.001$) with improvement in function ($p < 0.001$) and range of movement ($p < 0.001$). The mean pre-operative and post-operative Constant scores were 46.7 (39.0 to 61.0) and 85.4 (52.0 to 96.0), respectively ($p < 0.001$). The mean patient satisfaction score was 90%. There were two failures, one due to a ruptured ligament after one year and the other due to deep-seated infection. The MR scan at the final follow-up confirmed intact and thickened bands in 15 of 17 patients.

This technique of augmentation gives consistent relief from pain with improved shoulder movement in patients with symptomatic massive tears of the rotator cuff.

Chronic massive tears of the rotator cuff are a surgical challenge¹⁻⁵ because they are associated with atrophy and fatty infiltration of the cuff⁶⁻⁸ and arthritis of the shoulder, thereby making reconstruction difficult.⁹ This disabling condition is associated with a poor prognosis. Conservative management, simple debridement and decompression, partial repairs, tendon transfers and reconstruction have been advocated with variable results.^{1-5,7,10-19} Although the outcome after attempted reconstruction remains uncertain,²⁰ the use of a synthetic graft may provide a means of redirecting forces across the shoulder.^{15,21}

Polyethylene terephthalate (Dacron Xiros, Leeds, United Kingdom), has a high tensile strength with linear stress-strain and can resist forces of up to 3000 N. It has been used successfully in ligament augmentation reinforcement systems (LARS; Corin group plc, Cirencester, United Kingdom).²² It is a non-resorbable, biocompatible material with little tissue irritability and has excellent affinity for bone and tendon. These properties are similar to those of polytetrafluoroethylene (Davol Inc., Warwick, United Kingdom) or Teflon which

has been used for repairs of the rotator cuff.²³ It is used to move the point of insertion of the tendon of supraspinatus laterally in massive tears in order to optimise the lever arm.²⁴

We describe a technique for reconstruction of massive rotator-cuff tears using Dacron to augment the repair and present the clinical outcome.

Patients and Methods

The prospective study included 21 symptomatic patients (14 men, seven women) with a mean age of 66.5 years (55.0 to 85.0) who had MRI evidence of massive tears of the rotator cuff. The mean duration of symptoms was for 20.8 months (6.0 to 48.0). The dominant limb was involved in 76% of cases (16 right, five left). Three patients had a previous repair which had failed.

The inclusion criteria were the presence of a full-thickness massive tear of the rotator cuff confirmed by MRI and intra-operative assessment, unacceptable pain and disability after failure of conservative treatment, a functional deltoid muscle, and compliance with a strict post-operative regime of rehabilitation. The exclusion criteria were cuff tear arthropathy

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©2010 British Editorial Society
of Bone and Joint Surgery
doi:10.1302/0301-620X.92B10.
24299 \$2.00

J Bone Joint Surg [Br]
2010;92-B:1397-402.
Received 17 December 2009;
Accepted after revision 2 June
2010

with stiffness, a history of infection, and any neurological condition affecting the function of the shoulder girdle.

Massive tears were defined as those involving ≥ 5 cm of the diameter and at least two of the four musculotendinous units.²⁵ All the patients had pain, but no stiffness. They had received conservative treatment for a minimum of six months including injection of steroid (40 mg of Depo-Medrone and 1% lignocaine) through a posterior approach, and physiotherapy. The response to injection varied from none to temporary relief for three months, but without improvement in function. They had also undergone a progressive strengthening programme, incorporating scapular stabilisation and active assisted, isometric and proprioceptive exercises. Manual therapy to facilitate movement was incorporated if required.

Imaging studies included plain radiography and MRI. The former was also used to exclude glenohumeral osteoarthritis and the latter was also performed at the final mean follow-up of 36 months (30 to 46). All the images were taken using a 1.5T Siemens MR scanner (Siemens Medical Solutions, Malvern, Pennsylvania) with a dedicated 16-channel shoulder coil. Proton-density fat-saturated images were obtained in the axial, parasagittal and coronal oblique plains along with T1 coronal/oblique turbo spin echo images. The mean slice thickness was 3 mm. All the pre- and post-operative MR scans were graded according to the system of Goutallier et al⁸ as follows: grade 0, normal; grade 1, muscle contains some fatty streaks; grade 2, fatty infiltration, but more muscle than fat; grade 3, fatty infiltration equal to muscle fibres; and grade 4, more fatty infiltration than muscle fibres.

