Treatment of massive rotator-cuff tears with a polyester ligament (LARS) patch

Michael J. Petrie, A. Hany Ismaiel

From Barnsley Hospital NHS Foundation Trust, Barnsley, South Yorkshire, UK

We describe and analyse the results of our technique for repairing chronic massive tears (Goutallier grade 3 or 4) of the rotator cuff using a ligament augmentation and reconstruction system. This prospective, single surgeon series included 29 symptomatic patients (21 male, 8 female) with a mean age of 67.1 years who underwent 31 ligament augmentation and reconstruction system procedures (two bilateral procedures) with a mean follow-up period of 3 years. All patients had clinical, radiographic, magnetic resonance imaging and arthroscopic evidence of a chronic massive rotator cuff tear. The primary outcome measure was assessed using the Oxford Shoulder Score and visual analogue score pre-operatively and at follow-up. Post-operative overall Oxford shoulder score and visual analogue score results demonstrated a statistically significant improvement at follow-up, compared with pre-operative values ($p < 0.0001$). Post-operative acromio-humeral interval showed a statistically significant increase when compared to pre-operative radiographs ($p = 0.0004$). Two patients required revision with good postoperative results. We believe that, in the appropriate age group, the ligament augmentation and reconstruction system repair offers a good option for chronic, primary, non-closable rotator cuff defects in terms of pain relief and function.

Keywords : shoulder ; rotator cuff repair ; LARS polyester ligament.

INTRODUCTION

Rotator cuff tears (RCT) are common disorders, largely affecting patients between 55 and 85 years of age, leading to shoulder pain and varying degrees of disability. The reported incidence of rotator cuff tears varies from 5 to 40% [1,8,22]. Tears may be partial thickness or full thickness and can be classified as acute or chronic [21,34]. In massive rotator cuff tears the concavity compression effect the supraspinatus exerts is lost thus the superiorly directed force of the deltoid results in superior migration of the humeral head [15,32]. The normal acromio-humeral (AH) interval has been described as between 7 and 14 mm, with massive rotator cuff tears resulting in a reduction in the AH interval, the one unequivocal sign on plain radiography [25,29,33].

■ Michael J. Petrie, MD, MBChB, MRCS (Ed), Orthopaedic Registrar.
■ A. Hany Ismaiel, MB BCh, FRCS, MSc(Orth).
Barnsley Hospital NHS Foundation Trust, Barnsley, South Yorkshire, UK.
Correspondence : Michael J. Petrie, Department of Orthopaedic Surgery, Barnsley Hospital NHS Foundation Trust, Gawber Road, Barnsley, South Yorkshire, UK, S75 2EP.
E-mail : Mike.petrie@doctors.org.uk
© 2013, Acta Orthopædica Belgica.

Full thickness rotator cuff tears are generally defined as massive when greater than 5 cm or the involvement of at least two musculotendinous units (most frequently supraspinatus and infraspinatus) with retraction of the torn rotator cuff to at least level with the joint line (*4,19*). Goutallier *et al* graded rotator cuff tears in terms of the extent of fatty infiltration, although this is based on CT imaging as opposed to magnetic resonance imaging (MRI), which is now the gold standard (*10,30*).

Treatment for rotator cuff tears varies from activity modification, non-steroidal anti-inflammatory medications and corticosteroid injections (*5*), operative procedures of simple debridement, decompression and excision, to RCT repair, tendon transfers and reconstruction (*1,3,9,24*). Since the introduction of rotator cuff tendon repair, surgical techniques have rapidly advanced and yield good clinical results of pain relief and improved function (*11,12,14, 16,17,18,28,35*). The goal of treatment is to decrease pain and restore overhead function of the affected shoulder (*11,13*).

In an effort to improve healing rates and reinforce the deficient rotator cuff tissue while maintaining the anatomic integrity of the shoulder, the Ligament Augmentation and Reconstruction System (LARS) was developed. It has previously been successfully described in knee ligament reconstruction (*7*). The graft joins subscapularis and infraspinatus to depress the humeral head and also rejoins the "stump" of supraspinatus to the greater tuberosity.

The purpose of our study is to assess the effectiveness of surgical repair with the LARS (Ligament Augmentation & Reconstruction System) in patients with massive RCT.

