Evaluation of the modified CC stabilization using LARS artificial ligament in unstable distal clavicle fracture

Yongchuan Li
orthopaedic institute of PLA
Nan Lu
orthopaedic institute of PLA
Di Shen
orthopaedic institute of PLA
Fan Zhang
orthopaedic institute ot PLA
Jiajia Lu
orthopaedic institute of PLA
Aimin Chen (aiminchen64@sina.com)
orthopaedic institute of PLA

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Abstract

Purpose: Unstable distal clavicle fracture is common, and there is no consensus regarding the gold standard treatment for this fracture. The purpose of this study was to report a new surgical technique for the treatment of unstable distal clavicle fracture with modified coracoclavicular (CC) stabilization using ligament augmentation and reconstruction system (LARS) artificial ligament, and evaluate the clinical and radiographic outcomes.

Methods: From January 2009 to June 2018, eighteen patients with acute unstable distal clavicle fractures (type □b) treated by modified CC stabilization using LARS artificial ligament were retrospectively reviewed. Indexes for evaluation included fracture healing, quality of reduction, and complications (infections, nerve injuries, iatrogenic clavicle or coracoid fracture, the fixation loop failure, loss of reduction, etc.). Shoulder function was evaluated using the Constant-Murley score.

Results: The patients were assessed at a mean time of 31.8 months follow-up. All 18 patients experienced radiographic union. Follow-up radiographs showed anatomical reduction in 15 patients and slight loss of reduction in 3 patients. There were 2 cases of calcification of CC ligament, 1 case of degenerative change around the acromioclavicular (AC) joint, and 1 case of clavicular osteolysis around screws noted during the follow-up. The Constant scores were 91.2 ± 6.9 at last.

Conclusions: The modified CC stabilization using LARS artificial ligament resulted in a high union rate, satisfactory fracture reduction, a low complication rate, and excellent shoulder function for unstable distal clavicle fractures (type □b). We consider this simple surgical technique that naturally restores stability to the distal clavicle fracture is an efficient method for treating the fracture.

Introduction

Clavicle fractures have been estimated to make up to 5 ~ 10% of all fractures, and distal clavicle fractures account for approximately 20% of all clavicle fractures[1]. The most frequently used classification for these fractures is Neer classification that is based on the location of the fracture line relative to the coracoclavicular (CC) ligaments and acromioclavicular (AC) joint[2]. According to Neer classification, Neer type □ and type □ fractures are stable and can be successfully treated nonoperatively[3]. However, Neer type □ and □fractures are displaced and unstable, and always need a surgery treatment[3, 4].

A variety of surgical methods[2, 5–10], such as Kirschner (k)-wire fixation, anatomic locking plate, hook plate fixation, tension band wiring, CC screw, CC sling, and arthroscopic TightRope, are currently used for the treatment of Neer type □ distal clavicle fractures. However, these methods reported high complication rates, including implant failure, clavicle or coracoid fracture, non-union, and subacromial impingement, etc.[11–14] Moreover, to avoid implants related complications, second operations are usually needed to remove the metallic implants. There is no consensus regarding the gold standard treatment for this fracture.

In recent years, we treated acute unstable distal clavicle fractures (type Ⅱb) by modified CC stabilization using ligament augmentation and reconstruction system (LARS) artificial ligament (Surgical Implants and Devices, Arc-sur-Tille, France). The objective of this study was to assess the clinical and radiographic outcomes and complications after CC ligament reconstruction. We hypothesized that satisfactory clinical and radiographic results could be achieved.

Patients And Methods

From January 2009 to June 2018, eighteen patients with acute unstable distal clavicle fractures (type Ⅱb) were treated by CC ligament reconstruction with LARS artificial ligament at the department of Orthopedics in XXXX Hospital. The criteria for inclusion were as follows: (1) being aged at least 18 years; (2) type Ⅱb distal clavicle fractures according to Neer classification. Exclusion criteria were other fracture patterns; open fractures; old fractures (> 6 weeks after trauma); multiple injuries; fractures associated with vascular or nerve injury requiring repair; suspected pathologic fractures; previous surgery performed in the injured shoulder; and patients with failed conservative treatment.