The patients were informed that they would undergo a standard arthroscopic repair but if the edge of the rotator cuff could not be mobilised to its insertion then a mini-open Dacron ligament augmentation procedure would be performed. The study had ethical approval and the patients gave informed consent.

Operative technique. A band of polyester fibre mesh (Dacron) ligament (Xirox plc, Leeds, United Kingdom) 500 mm long and 10 mm wide was used for the augmentation (Fig. 1).

All the procedures were performed by the senior author (AMN) in the beach-chair position under general anaesthesia and/or interscalene block and with an intravenous injection of 750 mg of Cefuroxime. Arthroscopy was undertaken using standard posterior and lateral portals and the edge of the torn cuff identified. The subacromial space was decompressed. An attempt to bring the cuff to its insertion failed in all patients.

The incision at the lateral portal was extended superiorly from the tip of the acromion by approximately 5 cm. A deltoid split was carried out and the cuff was mobilised by blunt dissection. Curved artery forceps were introduced through healthy cuff tissues via the Neviaser portal in the notch between the posterior acromio-clavicular joint and the spine of the scapula. The Dacron ligament was grasped and withdrawn through this portal (Fig. 2a). A hook was introduced over the upper surface of the cuff and the upper

Fig. 1

Photograph of the Dacron ligament (500 mm $\times$ 10 mm).

aspect of the ligament was delivered through the lateral wound (Fig. 2b). Depending on the extent of the tear, the same procedure was repeated either through the Neviaser or anterosuperior portals to deliver the lower aspect of the ligament through the cuff from its inferior to superior surface (Figs 2c and 2d). The configuration should be such that both aspects of the ligament are situated at the middle of the torn cuff. The footprint of the insertion of the cuff was identified and two tunnels made with a 2.5 mm drill. Having tensioned the ligament, its two ends holding the cuff were passed through the tunnels using a snare. Keeping the arm in 20° to 30° of abduction, the ligament was tied securely over the humeral cortex (Fig. 2d). The remnant of the cuff was sutured to the flattened ligament to close the defect as much as possible and the resultant augmentation thereby bridged the gap between the edge of the cuff and its insertion. This prevented buttonholing of the humeral head and maximised the function of the deltoid muscle.

A polysling was used for five days and then intermittently for a maximum of two weeks. Active hand, wrist and elbow movements were instituted from the first day. Gentle active and passive shoulder mobilisation, including pendulum exercises, were started after five days and continued for the first six weeks. Scapular stabilisation exercises were begun after six weeks with gradual progression to resisted exercises. All mobilisation and exercises were performed within the pain-free range of movement (ROM).

Functional evaluation. The patients were evaluated pre-operatively by an experienced physiotherapist (CJ). Supraspinatus was weak in all cases. Pain, activities of daily living and movement, strength and function were assessed using the Constant-Murley score.²⁶ Pain was assessed using a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (severe). The active ROM of flexion and external rotation were assessed in multiple positions. Strength was tested manually and graded using a standard MRC five-

Fig. 2a

Fig. 2b

Fig. 2c

Fig. 2d

Diagram showing a) the Dacron ligament passed through the retracted rotator cuff via a supraspinatus portal (Nevaiser) using curved artery forceps, b) the upper aspect of the ligament is passed through the inferior and then superior surface of the rotator cuff using a hook through the lateral incision (not the same portal as in a), c) mobilisation of supraspinatus by constant tension on the ligament and the creation of two tunnels at footprint on the greater tuberosity and d) the ligament passed through the two bony tunnels while maintaining the tension on the rotator cuff. The two ends of the ligament are tied with a triple knot maintaining the tension in the rotator cuff.

point scale for muscle strength. The same physiotherapist supervised the rehabilitation programme.