PATIENTS AND METHODS

We report our prospective cohort study of a single surgeon (HI) series of LARS graft repair for massive RCT. The inclusion criteria were the presence of a symptomatic, full-thickness, massive RCT clinically and radiologically, defined as a Goutallier grade 3 or 4 tear (*10*) on MRI that was not amenable to primary arthroscopic repair. Any patients over the age of 75 with arthritis of the shoulder underwent an arthroplasty procedure if indicated.

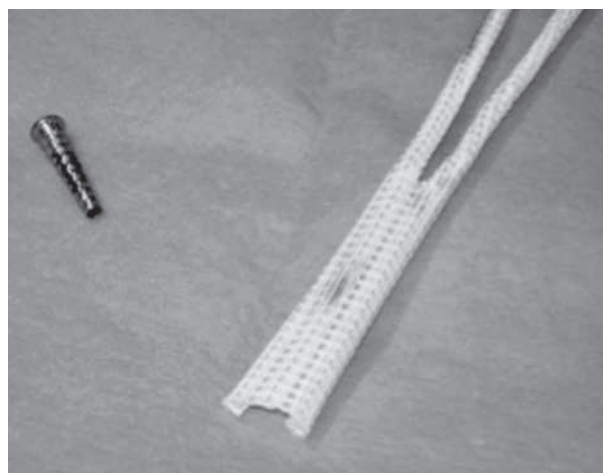We have performed 53 graft repairs on 50 consecutive, symptomatic patients (one bilateral and two revision

Fig. 1. — The LARS graft for rotator cuff repair with the fixation screw.

procedures) since 2006. Seventeen of 50 patients have been excluded as they are yet to reach at least 2 years follow-up with a further 5/50 patients lost to follow-up. Our final data set included 28 patients who underwent 31 LARS graft repair operations (one bilateral and two revision procedures). There were 21 male and 8 female patients with an average age of 67.2 years and a mean follow-up period of 3 yrs 4 mths (range 2-6 yrs).

The primary outcome measure was symptomatic and functional improvement, evidenced by a statistically significant decrease in the Oxford Shoulder Score (OSS) (*6*) and visual analogue score (VAS). Secondary outcome was based upon a radiological assessment, evidenced as an increase in the AH interval. The data was analysed for statistical significance using the Student *t*-test with a p value < 0.05 deemed statistically significant.

Operative Technique

The surgeon (HI) performed all the procedures using the LARS graft for the augmentation (LARS, Arc sur Tille, France) (Fig. 1). Glenohumeral and subacromial arthroscopy, decompression and acromioclavicular joint excision was initially performed and the edges of the torn cuff were identified. Long head of biceps tenodesis was performed if grossly degenerate. Primary repair was attempted if the retracted tendon edge was of adequate quality so that sutures did not pull through and could be advanced to allow a tension-free repair. An open approach was utilised for the rotator cuff graft. The foot print area was freshened using arthroscopic rasps and
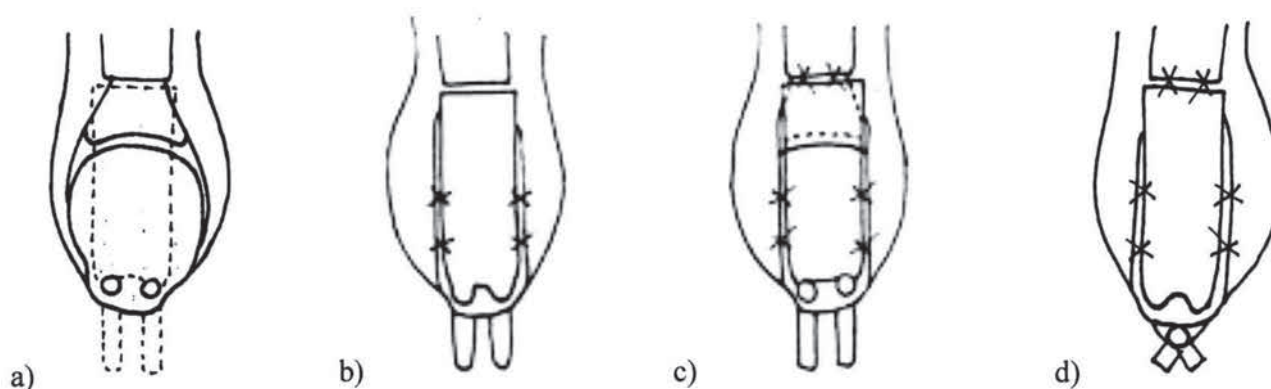
Fig. 2. — Diagrams illustrating staged repair a) Creation of two tunnels at the footprint on the greater tuberosity, b) Initial sutures of graft to subscapularis and infraspinatus, c) Completion of suturing the graft to the cuff, d) Securing the LARS graft by tying the 2 legs.

