J Shoulder Elbow Surg (2015) 24, 587-592

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

SHOULDER

Surgical treatment of displaced middle-third clavicular fractures: a prospective, randomized trial in a working compensation population

Patricio A. Melean, MD[a,*], Adrian Zuniga, MD[a], Michael Marsalli, MD[a], Nelson A. Fritis, MD[a], Erik R. Cook, MD[a], Matías Zilleruelo, MD[a], Cristian Alvarez, MD[b]

[a]*Shoulder Surgery Unit, Orthopedics Department, Hospital del Trabajador, Santiago, Chile*
[b]*Meds Sports Medicine Clinic, Orthopedic Department, Santiago, Chile*

Background: Surgical treatment with open reduction and internal fixation (ORIF) of displaced middle-third clavicular fractures resulted in shorter complete return to work periods with earlier consolidation documented on computed tomography (CT) scans in this prospective, randomized controlled trial.
Methods: The study randomized 76 consecutive patients with displaced fractures (2B1-2B2 according to Robinson) to conservative (C, n = 42) and surgical (S, n = 34) treatment with plates and screws. Bone union was documented with CT scans at 6 and 12 weeks.
Results: Risk factors known to increase the risk of nonunion were similar between groups. Time until discharge for complete return to work was 3.7 ± 1.1 months for C and 2.9 ± 0.8 months for S ($P = .003$). On the CT scan at 6 weeks, 24.1% of the patients presented advanced bone union in S vs 5.3% in C ($P = .05$). At 12 weeks, 81% of the patients presented advanced bone union in S vs 16.7% in C ($P = .005$). At final follow-up, 4 nonunions were present in the C group that required surgery; in the S group, 4 patients underwent revision surgery for plate removal. At 6 and 12 months of follow-up, Constant scores were higher for the S group.
Conclusions: Surgical treatment with ORIF of displaced middle-third clavicular fractures achieved good and excellent functional results, shorter time to complete return to work, earlier bone union, and fewer cases of nonunions in a working population under injury compensation.
Level of evidence: Level I, Randomized Controlled Trial, Treatment Study.

Keywords: Clavicular fracture; middle third; operative treatment; nonoperative treatment; nonunion; off-work period

Middle-third clavicular fractures are frequent injuries amongst the general population, with a greater incidence in individuals exposed to work-related risks or who participate in contact sports.[12,15,18] Currently, there is evidence that supports conservative or surgical treatment with open reduction and internal fixation (ORIF) of displaced middle-third fractures, causing some confusion.[2,3,8,15] Historically,

Hospital de Trabajador Ethical Committee approval was obtained before the study was initiated.

*Reprint requests: Patricio A. Melean, MD, Ramón Carnicer 185, Third Flr, Providencia, Santiago, Chile.
E-mail address: pmelean@hts.cl (P.A. Melean).

1058-2746/$ - see front matter © 2015 Journal of Shoulder and Elbow Surgery Board of Trustees.
http://dx.doi.org/10.1016/j.jse.2014.11.041

the standard of care has been conservative treatment, because in most cases, clavicular fractures heal or progress toward an asymptomatic nonunion.[4,6,8,11,19] Fractures that do not heal and progress to a symptomatic nonunion represent a complex problem for patients, ultimately causing prolonged work absence periods in some cases.

Most of the published studies regarding clavicular fracture outcomes were performed in the general population, including pediatric cases in some studies. When the patient is an active young individual, a more demanding function is required from a working and sports perspective; therefore, an earlier return to normal function might result in important improvements concerning these activities.[6,12,13,15,19]

Displaced middle-third clavicular fractures represent an important subgroup to analyze, because of the higher rates of nonunion and longer periods out of work. For this reason, we consider that middle-third clavicular fractures, classified according to Robinson[14] as 2B1 and 2B2, should be subject to an isolated analysis when diagnosed in young patients who perform demanding labor activities.

The objective of the present study was to compare union rates, functional outcomes at follow-up, and time until complete return to work in displaced middle-third clavicular fractures, classified according Robinson[14] as 2B1 and 2B2, between patients treated conservatively and those treated surgically with ORIF. The hypothesis of the present study was that ORIF for the treatment of displaced midshaft clavicular fractures results in better functional and radiologic outcomes at follow-up and earlier an earlier complete return to work.