The patients were seen at six, 12, 24 and 36 months post-operatively and the same outcome measures were used. The Constant scores were also calculated without the strength component. At the final follow-up, all the patients were scored subjectively for satisfaction on a four-point Likert scale²⁷ ranging from very satisfied, satisfied, somewhat satisfied to dissatisfied. Their work status was recorded.

Radiological assessment. A consultant musculoskeletal radiologist (DAR) was familiarised with the operative technique and independently assessed the MR scans. The scans of 17 patients were evaluated at the final follow-up to determine the integrity of the augmented cuff and the amount of fatty infiltration of the cuff muscles.

Two patients with multiple metal anchors in the humeral tuberosity were excluded because a severe artefact signal obscured the repair. In the other 15 scans, the augmented cuff had a low/intermediate signal on the proton density fat-saturated images, becoming almost black in most repairs, presumably because of progressive infiltration of collagen across the Dacron mesh. The fatty infiltration was visualised on the T2-weighted images.

Statistical analysis. The data were tested for normality before statistical analysis which was performed using

Student's *t*-test (SPSS version 15; SPSS Inc., Chicago, Illinois). A *p*-value ≤ 0.05 was considered to be significant.

Results

Pre-operatively, 16 patients (76.2%) had night pain and 19 (90.5%) described their pain as intolerable with a VAS > 7.0 . No patient had stiffness.

All but one had considerable relief from pain. The mean pain score improved from 7.0 pre-operatively to 1.0 post-operatively (Table I). Only two patients had occasional pain with overuse which was relieved by analgesics. There was also significant improvement in the mean scores for the activities of daily living, from 8.6 pre-operatively to 16.9 post-operatively (*t*-test, $p < 0.001$, Table I).

The mean active flexion improved from 65° (55° to 85°) pre-operatively to 120° (90° to 160°) post-operatively (Table I). The mean active abduction improved from 60° (50° to 70°) pre-operatively to 120° (90° to 140°) post-operatively and 18 patients could elevate forward beyond 105°. The mean external and internal rotation of the operated shoulder improved significantly (Table I).

The strength of abduction improved by at least one grade in all patients, allowing them to perform regular activities, with a few returning to leisure pursuits such as fishing and golf. A 60-year-old woman was able to return to playing

Table I. Pre- and post-operative mean Constant and Murley²⁶ scores

Score	Pre-operative	Post-operative	Mean difference	p-value
Total score (out of 100)	46.7 (39 to 61)	84.5 (52 to 96)	37.8	< 0.001
Score without strength (out of 75)	28.3 (21 to 35)	61.4 (32 to 71)	33.1	< 0.001
Pain	7.0 (5.0 to 8.0)	1.0 (0.0 to 2.0)	6	< 0.001
Activities of daily living	8.6 (7 to 11)	16.9 (15 to 20)	8.3	< 0.001
Active movement (°)				
Flexion	65 (55 to 85)	120 (90 to 160)	55	< 0.001
Abduction	60 (50 to 70)	120 (90 to 140)	60	< 0.001
External rotation	39 (30 to 50)	57 (30 to 70)	18	= 0.01
Internal rotation (score)	4.2 (4 to 6)	8.4 (6 to 10)	4.2	= 0.008
Abduction strength (score)	3.9 (3 to 5)	5.0	1.1	= 0.03

Fig. 3a

Fig. 3b

MR scans of the right shoulder of a 62-year-old woman showing a) pre-operatively (T2-weighted) the chronic massive tear and b) post-operatively at three years (proton density fat-saturated) the intact ligament reconstruction.

the violin professionally within four months of the operation. In 19 patients the mean overall Constant score improved significantly from 46.7 pre-operatively to 84.5 at the final follow-up. The overall results were excellent in 17 patients, good in two, fair in one and poor in one. The Constant scores were recalculated without the strength component (Table I). This made no difference to the final outcome. Subjectively, 19 (90%) were satisfied with the result and satisfaction correlated significantly with the post-operative Constant score (Spearman's correlation coefficient, $p = 0.001$). A better functional outcome was associated with a higher degree of satisfaction in all 19 patients. The two patients with metal anchors had high Constant scores and were satisfied with the outcome.

