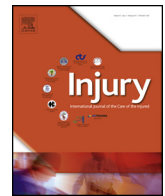




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Is AC TightRope fixation better than Bosworth screw fixation for minimally invasive operative treatment of Rockwood III AC joint injury?

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ABSTRACT

Introduction: Injuries to the acromioclavicular (AC) joint are common in sports participants and may lead to instability or degenerative changes that require surgical intervention. Diagnostics include X-ray projections; MRI could also be a useful method. Surgical treatment of acute Rockwood type III AC dislocation varies on a case-by-case basis and includes coracoclavicular (CC) stabilisation with two techniques of minimal invasive fixation: the Bosworth screw and AC TightRope fixation (Arthrex, US). The aim of this study was to analyse whether there is a difference between these two surgical procedures in the quality of repair of CC ligaments by comparing preoperative and postoperative AC joint radiological and clinical findings.

Patients and methods: In this study, we evaluated our 5 years' experience of surgical management of Rockwood type III AC dislocation. Radiological analyses included measurement of CC distance at the AC joint, X-ray and MRI evaluation of CC ligament scar tissue continuity; clinical outcome was assessed using the Constant Murley, Oxford Shoulder and DASH scores preoperatively and during 6 months of postoperative follow-up.

Results: A total of 68 patients with Rockwood type III AC dislocation were treated surgically with minimally invasive CC fixation using either the AC TightRope implant (34 patients, TR group) or the Bosworth screw (34 patients, BS group) in a prospective, randomised clinical trial. There was no statistically significant difference in radiological X-ray and MRI evaluations of postoperative results between the two groups of patients at the end of follow-up. Patients in the TR group reported significantly less inconvenience with treatment as the patients in the BS group had to undergo a second operation to remove the Bosworth screw. Postoperative recurrence of dislocation was observed in two patients in the TR group (5.88%) and in four patients in the BS group (11.76%) 6 months postoperatively. The difference between the two groups was not statistically significant ($p = 0.4$).

Conclusion: MRI could be a useful method to evaluate quality of repair of CC ligaments. The minimally invasive surgical techniques used in this study showed similar radiological and clinical efficacy in the treatment of acute Rockwood type III AC dislocation, but AC TightRope fixation provided patients with significantly more treatment satisfaction and less inconvenience than Bosworth screw fixation.

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Introduction

Injuries to the acromioclavicular (AC) joint are common in sports participants and may lead to instability or degenerative changes that require surgical intervention. The severity of injury depends on the direction and degree of forces across the joint. The spectrum of injury ranges from sprain to disruption of the AC ligaments, which are typically injured first, and the coracoclavicular (CC) ligaments, which are disrupted with more significant force [1–5]. Diagnostics include physical examination and X-ray imaging studies [6–10]. MRI should not be the imaging modality of first choice, but could be useful to clinically assess low-grade injuries that have not settled to exclude higher-grade injury or if there are associated glenohumeral soft tissue injuries [10–12]. The Rockwood classification system is currently almost universally used and is based on the degree and direction of disrupted anatomy [13–15].

Various conservative and surgical procedures are available; however, most require a period of short immobilisation and consequent early rehabilitation, which lead to the rapid healing of the conoid and trapezoid CC ligaments [15–22].

Surgical treatment of acute Rockwood type III AC dislocation varies on a case-by-case basis and includes CC stabilisation with the two most useful techniques of fixation: the Bosworth screw and AC TightRope implant (Arthrex, US) [22,23].

The aim of the present study was to analyse whether there is a difference between these two surgical procedures in the quality of repair of CC ligaments by comparing preoperative and postoperative AC joint X-ray, MRI and clinical status of operated patients.

Patients and methods

In this study, we evaluated our 5 years' experience of surgical management of Rockwood type III AC dislocation. This prospective, randomised, double-blind, Evidence Level 1 clinical trial was performed in accordance with the provisions of the Declaration of Helsinki and local regulations. Each patient was fully informed about the purpose of the trial, expected benefits, possible risks, and all the other details pertaining to the study. All participants signed an informed consent. The approval for this study was granted by the Ethics Committee of the Clinical Hospital Centre, prior to inclusion in the study. All demographic data, clinical and operative information, and time intervals, were taken from the patients' chart review.