Methods

This was a prospective, randomized study of a consecutive case series that included 76 displaced midshaft clavicular fractures diagnosed in 76 patients, classified according to Robinson[14] in 2B1 and 2B2, between February 2010 and February 2012. All patients were treated in our hospital.

Randomization was performed following the Consolidated Standards of Reporting Trials (CONSORT) guidelines by the method of tables of 4. This resulted in a list, with randomized consecutive numbers appointed to each patient, and those with 0 were assigned to conservative treatment and with 1 were assigned to surgical treatment. These results were placed in envelopes that were given to each patient at the initial consultation. A sample size of 34 patients per group was calculated with a power of 80% and an α error of 0.05.

Of the 76 patients included in the study, 42 were treated conservatively (C) and 34 were managed surgically (S) with ORIF with plates and screws. Inclusion criteria were:

1. displaced middle-third clavicular fractures (without cortical contact);
2. age older than 18 years;
3. signed approval to participate in the study;
4. isolated clavicular fracture;
5. patients with labor accidents that were treated under the national workers insurance laws and compensations; and
6. fracture classified 2B1 or 2B2 according to Robinson et al.[15]

Exclusion criteria were:

1. Fractures in the lateral or medial segment of the clavicle;
2. neurovascular associated injuries;
3. open fractures; and
4. more than 21 days of evolution from the accident.

Clinical and radiologic evaluations were performed at follow-up. Constant[4] scores were obtained at 12 weeks and at 6 and 12 months of evolution after the fracture or after surgical treatment.

Anterior-posterior and axial X-rays of the clavicle were obtained during the initial evaluation, at 4 weeks, 8 weeks, and at 4 months of follow-up, mainly with the purpose to determine displacement and nonunion. A computed tomography (CT) scan was obtained at 6 and 12 weeks of follow-up, primarily to document bone union.

We arbitrarily classified bone union according to subjective observations of each image as ''with'' or ''without'' healing signs, when current images were compared with prior evaluation, observing the presence of trabecular bone or cortical continuity, or both, in areas where a fracture line was evident on the first assessment.

For the C group, a shoulder sling was used for 6 weeks (permanent for 3 weeks and intermediate use for 3 more weeks). Physical therapy was started at 4 weeks, with passive range of motion (ROM) and analgesic physiotherapy for 3 weeks, following active ROM and strengthening exercises.

For the S group, ORIF was performed using the 3.5-mm Locking Compression Plate (LCP) system (Anatomic; Synthes, Solothurn, Switzerland) in 12 patients and LCP reconstruction plates (Synthes) in 22. Different implants were used according to availability at the day of the surgery. A sling was used after surgery for pain management and soft tissue care for 4 weeks (continuous for 2 weeks and intermittent afterwards). Physical therapy was started at 3 weeks, with passive ROM and analgesic physiotherapy for 3 weeks, following active ROM and strengthening exercises.

Complete return to work was determined the moment when the patient was sent back to work without functional restrictions. We documented this time in months.

Statistics

The statistical analysis was performed with SSPS 11.0 software (SPSS Inc, Chicago, IL, USA). Fisher and analysis of variance instruments were used to obtain P values, with $P < .05$ indicating significance.

Results

At an average follow-up of 12 $\pm$ 2 months (range, 10-14 months), we did not find statistical differences regarding patient age between the C (37.2 $\pm$ 11.2 years) and S (38.1 $\pm$ 13 years) groups ($P = .743$). When tobacco use was evaluated, no statistical differences were

Table I Outcomes for the complete series of patients analyzed according to treatment, Robinson[14] classification, and percentage of each subgroup*

Variables	Robinson classification		Total
	2B1	2B2	
Conservative			
Fractures, No.	35	6	41
%	85.4	14.6	100
Surgical			
Fractures, No.	21	14	35
%	58.8	41.2	100
Total			
Fractures, No.	56	20	76
%	73.3	26.7	100

* In the conservative group, 2B1 fractures predominated the sample.

found between the C (51.6%) and S (41.7%) groups ($P = .323$).

The study included 76 fractures in 76 patients; of these, 73.3% were Robinson[14] 2B1 ($P = .01$). No difference in the distribution of these fractures between the groups was documented, although these fractures were more frequent in the C group (85.4%) than in the S group (58.8%; $P = .09$). In Table I, we describe findings regarding type of fracture and treatment group.