On admission, a standard radiologic protocol, including x-rays, has been conducted for all the patients. All the cases were assessed by different team leaders (we have five trauma teams). If the case was considered to be fit for CC ligament reconstruction, he or she was transferred to the authors' team. All of these 18 cases were operated on by the authors (XXXX, XXXX, XXXX, XXXX, and XXXX). Surgery was performed within seven days (mean 3.2 days) of the traumatic event in all cases.

Operative procedure

Under general anesthesia, the patient was placed in the beach-chair position on a radiolucent table. A 6-cm vertical skin incision from the tip of the coracoid process to the clavicle (2 cm medial from AC joint) was made. Then the deltoid fibers were separated to expose the fractured clavicle, the coracoid process, and the ruptured CC ligaments. Avoiding injury of the musculocutaneous nerve, we made a subperiosteal dissection at the medial side of the coracoid process[15]. Sutures were first placed into the ruptured CC ligament and kept untied. A 3.5-mm hole was drilled 1 cm medial to the fracture in the superior-inferior direction through the clavicle, and a second hole was then placed 2-2.5 cm medially. The LARS artificial ligament was passed around the base of the coracoid process and through holes of the clavicle with a guiding device. After reducing the fracture manually, we fastened the ligament on the clavicle with two titanium interference blunted thread screws. Once complete reduction was confirmed visually and fluoroscopically, the LARS artificial ligament was tied tightly for strengthening. (Fig. 1, Fig. 2)

Postoperative care

Intravenous antibiotics consisting of a first-generation cephalosporin or alternative were administered pre-operatively and for 24 hours post-operatively. We treated all patients with a similar post-operative rehabilitation protocol that emphasized early passive and active motion exercises. An arm-pouch sling protected the involved shoulders for 4–6 weeks postoperatively. We encouraged patients to do isometric

deltoid, biceps, and triceps strengthening exercises immediately on the first post-operative day. Passive range of motion exercises, after the dressing change, was begun on the second or third day after surgery. Three weeks later, the sling was taken out intermittently while active or active-assisted exercises of the affected limb were allowed gradually. Patients continued with the above activities post-operatively until radiographic evidence of fracture healing, and then patients began weight training and supervised physical therapy. As the fracture ultimately union at 12 weeks post-operatively, further stretching and strengthening exercises were allowed.

Clinical and radiographic evaluation

The patients were followed up by an orthopedic surgeon without participating in the surgical treatment. The radiographic examination consisted of Zanca radiographs for both AC joint and axillary radiographs for the injured shoulder. Data evaluating fracture healing, quality of reduction, and complications (infections, musculocutaneous nerve injuries, iatrogenic clavicle or coracoid fracture, the fixation loop failure, loss of reduction, etc.) was obtained during clinical and radiographic examinations post-operatively at 2, 6, 12, 26 and 52 weeks. Shoulder function was evaluated using the Constant-Murley score[16]. The visual analog scale (VAS) was also used to assess the patient's pain at rest.

Statistical analysis

Constant Scores and VAS were analyzed with the Wilcoxon signed-rank test. Computerized statistical analysis was performed using SPSS software (version 11.0; SPSS Inc., Chicago, IL). $P < 0.05$ was considered statistically significant.

Results

From January 2009 to June 2018, 21 patients with acute unstable distal clavicle fractures (type Ⅴb) were treated by CC ligament reconstruction with LARS artificial ligament in our department. Three patients lost follow-up due to migration, death, and other reasons. At last, 18 cases were included in the final analysis of fracture healing, quality of reduction, complications, and functional outcomes. There were 11 men and 7 women with a mean age of 46 years (range 23–61). All patients were right-hand-dominant, and 12 of them sustained the injury on the dominant side.

