

Evaluation of Modified CC Stabilization Using LARS Artificial Ligament in Unstable Distal Clavicle Fracture

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Abstract

Background: Unstable distal clavicle fracture is common, and there is no consensus regarding the gold standard treatment. 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 a ligament augmentation and reconstruction system (LARS) artificial ligament, and to evaluate the clinical and radiographic outcomes.

Patients and methods: We retrospectively reviewed 18 patients with acute unstable distal clavicle fractures (type IIb) treated between January 2009 and June 2018 with modified CC stabilization using LARS artificial ligament. Indexes for evaluation included fracture healing, quality of reduction, and presence of complications (e.g., infections, nerve injuries, iatrogenic clavicle or coracoid fracture, the fixation loop failure, or loss of reduction). Shoulder function was evaluated using the Constant-Murley score.

Results: 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 the 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. At the final follow-up, Constant scores were 91.2 ± 6.9 .

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

Background

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 the Neer classification, which 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 I and type II fractures are stable and can be successfully treated nonoperatively^[3]. However, Neer type III and IV fractures are displaced and unstable, and always need surgical 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 III distal clavicle fractures. However, these methods result in high complication rates, including implant failure, clavicle or coracoid fracture, non-union, and subacromial impingement.^[11-14] Moreover, to avoid implant related complications, second operations are usually needed to remove the metallic implants. There is no consensus regarding the gold standard treatment for this fracture.

Between 2009 and 2018, 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 the current study was to assess the clinical and radiographic outcomes and complications following CC ligament reconstruction. We found evidence that satisfactory clinical and radiographic results can be achieved with this method.

Patients And Methods

From January 2009 to June 2018, 21 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 and (2) having a type IIb distal clavicle fracture 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, or patients with failed conservative treatment.

On admission, a standard radiologic protocol, including x-rays, was conducted for all patients. The cases were assessed by team leaders in one of five trauma teams. If the case was considered to be fit for CC ligament reconstruction, the patient was transferred to the authors' team. All of the included cases were operated on by the authors. 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. 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 the holes in the clavicle using 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, which emphasized early passive and active motion exercises. An arm-pouch sling protected the affected shoulder for 4–6 weeks post-operatively. 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, were 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. If the fracture union was deemed successful 12 weeks post-operatively, further stretching and strengthening exercises were allowed.

Clinical and radiographic evaluation

The patients were followed up by an orthopedic surgeon who had not participated in the surgical treatment. The radiographic examination consisted of Zanca radiographs for both AC joint and axillary radiographs for the injured shoulder. Measures of fracture healing, quality of reduction, and the presence of complications (e.g., infections, musculocutaneous nerve injuries, iatrogenic clavicle or coracoid fracture, the fixation loop failure, or loss of reduction) were obtained during clinical and radiographic examinations at 2, 6, 12, 26 and 52 weeks post-operatively. 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 Wilcoxon signed-rank tests. Statistical analysis was performed using SPSS software (version 11.0; SPSS Inc., Chicago, IL). $P < 0.05$ was considered statistically significant.

Results

Three patients were lost at follow-up due to migration, death, or other reasons, so that 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), and operation and follow-up data are summarized 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 of 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 any 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. There were no occurrences of

superficial infection, vascular or neurological complication, screws pull-out, iatrogenic clavicle or coracoid fracture, or fixation loop failure. Complications during the follow-up are presented 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 time (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 observed at 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 promptly (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

There are several factors which increase the instability and complications associated with fixation in unstable distal clavicle fractures. First, 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. Second, 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]. Third, the fracture is 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 or malunion rates^[3, 4]. Thus, surgical treatment is widely accepted as the necessary 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 disadvantages which can lead to specific complications, such as fixation failure, metal breakage, migration, secondary clavicle or coracoid fracture, acromial erosion, impingement, or rotator cuff injury.^[8-11, 17] In a meta-analysis, Stegeman et al.^[18] even recommended avoiding using hook plate due to the high rate and severity of the complications. Moreover, second operations for implant removal are usually needed.