Analysis of variance using as dependent variables "time to complete return to work" and as constant variables "Robinson classification"[14] and "group of treatment" found that the Robinson classification (analyzing only the 2B1 and 2B2 subgroup) did not correlate with time to complete return to work ($P = .546$). A positive correlation was observed between "groups of study" (C vs S) for the variable "time to complete return to work" ($P = .008$).

Concerning fracture displacement (measuring amongst largest medial and lateral fragments of the fracture), the values did not differ significantly, with average results of 19.3 ± 7.8 mm for the C group and 21.4 ± 6.1 mm for the S group ($P = .533$).

Clavicular shortening after the fracture (measuring among the largest medial and lateral fragments of the fracture) was similar between the groups, with average shortening of 7.5 ± 7 mm for C and 9 ± 9.8 mm for S ($P = .450$). Time to complete return to work was achieved earlier in the S group (2.9 ± 0.8 months) than in the C group (3.7 ± 1.1 months; $P = .003$). Nevertheless, we documented greater dispersion on "time to complete return to work" results in the C group (Fig. 1).

Constant scores were similar at 3 months of follow-up. At 6 months, an average of 4 points of difference in the Constant scores was observed in favor of the S group. At 12 months of follow-up, the S group had an average Constant score 6 points higher than the C group ($P = .003$; Table II, Fig. 2).

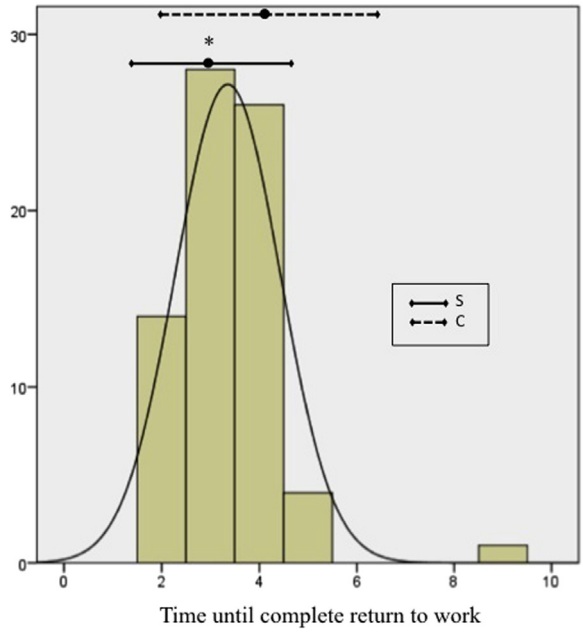

Figure 1 The average time in months until medical discharge is presented. The greater results dispersion for the group with conservative (*C*) treatment compared with surgical (*S*) treatment is noteworthy. *$P = .003$.

Table II Clinical findings documented at follow-up*

Treatment	Constant score, mean (range)		
	3 months	6 months	12 months
Conservative	74 (31-95)	81 (23-125)	87 (79-95)
Surgical	76 (48-93)	85 (75-98)	93 (91-95)
P value	.06†	.004	.003

* Significant differences in favor of the surgical group were registered at 6 and 12 months.
† Statistically significant ($P < .05$).

Signs of radiologic bone healing in the CT scan at 6 weeks were present in 5.3% of patients in the C group and 24.1% of the S group ($P = .005$; Fig. 3). At 12 weeks, CT scans showed signs of fracture healing in 16.7% of patients in the C group and in 81% in the S group ($P = .004$; Fig. 4).

There were 4 patients (9.6%) with nonunion (defined as more than 4 months without radiologic signs of bone healing) in the C group. All 4 were treated with ORIF with plates and screws with additional bone allograft. Four patients (11.7%) in the S group required implant removal due to symptomatic plate or screws. We did not see any nonunions in the S group.