All patients had an average follow-up time of 31.8 months (range 12–63). The results are presented in Table 1. Patients stayed in the hospital for an average of 8.3 days (range 5–16). Operative management took a mean total operation time (inclusive anesthesia) of 78.0 minutes (range 55–104). All 18 patients experienced radiographic union. Follow-up radiographs revealed maintenance of anatomical reduction in 15 patients (83.3%) and slight loss of reduction in 3 patients (16.7%). No significant horizontal displacement of the distal clavicle fracture was seen on the axillary view radiographs in each patient. There were 2 cases of calcification of CC ligament, and 1 case of degenerative change around the AC joint noted during the follow-up. No superficial infection, vascular or neurological complication, screws

pull-out, iatrogenic clavicle or coracoid fracture, fixation loop failure occurred. Complications during the follow-up could be seen in Table 2.

Table 1
Operation and follow-up data

Characteristic	Mean
Time from injury to surgery, day	3.2
Operative time, min	78
Hospital stay, day	8.3
Follow-up, month	31.8
Union rate, n (%)	18 (100%)
Anatomical reduction rate, n (%)	15 (83.3%)
Slight loss of reduction rate, n (%)	3 (16.7)

Table 2
Complications during the follow-up

Complications	Number
Superficial or deep infection	0
Nerve injury	0
Iatrogenic clavicle or coracoid fracture	0
Clavicular osteolysis around screws	1
Calcification of CC ligament	2
AC joint degeneration	1
Fixation loop failure	0
Loss of reduction	0

Clavicular osteolysis around screws was found in one patient, and we removed the screws timely (Fig. 3). The Constant scores rose from 63.8 ± 7.3 preoperatively to 91.2 ± 6.9 at the final evaluation (P□0.05). Preoperative VAS scores were 4.7 ± 1.9, and the VAS scores at the last review were 0.6 ± 1.4 (P□0.05).

Discussion

The instability and complications of fixation in unstable distal clavicle fractures were affected by several factors. First of all, there is upward displacement of the medial fragment by the trapezius muscles due to

ruptured CC ligament and downward displacement of the lateral fragment by the weight of the arm. Secondly, the lateral fragment is usually small, comminuted, and consists of soft cancellous bone, which may be not long enough to hold at least two bi-cortical screws[7, 12]. Thirdly, the fracture located near the AC joint. Because of the particular anatomy and biomechanics of joints in unstable distal clavicle fracture, non-operative treatment cannot reduce and fix the fracture site, which often leads to high non-union and malunion rate[3, 4]. Thus, surgical treatment is widely accepted as a choice. Although many operative techniques, including K-wire fixation, anatomic locking plate, hook plate fixation, tension band wiring, CC screw, CC sling, and arthroscopic TightRope, have been used alone or in combination to treat these unstable fractures[5–10], no “gold standard” exists. Most of these techniques have their disadvantages and could lead to certain complications, such as fixation failure, metal breakage, migration, secondary clavicle or coracoid fracture, acromial erosion, impingement, or rotator cuff injury, etc.[8–11, 17] Stegeman et al.[18] even recommended avoiding using hook plate due to the high rate and severity of the complications, according to a meta-analysis. Moreover, second operations for implant removal are usually needed.

The fracture mechanism of a Neer type Ⅴb distal clavicle fracture is considered the same as AC joint dislocation (Rockwood classification type-Ⅲ or higher). Therefore, it is important to perform CC ligament stabilization for the treatment of unstable distal clavicle fracture, and current surgical techniques have focused more on this[17, 19–21]. These studies aimed to provide anatomic augmentation of the CC ligaments using open or arthroscopic approaches. Although arthroscopic TightRope is an excellent procedure for CC reconstruction with minimal invasion, it requires a high level of arthroscopic skill and can be complicated by coracoid and clavicle fracture[21]. Our previous work[22] has shown satisfactory clinical and radiographic outcomes in the treatment of acute AC joint dislocation by reconstruction of CC with LARS artificial ligament. Yagnik GP et al.[23] described a new technique, which may have more complex devices/materials and steps than ours, to treat distal clavicle fractures using cortical button fixation with coracoclavicular ligament reconstruction.

The LARS ligament is regarded as a new generation of artificial ligaments due to its unique design and material. It is made of industrial-strength polyester fibers and has excellent biomechanics in terms of resisting tension, flexion, and torsion load [24, 25]. Since native CC ligaments can withstand tensile forces of up to 621 ± 209 N, the LARS artificial ligament has sufficient strength as a graft for CC reconstruction, 2,500 N or 3,600 N corresponding to 60 fibers or 80 fibers[26]. High biocompatibility of the LARS ligament has been demonstrated in vitro and in vivo, with the observation of a complete cellular and connective tissue growth into the artificial ligament after six months[27]. Thus, the stable joint environment and the “scaffold” function of the LARS ligament can promote the healing procedure.

