



The long-term efficacy of the GraftRope technique

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Background: Acromioclavicular joint separations continue to be a challenge for surgeons, and modern arthroscopically assisted techniques are becoming increasingly widespread. The aim of this study is to evaluate if the use of a biological support in association with a nonresorbable subcoracoid fixation can improve long-term stability in acromioclavicular joint dislocation surgically treated. We assessed clinical and radiographic results, patients' return to daily activities and the risk of complications.

Materials and methods: Fourteen patients underwent subcoracoid fixation with the GraftRope system for chronic Rockwood type IV acromioclavicular joint dislocation. A total of 12 patients were evaluated clinically and radiologically with a minimum of 7 years of follow-up.

Results: Good reduction was obtained in all patients. All patients returned to work and sports at the pretrauma level with high mean scores on clinical evaluation. Regarding complications, 3 patients developed acromioclavicular arthritis. Ossifications were a common finding on x-rays, but they did not worsen the clinical outcome.

Conclusions: The GraftRope surgical technique allows us to obtain an anatomical reduction of the acromio-clavicular joint, along with the restoration of the mechanical properties of the joint, owing to the use of a biological material with rigidity and load resistance features. Clinical results over the long term are encouraging. However, a 6-mm bone tunnel is too large since the average thickness of the coracoid process is only approximately 12 mm. This technique has some advantages over others: it avoids detachment of the deltoid, avoids the use of bulky metal implants with an important dissection of soft tissue, while it has all the advantages of an arthroscopic procedure.

Level of evidence: Level IV; Case Series; Treatment Study

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Acromioclavicular joint separations continue to be a challenge for surgeons, given that there is no risk-free procedure even though many techniques have already been

described. Modern arthroscopically assisted techniques focus on anatomical reconstruction of coracoclavicular (CC) ligaments or rerouting the coracoacromial ligament to the distal clavicle.^{2,8} The GraftRope technique (Arthrex, Naples, FL, USA) uses a clavicular tunnel and a coracoid tunnel to grant both a temporary high primary mechanical stability with a wire suture and a long-term viability of the construct with biologic graft.

This study reports a series of patients who underwent CC stabilization using this technique between 2009 and 2011.

Patients gave their informed consent both for the treatment and for the collection and storage of data before the surgery. The study was authorized by the local Institutional Revision Board and was performed in accordance with the ethical standards.

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Materials and methods

This is a case series study. The GraftRope technique was used to treat acromioclavicular separation in 14 subjects (12 males, 2 females), in the Centro Traumatologico Ortopedico (CTO), Shoulder Unit, Torino, Italy, from 2009 to 2011. All patients had grade IV dislocation. Two patients were lost to follow-up; the others (mean age at the time of surgery, 36 years; range, 24-56 years) were available for long-term follow-up with an average duration of follow-up of 91 months (minimum duration of 83 months and a maximum duration 112 months) and underwent an x-ray (comparative bilateral Zanca view and axillary view) and a clinical evaluation. The average time between trauma and surgery was 125 days, ranging from a minimum of 2 days to a maximum of 795 days. Of 12 patients analyzed, 8 had a chronic dislocation at the time of surgery.

Aim of the study

The aim of the study was to evaluate:

1. the long-term efficacy of the GraftRope intervention for the surgical treatment of acromioclavicular dislocations;
2. whether drilling a 6-mm CC tunnel increases the risk of fracture intraoperatively or during follow-up; and
3. whether the osteolysis surrounding the buttons is comparable to the techniques without using the graft.

Radiological evaluation

It was assessed whether the presence of a fixation system resulted in osteolysis or acromioclavicular arthritis. The grade IV dislocation, already clinically evaluated, was confirmed using an x-ray in axillary view to assess the posterior displacement of the clavicle.