Eligible patients were aged 18–68 years. The indication for surgery was based on clinical examination, X-ray and MRI of the affected AC joint to identify existing pathology and to enable the dislocation to be graded according to the Rockwood classification. This ensured that we had information on the existing joint pathology within each group and that prognostic variables between the groups were sufficiently balanced (i.e. comparable rates of similar pathology per group).

Inclusion criteria were injury within the previous 2 weeks, no concomitant shoulder injury or previous surgery for AC joint dislocation, and full accounting data. Exclusion criteria were concomitant clavicular or humeral fracture, head and neck trauma, or polytrauma.

Demographic and baseline disease characteristics

A total of 84 patients were screened for possible inclusion in the study. Sixteen of these patients were ineligible for the study according to the inclusion/exclusion criteria or withdrew voluntarily after receiving written and oral information. Sixty-eight patients were eligible for the study and were randomised to

sustain operative CC fixation with the AC TightRope implant (TR group, $n = 34$) or the Bosworth screw (BS group, $n = 34$). No patient was completely lost to follow-up. We were unable to collect complete data sets for four patients from the TR group and three patients from the BS group (Fig. 1). The data sets for the participants were completed using the “last observation carried forward” (LOCF) method. Baseline values for both treatment groups were comparable. There were no significant differences between the treatment groups with respect to age ($p = 0.22$), sex, weight or body mass index. The characteristics of each group of patients are presented in Table 1.

Surgical techniques

Surgery comprised minimally invasive CC fixation using the AC TightRope implant in the TR group or the Bosworth screw in the BS group [22,23]. Patients received single shot antibiotics before surgery. All patients were under general anaesthesia and in the beach chair position during the operation.

Radiological evaluation

Radiological analyses were assessed by two independent experts (intra- and inter-observer blinded).

These analyses included measurements of CC distance at the AC joint using plain films (Alexander view; normal <11–13 mm, R/L differ by <5 mm) and were routinely provided at the patient's admission and on Day 1 (Fig. 2), and at Months 1, 3 and 6 postoperatively (Fig. 3). A 50% difference in size between the two shoulders was considered significant. The extent of CC separation had a direct effect on the degree of AC separation [6,10,24].

MRI of the AC joint was chosen for the evaluation of CC ligament scar tissue continuity and was conducted preoperatively (Fig. 4) and 6 months postoperatively (Fig. 5). The MR protocol described by Alyas et al. [12], for imaging AC joint dislocation was used and included T1 and T2 and fat suppressed sequences in three planes. Coronal images were obtained in the plane parallel to a line drawn from the coracoid process to the lesser tuberosity. Sagittal oblique images were obtained in the plane parallel to the line of the glenoid articular surface. Axial images were parallel to the line of the supraspinatus tendon. Soft-tissue injuries were nicely depicted with MRI, which enables a direct method of classification rather than relying on measurements from routine radiography as an indirect sign of CC ligament lesion. In addition to CC ligament assessment, possible postoperative complications were assessed, including soft tissue and bone oedema, inflammation and infection [12].

Clinical assessment

The clinical efficacy and the possible difference in effectiveness, safety and patients' state of health with treatment between the TR and BS groups were evaluated using three different evaluation scores: Constant Murley score [7], Oxford Shoulder score [8] and DASH score [9].

The Constant Murley score was defined as follows: 90–100 points = excellent, 80–90 points = good, 60–79 points = fair, and ≤ 70 points = poor [7]. The Oxford shoulder score was defined as follows: 40–48 = excellent, 30–39 = good, 20–29 = fair, and 0–19 = poor [8]. The DASH score was interpreted from 0 (no disability) to 100 (great disability) and defined as follows: 0–10 = excellent, 10–20 = good, 30–50 = fair and 50–100 = poor [9]. Assessments and checks for adverse events and changes in analgesic use were conducted preoperatively and 6 months postoperatively.

