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Open Reduction and Tunneled Suspensory Device Fixation of Displaced Lateral-End Clavicular Fractures

Medium-Term Outcomes and Complications After Treatment

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Investigation performed at The Royal Infirmary of Edinburgh, Edinburgh, United Kingdom

Background: Fractures of the lateral aspect of the clavicle with complete displacement have a high nonunion rate and are associated with poor functional outcomes following nonoperative treatment. Various techniques are available to treat these fractures, but preliminary studies of open reduction and tunneled suspensory device (ORTSD) fixation have shown good early functional outcomes with a low rate of complications; our goal was to assess the functional outcomes and complications in the medium term in a larger series of patients treated using this technique.

Methods: Sixty-seven patients with displaced lateral-end clavicular fractures were treated with ORTSD fixation. Outcome was assessed with the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire and the Oxford shoulder score at 6 weeks and 3, 6, and 12 months postoperatively. Fifty-five of 64 surviving patients were subsequently contacted at a mean of 69 months (range, 27 to 120 months) postoperatively to complete DASH and Oxford shoulder scores, to evaluate their overall level of satisfaction, and to document any further complications.

Results: At 1 year postoperatively, the mean Oxford shoulder score was 46.4 points and the mean DASH score was 2.4 points in 59 of the 67 patients assessed at this time interval. At the later follow-up (mean, 69 months), the mean Oxford shoulder score was 46.5 points and the mean DASH score was 2.2 points in the 55 surviving patients who were able to be contacted. There were no significant differences between the 1-year functional scores and those at the latest follow-up. Two patients developed a symptomatic nonunion requiring reoperation, and 2 patients developed an asymptomatic fibrous union not requiring a surgical procedure. The 5-year survival when considering only obligatory revision for implant-related complications was 97.0%.

Conclusions: ORTSD fixation for isolated displaced lateral-end clavicular fractures in medically fit patients is associated with good functional outcomes and a low rate of complications in the medium term. Routine implant removal was not necessary.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Displaced fractures of the lateral aspect of the clavicle are less common than mid-shaft fractures, but have a relatively high risk of nonunion[1-5] and poorer functional outcomes after nonoperative treatment[1,6,7]. Operative treatment is therefore typically recommended in medically fit patients[5].

Various operative techniques have been described to treat lateral clavicular fractures. Most contemporary methods describe open reduction and either rigid plate fixation[8-10] or coracoclavicular fixation[11,12]. Plate fixation, using either a locking plate or a hook plate, offers the advantage of anatomic reduction and rigid internal fixation, and excellent results have been reported[9,10]. However, poor bone quality distal to the fracture may lead to fixation failure[13,14]. Late plate removal may be required because of implant prominence or restricted motion[10].

We previously reported satisfactory early results using a new technique of open reduction and tunneled suspensory device (ORTSD) fixation for these injuries[15]. However, concerns have been raised about whether this minimally invasive, less rigid fixation technique is associated with a higher risk of nonunion, as well as a higher risk of osteolysis or stress fracture

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of the clavicle or coracoid from the retained implant[16]. We set out to assess the functional outcomes and the risk of medium-term complications in a larger series of patients treated using this technique.

Materials and Methods

Study Group

Approval to proceed with this study was received by the local research ethics service. Between January 2007 and September 2014, 67 patients with a displaced lateral-end clavicular fracture were treated with ORTSD fixation. The mean age was 41.4 years (range, 15 to 65 years), and there were 15 female patients and 52 male patients. Fractures were sustained in cycling injuries in 35 patients, in other sports injuries in 13 patients, in domestic falls in 12 patients, in assault in 2 patients, and in falls from >2 m in 5 patients. Five patients had associated chest injuries, 2 patients had pelvic fractures, and 1 patient each had an ipsilateral fracture of the distal part of the radius, fibula, scaphoid, triquetrum, and tibial plateau. No clavicular fractures were open or were associated with neurovascular injury. No patients had previous shoulder injuries or clinical evidence of symptomatic acromioclavicular osteoarthritis, although 6 patients had radiographic evidence of degenerative acromioclavicular joint disease on post-injury radiographs. Only patients presenting within 3 weeks of the injury and in whom the primary fracture line was located at the level of or lateral to a line drawn vertically upwards from the center of the coracoid process on a standardized anteroposterior radiograph of the shoulder girdle were considered appropriate for the use of the technique. We considered 3 weeks to be the cutoff after which the fracture is no longer acute and is not amenable to anatomic reduction because of the presence of callus or established fibrous tissue. Our protocol of primary operative treatment was only adopted for patients who had fractures with ≥100% displacement and who were medically fit for operative management.