Patients who underwent surgery were evaluated with a bilateral comparative x-ray Zanca view, followed by stressed projections with 5 kg (suspended at the elbow). At the follow-up, a similar instrumental assessment was performed. The parameters evaluated were as follows:

1. Acromion-clavicle reduction:
 - type A: equal to the contralateral (Fig. 1)
 - type B: subluxation with a dislocation of less than 50% of the thickness of the clavicle
 - type C: subluxation with a displacement greater than 50% of the clavicle thickness
 - type D: recurrence of acromioclavicular dislocation.
2. Clavicular osteolysis under the button:
 - type A: no osteolysis
 - type B: osteolysis <1.5 mm
 - type C: clavicular component sinking.
3. Ossifications
 - type 0: no ossification
 - type 1: loose bodies in the coracoid space
 - type 2: ossifications adherent to the clavicle or coracoid process
 - type 3: bone bridging between the clavicle and coracoid process (Figs. 2 and 3).



Figure 1 Type A reduction.

4. Osteoarthritis of the acromioclavicular joint:
 - type 0: equal to the contralateral side
 - type 1: greater than the contralateral side (Fig. 3).
5. Size and shape of the clavicular tunnel for the graft:
 - type A: regular, small size, and cylindrical shape
 - type B: increased dimension and trapezoidal shape (Fig. 4).
6. Position of the button on the clavicle compared with the coracoid process on the coronal plane:
 - type A: same level of the coracoid process
 - type B: lateralized position
 - type C: medialized position.

Clinical evaluation

Range of movement (flexion, abduction, external rotation, internal rotation), presence of pain, impairment during daily activities, quality of sleep, recreational time, and reduction of the strength were clinically evaluated at the follow-up.

Two classical scores were adopted to quantify the clinical findings:

1. Constant score
2. Simple Shoulder Test.

The stability of the acromioclavicular joint was evaluated through dynamic tests: the cross-arm test was used to assess the joint in the horizontal plane, and a test performed by positioning the arm at 90° of elevation and 0° of internal rotation was used to assess the joint in the coronal plane. The mobility of the clavicle was also considered:

1. Normal: movement in both the planes equal to the normal side
2. Hypermobile: a single test positive
3. Unstable: both tests positive.

These tests along with the presence of pain and radiological findings of osteoarthritis were indicative of symptomatic joint degeneration. An important parameter that was also assessed was the probability of patients' return to the same level of sport and work activities as they had before injury.

Associated lesions

The most important advantage of arthroscopically assisted techniques is the possibility to diagnose and treat associated lesions. We found 1 case of a grade II SLAP (superior labral tear anterior to posterior) lesion and 1 case of a Bankart lesion (both repaired with 2 resorbable anchors) with a predictable increase in surgical time.

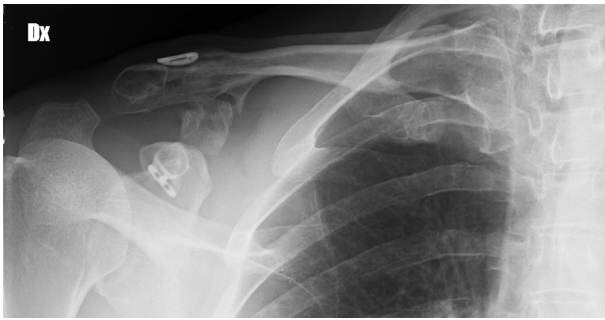


Figure 2 Bridging ossifications.



Figure 3 Bridging ossifications and osteoarthritis.

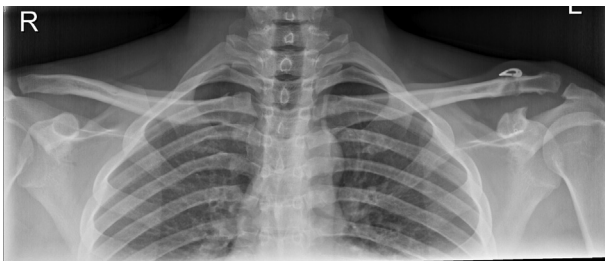


Figure 4 Trapezoidal tunnel.

