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Original Article

Locking versus nonlocking superior plate fixations for displaced midshaft clavicle fractures: A prospective randomized trial comparing clinical and radiografic results

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ABSTRACT

Background: It is unknown whether locking or nonlocking superior plate fixation is better for managing displaced midshaft clavicle fractures. Therefore, we aimed to compare the clinical and radiographic outcomes of locking and nonlocking superior plate fixation of displaced midshaft clavicle fractures.
Methods: A total of 102 consecutive patients with displaced midshaft clavicle fractures (2B1 and 2B2 in Robinson classification) participated in this randomized controlled trial; 12 patients were excluded. Surgeries were performed using a 3.5-mm Locking Compression Plate (LCP) between 2007 and 2015. Patients were treated either with a locking plate (group L, n = 45) or a nonlocking plate (group N, n = 45). In both groups, the plates were fixed to the proximal and distal clavicle with two and/or three screws, respectively.
The main outcome measures were complication rates, time to bone union, and Constant score.
Results: Forty-two patients in group L (mean age, 45.9 years) and 41 in group N (mean age, 43.6 years) were followed. The overall complication rates in groups L and N were 7.2% (three peri-implant fractures) and 7.3% (non-union, deformed plate, and peri-implant fracture), respectively ($p = .98$). The average time to union significantly differed between groups (L vs. N: 13.0 ± 4.1 vs. 17.5 ± 6.3 weeks; $p < .01$). However, the Constant score at the final follow-up was not significantly different between groups (L vs. N: 87.0 ± 12.3 vs. 89.8 ± 9.1).
Conclusions: Similar complication rates and clinical results were found for locking and nonlocking superior plate fixation for displaced midshaft clavicle fractures. However, the time to bone union was shorter with the locking plate. This study suggests that both plating systems are effective for treating displaced midshaft clavicle fractures.
Level of evidence: Therapeutic, level I.

1. Introduction

Clavicle fractures are one of the most common fractures in adults, accounting for 5%–10% of all fractures and 35%–45% of all shoulder injuries [1]. Such fractures have classically been treated nonoperatively. The treatment for clavicle fractures has been extensively studied and the differences between nonoperative and operative treatment have been compared in various studies [2–4]. High-quality randomized controlled trials have confirmed that nonoperative interventions may increase the initial fracture displacement, the incidence of non-union and malunion, and the time to return to sports [5–7]. Hence, over the past decades, there has been a shift toward operative treatment of displaced midshaft clavicle fractures (DMCF). The rationale for operative fixation includes higher reported non-union rates and functional deficits following nonoperative DMCF treatment [3,8]. Previous studies have reported that internal fixation of the clavicle can provide immediate rigid stabilization and facilitate early mobilization [9–11]. Since their introduction, locking plates have been used to stabilize various upper extremity fractures. Their utility for fractures of the distal portion and shaft of the radius and ulna and the proximal and distal humerus has been reported [12,13]. However, it

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remains unknown whether locking or nonlocking plates are better in superior plate fixation for the treatment of DMCF.

Therefore, this study aimed to prospectively compare the clinical and radiographic outcomes between locking and nonlocking superior plate fixation for DMCF. We hypothesized that bone union after locking fixation would be safer and faster than nonlocking fixation.

2. Methods

2.1. Study design

This study was performed in accordance with the tenets of the Declaration of Helsinki [14] and was approved by the Institutional Review Board of our hospital. From January 2007 to August 2015, 102 consecutive patients with DMCF were included in this randomized trial. Displacement was defined as the presence of at least a one-shaft width of distance between major fracture fragments on any radiograph, regardless of fracture shortening.

2.2. Power analysis and randomization

The statistical power of this study was sufficient to detect the difference between the time to bone union (in weeks) in the locking (group L) and nonlocking (group N) groups. According to the power analysis (effect size = 0.3, dfa = 0.05, power = 0.90), at least 82 subjects were needed.

Patients were recruited from the emergency department and were provided with information about the study if they met the following inclusion criteria: unilateral fracture, age >18 years, absence of pre-existing shoulder pathology, absence of open fractures, absence of neurovascular disorders, and occurrence of injury within a period of 21 days. Follow-up for study inclusion was scheduled after informed consent. Fractures were classified as either type 2B1 or 2B2, according to the Robinson classification of clavicle fractures.