In this study, we reported a new surgical technique for the treatment of unstable distal clavicle fractures (type Ⅴb) with modified CC stabilization using LARS artificial ligament and evaluated the clinical and radiographic outcomes and complications. The aim of this technique was to restore a strong and stable anatomical reduction and provide sufficient strength to hold the distal clavicle to the coracoid process.

Thus, this CC stabilization was strong enough to achieve CC ligament and fracture healing. Successful fracture union in an anatomic position by CC reconstruction using LARS artificial ligament was obtained. There is relatively little soft tissue damage during the operation, which may lead to this high rate of bony union. Anatomical reduction in 15 patients and slight loss of reduction in 3 patients were found at last radiographic examinations. There was no loss of reduction cases during the follow-up. The same fixation method for unstable distal clavicle fractures has not been reported on in the English literature.

This technique uses only one LARS artificial ligament and two interference screws and thus can avoid the risk of hardware irritation and the need for the second operation as much as possible. There is no risk of coracoid fracture because of no drilling through the coracoid during the procedure. As we talked above, the lateral fragment is usually small and comminuted, and hardly obtained purchase. CC reconstruction using LARS ligament around the coracoid indirectly reduces the medial fracture fragment and leads to a complicated CC ligament healing process, which solves the “lateral problem” perfectly.

Although Choi S et al. [17] reported high union rate and good functional outcome in the treatment of unstable distal clavicle fracture with modified tension band fixation and coracoclavicular stabilization, they indicated the possibility of clavicle erosion or fracture. The risk of iatrogenic clavicle fracture also rises while drilling two tunnels through the clavicle for the fixation of LARS artificial ligament in our technique. The clavicle is weakened due to erosion of the clavicle cortex by the implants or a bigger drill hole in the clavicle. A reoperation was performed for one patient as a result of clavicular osteolysis around screws, four months postoperatively. No iatrogenic clavicle fracture occurred. At the final follow-up, the Constant scores were 91.2 ± 6.9, and VAS scores were 0.6 ± 1.4, respectively. All 18 patients had returned to their normal daily activities. Similar results were also reported by Kanchanatawan W et al. [28] whereby 100% of distal clavicle fracture cases displayed clinical union and good to excellent shoulder function, who were treated by a modified coracoclavicular stabilization technique using a bidirectional coracoclavicular loop system. This may be related to the advantages of CC ligament stabilization.

Despite satisfactory clinical and radiographic outcomes in the treatment of unstable distal clavicle fractures, our study also has some limitations. First of all, the sample size was small and may bring a statistical bias in the evaluation of the results. Secondly, a control group was not included to demonstrate the advantages of this procedure over other fixation techniques or even non-operatively. Thirdly, the average follow-up was 31.8 months, which is a relatively short evaluation period, and thus some complications such as posttraumatic arthritis or clavicle erosion would not have developed yet. Larger sample size with control group and longer follow-up would be helpful in a future study.

Finally, this new technique for the treatment of unstable distal clavicular fracture is worthy of further study because of its high union rate and good functional outcome.

Conclusion

The modified CC stabilization using LARS artificial ligament resulted in a high union rate, satisfactory fracture reduction, a low complication rate, and excellent shoulder function for unstable distal clavicle fractures (type Ⅱb). We consider this simple surgical technique that naturally restores stability to the distal clavicle fracture is an efficient method for treating the fracture.

Abbreviations

CC: coracoclavicular; LARS: ligament augmentation and reconstruction system; AC: acromioclavicular; VAS: visual analog scale

Declarations

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Availability of data and materials

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary material.