Surgical technique

The allograft is cleaned and prepped: the graft length should be 12-15 cm and the size of the folded graft should be 4.5-5.5 mm. The graft should be whip stitched at each of the free ends, and after being doubled, it should pass through a 6-mm hole. A traction fiberwire is applied at the middle of the folded graft and a button is loaded on it. The patient is positioned in the beach chair position under general anesthesia and supplemented with an interscalene block. Standard posterior and anterior portals are made, and the coracoid is progressively exposed up to its base. The inferior surface needs to be completely cleared. A mini-access incision or portal is made on the superior surface of the clavicle, and a unicortical 2.4-mm hole is drilled 35 mm medial to the distal end of the clavicle and then reamed up to 6 mm. The AC Tight Rope (Arthrex, Naples, FL, USA) drill guide is positioned in the previously drilled clavicle pilot hole, with the coracoid target placed on the inferior surface of the coracoid, close to the base.

Another 2.4-mm guidewire is drilled through the inferior cortex of the clavicle and through the coracoid. A 6-mm cannulated reamer is then used over the guidewire to ream through the clavicle and coracoid. A SutureLasso loop is passed through the reamer (left in place) and is used to load the traction fiberwire suture of the graftrope construct. The traction suture is pulled from the anterior portal until the button has passed through the clavicle and the coracoid holes and is located on the inferior surface of the coracoid. The clavicle is then reduced, and the superior clavicle washer is used to fix the construct with a number 5 fiberwire through the endobutton. At this point, the 2 limbs of the graft are separated and pulled tight, and a 5-mm tenodesis screw is inserted until flush.

Results

Radiological results

Reduction

Eight patients had reduction comparable with the normal side. Four patients had less than 50% of the thickness of the clavicle.

Clavicular osteolysis

No patient showed clavicular osteolysis at the level of the button.

Ossifications

Four patients' radiographs did not show ossifications; 1 patient had loose bodies in the subcoracoid space; 4 patients had ossifications adhering to the clavicle and coracoid; and 2 cases had bone bridging between the clavicle and the coracoid process, forming synostosis.

Osteoarthritis

Three patients developed severe osteoarthritis compared with the contralateral side. One of these patients developed osteoarthritis associated with synostosis, with worsening of the clinical outcome (the patient complained about disturbance of sleep owing to pain).

Clavicular tunnel

In all cases, the coracoid tunnel showed similar characteristics: cylindrical shape, parallel and closed edges. In contrast, differences were found in the clavicular tunnel: 6 patients showed narrow regular with parallel edge tunnels; 5 patients showed a bigger tunnel with trapezoidal shape. Patients with more prominent ossifications had less enlarged and more regular tunnels.

Position of the tunnel on the clavicle

Eight patients showed a lateralized button compared with the coracoid process on the coronal plane. Even patients with a very lateralized button showed a good reduction achieved maximum clinical scores.

Clinical results

Of 12 patients, 8 scored 100/100 at the Constant score and 12/12 at the Simple Shoulder Test. One patient reported a score of 98/100 due to pain during the night: it was a case of synostosis associated with osteoarthritis, as already mentioned. One female patient reported a Constant score of 94/100, complaining of mild pain during sleep, mild impairment of working activity (cleaner) and recreational activity.

One patient, who scored 92/100 at the Constant score, reported lower values of flexion and abduction (both between 91° and 120°). However, his range of movement was similar to the contralateral shoulder, and the restriction of movement was found to be the same as that before the injury. One patient scored 96/100 due to limited abduction in both shoulders.

Regarding the Simple Shoulder Test, the results were similar: all patients reported the highest score, except 2 patients, who complained of pain during nighttime, scoring 11/12.

All functional tests showed a joint stability equal to the contralateral one.

Of 12 patients, who resumed their pretrauma work activity, 7 practiced amateur sports and all of them returned to the preinjury activity level.

Some patients complained of discomfort while carrying backpacks or shoulder bags because of the button protruding into the subcutaneous tissue, but in none of these cases it was necessary to remove it.