During the study period, an additional 82 patients were treated nonoperatively, either because they were medically unfit or the fracture was incompletely displaced (<100% translation of bone ends on anteroposterior and Velpeau radiographs of the shoulder girdle). Eight patients with displaced fractures managed surgically >3 weeks after the initial nonoperative treatment were excluded. Three patients who were local residents and were treated operatively did not appear for follow-up.

Fracture Classification

Fractures were classified using the Neer and Edinburgh systems[3,4], based on standardized shoulder and acromioclavicular anteroposterior and Velpeau radiographs at initial clinic attendance. Fifty-two fractures were entirely extra-articular (Neer Type II, Edinburgh 3B1). In 18 of these cases, the conoid and trapezoid ligaments were found to be intact at the time of the surgical procedure and were attached to the lateral fragment (Neer Type IIA). In 17 cases, the conoid ligament was torn and the trapezoid ligament was intact and was attached to the lateral fragment (Neer Type IIB). In 17 cases, the ligaments were intact and in continuity with a third, inferior fragment. In the other 15 cases, intra-articular involvement of the acromioclavicular joint was noted at the time of the surgical procedure (Neer Type III, Edinburgh Type 3B2), with 9 having partial articular involvement and 6 having comminution and complete involvement.

Surgical Technique

The operative technique has been previously described[15], but is described in more detail below and is depicted in Figures 1-A through 1-D. All surgical procedures were performed under general anesthesia in the beach-chair position by the senior author. The skin incision was infiltrated with 1:200,000 epinephrine solution to reduce cutaneous bleeding. A 6-cm vertical ("bra-strap") incision was made with the anterior extent centered on the coracoid process. After raising minimal skin flaps, the deltotrapezius fascia was developed by sharp dissection from the clavicle and was incised to expose the fracture.

Bone tunnels were created after initial guidewire placement using a 4.5-mm cannulated drill (Fig. 1-A). The lower tunnel was created under direct vision in the center of the coracoid (Fig. 1-B). This was achieved by splitting the deltoid in the lower aspect of the wound to expose the coracoid. The flat superior aspect of the coracoid is inclined medially between 30° and 45° in the coronal plane, and the tunnel was placed 20 mm from the coracoid tip and perpendicular to this surface by orientating the guidewire inferolaterally.

For the initial 31 cases, a single, customized, tunneled loop fixation construct was constructed from 2 ENDOBUTTON devices (Smith & Nephew) and #2 ORTHOCORD (Ethicon) sutures. These were looped through the ENDOBUTTON devices, generating a 6-ply sliding pulley effect. The lower button was inserted through a solitary clavicular tunnel inserted 15 mm medial to the fracture site and then passed through the coracoid tunnel and was toggled on its undersurface. The fracture was reduced either directly by using a reduction forceps, if the bone quality was satisfactory, or indirectly by tensioning the implant if the bone quality was poor or there was extensive comminution. Accurate fracture reduction and toggling of the lower ENDOBUTTON below the coracoid were confirmed fluoroscopically before final tensioning and tying of the suture ends over the proximal ENDOBUTTON.

Later in the series, a preassembled construct (Fig. 1-C) was used in 36 cases. As this loop fixation construct (TightRope; Arthrex) had only a solitary core suture, we used 2 separate implants inserted through separate clavicular tunnels (drilled 15 and 35 mm medial to the fracture site) (Figs. 1-D and 2).

In the 17 patients in whom there was a 3-part fracture configuration, with a separate inferior fragment attached to the coracoclavicular ligaments, cerclage fixation was achieved to the undersurface of the clavicle, using ORTHOCORD sutures (Fig. 3).

