Original Article

Clavicular Hook Plate versus TightRope Fixation in Acromioclavicular Joint Dislocation: A Randomized Prospective Controlled Trial

Wanjak Pongsamakthai MD[1], Suthee Tharakulphan MD[1]

[1] Department of Orthopaedics, Khon Kaen Hospital, Khon Kaen, Thailand

Background: There are several surgical treatment options for acromioclavicular joint dislocation including clavicular hook plate and TightRope fixation, both of which are capable of achieving satisfactory outcomes. However, there is no single procedure of choice and there have been no randomized controlled trials of alternative procedures.

Objective: To evaluate and compare the functional outcomes of the clavicular hook plate fixation and the TightRope fixation techniques for acute acromioclavicular joint dislocation in adults.

Materials and Methods: Forty-four patients presenting with acute acromioclavicular joint dislocation Type III to V who met the criteria for operative treatment were randomized and allocated to undergo either clavicular hook plate or TightRope fixation within one month after injury. This randomized controlled trial recorded Constant Shoulder Scores at three months post-operation to compare functional outcomes as well as operative time, early and late surgically-related complications, and percentage of remaining joint displacement.

Results: The mean Constant Shoulder Score was 81.6±5.7 for the clavicular hook plate group and 90.4±3.5 for the TightRope group. The mean difference, -8.8±1.4 (95% CI; -11.6, -5.9), was statistically significant ($p = 0.005$). The clavicular hook plate group also achieved a significantly lower percentage of remaining joint displacement compared with the TightRope group (0.9±1.9% and 5.3±5.0%, respectively ($p<0.001$). There was no difference in operative times or in incidence of early or late surgically-related complications.

Conclusion: The TightRope fixation is more effective than the clavicular hook plate fixation for patients with acute acromioclavicular joint dislocation (Type III to V) as evidenced by a higher Constant Shoulder Score three months post-surgery. However, clavicular hook plate fixation achieve a greater quality of joint reduction.

Keywords: Acute acromioclavicular joint dislocation, Clavicular hook plate, TightRope

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Acromioclavicular joint dislocation is one of the common upper extremity injuries in adults, occurring in about 1.8 per 10,000 population, or 9% of all shoulder girdle injuries. More common in males, the most common etiology is sport injury[1,2]. According to the Rockwood Classification of severity and direction of dislocation, a Type I or II acromioclavicular joint injury involving subluxation or partial displacement with an intact coracoclavicular ligament can be effectively treated with conservative treatment. For Type IV to VI injuries involving complete dislocation with torn acromioclavicular and coracoclavicular ligaments, there is a general consensus that operative treatment results in a better functional outcome than conservative treatment[3,4]. However, a controversy remains regarding acromioclavicular joint dislocation Type III, where treatment selection depends on several factors[5-13]. Ineffective treatment may lead to many additional shoulder problems related to decreased functional shoulder mobility including chronic pain, osteoarthritis, deformity, osteolysis, and diminished shoulder range

Correspondence to:
Pongsamakthai W. Department of Orthopaedics, Khon Kaen Hospital, 54 Srichan Road, Muang, Khon Kaen 40000, Thailand.
Phone and Fax: +66-43-232555, ext. 1226
E-mail: wanjakp@hotmail.com, wanjakpp@gmail.com

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of motion.

Operative treatment provides many benefits including anatomical joint reduction, better cosmetic appearance, and early return to full range of motion[14-16]. On other hand, there are also many unsatisfactory consequences which can occur following operative treatment, i.e., surgical wound complications, delayed return to work, and implant complications[14,17-20]. Several surgical treatment options for acromioclavicular joint dislocation have been described, but no single surgical procedure of choice has become the standard. Options include Kirschner wire, tension band, plate, suture anchors, TightRope, screws, and ligament reconstruction[21-27].

Clavicular hook plate and TightRope fixation are recently developed fixation implant methods. The surgical techniques provide a more stable fixation and decrease implant-related complications[28-35]. According to previously published reports, both techniques are capable of providing satisfactory results. However, as yet there have been no randomized controlled prospective trials comparing these two techniques. The purpose of this study was to analyze and compare outcomes with these two techniques in a randomized controlled trial.