Because the fracture mechanism of a Neer type α b distal clavicle fracture is the same as in AC joint dislocation (Rockwood classification type α or higher), it is important to perform CC ligament stabilization and recent surgical approaches have focused on improving this method^[17, 19-21]. Previous studies have 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]. The method reported here is based on our previous work^[22], which has shown satisfactory clinical and radiographic outcomes in the treatment of acute AC joint dislocation by reconstruction of CC with LARS artificial ligament. Likewise, Yagnik GP et al.^[23] described a new technique to treat distal clavicle fractures using cortical button fixation with CC ligament reconstruction, although we note that this method involves more complex devices and materials as well as more steps than the method reported here.

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]. The high biocompatibility of the LARS ligament has been demonstrated in vitro and in vivo, with the observation of 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 process.

In this study, we reported a new surgical technique for the treatment of unstable distal clavicle fractures (type α b) with modified CC stabilization using LARS artificial ligament, and we 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,

thereby promoting CC ligament and fracture healing. Results indicated successful fracture union in an anatomic position, with relatively little soft tissue damage during the operation, which may lead to this high rate of bony union. Follow-ups revealed anatomical reduction in 15 patients and slight loss of reduction in 3 patients, with no loss of reduction cases at follow-up. This is the first report of this fixation method for unstable distal clavicle in the English literature.

Our technique uses only one LARS artificial ligament and two interference screws, reducing the risk of hardware irritation and the need for a second operation. There is no risk of coracoid fracture because there is no drilling through the coracoid during the procedure. As mentioned above, the lateral fragment is usually small and comminuted, so it is difficult to obtain purchase. CC reconstruction using LARS ligament around the coracoid indirectly reduces the medial fracture fragment and leads to a completed 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 CC stabilization, their results 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. In the current study, 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], who treated distal clavicle fracture with a modified CC stabilization technique using a bidirectional CC loop system, and found that 100% of cases displayed clinical union and good to excellent shoulder function. This excellent success rate suggests that modified CC stabilization techniques similar to ours can also provide good outcomes.

Despite satisfactory clinical and radiographic outcomes in the treatment of unstable distal clavicle fractures, our study also has some limitations. First, the sample size was small and may bring a statistical bias in the evaluation of the results. Second, a control group was not included to demonstrate the advantages of this procedure over other fixation techniques or even non-operative treatment. Third, 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. Future research to confirm the benefits of this approach should include a larger sample size, control group, and longer follow-up. We are confident our technique is worth further study because of its high union rate and good functional outcome.

Conclusion

Modified CC stabilization using LARS artificial ligament as a treatment for unstable distal clavicle fractures (type IIb) resulted in a high union rate, satisfactory fracture reduction, a low complication rate,

and excellent shoulder function. We suggest that this simple surgical technique, which 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

Ethics approval and consent to participate

This study was approved by our institution's Committee for Research Ethics. Informed consent was obtained from all individual participants included in the study.

Consent for publication

All subjects participating in this study received a thorough explanation of the risks and benefits of inclusion and gave their oral and written informed consent to publish the data.

Availability of data and materials

The dataset supporting the conclusions of this article is available at our institution contacting the corresponding author.

Competing interests

All authors declare that they have no conflict of interests related to the publication of this manuscript, and they have not received benefits or financial funds in support of this study.

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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.