Following the surgical procedure, all patients were immobilized in a sling with the shoulder held in neutral rotation for 4 weeks. After sling removal, a staged physiotherapy regimen was commenced. This progressed from range-of-motion exercises to shoulder strengthening once patients had regained

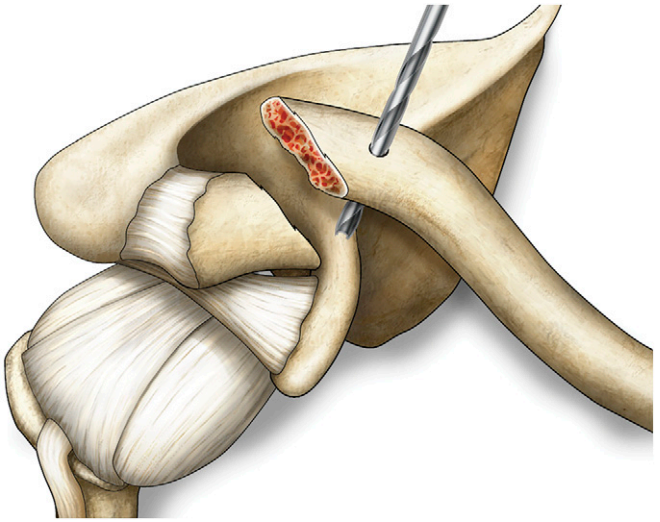
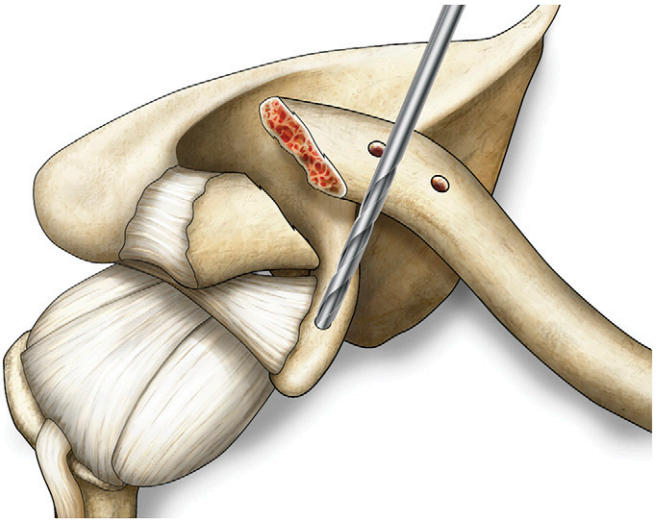


Fig. 1-A



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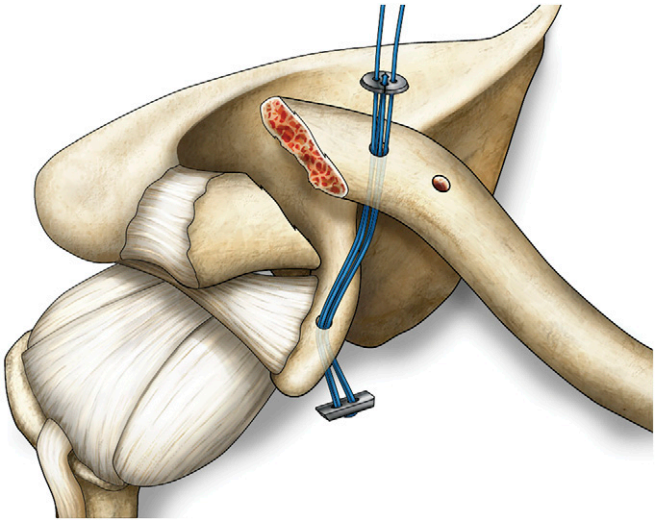