Patients were assigned into either the locking or the nonlocking superior plate fixation groups via central computerized block randomization. Analysis after treatment was performed according to the intention-to-treat principle. Patients were distributed among four senior surgeons (YU, HO, AH, and TI) according to the surgeons' scheduled shifts. All of the surgeons were experienced in using both locking plates and nonlocking plates for the treatment of DMCF.

2.3. Surgical techniques and postoperative management

After general anesthesia, the patient was placed in the beach-chair (semi-sitting) position. An incision was made along the longitudinal axis of the clavicle and centered over the site of the fracture. Careful dissection, preferably with loupe magnification, was performed to identify and safeguard branches of the supraclavicular nerves that traverse the surface of the clavicle. The local area was thoroughly debrided.

After fracture reduction, a 3.5-mm titanium Locking Compression Plate (LCP) Reconstruction Plate (Depuy Synthes, West Chester, PA) was positioned and fixed on the anterosuperior surface of the clavicle, starting medially, using either locking screws and holes (in group L) or nonlocking screws and holes (in group N). Each LCP had 5–7 holes. To ensure rigidity, the LCP Reconstruction Plate was then fixed with two and three bicortical screws on the proximal and/or distal sides of the fracture, respectively, using either locking or nonlocking screws according to group (Fig. 2C and D). The LCP Reconstruction Plate is designed to permit multiplanar bending at any position in the plate rather than through the screw holes. Therefore, we bent the plate to fit the shape of the clavicle if necessary. Furthermore, if compression of an additional third fragment was necessary or possible, a lag screw was placed on one side only. A bridging plate technique was used in fractures with multi-fragments. Finally, the fascia and the skin were closed in layers. Patients were administered 1 g of intravenous cefazolin for three days after surgery as antibiotic prophylaxis.

The postoperative management of both groups was the same. The affected extremity was immobilized with a sling for four weeks after surgery. The sling was removed initially for shoulder pendulum, overhead, and elbow flexion range-of-motion exercises. We gradually permitted abduction and elevation over 90° at seven weeks after surgery because the clavicle performs a rotating motion at this range [15]. Heavy lifting and return to sports were restricted for a minimum of three months postoperatively to protect against fractures.

2.4. Outcome measures

For both groups, outcome measures were complication rates, time to bone union, and Constant score (pain, 15; function, 20; strength, 25; motion, 40; total, 100 points) [16]. Non-union, postoperative infection, bent plate, and peri-implant fracture around the clavicular plate were considered postoperative complications. After osteosynthesis, bone union was monitored in all patients on anteroposterior and 30° oblique radiographs of the clavicle obtained fortnightly until union was observed. The radiographs were evaluated for fracture healing and implant position. Radiographic healing was defined as evidence of a bridging callus across a fracture site or obliteration of fracture lines. Two orthopedic senior surgeons with more than 15 years experience evaluated the radiographs also with regard to bone union: that within 20 weeks was considered normal union, and that after 20 weeks was considered delayed union. Postoperative clinical outcome was defined as Constant score at the final follow-up.

2.5. Statistical analysis

Data were analyzed using SPSS for Windows 7 (version 19.0; Armonk, NY, IBM Corp). Differences in primary outcome percentages were analyzed using the chi-square test, and Constant scores and the time to bone union were compared between the groups using the Student's t-test. Multivariate logistic and linear regression analyses were performed to assess the effect of the stratification of age and sex and other preoperative intrinsic, injury-related, and surgical variables on the outcome measures. A p-value <0.05 was considered statistically significant difference.

3. Results

A total of 102 patients were enrolled in the study. Ninety patients were randomized to each of group L and group N, and 12 were excluded because of under 18 years (Fig. 1). There were no significant differences between the groups in terms of age, sex, dominant arm, mechanism of injury, smoking status, type of fracture (Robinson classification), period until surgery, or follow-up period (Table 1).

There was a significantly higher rate of use of long plates in group N compared with group L (p = .012). At 10 months after surgery, three patients in group L and four patients in group N did not attend the final follow-up. Therefore, the final analysis included 42 patients in group L and 41 in group N (Fig. 1).

The overall complication rate was 7.5% (n = 3) in group L and 7.7% (n = 3) in group N (p = .97). The rates of non-union and plate bending were 0% in group L and 2.4% (n = 1) in group N (p = .308).