Materials and Methods

Study design

This study was conducted as a randomized prospective controlled trial at Khon Kaen Hospital between May 2015 and March 2017. Inclusion criteria consisted of adult patients (18 to 65 years old) with acute acromioclavicular joint dislocation Type III to VI who were eligible for surgical treatment and whose injury had occurred less than one month prior to surgery. Exclusion criteria were any associated ipsilateral shoulder injuries including other fractures or dislocations, neurovascular injury, or associated uncontrolled underlying diseases which could compromise the surgical outcome or postoperative rehabilitation, e.g., diabetes mellitus, dementia, Alzheimer's disease, seizures, and previous ipsilateral shoulder surgery or ipsilateral pain impairing shoulder function. A total 44 of acute acromioclavicular joint dislocation patients who met the eligible criteria were recruited into the study. The sample population was randomized using the varying box size technique, and group allocation was concealed in opaque sealed envelopes. Patients were randomly divided in two groups: 22 for clavicular hook plate fixation and 22 for TightRope fixation. The study was registered with the Thai Clinical Trials Registry (www.clinicaltrials.in.th), and approved by The Ethical Committee of Khon Kaen Hospital. All patients received the same pre-operative and post-operative care protocol as well as the same rehabilitation program.

At the time of admission, baseline characteristics of each participant were collected. Operative treatments were performed by qualified surgeons in the hospital. The patients underwent operative treatment either in the supine or the beach chair position. Skin was incised using an anterior/superior approach (longitudinal incision for clavicular hook plate fixation and saber cut for TightRope fixation) which directly approached the acromioclavicular joint. With both methods, the dislocated acromioclavicular joint was reduced with an open technique, and temporary fixation was achieved using Kirschner wire. Either clavicular hook plate or TightRope implant fixation was performed, and the quality of the reduction was confirmed by fluoroscopic examination. Arm sling support was applied in during the early postoperative period.

Study outcomes

The primary outcome measure, the Constant Shoulder Score, which has a total maximum of 100 points and includes both subjective and objective assessments, was recorded three months postoperatively. Higher scores indicate better outcomes. Operative time (time of skin incision to skin closure) was recorded upon completion of the procedure. Percentage of remaining joint displacement, calculated based on the distance of displacement and the thickness of the distal clavicle, were recorded using post-operative radiographs examined by an un-blinded second assessor. Early and late surgically-related complications were collected throughout the three-month post-operative period.

Statistical analysis

Sample size calculation was based on the mean value of the Constant Shoulder Score. Pooled standard deviation was 7.99, calculated from the standard deviation of Constant Shoulder Score of the clavicular hook plate group (8.77) and the standard deviation of the Constant Shoulder Score of the TightRope group (6.03) with 10 points of the minimal clinical difference from previous study, with alpha = 0.05 and power = 90%[18,22,36].

Baseline characteristics of the patients in each group, including age, gender, dominant side injury, time

to surgery, as well as cause and type of injury, are reported as percentages for categorical data and means with standard deviation for continuous data. The Constant Shoulder Score, the primary outcome measure, is reported as the mean difference with a 95% confidence interval using Student's t-test. The alpha (Type I error) level was set at 0.05, and a *p*-values less than 0.05 were considered statistically significant. Fisher's exact test was used to analyze any surgically-related complications post-surgery. For patients who were lost to follow-up, the intention to treat principle was applied in order to maintain the goal of randomization and to correct for possible attrition bias.

Results

Forty-four patients that underwent operative fixations of an acute acromioclavicular joint dislocation were included in this study. No patients met the exclusion criteria; No patients were excluded from the analysis. Half the patients were allocated to the clavicular hook plate group and half to the TightRope group. The flow of the patients through the study is illustrated in Figure 1. Mean age of patients in the clavicular hook plate group was 39.6±9.6 years, and 37.1±11.5 years in the TightRope group. There were 17 male patients (77.3%) in the clavicular hook plate group and 16 (72.7%) in the TightRope group. Fourteen patients (63.6%) in the clavicular hook plate group and 13 patients (59.1%) in the TightRope group presented with injuries on their dominant side. Mean duration from injury to operation were 6.9±4.0 days in the clavicular hook plate group and 7.8±4.4 days in the TightRope group. The most common cause of injury was a motor vehicle accident. The most common type of injury was Type III in the clavicular hook plate group and Type V in the TightRope group. There were no patients with a Type VI injury. The baseline characteristics of the 44 patients are presented in Table 1.

