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Challenges and opportunities in trauma research: study designs and patient-reported outcome measures

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PART 2

PATIENT-REPORTED OUTCOME MEASURES

CHAPTER 7

Surgical treatment of acute and chronic AC joint dislocations:
five-year experience with conventional and modified LARS
fixation by a single surgeon

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Abstract

Background

Different surgical fixation methods are available for the treatment of acromioclavicular (AC) joint dislocations. The aim of this study was to present the results of five years of experience with the Ligament Augmentation and Reconstruction System (LARS) fixation technique by a single surgeon.

Methods

A single-center retrospective cohort study was performed. All patients treated for an AC joint dislocation with LARS fixation by the same surgeon between 2012 and 2016 (n=20) were eligible for inclusion. All these dislocations were unstable injuries, Rockwood type-III or higher, requiring acute or chronic repair. The primary outcome was the QuickDASH score. Secondary outcomes were the Subjective Shoulder Value (SSV), Numerical Rating Scale (NRS) pain score, return to work, complications, and implant removal.

Results

17 patients (85%) were available for final follow-up. The median follow-up was 23 months (IQR; 17–34). The median QuickDASH score was 7 (IQR; 2–18), the median SSV was 90 (IQR; 80–90), and the median NRS pain score was 2 (IQR; 1–3). Patients returned to work after a median of 8 weeks (IQR; 6–12). There was no significant difference in functional outcome scores between acute and chronic repair, or between the conventional and modified LARS fixation groups. There were two major complications requiring revision surgery, one ruptured LARS ligament and one case of deep wound infection. Implant removal was performed in one patient.

Conclusion

The LARS ligament fixation technique seems to be effective for the treatment of AC joint dislocations, resulting in good short- and mid-term patient-reported functional outcome. LARS fixation might also be an acceptable treatment option for active patients with symptomatic chronic AC dislocations.

Introduction

Dislocation of the acromioclavicular (AC) joint is a frequently encountered injury, with an incidence of 8.9/100,000 per year and most common in the young to middle-aged population.¹ Furthermore, dislocation of the AC joint represents 9% of injuries in the shoulder region.²

AC joint dislocations can be classified according to the Rockwood classification based on the relation to the coracoclavicular (CC) ligament, the deltoid muscle, the trapezius muscle and the direction of dislocation. The Rockwood classification consist of six types, from minor subluxation to complete dislocation. The less severe Rockwood type-I or II AC dislocation are incomplete separations with an intact CC ligament, and generally treated conservatively. The optimal treatment of the most common AC joint dislocation, Rockwood type-III, remains unclear. The Rockwood type-III dislocation involves tears of both the AC and CC ligaments, with 25% to 100% displacement compared with the contralateral side. Operative treatment is recommended for Rockwood type-IV, V, and VI due to severe dislocation and >100% displacement compared with the contralateral side.²⁻⁷ However, the management of AC joint dislocations also depends on a variety of factors, including the patient's level of activity and age.⁷

Different surgical fixation methods are available for the treatment of AC dislocations. However, no consensus has been reached regarding the optimal fixation method. In general, the operative management includes repair of the AC ligament, CC ligament repair or rigid internal fixation of the AC joint.⁵⁻⁷

The use of rigid fixation methods is commonly used for the treatment of AC dislocations. However, these implants have been related to complications such as implant irritation, implant dislocation, implant migration and loss of reduction. Moreover, implant removal is often required due to implant-related complications and impingement syndrome.^{5,8}

Several synthetic ligament devices such as PDS, the Gore-Tex, Dacron, Tightrope system, carbon fiber and Mersilene tape have been used to overcome the shortcomings of rigid implants.^{5,6,8} Complications related to the use of these synthetic devices include ligament failure, incomplete reduction, foreign body reaction, bony erosion, coracoid fractures, and clavicle fractures.⁸

The Ligament Augmentation and Reconstruction System (LARS) is a more recently developed artificial ligament. The LARS fixation act as a non-rigid and extra-articular reinforcement, allowing stabilization and reduction of the CC ligament. The LARS artificial ligament is composed of industrial strength polyester fibers, providing superior strength to the original CC ligaments.⁷

The mid-term results after the use of LARS fixation for the treatment of acute and chronic AC joint dislocations have not been widely studied. The aim of this study was to present five years of experience with the conventional and modified LARS fixation technique by a single surgeon, evaluating functional outcome scores, return to work, and complications.