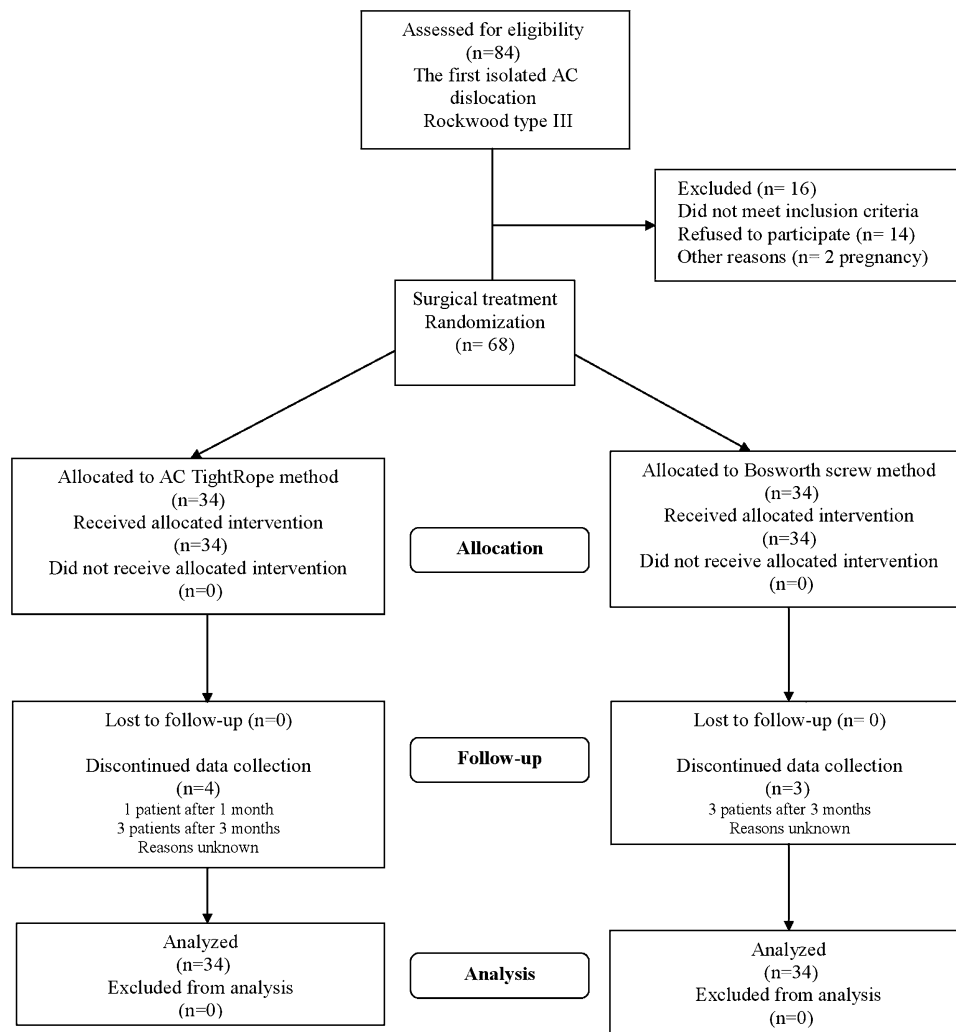


Fig. 1. The consort flow chart.

Statistics

Statistical analysis was conducted using the SAS 9.2 software package.

The Kolmogorov–Smirnov test was used on all data to test for normal distribution. Metric data were compared using the Student *t*-test. Descriptive results are demonstrated as the mean (range). The level of significance was defined as $p \leq 0.05$. Graphics were illustrated using Windows EXCEL®.

Results

A total of 68 patients with Rockwood type III AC dislocation were assigned to one of the two parallel groups and treated

Table 1
Sample characteristics of study groups.

	TightRope	Bosworth
Number of patients	34	34
Age	37.25	41.18
SD	11.77	14.1
Gender		
Male	30 (88%)	34 (100%)
Female	4 (12%)	0 (0%)
Shoulder		
Left	15 (44%)	0 (0%)
Right	19 (56%)	20 (59%)

surgically with minimally invasive CC fixation using either the AC TightRope™ implant (34 patients, TR group) or the Bosworth screw (34 patients, BS group) in the period from January 2009 to January 2014. The mean age of all patients was 38.87 years (range 18–68 years) and mean BMI was 24.5 kg/m² (range 19–30 kg/m²). All patients received prophylactic treatment for deep vein thrombosis (DVT) and antibiotics preoperatively.

Surgical procedures

A 4-cm strap incision was made 1 cm medially to the AC joint. The full extent of the injury was seen only after the deep fascia had been incised in the line of the skin incision. Some fibres of trapezius could be incised posteriorly to enable the “buttonholed” joint to be reduced. The AC joint superior capsule was repaired, and then the joint was held reduced using a bone hook with downward traction. The deltoid with the attached periosteum and capsule was elevated off the anterior edge of the distal 2 cm of the clavicle and was split in the direction of its fibres until the coracoid process was exposed.