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Figures

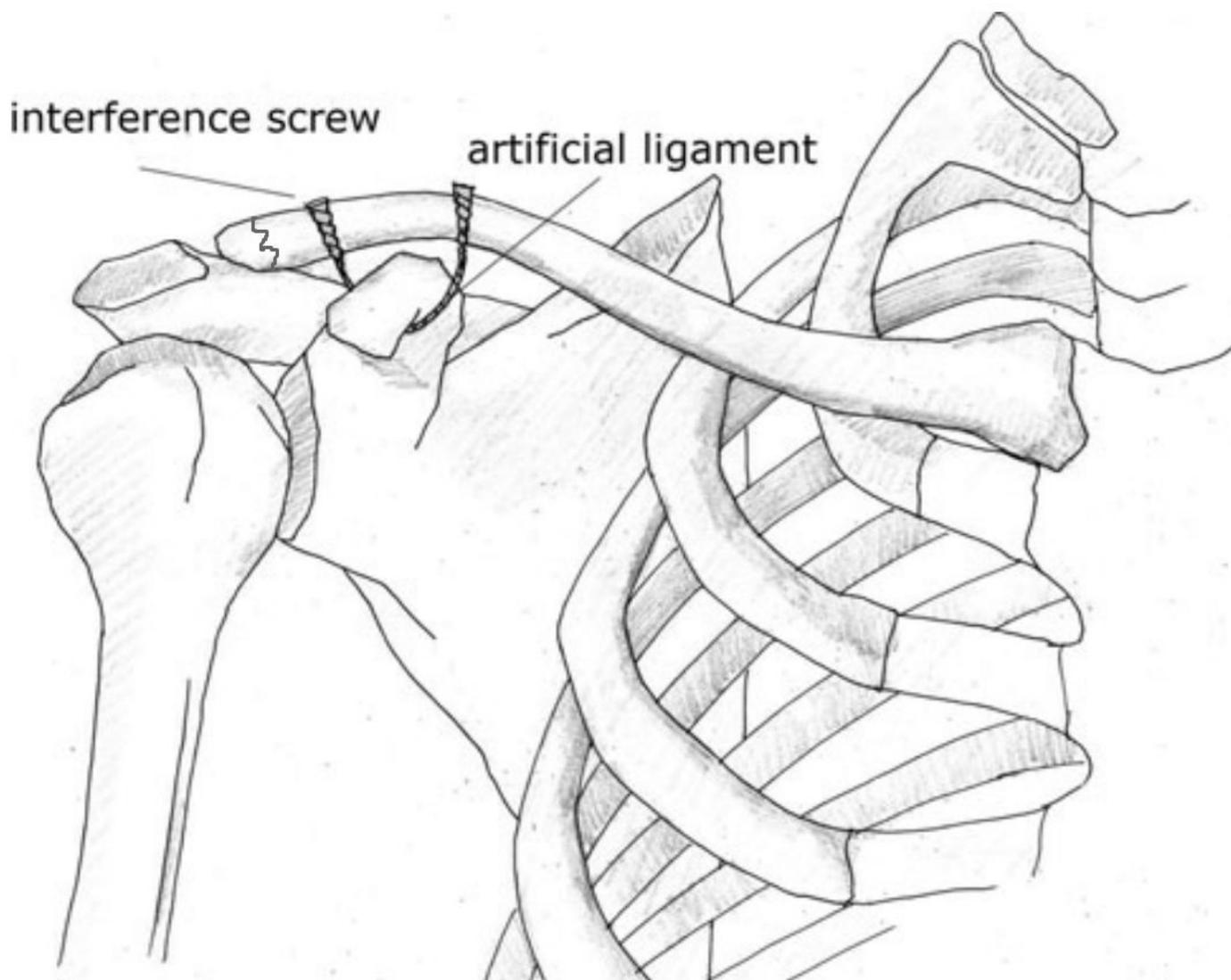


Figure 1

Illustration of the surgical technique for CC reconstruction with LARS artificial ligament in unstable distal clavicle fracture.