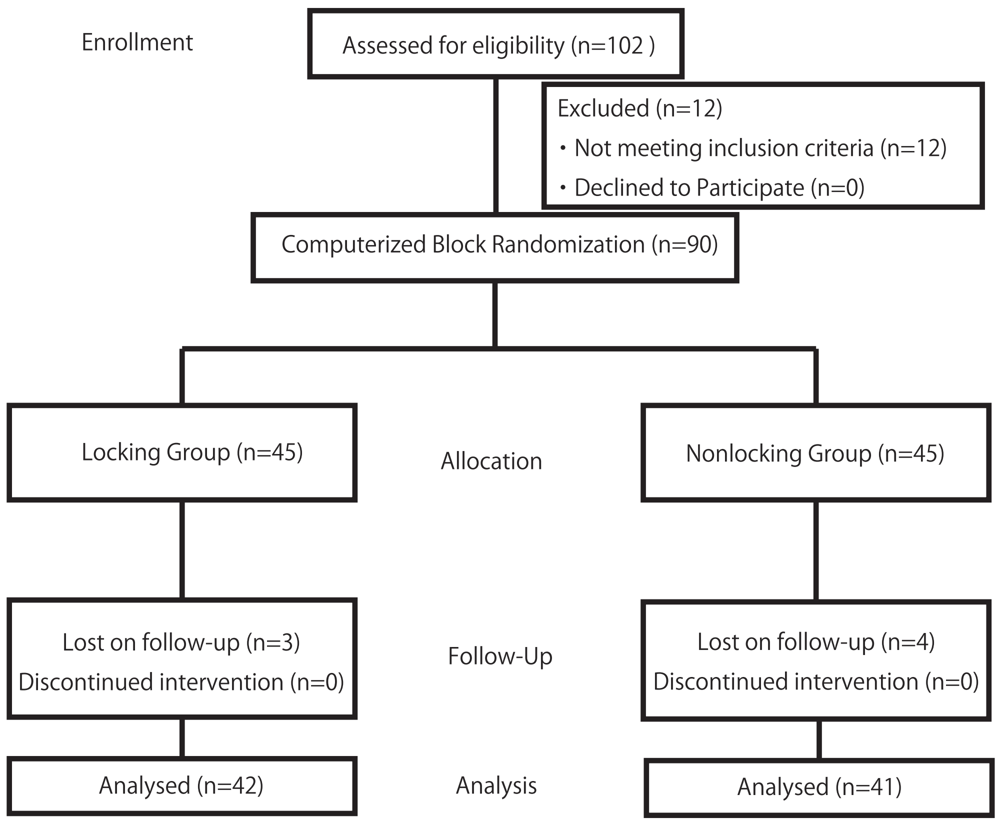

Fig. 1. Flowchart of patient selection.