One of the minimally invasive techniques used in the study was the TightRope implant. A non-absorbable string was positioned through boreholes between the coracoid process and the clavicle. A reduction was performed and the string was held in position by anchors placed underneath the coracoid process and above the clavicle.

The other method used in the study was stabilisation with the Bosworth screw. The base of the coracoid was palpated to prepare



Fig. 2. CC distance measured preoperatively – X-ray.

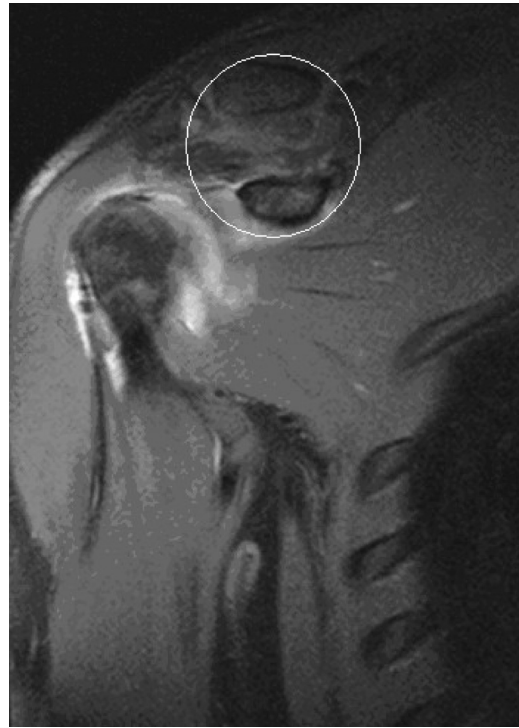


Fig. 4. MRI AC joint preoperatively – CC ligament rupture.

it for the Bosworth screw. With a finger on the base of the coracoid, the clavicle was drilled, aiming the drill to the base of the coracoid. The joint was held reduced, the screw was inserted through the clavicle to the base of the coracoid and the joint was stabilised in the anatomic position.

Trapezius and deltoid tears were meticulously repaired, and a subcutaneous suture was inserted for skin closure [15–20].

Postoperative management

All patients had their affected arm placed in a sling for 4 weeks with only pendulum exercises allowed during this time. At 3 weeks, the patients actively mobilised the shoulder below 90 degrees abduction or flexion until approximately 6 weeks, when the screw was removed from the BS patients under a local



Fig. 3. CC distance measured at Month 6 postoperatively – X-ray.

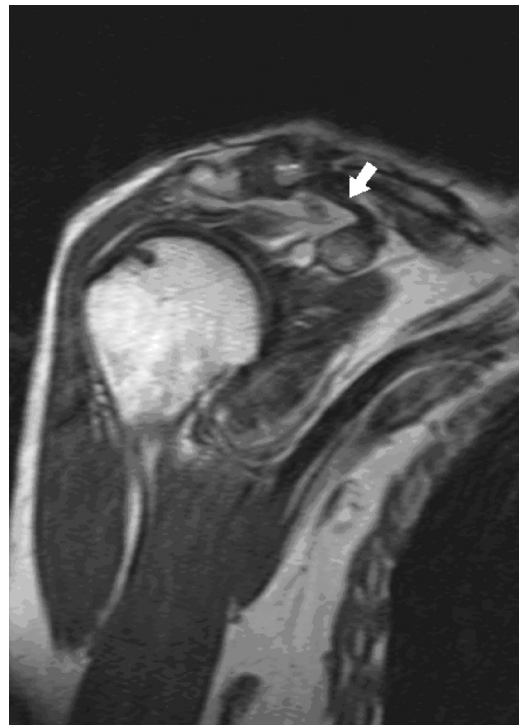


Fig. 5. MRI AC joint at Month 6 postoperatively – correct CC ligament scar tissue continuity.

Table 2
Radiological and clinical evaluation of results – statistical analyses.