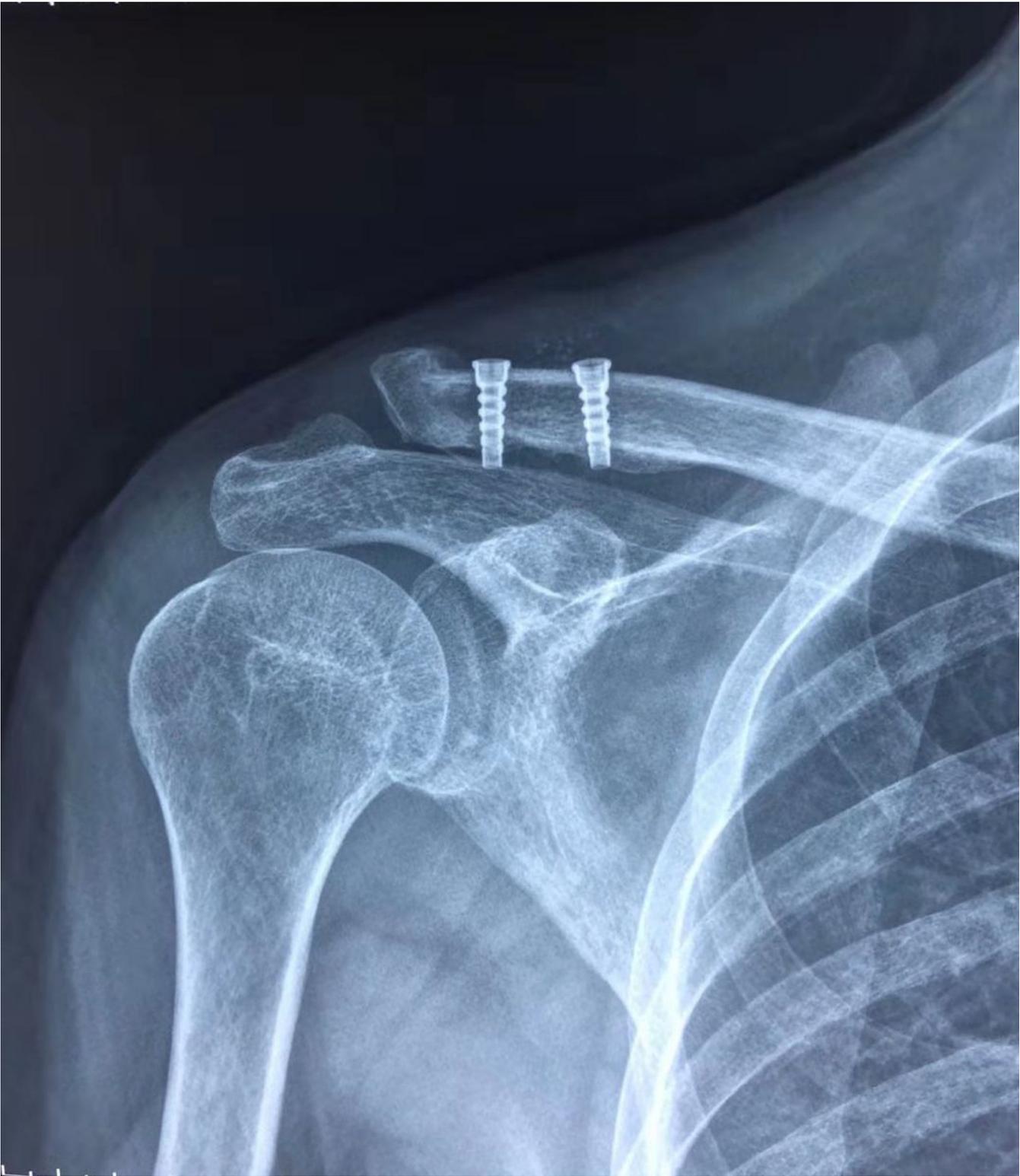


Figure 2

Radiographs showing a satisfactory reduction for CC reconstruction with LARS artificial ligament.