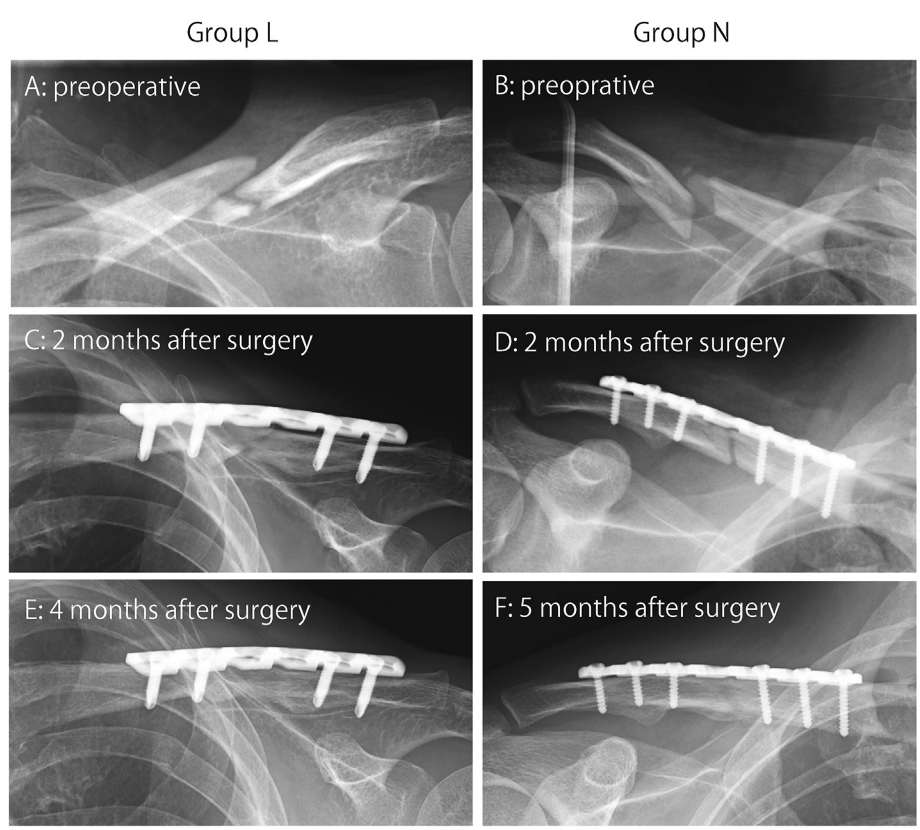

Fig. 2. Preoperative (A, B) and postoperative (C–F) radiographs of the clavicle showing displaced midshaft fractures. Fractures of the left clavicle (A, C; group L) and the right clavicle (B, D; group N) were each classified as Robinson 2B-1. Callus bone formation was seen earlier in E (group L) than in F (group N).

Table 1
Patient demographics and clinical parameters.

Parameter	Group L		Group N		p value
	(n = 42)	range	(n = 41)	range	
Age (years)	45.9	18–76	43.6	18–73	0.33
Male:female ratio (n)	33 : 7		31 : 8		
Injury at dominant arm (n)	28		22		0.21
Mechanism of injury (n)					
Traffic accident	25		22		0.792
Simple fall	6		8		
Sports	4		3		
Other	5		6		
Smoker (n)	20		18		0.73
Robinson type IIB1: IIB2 (n)	34 : 8		34 : 6		0.63
Period until surgery (days)	13.8	1–21	15.1	4–21	0.53
Plate length (5/6/7 holes)	17/21/4		7/21/13		0.012[a]
Total follow-up duration (months)	14.3	10–20	15.6	10–25	0.83

n: number of patients.
[a] Statistically significant.

No postoperative infection occurred in either group. There was no significant difference between group L (7.2%, n = 3) and group N (2.4%, n = 1) in terms of the postoperative peri-implant fracture rate (p = .317). Overall, there were no significant differences in complications between the groups (Table 2).

We compared the time to bone union between the 37 patients in group L and the 36 patients in group N, excluding 6 patients (3 in each group) who suffered complications (non-union, deformed plate, peri-implant fractures). The average time to bone union in group L (13.0 ± 4.1 weeks) was shorter than that in group N (17.0 ± 7.8 weeks, p = .009). The rate of delayed bone union was significantly higher in group N (31%, n = 11) than group L (5%, n = 2; p = .005) (Table 3).

The Constant score at final follow-up was not significantly different between group L (87.0 ± 12.3) and group N (89.8 ± 9.1, p = .365). Clinical results were good in both groups (Table 4).

4. Discussion

Operative treatment has been recommended for DMCF [3,8] because of the various problems that can occur with nonoperative DMCF treatment, including pain, instability, difficulty in daily care due to multiple trauma, and high non-union rates in cases of severe displacement and initial shortening >2 cm [5,10,17,18]. The two most commonly used techniques for surgical treatment are open reduction and internal fixation using a plate, and intramedullary nailing [19]. However, the optimal fixation method for these fracture types remains unresolved [20,21]. Currently, superior plate fixation is commonly used for the treatment of DMCF. This technique provides immediate rigid stabilization and pain relief, and facilitates early mobilization [5,21,22]. Celestre et al. [9] evaluated the biomechanical properties of two plate locations and two plate types for fixation of midshaft clavicle fractures: anterior vs superior locking plate, and standard vs locking plate. They concluded that superior plate location of a locking plate provides the best combination of axial compression/torsion stiffness and bending failure stiffness/strength.

Several types of plates and fixation methods have been described, including limited-contact dynamic compression plates (LC-DCPs), reconstruction plates, and locking plates [23]. Currently, locking plates are the most commonly used, and reconstruction plates have become less frequently used because they are susceptible to deformation at the fracture site of extremity bones, leading to malunion. Locking plates have the following advantages: strong fixation due to locking between the screw and plate, and preservation of blood supply because there is minimal contact between the plate and cortical bone [24,25]. The recent introduction of minimally invasive percutaneous plate osteosynthesis along with a locking plate is an ideal combination in terms of bone fixation and sparing of soft tissue, as periosteal stripping can be minimized to promote rapid union [26]. Site-specific pre-contoured locking plates, also introduced recently, are less prominent after healing and have lower rates of implant removal after union [27]. Although locking plates for the treatment of DMCF have been described and evaluated in previous reports, no previous prospective clinical trial has compared locking plates and conventional nonlocking plates in adult patients.