Discussion

The long-term efficacy of the GraftRope technique for the surgical treatment of acromioclavicular dislocations was investigated in this study. A 6-mm CC tunnel reportedly increases the risk of fracture, although no such fracture was reported in any of our cases. The osteolysis in proximity to the buttons is not comparable to those techniques that do not use a graft.

The goal of surgery in acromio-clavicular joint (ACJ) reconstruction is to obtain an anatomical reduction and to maintain the reduction over time. Various complications are reported in literature. Numerous techniques have been proposed to achieve these goals. However, the fact is that there is no gold standard treatment for this pathology.

A recent review by Moatshe et al¹⁰ compared different surgical techniques for acromioclavicular joint instability. They showed an improved clinical outcome using all surgical treatments (free tendon graft, suspensory devices, synthetic ligament devices, ligament transfers, hook plates, and K-wires). Although there is no clear consensus as to which treatment method is preferable, free tendon graft reconstruction provides the highest subjective score and

lesser complications (even compared with other suspensory devices like tight rope), whereas hook plates and K-wires have the highest rate of complications. Ligament transfers (like modified Weaver-Dunn) have the highest unplanned reoperation rates.

The first clinical report of the Graft Rope device was by DeBerardino et al.⁵ They used and described this technique in 2010 treating 10 patients with full return to the preinjury activity level at a minimum of 6 months' follow-up and no loss of reduction.

Another study by Cook et al⁴ reported loosening of intraoperative reduction in 80% of cases (10 patients' study at an average of 7 weeks). They had a high percentage of radiographic re-displacement and clinical failure. Subjective patient outcomes included 5 excellent/good results, 1 fair result, and 4 poor results; tunnel widening was universally noted and the reason for failure in most patients seemed to be at the holding suture (slippage or breakage of the suture in 7 patients). Coracoid fracture was observed in 1 patient. Four of 10 patients treated required a revision.

Kocaoglu et al⁷ used the AC-GraftRope technique to reconstruct CC ligaments with an autologous palmaris longus tendon graft. In this retrospective study (which compared this technique with the modified Weaver-Dunn procedure), tolerable loss of reduction (with a mean difference of CC distance compared with the uninjured side of 1.1 mm) within the follow-up was observed, but patients still achieved functional (tested with American Shoulder and Elbow Surgeons and the Constant scores) and radiologic benefits. No serious complications occurred in either group (a superficial wound infection occurred in 1 patient in the Weaver-Dunn group, which healed with oral antibiotic therapy). There were neither complications nor complaints related to the palmaris longus graft donor site.

Nordin et al¹³ performed the only prospective study on the GraftRope system; the purpose of this study was to treat 30 patients and evaluate their shoulder function at 3, 6, 12, and 24 months postoperatively. But within the first year postoperatively, 4 of 8 patients suffered a loss of reduction. Because of the high rate of complications, the trial was stopped prematurely. The reasons for loss of reduction were coracoid fracture in 3 cases and graft failure in 1 case. There were no signs of loss of reduction or coracoid fractures immediately after surgery. One of the patients who suffered a loss of reduction had pain and severely impaired shoulder function and needed a revision surgery. Three of the 4 patients who did not have any complications showed excellent results. At 1 year postoperatively, these 3 patients had returned to their preinjury level of activity and were satisfied with their shoulder function. One patient in this group still experienced pain when sleeping on the injured side and when lifting the injured arm above the shoulder level. They concluded that a 6-mm bone tunnel is not a safe way to provide an anchor point in the base of the coracoid process.

Milewski et al⁹ reviewed 27 cases of anatomic reconstruction of CC ligaments with different techniques. Of 10 patients who underwent a coracoid tunnel technique, 8 patients had complications: 2 of which were coracoid fractures and both were treated with the GraftRope technique.

The most common complications as mentioned in another systematic review and meta-analysis by Gowd et al⁶ were infection (6.3%), fracture of the coracoid or distal clavicle (5.7%), and hardware/button failure (4.2%).