Methods

Study design

Approval was granted by the Institutional Review Board and informed consent was obtained from all subjects. A retrospective cohort study was performed using data from a level II trauma center. All patients with AC joint dislocations who were treated with LARS fixation by the same surgeon between 2012 and 2016 were eligible for inclusion. Inclusion criteria were: (1) unstable AC joint dislocation, (2) acute and chronic repair, (3) age 18 years or older, (4) LARS fixation, (5) minimum of six months' follow-up, and (6) operated by a single surgeon. Acute repair was defined as AC dislocation treated within eight weeks of injury. Chronic was defined as persisting AC dislocation requiring repair more than eight weeks following injury, despite nonoperative treatment. Data collection was performed by reviewing electronic medical records, operative reports, radiology reports and telephone interviews by an independent research fellow. Electronic medical records were reviewed to collect the following baseline characteristics: age, gender, trauma date, trauma mechanism, time from injury to fixation, Rockwood classification, surgical indication, complications and revision surgery.

Surgical procedure

Operations were performed under general anesthesia with the patient placed in a beach chair position. An incision was made over the AC joint using a sagittal incision. The deltoideus and trapezius muscles were detached from the lateral clavicle. The AC joint was exposed, after which debridement of fibrotic tissue was performed. If necessary, the lateral end of the clavicle was resected to allow adequate anatomical reduction. A guide wire was used to place a LARS ligament

around the base of the coracoid process. Two bony tunnels were drilled through the superior clavicle. A 4-mm hole was drilled from craniodorsal to caudoventral through the clavicle, lateral from the coracoid. Medial from the coracoid, a 4.5mm hole was drilled through the clavicle from cranioventral to caudodorsal. The LARS ligament was fixated in the lateral clavicle drill-hole with an interference screw. Subsequently, reduction was performed under direct visualization by putting the LARS ligament under tension. Following adequate reduction, the medial clavicle site was also fixated with an interference screw. From 2015 onwards, a modified LARS fixation technique was used.⁹ Following the fixation with interference screws, excess ligament was passed around the coracoid a second time medial from the coracoid. The LARS ligament was then fixated with a figure eight knot and secured with fiber wire (Figure 1). AC joint reduction and screw placement were checked under fluoroscopic guidance. Finally, the m. deltoideus muscle was reinserted to the lateral clavicle and the fascia was closed in layers.

Postoperative management

Patients were immobilized in a sling for four weeks postoperatively. During this period patients were allowed early active mobilization and performed daily shoulder pendulum exercises. Weight-bearing activities and resisted exercises were not permitted until approval from the treating surgeon. Follow-up visits with control radiographs were scheduled after four weeks (Figure 2), after which patients could start with resisted exercises and physiotherapy. Removal of the LARS ligament and interference screws was not routinely performed.

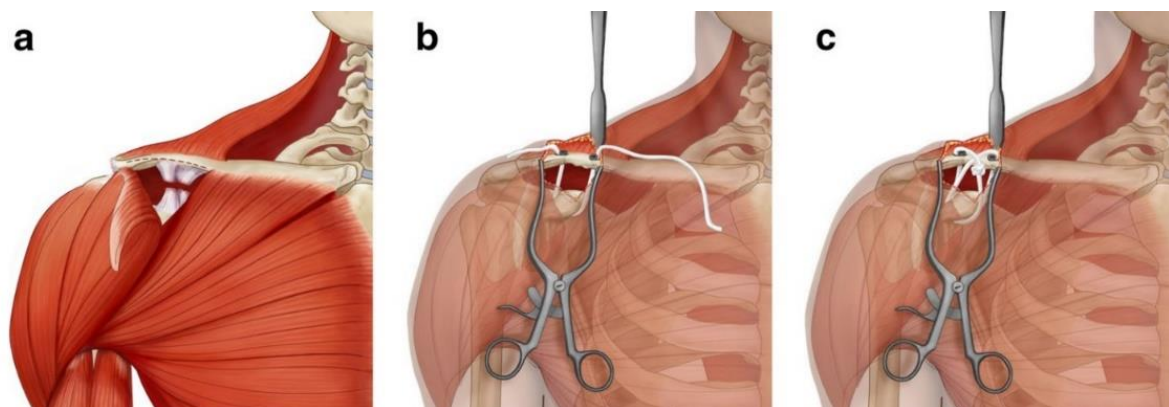


Figure 1. Surgical technique for modified acromioclavicular joint reconstruction with LARS ligament. **A.** Opened trapeziusdeltoid fascia. **B.** Clavicle reduction and LARS fixation on the clavicle. **C.** Figure of eight reconstruction.