Authors' contributions

Yongchuan Li and Aimin Chen designed the research; Yongchuan Li, Nan Lu and Di Shen searched the databases; Yongchuan Li, Nan Lu, and Di Shen extracted the data; Yongchuan Li, Nan Lu, Di Shen, Fan Zhang, and Jiajia Lu analyzed the data; Yongchuan Li, Nan Lu, Di Shen, Fan Zhang, Jiajia Lu, and Aimin Chen wrote the paper. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Our study was approved by the Ethical Committee of the Navy Military Medical University. Informed consent was obtained from all individual participants included in the study.

Consent for publication

Since this is a retrospective study, no consent is needed from patients. All authors consent to the publication of this manuscript.

Competing interests

The authors declare that they have no competing interests.

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Figures

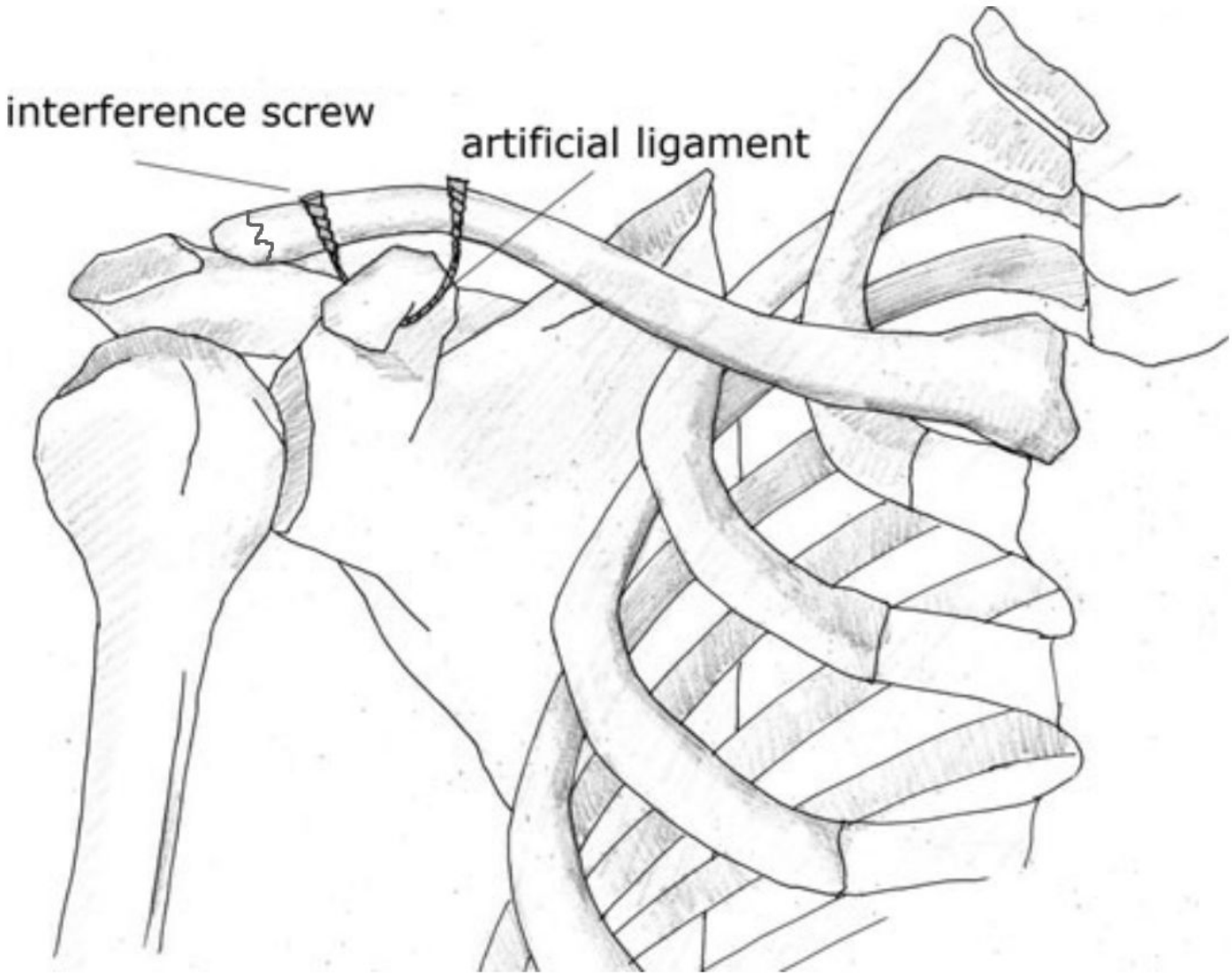

Figure 2

Illustration of surgical technique

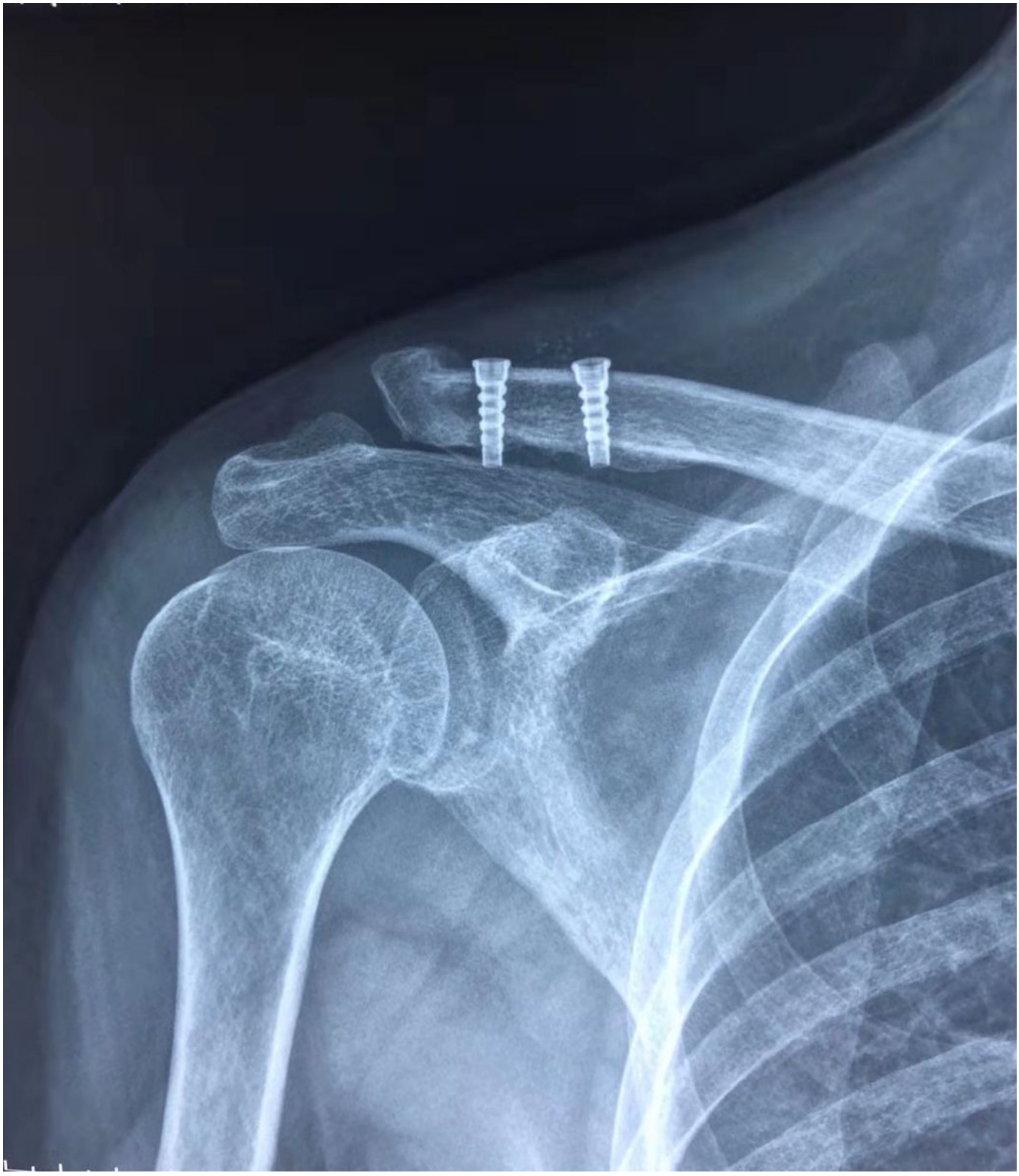

Figure 4

Radiographs showed satisfactory reduction

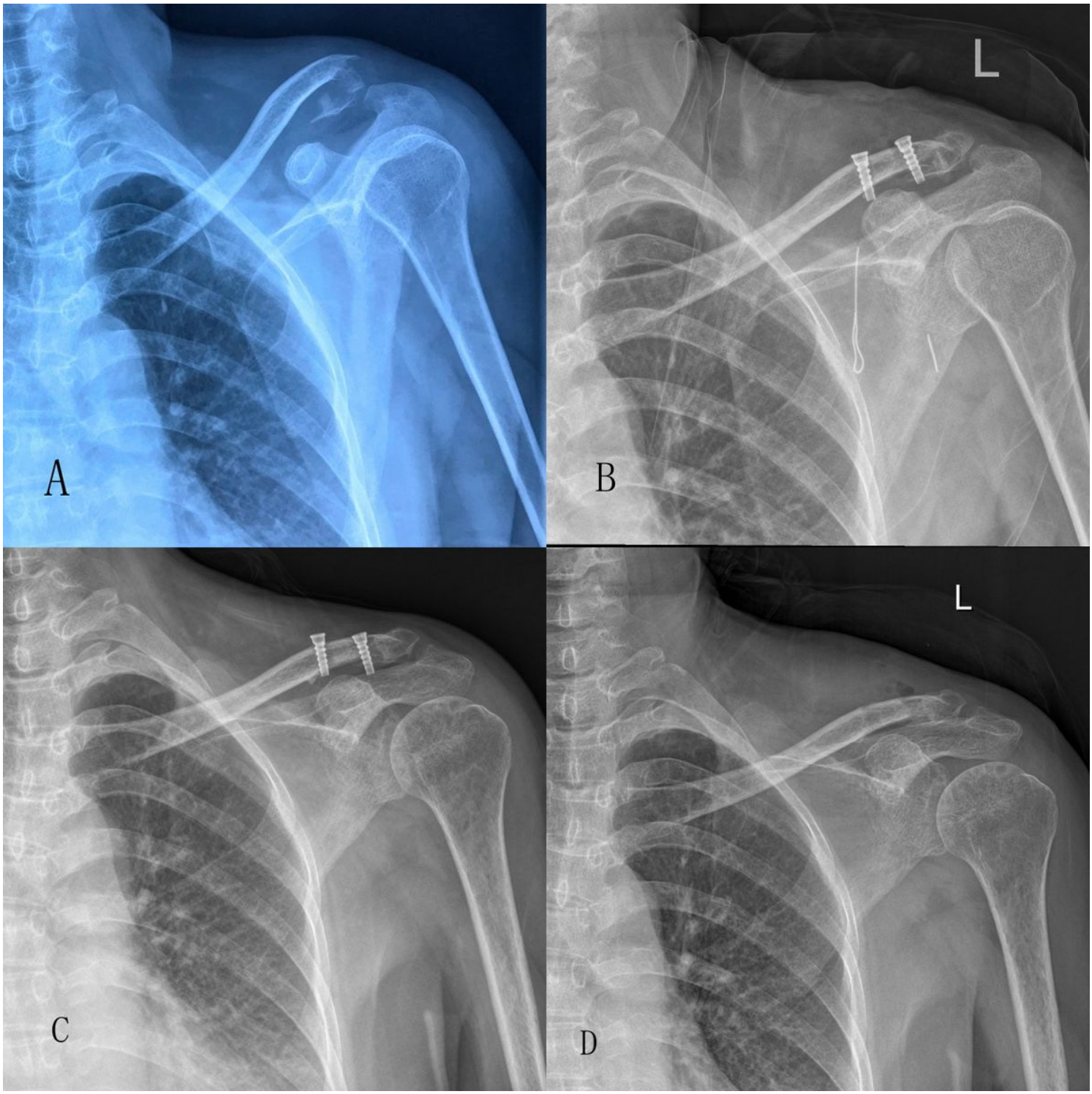

Figure 6

Clavicular osteolysis around screws