Fig. 1-C

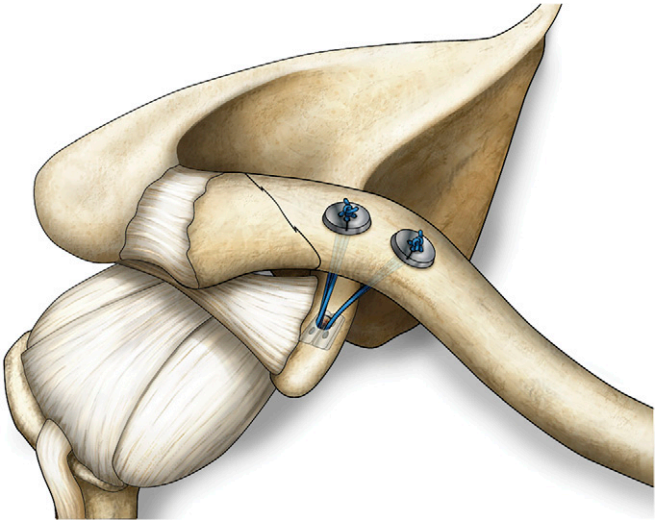

Fig. 1-D

Figs. 1-A through 1-D The key steps of the operative technique. **Fig. 1-A** The 2 clavicular tunnels are created using a 4.5-mm cannulated drill-bit. **Fig. 1-B** The coracoid tunnel is oriented 30° to 45° superomedially using the same drill diameter. **Fig. 1-C** The ORTSD constructs are "railroaded" through the clavicular and coracoid tunnels and the lower buttons are then toggled against the undersurface of the coracoid. **Fig. 1-D** After the fracture has been reduced under direct vision and on fluoroscopic imaging, the devices are tensioned and the suture ends are tied.

full range of movement, which was usually between 4 and 8 weeks postoperatively.

Outcome Assessment

The patients were assessed at 1 week, 6 weeks, 3 months, 6 months, and 12 months postoperatively. The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire (specific to the upper limb)[17] and the Oxford shoulder score[18] (a minimum of 0 points to a maximum of 48 points) were assessed at 6 weeks, 3 months, 6 months, and 12 months postoperatively. Anteroposterior and Velpeau radiographs of the shoulder girdle were obtained at each of these time points. The timing of return to work and the return to normal daily activities was noted. Range of motion of the shoulder and clinical testing for residual fracture tenderness, rotator cuff weakness, subacromial impingement, labral dysfunction, and acromioclavicular joint dysfunction were also performed up to 1 year. Pain was assessed on a visual analog scale. Seven patients with healed fractures and near normal shoulder function at their 6-month assessment were lost to follow-up at 1 year, and 1 patient died during the first year. We therefore obtained final 1-year follow-up assessment in 59 patients.

All patients were contacted by letter or telephone (for nonresponders) in December 2016 and were asked to complete the DASH questionnaire and Oxford shoulder score to evaluate their overall level of function and satisfaction (as a percentage, in which 0% was the worst function or satisfaction and 100% was perfect satisfaction or shoulder function) and to

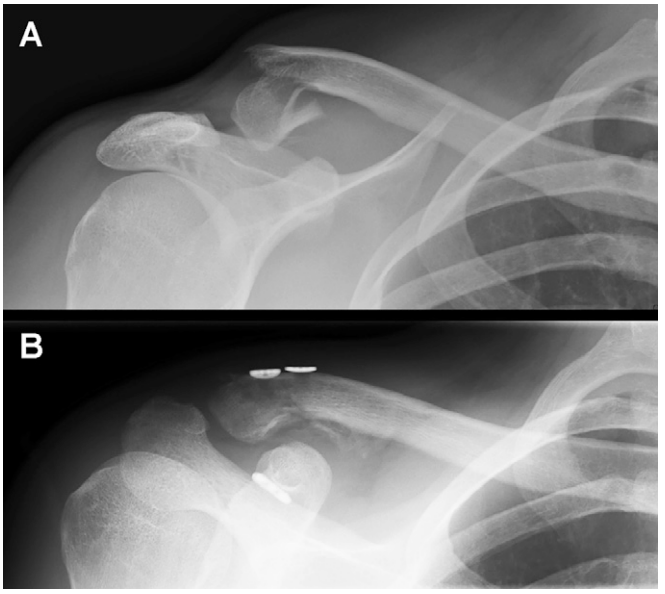

Fig. 2

Figs. 2-A and 2-B Radiographs of a displaced fracture of the lateral end of the clavicle. **Fig. 2-A** Preoperative radiograph. **Fig. 2-B** Radiograph made 1 year after injury, showing the maintenance of reduction and osseous union.

document any further complications. The complications specifically assessed included reoperations, infection, prominence of the implant, numbness, and change in appearance. Of the original cohort of 67 patients, 3 patients had died, and we were able to contact 55 of the 64 surviving patients, for a mean follow-up of 69 months (range, 27 to 120 months) after the original surgical procedure.

Initial preoperative and postoperative fracture displacement was assessed on anteroposterior radiographs using calibrated software that adjusted for magnification (Carestream Vue PACS [Picture Archiving and Communication System], Carestream Health) by measuring the distance between the superior aspects of the proximal and distal fragments. Fractures were considered to have united if no shoulder pain or only mild discomfort was reported by patients, with no radiographic evidence of bridging bone, loosening, or implant compromise.