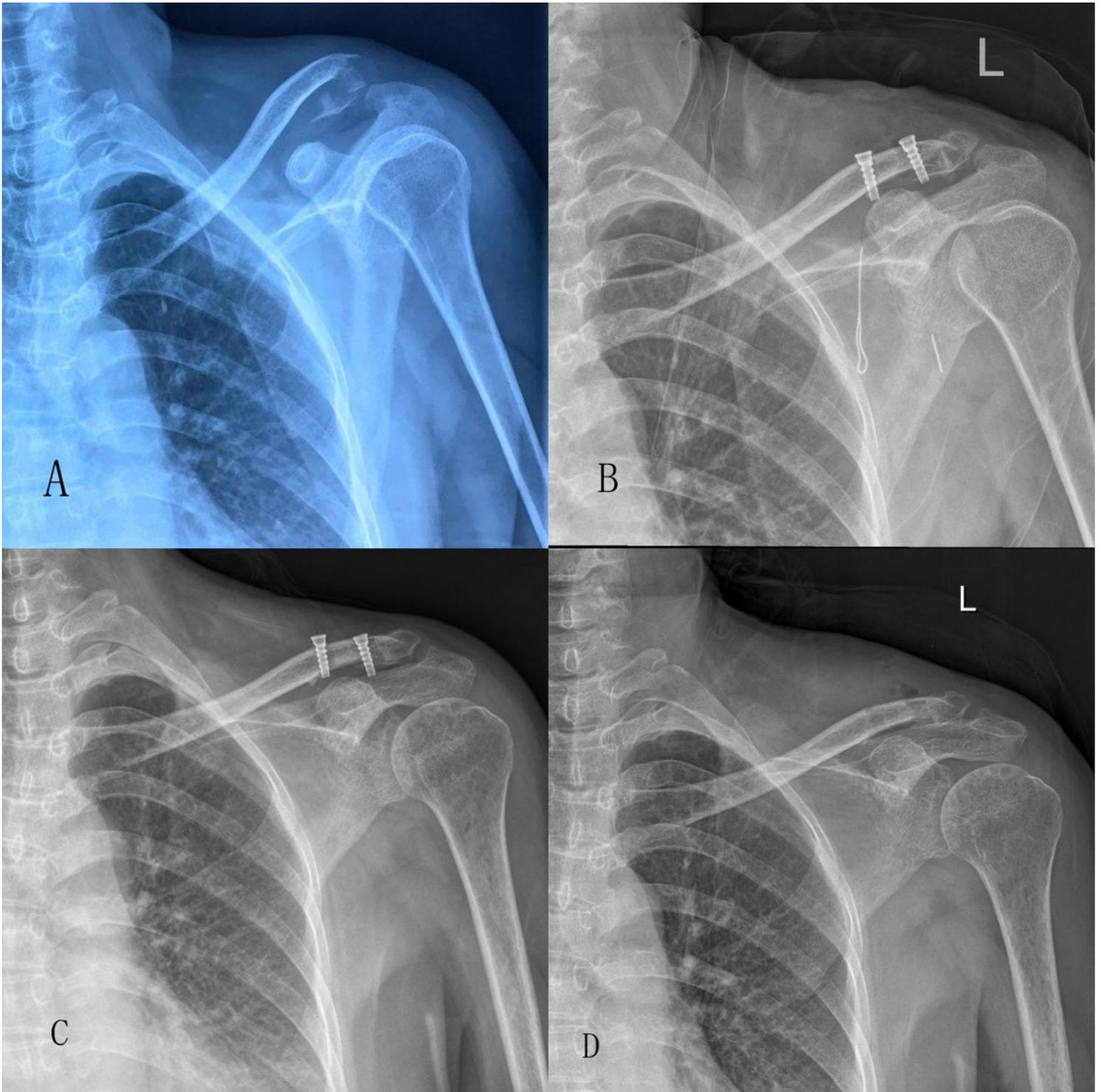


Figure 3

(A) A 60-year-old female who sustained an unstable distal clavicle fracture due to a fall. (B) Post-operative radiographic views showed a reduction of fracture with LARS artificial ligament. (C) Clavicular osteolysis around screws occurred in the 4th month postoperatively. (D) Post-operative radiographic view showing the results of removing the interference screws in a timely manner, with no resulting clavicle fracture.