two drill holes were inserted to exit from the lateral surface of the humeral head. The LARS was then introduced into the foot print area with the legs of the graft inserted via the two bony tunnels through the head of the humerus. The graft was secured with fibre-wire sutures anteriorly and posteriorly to the subscapularis and infraspinatus tendons respectively (Fig. 2) and restoration of the subacromial space was observed. The free medial edge of the graft was then sutured to the stump of the supraspinatus if within reach. The graft was secured with interference screws and the two legs were sutured to each other.

Post-operatively patients were put in a shoulder immobiliser with only pendular shoulder exercises allowed but full active movement distally encouraged. All patients followed a physiotherapy protocol on both an inpatient and outpatient basis with active assisted abduction allowed from 6 weeks and strengthening delayed for a further 4 to 6 weeks.

All patients were seen in clinic at two weeks postoperatively for a wound check and removal of sutures. An independent assessor examined each patient, a functional assessment was made and OSS was completed at 4 and 24 months postoperatively. Pre- and post-operative radiographs were compared and the AH interval measured. Post-operative magnetic resonance imaging was obtained on most of the patients in the series. The postoperative scans of the patients who had metal anchors showed significant artefact signal obscuring the repair.

RESULTS

The average overall OSS improved from 46.7 preoperatively to 30.6 at follow-up, an improve-

ment of 16, ranging from -15 to 35 ($p < 0.0001$, 95% CI +/- 4.60).

The greatest improvement was noted as a reduction in the worst pain experienced from the shoulder with a mean OSS of 2.5, compared to 4.4 preoperatively ($p < 0.0001$, 95% CI +/-0.50).

Table I presents the mean pre and post-operative score for each of the 12 OSS questions, with statistically significant improvement in all areas.

VAS also improved from a mean of 7.7 to 4.4 post-operatively ($p < 0.0001$, 95% CI 0.96).

The AH interval was also measured in 26/31 (84%) cases with a statistically significant increase in the distance from a mean of 3.5 to 6.9 mm post-operatively ($p = 0.0004$, 95% CI +/-1.6).

Two patients required revision procedures, as they did not receive symptomatic relief post-operatively. At revision of one patient only a small stump and the two legs of the graft were found with the rest of the graft having disintegrated. A new LARS graft was inserted with the patient experiencing a good post-operative recovery with symptom relief and outcome results that matched the rest of our patient population.

The second patient developed a stiff symptomatic shoulder and had two procedures that included arthrolysis, replacement and re-suturing of the LARS with similar post-operative outcomes.

There were no cases of infection in our series of rotator cuff grafts. One patient underwent successful, uncomplicated LARS graft procedure following

Table I. — Statistics for the Oxford Shoulder Score (OSS), visual analogue score and Acromio-Humeral Interval

Parameter	Mean A	Mean B	P Value	0.95 CI
Worst Shoulder pain	4.4	2.5	< 0.0001	+/-0.50
Able to brush/comb hair	4.1	3.3	0.002	+/-0.55
Trouble dressing	3.6	2.5	< 0.0001	+/-0.52
Describe usual shoulder pain	4.5	2.5	< 0.0001	+/-0.55
Trouble getting in car/transport	3.3	2.0	0.0001	+/-0.57
Able to hang clothes	4.3	3.6	0.014	+/-0.58
Able to use knife and fork	3.1	1.8	< 0.0001	+/-0.47
Able to wash/dry underarms	3.5	2.1	< 0.0001	+/-0.55
Household shopping alone	3.8	2.7	= 0.0007	+/-0.68
Pain affected work	4.0	2.6	< 0.0001	+/-0.50
Carry tray of food	3.9	2.7	= 0.0001	+/-0.58
Troubled by pain at night	4.2	2.4	< 0.0001	+/-0.59
Overall OSS	46.7	30.6	< 0.0001	+/-4.60
Visual Analogue Score	7.7	4.4	< 0.0001	+/- 0.96
Acromio-Humeral Interval	3.5 mm	6.87 mm	0.0004	+/-1.6

an infected arthroscopic primary cuff repair after adequate debridement and antibiotic therapy.