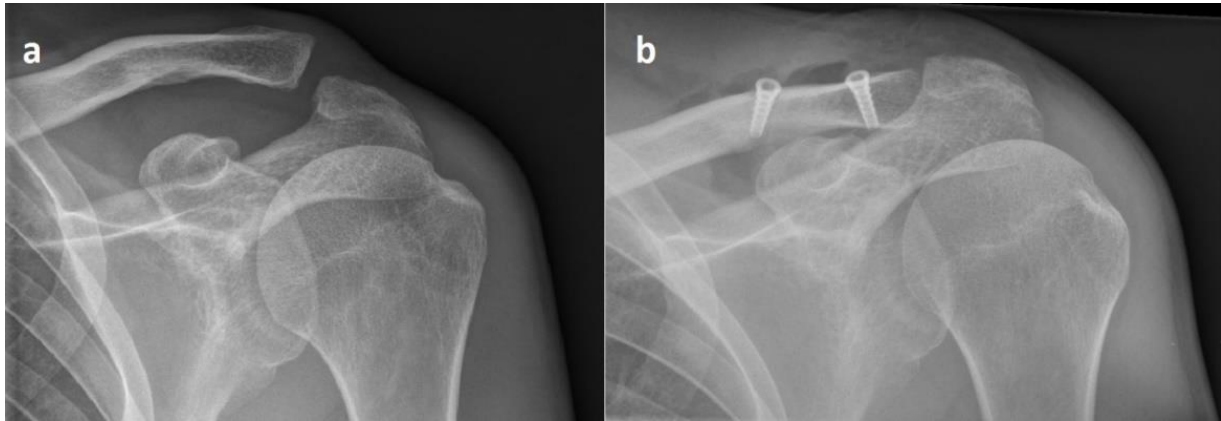


Figure 2. **A.** Anteroposterior view of an acromioclavicular dislocation Rockwood type-III. **B.** Anteroposterior view after coracoclavicular ligament repair with a LARS ligament.

Evaluation

Outcomes were assessed at least 6 months following LARS fixation using the QuickDASH score, Subjective Shoulder Value (SSV), Numerical Rating Scale (NRS) pain score and return to work. The QuickDASH is a validated and shortened version of the Disabilities of the Arm, Shoulder and Hand questionnaire (DASH). The QuickDASH is a patient-reported outcome instrument developed to measure upper extremity disability and symptoms, resulting in a score ranging no disability (0) to most severe disability (100).^{10,11} The SSV is a subjective value for shoulder function expressed as a percentage of an uninjured shoulder, which would score 100%.^{12,13} The NRS is a 11-point scale to measure pain intensity, ranging from no pain (0) to worst imaginable pain (10).¹⁴ Return to work was defined as the duration in weeks before resuming work.

Statistical analysis

Descriptive results are presented as mean values with standard deviations and range (SD, range), median values with interquartile range (IQR) or absolute numbers and percentages (%).

Continuous variables were evaluated using the Mann–Whitney U test. The significance level was defined as a p value <0.05. All statistical analyses were performed using STATA 13.1 (StataCorp LP, TX, USA).

Results

Study population

In total, 20 patients met the inclusion criteria. Two patients could not be contacted, and one patient was not able to answer the questions due to progressive dementia. Resulting in the

Table 1. Baseline characteristics (n=20)

	n (%)
Age [mean, SD]	46 (18)
Gender	
Male	17 (85)
Female	3 (15)
Side injury	
Right	8 (40)
Left	12 (60)
Trauma mechanism	
Sports-related	7 (35)
Bicycle accident	5 (25)
Motor vehicle accident	5 (25)
Fall	3 (15)
Rockwood classification	
III	11 (55)
IV	6 (30)
V	3 (15)
Indication for surgery	
Persistent or progressive pain	12 (60)
Rockwood classification	7 (35)
Patient's request	1 (5)
Repair	
Acute	9 (45)
Chronic	11 (55)
LARS fixation technique	
Conventional	14 (70)
Modified	6 (30)
Follow up in months [median, IQR]	23 (18-34)
n number; SD standard deviation; IQR interquartile range	