One patient with a previously failed repair did well for one year after the augmentation. He then returned with further symptoms. At arthroscopy, the Dacron ligament was torn. He underwent a further augmentation of the remaining rotator-cuff tissue with Dacron ligament. At two years follow-up, his pain had eased, but his ROM had not improved. This outcome was rated as fair.

A 55-year-old right-handed woman had deep-seated infection at the end of the first post-operative week. Arthroscopic wound irrigation and debridement did not

Table II. Grading of fatty degeneration on the pre-operative MR scan according to Goutallier et al⁸

Rotator cuff	Goutallier grade			
	1	2	3	4
Supraspinatus	0	9	5	1
Infraspinatus	0	8	6	1
Subscapularis	7	4	3	1

clear the infection and the ligament was removed, which allowed her wound to heal. No further reconstruction was undertaken and her result was poor.

Radiological findings. MRI was used to visualise the two bands of the augmented cuff and the persistent central defect between the bands. This was not misinterpreted as a failure of the reconstruction. In four patients the edge of the cuff was at the same site as in the pre-operative MR scan but in 11 it was at the crest of the curve of the humeral head (Fig. 3).

The pre-operative fatty degeneration of supraspinatus was grade 2 in nine patients, grade 3 in five and grade 4 in one (Table II). In the grade 2 group five patients remained unchanged post-operatively, three improved and one deteriorated. In the grade 3 group, four were unchanged and one improved and in the grade 4 group one improved. Therefore, the overall improvement in supraspinatus was by one grade in five patients.

The pre-operative fatty degeneration of infraspinatus was grade 2 in eight patients, grade 3 in six and grade 4 in one (Table II). In the grade 2 group four were unchanged post-operatively, one improved and three deteriorated. In the grade 3 group six remained unchanged and in the grade 4 group one remained unchanged. Therefore, most infraspinati (11 of 15, 73%) remained unchanged and three deteriorated. The degeneration in subscapularis was unchanged in 14 of 15 patients; in one it improved from grade 3 by one grade.

Clinicoradiological correlation. Most patients (8 of 9) with grade 2 fatty degeneration of supraspinatus had an excellent functional outcome. Although one showed

deterioration, it did not affect the final outcome. Although there was radiological improvement in the degeneration in the grade 3 group in only one patient, all five in this group had a clinically significant improvement in function ($p < 0.001$). The only patient in the grade 4 group who had radiological improvement also had a higher Constant score at the final follow-up. The radiological fatty degenerative changes in infraspinatus and subscapularis did not seem to influence the final clinical outcome.

Discussion

The natural history of massive tears of the rotator cuff is not known. A considerable proportion defy traditional techniques of repair or reconstruction and a number of operative techniques have been described for these irreparable tears with variable success.^{1,4-7} The results of repair have been reported to be good in many series with relief from pain in 90% of patients and restoration of function.^{1,10-12} The size of the tear has not been shown to be an indicator of patient satisfaction.²⁸

Autogenous grafts for reconstructing the tears have had a high rate of failure in both primary and revision operations.⁴ Autogenous tissues, such as fascia lata or other tendons, tend to wear and stretch. Carbon fibre,²⁹ patch grafting¹¹ and xenografts³⁰ have also been used unsuccessfully.

Ozaki et al¹⁵ presented the first series of patients treated with synthetic polyester grafts for massive tears. At the end of two years, 23 of 25 patients were pain free and had improved abduction of 120° to 160°. Two patients had an injury to the axillary nerve with poor results. No standardised scoring system was applied to evaluate their results. Ozaki et al¹⁵ suggested that Teflon felt and Marlex possess high tensile strength and low friction, and may be as thick as the rotator cuff when implanted. Kimura et al²³ also reported good results in 30 patients who had received Teflon felt grafts and in an experimental study involving the reconstruction of infraspinatus in dogs, they showed that these grafts improved their tensile strength over three months post-operatively.²³

The successful outcome after reconstruction with a Dacron ligament in our series suggests that these grafts can withstand loads during elevation and abduction. It is also known that collagen in bone and tendon bonds with synthetic polyester fibres.²³ The ligament has fibres 1 cm wide and a closed mesh to allow for collagen ingrowth, thereby increasing the stiffness and bonding.