DISCUSSION

It has been suggested that repair with a synthetic graft can redirect the mechanical forces into the glenohumeral (GH) joint with restoration of shoulder biomechanics (23,26). As previously described, massive tears disrupt the anatomical mechanics, as shown by both symptomatic expression and radiographic evidence of superior humeral migration. This alters the centre of rotation of the humeral head and decreases the mechanical force of the deltoid and rotator cuff (31). The LARS graft restores the anatomical shoulder mechanics by bringing the subscapularis and infraspinatus superiorly and securing them to the anterior and posterior borders of the graft respectively. This alters the direction of the mechanical vector of both the infraspinatus and subscapularis from medial to inferomedial, thereby contributing to both inferior and concavity compression. This restores the GH articulation and the anatomical centre of rotation of the head. If possible, the graft also reconnects the stump of supraspinatus to the greater tuberosity, assisting in

inferior displacement of the head. The combination of effects results in a restoration of the AH interval as evidenced on postoperative radiographs (Fig. 3) (2, 15,25,27,29,32,33).

Nada *et al* published their series of 21 patients treated with a polyester (Dacron) ligament. This study showed that augmentation gave a statistically significant improvement in both pain and function (24). Burkhead *et al* present their series of 17 patients who sustained a massive RCT treated with open repair and augmented with Graft jacket. They show an improvement in pain and function and statistically significant improvement in UCLA scores. They also comment on the difficulty in obtaining post-operative imaging. One-third of their patients either refused further imaging or the authors faced "logistical difficulties", hence, were unable to make claims of structural improvement (3). Meyer *et al* evaluated the use of MRI in assessing clinical and anatomical outcome following arthroscopic rotator cuff repair. They discovered that MRI showed low rates of tendon to bone healing following repair but that this had minimal influence on clinical outcome (20).

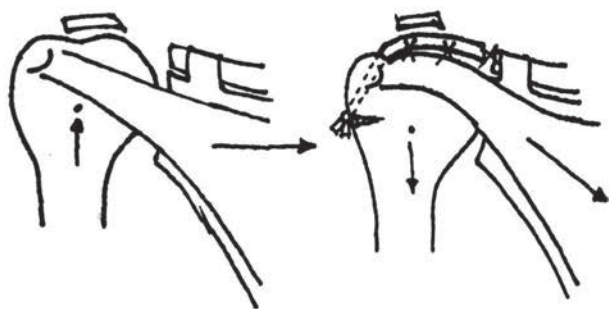The results from our study show that the LARS augmentation provides statistically significant

Fig. 3. — Restored mechanics of the rotator cuff after LARS insertion.

short-term improvement in pain and function, with an increase in the AH interval post-operatively. The results reinforce current published literature with greater patient numbers and extended follow-up (*3,20,24*).

The strengths of our study, which to our knowledge is the largest series in international literature, includes prospective data collection, the use of functional questionnaires, the involvement of an independent clinical assessor and a minimum follow-up period of 2 years.

The limitations include the absence of a control group. Not all patients received further imaging to assess repair integrity and this was a single-centre study with all procedures performed by a single surgeon.

Our findings indicate that the LARS repair can result in significant symptomatic and functional improvement in active, symptomatic patients with massive tears of the rotator cuff.

Acknowledgement

REFERENCES

1. **Arroyo JS, Flatlow EL.** Management of rotator cuff disease : intact and repairable cuff. In : Iannotti J, Williams G (eds). *Disorders of the Shoulder : Diagnosis and Management*. Lippincott, Williams & Wilkins, Philadelphia.1999 ; chapter 2 ; 31-56.