The average three-month postoperative Constant Shoulder Score of the TightRope group (90.4±3.5 points) was significantly higher than the clavicular hook plate group (81.6±5.7 points) ($p = 0.005$). Subgroup analysis by injury type showed similar results. The operative time of the clavicular hook plate group was shorter than the TightRope group at 44.0±5.9 and 65.7±8.4 minutes, respectively, but the difference was not significant ($p = 0.206$). Incidence of both early

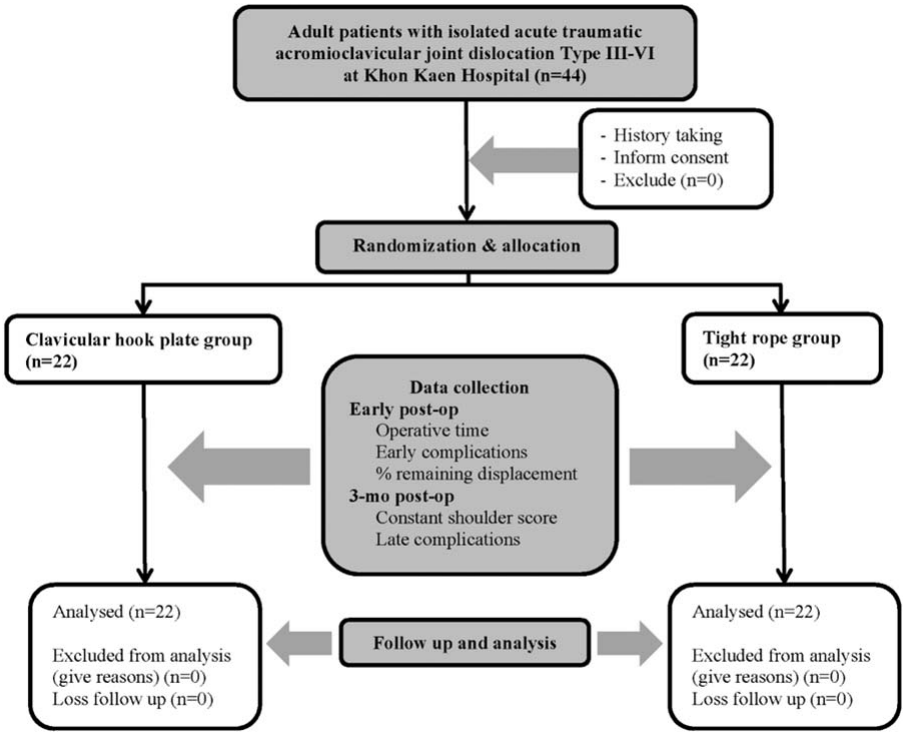

Figure 1. The study flow.

Table 1. Baseline characteristics of participants

Characteristic	Clavicular hook plate group (n = 22)	Tight Rope group (n = 22)	*p*-value
Age in years (mean ± SD)	39.6±9.6	37.1±11.5	0.431
Male gender (n, %)	17 (77.3)	16 (72.7)	0.728
Dominant side injury (n, %)	14 (63.6)	13 (59.1)	0.757
Time to surgery (days, mean ± SD)	6.9±4.0	7.8±4.4	0.476
Cause of injury (n, %)			1.000
Traffic injury	18 (81.8)	18 (81.8)	
Sport injury	1 (4.5)	1 (4.5)	
Bodily assault	3 (13.6)	3 (13.6)	
Type of injury (n, %)			
Type III	11 (50.0)	7 (31.8)	0.220
Type IV	1 (4.5)	1 (4.5)	1.000
Type V	10 (45.5)	14 (63.6)	0.226

Table 2. Comparison of outcomes of operative treatment techniques

Outcome	Clavicular hook plate group (n = 22)	Tight rope group (n = 22)	Mean difference ± SE	95% CI	*p*-value
Constant shoulder score (points ± SD)	81.6±5.7	90.4±3.5	-8.8±1.4	-11.6, -5.9	0.005
Type III	81.4±6.8	90.4±3.2	-9.1±2.8	-15.0, -3.2	0.005
Type IV	80.0	87.09	-7.0	-	-
Type V	82.1±4.7	0.6±3.7	-8.5±1.7	-12.1, -5.0	<0.001
Operative time (min)	44.0±5.9	65.7±8.4	-21.7±2.2	-26.1, -17.2	0.206
Early surgically-related complications (n, %)	0 (0)	3 (13.6)	-	-	0.233
Late surgicaly-related complications (n, %)	1 (4.5)	1 (4.5)	-	-	1.000
Remaining joint displacement (%)	0.9±1.9	5.3±5.0	-4.4±1.1	-6.7, -2.1	<0.001

and late complications in the two groups showed no statistically significant difference ($p = 0.233$ and $p = 1.000$, respectively). The percentage of remaining joint displacement, 0.9±1.9 in the clavicular hook plate group and 5.3±5.0 in the TightRope group, was statistically significant ($p<0.001$) (Table 2). The surgically-related complication of early loss of TightRope fixation requiring reoperation fixation occurred in one patient (Figure 2). Subacromial osteolysis with impingement was a late surgically-related complication in one patient in the clavicular hook plate group; that complication can be resolved during implant removal six months after the operation (Figure 3).