Statistical Analysis

All data were analyzed using SPSS software (IBM). The primary outcome measure was shoulder function at the time of the final follow-up. Secondary outcome measures included radiographic displacement and the prevalence of fracture-related complications. The Wilcoxon matched-pairs test was used to analyze differences of means at different times of follow-up. Nonparametric tests were used as a normal distribution could not be assumed. Survivorship analysis, with the end points of revision of the original surgical procedure for any reason and for removal of the implant, was performed as previous studies of operative fixation of lateral-end clavicular fractures have shown late implant-related complications.

Results

Functional Outcome

Progressive improvements in Oxford and DASH scores were observed in the first 6 months postoperatively. No significant differences were observed between 6 and 12 months (Wilcoxon matched-pairs test, $p = 0.7$). Fifty-nine patients were assessed at 1 year postoperatively. The mean Oxford shoulder score was 46.4 points (95% confidence interval [CI], 45.7 to 47.1 points), and the mean DASH score was 2.4 points (95% CI, 1.4 to 3.4 points) (Table I). Whether injury occurred to the dominant or nondominant limb did not affect the outcome (Wilcoxon matched-pairs test, $p = 0.6$).

At 1 year, 54 patients reported no shoulder pain and 5 patients had mild pain that was not associated with activities. The mean forward flexion was 174.2° (range, 155° to 180°), and the mean abduction was 174° (range, 140° to 180°). The mean external rotation at 90° of abduction was 97.2° (range, 60° to 120°), and the mean internal rotation was 79° (range, 60° to 100°).

Four of the 67 original series of patients were unemployed before their injury, and 3 were retired. Of the remaining 60 patients, the 40 patients who had been employed in sedentary jobs had all returned to full responsibilities by 3 months. The 20 patients with physical jobs all returned to their previous duties by 6 months. Fifty patients played regular sports (23 played contact sports and 27 played noncontact sports) prior to the injury. All but 4 returned to their chosen sports by 6

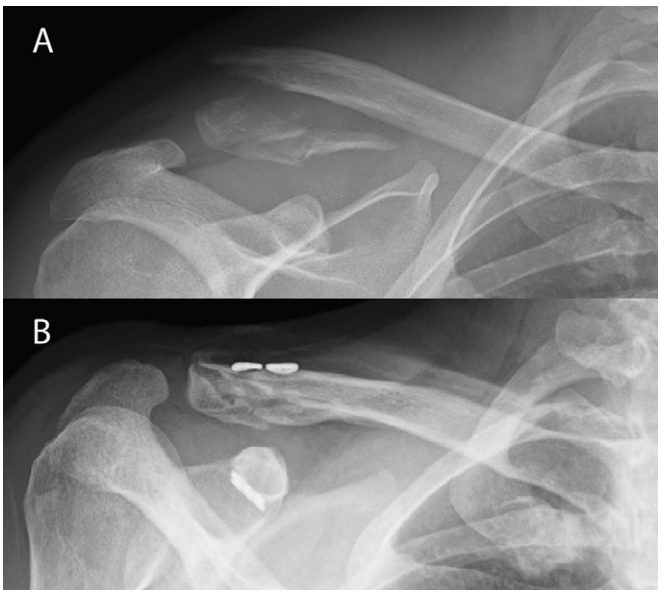

Fig. 3

Figs. 3-A and 3-B Radiographs of a displaced fracture of the lateral end of the clavicle in a 28-year-old man who sustained an injury in a fall from his bicycle. **Fig. 3-A** Preoperative radiograph. Note the variant in which there is a third, inferior fragment carrying the coracoclavicular ligaments, which was cerclaged to the main fracture fragments. **Fig. 3-B** Radiograph made 1 year postoperatively, showing maintenance of reduction and osseous consolidation at the fracture site.