Discussion

Currently, appropriate treatment of displaced middle-third clavicular fractures remains controversial, particularly if

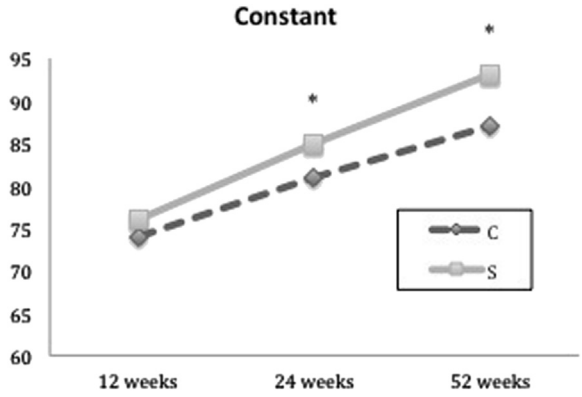

Figure 2 Constant scores at follow-up are presented for the patients who received conservative (*C*) and surgical (*S*) treatment. Linear progression was documented, with better values for the S group. *P value = 24 weeks, .004; 52 weeks, .003.

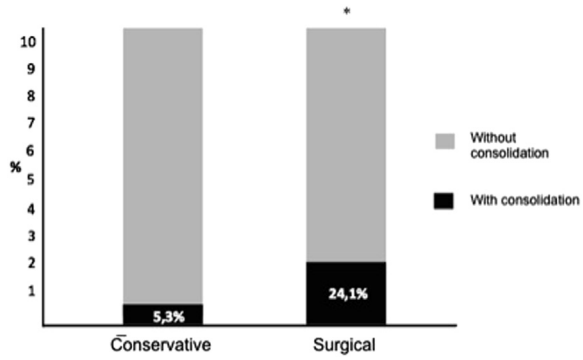

Figure 3 At 6 weeks of follow-up, consolidation was poor in both groups; nevertheless, this difference was significant in favor of the surgical group. *$P = .005$ (statistically significant).

these fractures are comminuted in a young and active population.[5,8,9,17] In a prospective, randomized study, Robinson et al[15] studied 200 patients aged between 16 and 64 years with displaced middle-third clavicular fractures, comparing operative and nonoperative treatment. Constant scores, Disabilities of the Arm, Shoulder and Hand (DASH) scores, and fracture healing signs on CT scans were analyzed. Nonunion risk was lower with ORIF with plates (relative risk, 0.07; $P = .007$). The Constant and DASH scores were higher in the operative group ($P = .01$). In our study, we found better Constant scores after 6 months in the S group, and this difference was maintained after 1 year. The Constant average differences were 4 points at 6 months and 6 points at 12 months. This achieved statistical significance, but we do not know if this correlates with clinical significance.

Also, radiologic signs of fracture healing on CT scan were present in a higher rate in the S group. At final follow-up, 9.6% of nonunion cases were found in the C group and no cases in the S group. Symptomatic nonunion was found only in the C group, and all were treated with plate fixation.

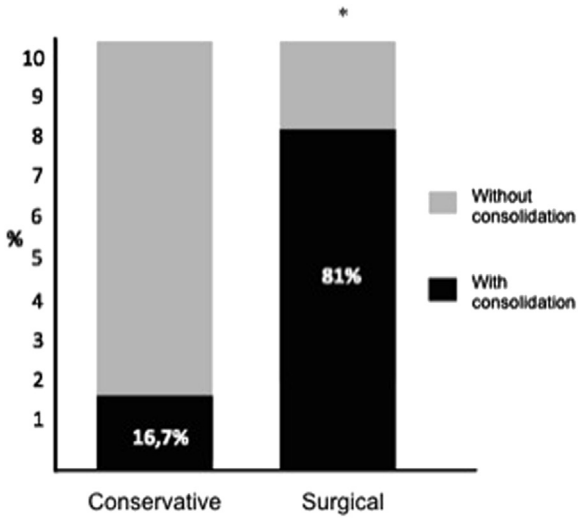

Figure 4 Higher consolidation was shown in the surgically treated group at 12 weeks of follow up. *$P = .004$ (statistically significant).

The reoperation rate of 11.7% in the S group was solely due to plate prominence. We did not observe refractures after plate removal. Outcomes documented in this study and those described by Robinson et al[15] suggest that ORIF achieves better functional outcomes and higher rates of bone healing in the short-term and midterm follow-up.

McKee et al[11] analyzed the results of Robinson et al[15] and found that fractures with greater degree of bone displacement and patients with high functional demands needed a more aggressive treatment strategy. Constant scores were higher (average of 5 to 10 points) with operative treatment. This finding could result in a shorter off-work time; nevertheless, McKee et al[11] did not report this in their analysis. Our report confirms these observations. Our study population was mainly young, active, heavy-labor workers, and we found shorter time to complete return to work in the S group.