2. **Burkhart SS.** Reconciling the paradox of rotator cuff repair versus debridement : A unified biomechanical ratio-nale for the treatment of rotator cuff tears. *Arthroscopy* 1994 ; 10 : 4-19.

3. **Burkhead WZ, Schiffern SC, Krishnan SG.** Use of Graft Jacket as an augmentation for massive rotator cuff tears. *Seminars in Arthroplasty* 2007 ; 18 : 11-18. doi :10.1053/j.sart.2006.11.017

4. **Cofield RH.** Subscapular muscle transposition for repair of chronic rotator cuff tears. *Surg Gynecol Obstet* 1982 ; 154 : 667-672.

5. **Dalton SE.** The conservative management of rotator cuff disorders. *Br J Rheumatol* 1994 ; 33 : 663-667.

6. **Dawson J, Fitzpatrick R, Carr A.** Questionnaire on the perceptions of patients about shoulder surgery. J Bone Joint Surg 1996 ; 78-B : 593-600.

7. **Dominkus M, Sabeti M, Toma C *et al.*** Reconstructing the extensor apparatus with a new polyester ligament. *Clin Orthop Relat Res* 2006 ; 453 : 328-234. doi :10.1097/01.blo.0000229368.42738.b6

8. **Ecklund KJ, Lee TQ, Tibone J, Gupta R.** Rotator cuff tear arthropathy. *J Am Acad Orthop Surg* 2007 ; 15 : 340-349.

9. **Gerber C , Maquieira G , Espinosa N.** Latissimus dorsi transfer for the treatment of irreparable rotator cuff tears . *J Bone Joint Surg* 2006 ; 88-A : 113-120.

10. **Goutallier D, Postel JM, Bernageau J, Lavau L, Voisin MC.** Fatty muscle degeneration in cuff ruptures : pre and post-operative assessment by CT scan. *Clin Orthop Relat Res* 1994 ; 304 : 78-83.

11. **Hanusch BC, Goodchild L, Finn P, Rangan A.** Large and massive tears of the rotator cuff : functional outcome and integrity of the repair after a mini-open procedure. *J Bone Joint Surg* 2009 ; 91-B : 201-205.

12. **Iannotti JP.** Full-thickness rotator cuff tears : factors affecting surgical outcome *J Am Acad Orthop Surg* 1994 ; 2 : 87-95.

13. **Iannotti JP, Bernot MP, Kuhlman JR, Kelley MJ, Williams GR.** Postoperative assessment of shoulder function : A prospective study of full-thickness rotator cuff tears. *J Shoulder Elbow Surg* 1996 ; 5 : 449-457.

14. **Iannotti JP , Codsi MJ , Kwon YW *et al.*** Porcine small intestine submucosa augmentation of surgical repair of chronic two-tendon rotator cuff tears (A randomized, controlled trial). *J Bone Joint Surg* 2006 ; 88-A : 1238-1244.

15. **Itoi E, Kuechle DK, Newman SR, Morrey BF, An KN.** Stabilising function of the biceps in stable and unstable shoulders. *J Bone Joint Surg* 1993 ; 75-B : 546-550.

16. **Jost B, Zumstein M, Pfirrmann CWA, Gerber C.** Long-term outcome after structural failure of rotator cuff repairs. *J Bone Joint Surg* 2006 ; 88-A : 472-479. doi :10.2106/JBJS.E.00003

17. **Kim KC, Shin HD, Lee WY.** Repair integrity and functional outcomes after arthroscopic suture-bridge rotator cuff repair. *J Bone Joint Surg* 2012 ; 94-A : 481-486.

18. **Lichtenberg S, Liem D, Magosch P, Habermeyer P.** Influence of tendon healing after arthroscopic rotator cuff repair on clinical outcome using single-row Mason-Allen

suture technique : a prospective, MRI controlled study. *Knee Surg Sports Traumatol Arthrosc* 2006 ; 14 : 1200-1206. DOI : 10.1007/s00167-006-0132-8

19. **Mellado JM, Calmet J, Olona M** *et al.* Surgically repaired massive rotator cuff tears : MRI of tendon integrity, muscle fatty degeneration, and muscle atrophy correlated with intraoperative and clinical findings. *AJR Am J Roentgenol* 2005 ; 184 : 1456-1463.