TABLE I Functional Recovery After the Surgical Procedure, Using the Oxford Shoulder and DASH Scores*

Time Point	Oxford Shoulder Score† *(points)*	DASH Score† *(points)*
6 weeks (n = 49)	12.9 (11.6 to 14.2)	54.1 (49.8 to 58.4)
3 months (n = 48)	36.4 (34.6 to 38.2)	11.0 (7.7 to 14.3)
6 months (n = 51)	44.3 (43.4 to 45.3)	5.3 (3.6 to 7.0)
12 months (n = 59)	46.4 (45.7 to 47.1)	2.4 (1.4 to 3.4)
Final follow-up‡ (n = 55)	46.5 (45.6 to 47.4)	2.2 (1.2 to 3.2)

*A higher Oxford shoulder score denotes better function (range of possible scores, 0 to 48 points), whereas a lower DASH score denotes better function (range of possible scores, 0 to 100 points). †The values are given as the mean and the 95% CI. ‡The mean follow-up was 69 months.

months. Two patients returned to sports by 1 year, and 2 patients returned to noncontact sports.

Of the 55 patients assessed at the time of the final follow-up, at a mean of 69 months (range, 27 to 120 months) postoperatively, the mean Oxford shoulder score was 46.5 points (95% CI, 45.6 to 47.4 points) and the mean DASH score was 2.2 points (95% CI, 1.2 to 3.2 points). There were no significant differences between the 1-year functional scores and those at the time of the latest follow-up (Wilcoxon matched-pairs test, $p = 0.85$). There were no significant differences in Oxford or DASH scores between the 2 implants used during the study or the different fracture patterns.

Patients rated the overall mean function for the injured shoulder to be 93.0% (95% CI, 90.3% to 95.6%) when compared with that for the uninjured shoulder. The overall mean satisfaction with treatment was 94.9% (95% CI, 92.5% to 97.4%).

On survivorship analysis, when considering only obligatory revision of the ORTSD (revision due to symptomatic nonunion, fixation failure, or infection), the 5-year survival was 97.0% (95% CI, 92.9% to 100%) (Fig. 4). The 5-year survival when considering both revision for implant-related complications and revision due to local prominence was 94.2% (95% CI, 88.3% to 99.7%).

Radiographic Outcome

The mean initial fracture displacement was 24 mm (range, 18 to 30 mm). On immediate postoperative radiographs, the mean residual displacement was 1.4 mm (range, −2 to 5 mm).

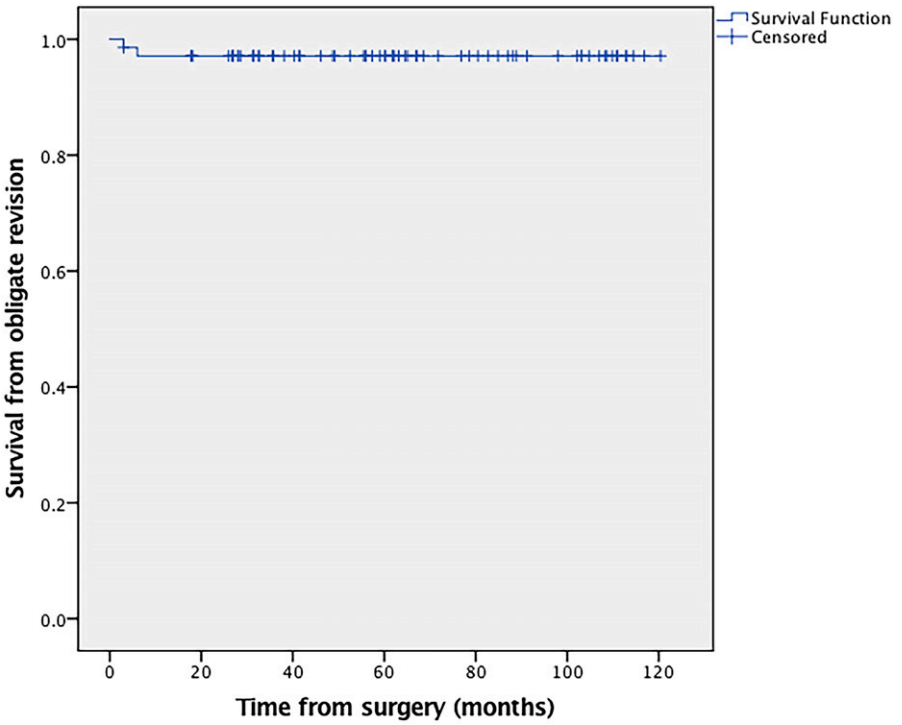

Fig. 4

Survivorship analysis considering only obligatory revision of the tunneled suspensory device (revision due to symptomatic nonunion, fixation failure, or infection).