Discussion

In the present study, the clavicular hook plate group had a significantly lower Constant Shoulder Score than the TightRope group, but achieved greater anatomical reduction. The operative time of the two groups was not significantly different. Both groups had a low incidence of early and late complications, with no statistically significant difference between the groups.

A previous literature of study by Andreani et al (2014)[29] reported a higher Constant Shoulder Score in the TightRope group than the clavicular hook plate group. That retrospective, non-randomized comparative study included 28 patients, 19 in the TightRope group and 9 in the clavicular hook plate group. In that study, the TightRope group and clavicular hook plate group had three-month postoperative Constant Shoulder Scores of 90 and 75, respectively. These results are consistent with the present study, both of which had the same three-month follow-up time. The present study

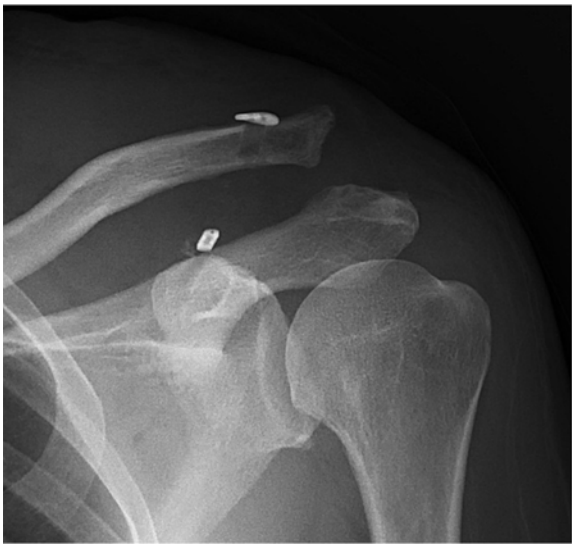

Figure 2. Loss of fixation requiring reoperation was an early surgical-related complication in the TightRope fixation group.

Figure 3. Subacromial osteolysis and impingement (A) was a late surgical-related complication in the clavicular hook plate group. That situation can be resolved after implant removal (B).

differs in tht a prospective randomized design was used and the additional factors of operative time, complications, and radiographic parameters were included.

Koukakis et al (2008)[34]; Salem et al (2009)[33], and Liu et al (2010)[35] all reported satisfactory outcomes in retrospective studies or case series of acromioclavicular joint dislocations treated with the clavicular hook plate method. Their results are similar to those of the clavicular hook plate group in the present study. Di Francesco et al (2012)[32] studied 42 patients with acromioclavicular joint dislocations of Types III and V. Acceptable alignment was achieved in all patients, similar to the present study findings. The lower Constant Shoulder Score of the clavicular hook plate group and the better quality of joint reduction in that group in the present study could have been the result of postoperative impingement or subacromial osteolysis.

Biomechanical strength is a controversial issue in TightRope fixation. Ladermann et al (2013)[30] conducted a biomechanical cadaveric study of three acromioclavicular joint stabilization techniques. The TightRope technique was found to provide the highest superoinferior and anteroposterior strength. That result contrasts with the present study which found poorer reduction quality with the TightRope method which was possibly due to unfamiliarity with this newly introduced technique. That factor may also have led to the slightly longer operative times of the TightRope group. Low incidence of complications with both surgical techniques has been mentioned in many reports[29], similar to the present study.

The main limitation of the present study is the short-term follow-up as only early functional outcomes were recorded. Prospective comparative studies which include a long-term follow-up to more fully evaluate actual functional outcomes is recommended.

Conclusion

TightRope fixation is more effective than clavicular hook plate fixation for patients with acute acromioclavicular joint dislocation (type III to V) as evidenced by the significantly better three-month postoperative Constant Shoulder Scores, although the quality of joint reduction may be lower. There are no differences in operative time between the two techniques and both have a low incidence of early and late surgical-related complications.

What is already known on this topic?

One previous retrospective comparative study of clavicular hook plate and TightRope fixation for acute acromioclavicular joint dislocation reported similar results, i.e., superior functional outcomes with the TightRope technique.

What this study adds?

The current study demonstrated that the clavicular hook plate technique has a lower operative time and better radiographic parameters than the TightRope technique, but that both have a low incidence of complications. In addition, this study achieved included a more detailed evaluation of the techniques accomplished through the use analysis of

radiographic parameters.

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Potential conflict of interest

The authors have no conflicts of interest.

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