In a prospective, randomized study of 132 patients, Altamimi et al[2] showed better functional outcomes, pain scores, and bone healing for patients surgically treated for clavicular fractures. They observed a 34% complication rate and an 18% reoperation rate in the operative treatment group. Complications were local irritation or plate prominence, plate failure, and surgical wound infections. These results were different from ours, where we showed 11.7% plate prominence in the S group. We did not document any other complications such as surgical wound infections, plate failure, or neurovascular injuries. It is important to mention that patients who underwent reoperations for plate removal required a shorter time for physical therapy before a complete return to work, given that this second surgery for plate removal was of a very low morbidity compared with ORIF with allograft and plates and screws in patients treated due to nonunions in the C group. We did not quantify this second off-work time in the present study.

Functional outcomes obtained in our study were comparable with those described in the literature for both groups, with better Constant scores for the S group, especially after 6 months, following a linear progressive correlation with bone healing on CT scans.

Fracture shortening or displacement did not affect the overall results in our analysis because no differences between the groups or correlation with nonunion were documented. Fracture comminution appears to be a more relevant point to consider when deciding appropriate treatment of midshaft clavicular fractures. This does not mean that we should overlook fracture shortening or displacement. A comprehensive analysis of the fracture, including all known clinical and radiologic variables, must be accomplished before deciding appropriate treatment. We did not evaluate whether clavicular shortening affected clinical outcomes in the C group when fracture healing was achieved. These parameters should be considered because there is evidence that clavicular shortening of more than 2 cm may affect shoulder strength and endurance.[10]

There is not enough evidence regarding return to work after a midshaft clavicular fracture. Alshameeri et al,[1] in a retrospective study, analyzed 35 patients with midshaft clavicular fractures treated with plates and screws of various types. They mainly compared 2 surgical approaches—direct and inferior—and present a succinct discussion on return to work. From their cohort, 29 patients were working at the time of injury. All went back to work at an average of 2.5 months (range, 2 weeks to 6 months). This is similar to our findings of 2.9 ± 0.8 months, The main difference is that our patients presented less standard deviation in total time off work. We have not found any other study where time to complete return to work was compared between surgical and nonsurgical groups. To our knowledge, our findings are the first that demonstrate that complete return to work is shorter for surgical treatment compared with conservative treatment in middle-third displaced clavicular fractures.

The most relevant weakness of our study is the short follow-up (1 year average). We have considered reevaluation of our patients at 2 years to assess longer-term results. Furthermore, 2 different implants were used in our study, and we do not know whether this could modify our surgical treatment results. We could not find a validated scale applicable to our research to describe bone healing in clavicular fractures; therefore, radiologic signs of bone healing were evaluated with our own subjective scale.

Regarding the randomization process, 34 patients for each group offered 80% power and an α error of 0.05; nevertheless, 42 patients were included in the surgical group after the randomization list was complete, going back to the first ones of the list again. This was performed in an attempt to have extra patients to avoid underpowered analysis in case of patient drop-out. This might have caused skewed groups.

Our patient population was covered by worker compensation insurance; for this reason, our clinical results at follow-up might be different in a diverse patient population.

Recent studies have evaluated the optimal treatment of displaced midshaft clavicular fractures[7,16]; nevertheless, optimal treatment of these fractures still is a difficult decision to make. We believe that this study helps in this decision-making process because surgical treatment of displaced midshaft clavicular fractures 2B1 and 2B2, according to the Robinson classification, resulted in earlier bone union and earlier time to complete return to work.

Conclusions

Surgical treatment with ORIF of displaced middle-third clavicular fractures results in good and excellent functional results, shorter time to complete return to work, earlier bone healing, and fewer cases of nonunions, in a working population under injury compensation.