Table 2. Distribution of Rockwood types according to timing of repair

Rockwood classification	Acute (n=9)	Chronic (n=11)
III	2 (22%)	9 (82%)
IV	5 (56%)	1 (9%)
V	2 (22%)	1 (9%)
n number		

inclusion of 17 patients (85%) for follow-up. The mean age was 46 years (SD 18, range 17-80) and 17 patients (85%) were male (Table 1). In most cases, patients sustained the shoulder injury in a sports-related accident (35%). Eleven patients (55%) sustained an AC dislocation Rockwood type-III, six patients (30%) a Rockwood type-IV, and three patients (15%) a Rockwood type-V. The main indication for operative treatment was persistent or progressive shoulder pain (60%). Acute LARS repair was performed in nine patients (45%). Conventional LARS fixation was performed in 14 patients (70%) and six patients (30%) were treated with the modified LARS fixation technique. The median follow-up was 23 months (IQR; 17–34). The distribution of Rockwood classification and timing of repair is provided in Table 2.

Functional outcome

The median QuickDASH score at final follow-up was 7 (IQR; 2–18), as shown in Table 3. The median SSV was 90 (IQR; 80–90) and the NRS pain score 2 (IQR; 1–3). Patients returned to

Table 3. Functional outcome measures (n=17)

	Median (IQR)
QuickDASH	7 (2-18)
SSV	90 (80-90)
NRS	2 (1-3)
Return to work (weeks)	8 (6-12)

n number; IQR interquartile range; SSV Subjective Shoulder Value; NRS Numerical Rating Scale pain score

Table 4. Functional outcome according to timing of repair and LARS fixation technique

	Acute (n=7)	Chronic (n=10)	p-value
QuickDASH [median, IQR]	2 (0-16)	8 (2-20)	0.183
SSV [median, IQR]	90 (80-100)	90 (75-90)	0.244
NRS [median, IQR]	0 (0-2)	2 (1-3)	0.089
Return to work (weeks) [median, IQR]	8 (6-22)	8 (6-10)	0.456
	Conventional (n=12)	Modified (n=5)	
QuickDASH [median, IQR]	5 (1-19)	9 (7-18)	0.632
SSV [median, IQR]	90 (70-93)	90 (90-90)	0.548
NRS [median, IQR]	2 (0-3)	2 (1-2)	0.914
Return to work (weeks) [median, IQR]	8 (6-12)	8 (8-12)	0.668

n number; IQR interquartile range; SSV Subjective Shoulder Value; NRS Numerical Rating Scale pain score

work after a median of 8 weeks (IQR; 6–12). There was no significant difference in functional outcome scores between acute and chronic repair, or between the conventional and modified LARS fixation groups (Table 4).

Complications and hardware removal

There were two patients (10%) with major complications, both requiring revision surgery. One patient who was treated with conventional LARS fixation sustained a rupture of the LARS ligament nine weeks after fixation, revision surgery was performed with repeat LARS ligament fixation. One patient who was treated with the modified LARS fixation technique was re-admitted to the hospital with a deep wound infection requiring incision and drainage. Screw removal due to irritation was performed in one patient (5%).

Discussion

This retrospective study evaluated outcome after conventional and modified LARS ligament fixation of both acute and chronically repaired AC joint dislocations performed by a single surgeon. LARS ligament fixation for the treatment of AC dislocations resulted in good mid-term functional outcome.

These findings are in accordance with previous studies that evaluated LARS ligament fixation. Lu et al.⁸ treated 24 patients with LARS artificial ligaments, they reported a mean Constant score of 94.5 (SD 9.3) after a follow-up of 36 months (range 6–60). Tiefenboeck et al.¹⁵ presented the

results after a mean of 7.4 years of 47 patients treated with the LARS ligament. They reported good-to-excellent outcome in all patients, with a mean DASH score of 2.6 and Constant score of 93. Giannotti et al.¹⁶ evaluated the use of the LARS artificial ligament in 17 patients, shoulder function was evaluated using the Constant score and Simple Shoulder test after a follow-up ranging from 1 to 41 months. They reported excellent results on both the Constant Score and the Simple Shoulder test for all 17 patients.