20. **Meyer M, Klouche S, Rousselin B** *et al.* Does arthroscopic rotator cuff repair actually heal ? Anatomic evaluation with magnetic resonance arthrography at minimum 2 years follow-up. *J Shoulder Elbow Surg* 2012 ; 21 : 531-536. doi : 10.1016/j.jse.2011.02.009.

21. **Miniaci A, Salonen D.** Rotator cuff evaluation : imaging and diagnosis. *Orthop Clin North Am* 1997 ; 28 : 43-58.

22. **Moosmayer S, Smith HJ, Tariq R, Larmo A.** Prevalence and characteristics of asymptomatic tears of the rotator cuff : an ultrasonographic and clinical study. *J Bone Joint Surg* 2009 ; 91-B : 196-200.

23. **Mura N, O'Driscoll SW, Zobitz ME, Heers G, An KN.** Biomechanical effect of patch graft for large rotator cuff tears : a cadaver study. *Clin Orthop Relat Res* 2003 ; 41 : 131-138. doi :10.1097/01.blo.0000092967.12414.4c

24. **Nada AM, Debnath UK, Robinson DA, Jordan C.** Treatment of massive rotator-cuff tears with a polyester ligament (Dacron) augmentation : clinical outcome. *J Bone Joint Surg* 2010 ; 92-B : 1397-1402. doi :10.1302/0301-620X.92B10.24299

25. **Nové-Josserand L, Edwards TB, O'Connor DP, Walch G.** The acromiohumeral and coracohumeral intervals are abnormal in rotator cuff tears with muscular fatty degeneration. *Clin Orthop Relat Res* 2005 ; 433 : 90-96. doi :10.1097/01.blo.0000151441.05180.0e

26. **Ozaki J, Fujimoto S, Masuhara K, Tamai S, Yoshimoto S.** Reconstruction of chronic massive rotator cuff tears with synthetic materials. *Clin Orthop* 1986 ; 202 : 173-183.

27. **Parsons IM, Apreleva M, Fu FH, Woo SL.** The effect of rotator cuff tears on reaction forces at the glenohumeral joint. *J Orthop Res* 2002 ; 20 : 439-446. doi :10.1016/S0736-0266(01)00137-1

28. **Rokito AS, Cuomo F, Gallagher MA, Zuckerman JD.** Long-term functional outcome of repair of large and massive chronic tears of the rotator cuff. *J Bone Joint Surg* 1999 ; 81-A : 991-997.

29. **Saupe N, Pfirrmann CWA, Schmid MR** *et al.* Association between rotator cuff abnormalities and reduced acromiohumeral distance. *AJR Am J Roentgenol* 2006 ; 187 : 376-382. doi :10.2214/AJR.05.0435

30. **Sclamberg SG, Tibone JE, Itamura JM, Kasraeian S.** Six-month magnetic resonance imaging follow up of large and massive rotator cuff repairs reinforced with porcine small intestinal submucosa. *J Shoulder Elbow Surg* 2004 ; 13 : 538-541. doi :10.1016/j.jse.2004.03.005

31. **Soslowsky LJ, Carpenter JE, Bucchieri JS, Flatow FL.** Biomechanics of the rotator cuff. *Orthop Clin North Am* 1997 ; 28 : 17-30.

32. **Warner JJP, McMahon PJ.** The role of the long head of the biceps brachii in superior stability of the glenohumeral joint. *J Bone Joint Surg* 1995 ; 77-A : 366-372.

33. **Weiner DS, Macnab I.** Superior migration of the humeral head : a radiological aid in the diagnosis of tears of the rotator cuff. *J Bone Joint Surg* 1970 ; 52-A : 524-527.

34. **Wolf BR, Dunn WR, Wright RW.** Indications for repair of full- thickness rotator cuff tears. *Am J Sports Med* 2007 ; 35 : 1007-1016. DOI : 10.1177/0363546506295079

35. **Zumstein MS, Jost B, Hempel J, Hodler J, Gerber C.** The clinical and structural long-term results of open repair of massive tears of rotator cuff. *J Bone Joint Surg* 2008 ; 90-A : 2423-2431.