In the current study, concerning reduction, 33.3% of patients reported a subluxation less than 50% of the thickness of the clavicle in the postoperative radiograph. Subsequent radiographs did not show worsening in the degree of subluxation; therefore, these cases are attributable to a technical error and not to a lengthening or failure of the graft. In the literature, a loss of up to 29% of reduction in the reconstructions in which a graft is used, especially in chronic dislocations, has been reported.¹⁴ In the current study, no real loss of reduction or hardware failure was observed. CC tunnels are technically difficult to perform, especially in smaller-sized coracoid bones due to the high risk of coracoid fracture. Rylander et al¹³ showed in their study that while employing a transcoracoid reconstruction technique, a 4-mm tunnel technique is significantly stronger than a 6-mm tunnel technique. Tunnel diameter is an independent risk factor for fixation failure of the coracoid after transcoracoid CC reconstruction. In contrast to what is found in literature, we had no fractures of the coracoid or distal clavicle nor osteolysis at the level of the button, although the hole required for the button is 6 mm in size (a huge value, considering that the thickness of the coracoid is approximately 12 mm¹) due to the careful positioning of the guidewire entry point in the posterior third of the clavicle and the guidewire exit point at the point of deflection of the coracoid.³ Evaluating the dimension of tunnels, differences were found in clavicular tunnels: the presence of larger edges in 41.7% of patients was probably due to erosion caused by the tendon and was associated with greater mobility of the clavicle.

One of the most important findings of this study was the high percentage of ossifications (66.7%), ranging from loose bodies to bone bridging between the clavicle and the coracoid. This could be due to the release of growth factors coming from the reaming of the tunnels. Radiological findings of ossifications have no correlations with a poor clinical outcome. Compared with the contralateral side, 16.7% of patients developed osteoarthritis and one of them had associated synostosis. These data show that despite the high rigidity of the system and the contribution of ossification to the stability of the construct, the mobility of the clavicle in the horizontal plane is probably still present. Unfortunately, the evaluation of clavicular rotations was not performed in our study. Also, there was no evidence of

osteolysis of the clavicle over time at the level of the button, as described in literature.^{11,12}

It is important to emphasize that all patients were satisfied with the results and came back to the preinjury activity level.

GraftRope provides a biological repair that more closely mimics the native anatomy than many previous techniques, and it can be simplified as an association between a free tendon graft and a suspensory device. Despite this, it is still not a real anatomical reconstruction because bone tunnels do not restore the normal anatomy of the CC complex and acromion-clavicular ligaments are not fixed at all, but the overall stiffness is sufficient to restore stability on both planes.

Mazzocca et al⁸ demonstrated that GraftRope reconstruction of the AC joint is a biological repair that results in a similar strength as the native intact ligaments.

Another advantage with the use of an arthroscopic technique is the possibility to diagnose and treat the associated lesions¹⁰ (thus avoiding the possibility of other pathologies that may have changed the clinical result) and the avoidance of an open procedure lessens the risk of infection and wound healing concerns. Thanks to the use of arthroscopy we have diagnosed and treated 1 case of a grade II SLAP lesion and 1 Bankart lesion (both repaired with 2 resorbable anchors).

Limitations of the study

The main limitation of this study is that it is a retrospective study. Furthermore, a control with a group of nontreated patients was not performed. This series includes acute and chronic diseases. The impact of the associated diseases (1 case of SLAP, 1 case of Bankart) on outcomes was not considered. Evaluation of clavicular rotations was not performed in the study.

Conclusions

The GraftRope surgical technique allows us to obtain an anatomical reduction of the acromion-clavicular joint, with the restoration of the mechanical properties of the joint, thanks to the use of a biological material with rigidity and load resistance characteristics similar to original ligaments. Clinical results over time are encouraging. A 6-mm bone tunnel is too large since the thickness of the coracoid is approximately 12 mm. This technique has some advantages over the others: it avoids detachment of the deltoid, avoids the use of bulky metal implants with an important dissection of soft tissue, while it has all the advantages of the arthroscopic procedure.

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