Giannotti et al.¹⁶ reported one patients with radiographic enlargement of the clavicular screw tunnels, although, reduction was maintained. Lu et al.⁸ concluded LARS fixation can provide immediate stability and allow early shoulder mobilization with good functional results and few complications. They performed follow-up radiographs showing slight loss of reduction in four patients, calcification of the CC ligament in four patients, degenerative changes around the AC joint in two patients and clavicular osteolysis around the screws in one patient. Tiefenboeck et al.¹⁵ reported complications in five patients (11%), with four patients requiring revision surgery. Major complications occurred in three patients consisting of one loss of reduction and two cases of late infection after a mean of 18.6 months. Additionally, implant removal was performed in one patient due to screw pullout and irritation after 36 months. These findings are in line with our study with two patients (10%) requiring revision surgery, due to a ruptured LARS ligament and one case of deep infection. Screw removal due to irritation was performed in one patient. Further research is needed to evaluate the development of potential late complications following LARS fixation.

Previous case series have shown LARS fixation to be an effective fixation method for the treatment of AC joint dislocations. However, previous studies have mainly focused on acute AC dislocations. Lu et al.⁸ and Tiefenboeck et al.¹⁵ only treated patients with acute Rockwood type-III or higher AC dislocations. Giannotti et al.¹⁶ evaluated the use of the LARS artificial ligament after both acute and chronic repair, however, they only treated Rockwood type-IV and V dislocations. The current study is the first to evaluate LARS fixation after both acute and chronically repaired for Rockwood type-III or higher AC dislocations. The results indicate LARS fixations to be an effective fixation method for the treatment of both acute and chronic AC joint dislocations. Therefore, LARS fixation is also an acceptable treatment option for active patients with symptomatic chronic Rockwood type-III or higher AC dislocations.

Early repair of AC dislocations has been reported to provide satisfactory results independent of surgical fixation method.¹⁷ However, there is no consensus for the treatment of chronic AC dislocations.¹⁷ Previous studies have shown the treatment of chronic AC dislocations to result in less favorable outcome and higher complication rates compared to acute repair.^{18,19} Fraschini et al.¹⁷ previously recommended LARS fixation for the treatment of chronic complete AC dislocations. Fraschini et al.¹⁷ retrospectively compared outcome of 90 patients with chronic Rockwood type-III or higher AC dislocations, 30 patients treated with Dacron vascular prosthesis, 30 patients with LARS ligament and 30 patients with conservative treatment. Their results showed operative treatment resulted in significant better functional outcome compared to conservative treatment. However, treatment with Dacron vascular prosthesis resulted in a higher complications rate (43%) compared to LARS fixation (3%). In the current study, treatment with LARS fixation resulted in good functional outcome in both patients with acute and chronic AC joint dislocations. Unfortunately, accurate comparison of outcomes in the acute and chronic group are not possible due to the small sample size. Further research could focus on the effect early and delayed LARS fixation have on functional outcome following treatment of the AC dislocations.

To our knowledge, this study and the study by Marcheggiani Muccioli et al.⁹ are the only two studies to report the use of a modified LARS fixation technique for the treatment of AC dislocations. The modified technique involves passing excess LARS ligament around the coracoid a second time. Thus, creating a figure of eight knot, which is then reinforced and secured with fiber wire. This modification adds an anterior translation force to the construct and increases the resistance to the opposing superior-inferior forces on the clavicle.²⁰ Following the use of the modified LARS fixation technique we did not encounter any cases of ligament rupture or loss of reduction.

This study has several limitations. First, this was a retrospective case series, outcome following LARS fixation was assessed in a relatively small number of patients without control group. However, the strength of this study is that all patients were treated in a single center by a single surgeon, which reduces the variability of the surgical skill and the clinical results. Second, functional outcome was only assessed by patient-reported outcome measures. However, both the QuickDASH, SSV and NRS are validated and reliable verbal outcome instruments, easily performed by telephone interview. Third, it was not possible to evaluate the degree of clinical

improvement, as preoperative functional outcome scores were not available. Unfortunately, the use of LARS fixation for the treatment AC joint dislocations has not been widely studied and comparison of literature remains difficult due to small sample sizes and inclusion of different types of AC joint dislocations. Therefore, a multicenter study might provide insight into the long-term results following LARS fixation of different Rockwood types, and in different patient populations.

Conclusion

The LARS ligament technique seems to be an effective and safe surgical fixation method for the treatment of AC joint dislocations, resulting in good short- and mid-term patient-reported functional outcome after a median follow-up of 23 months. In addition to acute AC dislocations, LARS fixation might also be an acceptable treatment option for active patients with symptomatic chronic Rockwood type-III or higher AC dislocations.

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