	TR group	BS group	p value
Preoperative X-ray	26.94	25.44	0.577
Postoperative X-ray Day 1st	7.03	7.74	0.481
Postoperative X-ray Month 1st	10.46	14.66	0.027
Postoperative X-ray Month 3rd	13.57	15.96	0.199
Postoperative X-ray Month 6th	15.74	19.22	0.149
MRI (continuity of scar tissue)	32/34	30/34	0.4
Constant score	92.22	87.42	0.38
Oxford shoulder score	44.59	43.17	0.51
DASH score	6.46	9.9	0.48

anaesthetic. As the clavicle undergoes rotation in the coronal plane above 90 degrees of abduction and flexion, mobilisation was allowed below shoulder height only to prevent implant loosening or breakage. Patients were prohibited from performing activities that stressed the AC joint and working overhead until Week 10. Muscle strengthening exercises were delayed until Week 12 [18,23].

Radiological efficacy

There was no statistically significant difference between the two treatment groups in preoperative X-ray measurements of CC distance, as shown in Table 2 and Fig. 6, which indicates that the sample is well balanced. The postoperative measurements in the TR group were consistently better than those in the BS group (Fig. 6), but there was no statistically significant difference between the groups, except at 1 month postoperatively ($p = 0.027$) (Table 2).

Postoperative recurrence of dislocation was observed in two patients in the TR group (5.88%) and in four patients in the BS group (11.76%) 6 months postoperatively due to fixation failure. This difference was not statistically significant ($p = 0.4$).

There was no statistically significant difference between the two groups regarding the preoperative MRI findings of complete CC rupture. MRI evaluation of CC ligament scar tissue continuity (2/34 patients TR, 4/34 patients BS) did not show statistically significant difference between the two groups ($p = 0.4$) in the 6-month postoperative period (Table 2).

Clinical efficacy

The six patients who experienced postoperative recurrence of dislocation 6 months postoperatively were also assessed clinically.

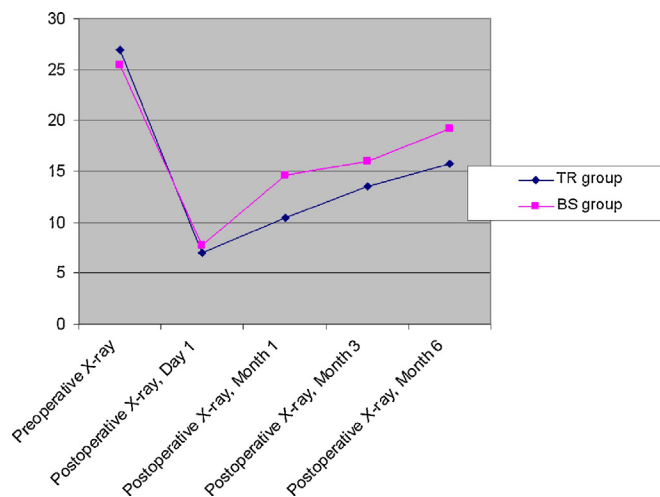


Fig. 6. CC distances at different time points – AC X-ray measurements.

Four patients in the BS group had screw breakage during removal of the screw 6 weeks postoperatively.

The mean Constant score was excellent in the TR group (92.22) and good in the BS group (87.42), but this difference was not statistically significant ($p = 0.38$).

The Oxford Shoulder score and DASH score showed excellent results in both groups. The results were better in the TR group, but this difference was also not statistically significant (Oxford Shoulder $p = 0.51$; DASH $p = 0.48$) (Table 2). There were no complications such as osteitis, superficial wound infection or irritation by the screw head or the AC TightRope anchor.

Discussion

AC dislocation is a common injury and accounts for 8% of all dislocations in the musculoskeletal system of the human body [5]. Sixty different types of surgical procedures have been reported for the treatment of these injuries. The most popular techniques are the Hook plate method, Bosworth screw method, K-wire pinning and tension banding, Tightrope method, PDS-sling and Weaver–Dunn procedure [22–25]. None of these techniques has proved to be good enough to become the gold standard supported by the majority of surgeons. In our department, AC dislocation is mainly treated with two minimally invasive techniques: Bosworth screw fixation and AC TightRope method. The aim of our study was to investigate which of these two techniques gives a better postoperative result based on the comparison between preoperative and postoperative measurement of CC distance at AC joint X-ray, quality of CC ligaments repair at AC MRI and clinical status of operated patients.