Disclaimer

The authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

References

1. Alshameeri ZA, Katam K, Alsamaq M, Sonsale P. The outcome of surgical fixation of mid shaft clavicle fractures; looking at patient satisfaction and comparing surgical approaches. Int J Shoulder Surg 2012;6:76-81. http://dx.doi.org/10.4103/0973-6042.102556
2. Altamimi SA, McKee MD, Canadian Orthopaedic Trauma Society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. Surgical technique. J Bone Joint Surg Am 2008;90(Suppl 2 Pt 1):1-8. http://dx.doi.org/10.2106/JBJS.G.01336
3. Canadian Orthopaedic Trauma Society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J Bone Joint Surg Am 2007;89:1-10. http://dx.doi.org/10.2106/JBJS.F.00020
4. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. Clin Orthop Relat Res 1987;214:160-4.
5. Donnelly TD, Macfarlane RJ, Nagy MT, Ralte P, Waseem M. Fractures of the clavicle: an overview. Open Orthop J 2013;7:329-33. http://dx.doi.org/10.2174/1874325001307010329
6. Hill JM, McGuire MH, Crosby LA. Closed treatment of displaced middle-third fractures of the clavicle gives poor results. J Bone Joint Surg Br 1997;79:537-9.
7. Hundekar BB. Internal fixation of displaced middle third fractures of clavicle with precontoured locking plate. J Orthop 2013;10:79-85. http://dx.doi.org/10.1016/j.jor.2013.04.003

8. Lenza M, Buchbinder R, Johnston RV, Belloti JC, Faloppa F. Surgical versus conservative interventions for treating fractures of the middle third of the clavicle. Cochrane Database Syst Rev 2013:CD009363. http://dx.doi.org/10.1002/14651858.CD009363.pub2
9. Liu GD, Tong SL, Ou S, Zhou LS, Fei J, Nan GX, et al. Operative versus non-operative treatment for clavicle fracture: a meta-analysis. Int Orthop 2013;37:1495-500. http://dx.doi.org/10.1007/s00264-013-1871-z
10. McKee MD, Pedersen EM, Jones C, Stephen DJ, Kreder HJ, Schemitsch EH, et al. Deficits following nonoperative treatment of displaced midshaft clavicular fractures. J Bone Joint Surg Am 2006;88:35-40. http://dx.doi.org/10.2106/JBJS.D.02795
11. McKee RC, Whelan DB, Schemitsch EH, McKee MD. Operative versus nonoperative care of displaced midshaft clavicular fractures: a meta-analysis of randomized clinical trials. J Bone Joint Surg Am 2012;94:675-84. http://dx.doi.org/10.2106/JBJS.J.01364
12. Nordqvist A, Petersson C. The incidence of fractures of the clavicle. Clin Orthop Relat Res 1994;300:127-32.
13. Rehn CH, Kirkegaard M, Viberg B, Larsen MS. Operative versus nonoperative treatment of displaced midshaft clavicle fractures in adults: a systematic review. Eur J Orthop Surg Traumatol 2014;24:1047-53. http://dx.doi.org/10.1007/s00590-013-1370-3
14. Robinson CM. Fractures of the clavicle in the adult. Epidemiology and classification. J Bone Joint Surg Br 1998;80:476-84.
15. Robinson CM, Goudie EB, Murray IR, Jenkins PJ, Ahktar MA, Read EO, et al. Open reduction and plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a multicenter, randomized, controlled trial. J Bone Joint Surg Am 2013;95:1576-84. http://dx.doi.org/10.2106/JBJS.L.00307
16. Stengel D. Operative versus nonoperative treatment of displaced midshaft clavicular fractures: a meta-analysis of randomized clinical trials. Unfallchirurg 2012;115:1041-3. http://dx.doi.org/10.1007/s00113-012-2279-8
17. Subramanian P, Joshi M, Shilston S, Wallace D, Pearce OJ. Treatment of middle-third clavicle fractures using anterior plating with a dynamic compression plate (DCP). Tech Hand Up Extrem Surg 2013;17:35-6. http://dx.doi.org/10.1097/BTH.0b013e318273f102
18. van der Meijden OA, Gaskill TR, Millett PJ. Treatment of clavicle fractures: current concepts review. J Shoulder Elbow Surg 2012;21:423-9. http://dx.doi.org/10.1016/j.jse.2011.08.053
19. Virtanen KJ, Remes V, Pajarinen J, Savolainen V, Bjorkenheim JM, Paavola M. Sling compared with plate osteosynthesis for treatment of displaced midshaft clavicular fractures: a randomized clinical trial. J Bone Joint Surg Am 2012;94:1546-53. http://dx.doi.org/10.2106/JBJS.J.01999