There were no fixation failures or loss of the initial reduction during the first year. With the exception of the 4 nonunions discussed below, all fractures had clear evidence of consolidation and remodeling at 1 year (Figs. 2 and 3). Mild ectopic bone formation on the inferior aspect of the clavicle was noted in 6 patients. The asymptomatic degenerative changes within the acromioclavicular joint that were evident on preoperative radiographs in 6 cases were nonprogressive on radiographs made in the year following the surgical procedure.

Complications

One patient developed a partial wound dehiscence at 5 days postoperatively; the wound was resutured and healed uneventfully. Two patients developed superficial wound cellulitis that resolved with oral antibiotic therapy.

Two patients had asymptomatic nonunion at 1 year, with no signs of bridging callus on computed tomography (CT). There was no evidence of loss of fracture reduction in either patient on CT at 1 year. Both patients declined a further surgical procedure and remained asymptomatic after a further year of follow-up. Two patients had persistent pain at the fracture site with radiographic nonunion and underwent a revision surgical procedure at 16 and 19 weeks. The nonunion was debrided, reduced, and compressed using a lateral-end locking plate supplemented with a coracoclavicular ENDOBUTTON fixation with the core suture passed through a lateral plate hole and secured superiorly. A morselized autogenous iliac crest bone graft was used. One of the patients healed uneventfully following revision fixation, and the other patient died from an unrelated condition.

Three patients developed persistent shoulder stiffness at 3 months postoperatively. All had clinical features of adhesive capsulitis with selective restriction of rotational movements. All regained full range of motion at 6 months following physiotherapy.

Two patients underwent elective removal of the superior button of the construct for symptomatic prominence at 6 and 8 months after fracture fixation. No patient had a revision surgical procedure for implant breakage or other complications after the last follow-up at 1 year.

Discussion

ORTSD fixation for isolated displaced lateral-end clavicular fractures is associated with a return to near normal shoulder function within 6 months following injury, with a high likelihood of union and few complications at 1 year. Furthermore, the excellent outcomes with the low rate of complications are maintained at the medium-term follow-up. Such follow-up is essential as previously described complications relating to this injury including pain secondary to acromioclavicular osteoarthrosis and stress fracture of the coracoid take over a year to develop. These complications have not been encountered to date in any of our patients.

These favorable results are comparable with smaller series reporting the use of suture-based open reduction and anatomic reduction of distal clavicular fractures. In a series of 19 patients undergoing coracoclavicular reconstruction using 2 suture anchors and supplementary interfragmentary fixation using 2 nonabsorbable suture tension bands for acute distal clavicular fractures, Shin et al. reported that 16 patients (84%) had pain-free shoulder without limitation in range of movement at 25.9 months (range, 24 to 40 months)[19]. Duralde et al.[20] reported a 100% union rate with high rates of satisfaction at 7.1 years (range, 3.1 to 14.3 years) in 20 consecutive patients undergoing suture fixation around the coracoid and interfragmentary suture fixation for distal clavicular fractures.

The key advantage of ORTSD fixation over non-suture-based implant fixation is the low rate of a secondary surgical procedure for implant removal. Implant retention following fixation with coracoclavicular screws, lateral clavicular plates, and hook plates has been associated with persisting stiffness, and most authors have suggested routine removal[10,21,22]. However, early removal may compromise stability and risk redisplacement if the fracture has not completely united. Only 2 patients in our series underwent elective removal of elements of the implant for symptomatic prominence. Three patients developed transient shoulder stiffness, which resolved after a short period of physiotherapy.

We acknowledge that this study had limitations. For medium-term follow-up data, patients were asked about late reoperations, revisions, or complications through postal questionnaires and telephone consultations. This may have underestimated the number of complications, as patients may not have recalled all adverse events that occurred.

We did not compare ORTSD fixation with existing techniques and are therefore unable to establish whether the excellent functional outcomes and low rates of complications reflect appreciable improvements over other treatment strategies. The surgical technique is likely to exhibit a learning curve, so the results in this large, single-surgeon series may not be generalizable.

In conclusion, ORTSD fixation for a displaced lateral clavicle fracture is a reliable technique with excellent functional outcomes and low complication rates. Routine implant removal is not required. ■

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