Mura et al²¹ suggested that a synthetic graft can provide a way of redirecting force to the glenohumeral joint and Burkhart³¹ described the biomechanical rationale for repair of massive tears of the rotator cuff. He suggested that as long as the tear does not extend below the equator of the humeral head, the remainder of the cuff can maintain the head in the glenoid without superior translation and guide the shoulder in forward elevation by coupling with the deltoid. Therefore, intact deltoid function is a prerequisite for reconstruction or repair of the rotator cuff.

In our technique every effort was made to bring the cuff over the crest of the humeral head before tying the knot in tension. The two bands of the Dacron ligament prevented the head from buttonholing superiorly and allowed the shoulder to regain function.

The final follow-up MR scans suggested that 15 patients (88%) had the edge of the augmented cuff at the crest of the humeral head. Many clinical studies of open and arthroscopic techniques of repair of the rotator cuff have emphasised the importance of stable fulcrum kinematics and force coupling around the shoulder as important factors predicting outcome.³²⁻³⁴ The closure of the rent in the rotator cuff is not essential for re-establishing stable kinematics.³⁵ The favourable outcome in our series strengthens this concept.

The correlation between the clinical and MRI assessment confirmed that grade 3 and grade 4 fatty infiltration of supraspinatus did not influence the outcome after augmentation. Deterioration in infraspinatus progressed in a few patients without affecting the outcome. These results substantiated those of Goutallier et al.⁸ Although it is difficult to draw conclusions from the small number of patients, the MRI findings suggested that augmented repair prevented further deterioration of supraspinatus and subscapularis.

The failure of the repair of massive tears using suture techniques was studied prospectively by Boehm et al³⁶ who suggested that the weakness was at the tendon-suture interface, the thread and the suture-to-bone interface. In confirmed re-tears of the reconstructed rotator cuff, the use of non-absorbable sutures gave a poorer outcome than that with absorbable sutures, with lower Constant scores in the failed group (77% *vs* 94%).

Zumstein et al³⁷ used a transosseous technique of repair in all patients and found a re-rupture rate of 37% at three years and of 57% at follow-up at nine years. Our method of reconstruction was made easier by drilling two holes at the footprint of the rotator cuff which gave good anchorage for the knot on the outer side of the bone. The mean post-operative Constant score was 84.5 which was similar to that of Gerber et al.⁴ Rokito et al³⁸ found that at least one year was needed before the strength of the shoulder was restored after repair of large tears. In our series, improvement in abduction strength was observed in 90% of patients at one year but improved very little thereafter.

Re-rupture after repair of tears of the rotator cuff is due to the weak link of the reconstructed muscle-tendon-bone unit and failed osteofibroblastic integration.^{17,39} Reduced strength after failed repairs has been reported.³⁴ Scheibel et al¹⁷ described the functional outcome after reconstruction of the rotator cuff using an autologous periosteal flap and demonstrated a re-rupture rate of 20% as seen on follow-up MR scans. Hanusch et al¹⁸ noted that four of 24 patients (17%) had a re-tear as diagnosed by ultrasonograph. In our series, only one patient had a torn Dacron ligament and the follow-up MRI findings strengthened the concept of using Dacron mesh for aug-

menting the repair of chronic massive tears with subjective satisfaction scores of excellent or good in 90% of patients.

The strengths of our study include the description of a new technique, prospective collection of data, the availability of pre- and post-operative scores, involvement of an independent assessor and a final follow-up MR scan to assess the integrity of the repaired rotator cuff. There were some limitations. This was a single-centre study and all the operations were performed by the senior author. There was no control group and the number of patients was relatively small.

However, our findings indicate that polyester (Dacron) ligament augmentation can result in a pain free successful return of function in active symptomatic patients with massive chronic tears of the rotator cuff.

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