Many studies have shown that the Bosworth screw method provides good or excellent results in the treatment of AC dislocation. This method was first described in 1951 and has not changed significantly since then. The advantage of this method is that it is a very simple and cheap operative procedure. The disadvantage is the need for screw removal 6 weeks after the surgical procedure, which could often lead to cracking and malposition of the screw [2,6]. The AC TightRope method was first described as a technique for the treatment of AC dislocation in 2007. Since then it has been accepted by lots of clinical centres, and excellent postoperative results with this treatment have been published [2,6,15,16,20]. Good results have also been reported with arthroscopic AC TightRope fixation with one, or possibly two, implants focused on better postoperative AC joint stability [20,21]. Aside of the discussion about whether an arthroscopic or a mini-invasive approach gives a better postoperative result, the most important advantage of the AC TightRope method over other techniques is that there is no need for a second surgical procedure for implant removal. A disadvantage is that the AC TightRope implant itself is rather expensive.

There are many clinical trials that assess and compare different operative mini-invasive techniques of AC dislocation [5,15–19,22–25], but none of them analyses the differences between the Bosworth screw and the AC Tightrope method of minimal invasive CC fixation from the radiological and clinical point of view.

The results of our study could be interpreted on three levels. The first level is as follows: in our study we used the Alexander modified scapular lateral X-ray view, which is the best view to demonstrate both vertical and horizontal AC dislocation. According to the X-ray measurements at five different time points, CC distance was greater in the BS group at all time points, but it was statistically significant ($p = 0.027$) only at one month after surgery. This may be because of loosening of the Bosworth screw due to active mobilisation of the shoulder below 90 degrees abduction or

flexion from the fourth week postoperatively. Nevertheless, there was no statistically significant difference ($p = 0.149$) between the two groups for the final results of CC distance, according to X-ray measurements.

Fixation failures have been found to be due to hardware breakage or migration, suture abrasion and breakage, or bone erosion because of the potential sawing action of the sutures through the clavicle or the coracoid. Postoperative recurrence of dislocation in our trial was observed in a statistically non-significant number of patients (two patients in the TR group, four patients in the BS) and the unique reason was implant failure due to its peripheral position at the coracoid in both groups. Screw head breakage during screw removal 6 weeks postoperatively in six patients in the BS group had no influence on the postoperative recurrence of dislocation.

The second level of the clinical trial was the use of MRI to evaluate repair quality of CC ligaments. Based on the MRI findings, we hypothesised that the better results obtained with AC TightRope fixation are due to the healing of the CC ligament, which reduces tissue dissection and enhances the local vascular supply. T1-T2-weighted images, and images with fat suppression revealed the ligament continuity and fibrotic scar tissue. The MRI images showed the preoperative complete CC ligament rupture and the presence of qualitative CC ligament scar tissue continuity 6 months postoperatively, which guaranteed the stabilisation of the AC joint in every patient. To our knowledge, no previous studies have included MRI to assess and compare the recovery of CC ligaments with the AC TightRope and Bosworth screw fixation techniques. The MRI findings in this study show that the use of both techniques in the acute phase equally reduces the CC dislocation and results in the formation of scar tissue, thereby stabilising the joint.

The third level of our research was clinical assessment using standardised orthopaedic questionnaires filled out by patients 6 months after surgery. Both surgical methods of AC stabilisation gave satisfactory results based on the Constant score analyses: excellent in the TR group (92.22), and good in the BS group (87.42). All three questionnaires showed that the AC TightRope method provided a better postoperative outcome compared with the Bosworth screw method, but none of the results was statistically significant ($p = 0.4$).

As well as the slightly better results with the AC TightRope method, patients emphasised its major advantage, which is that there is no need for a second surgical procedure, unlike the Bosworth screw method. The advantage of the Bosworth method is that it is much cheaper. Limitations of this study include a relatively short follow-up time, surgery was conducted by different surgeons and the patient cohorts were not large enough to draw statistical significance.

Conclusion

MRI could be a useful method to evaluate the quality of repair of CC ligaments. The minimally invasive surgical techniques used in this study showed similar radiological and clinical efficacy in the treatment of acute Rockwood type III AC dislocation, but AC TightRope fixation (the more expensive option) provided patients with significantly more treatment satisfaction and less inconvenience than Bosworth screw fixation.

Conflict of interest

The authors declare that they have no conflict of interest related to the publication of this manuscript.

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