The present randomized controlled trial compared the usefulness of locking and nonlocking fixation with the same plate component for treatment of DMCF, and the level of evidence of the study was high. Our study found no difference in clinical outcomes between the two groups during a mean follow-up period of 14.9 months. However, time to bone union was shorter in the locking group. There was a higher rate of bone union taking longer than 20 weeks in group N, which might be the cause of the higher incidence of delayed union in this group. Altamimi et al. [28] reported that the most distal and most proximal screws in a standard compression plate (straight plate) are most likely to dislodge from the center of the bone. This occurs because of the difficulty in achieving bicortical fixation when a standard compression plate (straight plate) is placed on the anatomically S-shaped clavicle, thereby suggesting insufficient fixation strength. Our study did not consider screw position; the results of our study suggest that bicortical fixation was not achieved for the most distal and most proximal screws because more long plates were used in group N than group L, which may

Table 2
Comparison of postoperative complications between the locking and nonlocking groups.

	Non-union	Infection	Bent plate	Peri-implant fractures	Overall
Group L (n = 42)	0	0	0	3 (7.2%)	3 (7.2%)
Group N (n = 41)	1 (2.4%)	0	1 (2.4%)	1 (2.4%)	3 (7.3%)
p value	0.308	ns	0.308	0.317	0.98

ns: not statistically significant.

Table 3
Comparison of time to bone union and delayed union between the locking and nonlocking groups.

	Time to bone union (weeks)	Union		Rate of delayed union (%)
		≦ 20 (weeks)	>20 (weeks)	
Group L (n = 39)	13 ± 4.1	35	2	5
Group N (n = 38)	17 ± 7.8	25	11	31
p value	0.009[a]			0.005[a]

Data was excluded for three patients in each group (nonunion, bent plate, and peri-implant fracture).
[a] Statistically significant.

Table 4
Comparison of Constant score between the locking and nonlocking groups.

	Constant score	
	(points)	range
Group L (n = 42)	87.0 ± 12.3	78–98.5
Group N (n = 41)	89.8 ± 9.1	76–95.5
p value	0.365	

have led to insufficient fixation strength and a higher rate of delayed union. Locking compression plates shaped to match the anatomy of the clavicle may be effective in the surgical treatment of midshaft DMCF. To investigate this possibility, it will be necessary to compare locking and nonlocking plates using anatomical designs in the future.

With the goal of improving the rate and quality of bony union, the following factors should be considered during implant selection: fracture location, degree of comminution, bone quality, and patient activity level and compliance. In particular, although clavicle bridging plating in osteoporotic bone may achieve stable fixation, it is not rigid. Clavicle plating in the elderly may result in more complications compared with intramedullary pin fixation (Knowles pinning) [29]. A disadvantage of DCP fixation is plate loosening related to poor bone quality. We believe that plate and screw loosening can be avoided by using a locking plate, which provides a more rigid fixation in osteopenic bone [29].

There were some limitations to the present study. These include the single-center setting and relatively short-term follow-up (mean, 14.9 months, range; 10–25 months). In addition, the evaluation of radiographic union was performed by two orthopedic surgeons and was not assessed by an independent radiologist.

In summary, both locking and nonlocking superior plate fixation in adult patients had similar complication rates and functional shoulder scores. However, the time to bone union was shorter in the locking plate group. We found that the use of the straight LCP Reconstruction Plate as the locking plate led to stable fixation and facilitated fracture healing. Our study suggested that locking and nonlocking plating systems are both effective for DMCF. Further study with a larger cohort is required to establish whether the locking plate technique offers earlier bone union than nonlocking plate fixation using an anatomically shaped plate.

Declaration of competing interest

None.

References

[1] Postacchini F, Gumina S, De Santis P, Albo F. Epidemiology of clavicle fractures. J Shoulder Elbow Surg 2002 Sep-Oct;11(5):452–6.
[2] Bernstein J. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. J Bone Jt Surg Am 2007 Aug;89(8):1866. author reply 1866-7.
[3] Robinson CM, Goudie EB, Murray IR, Jenkins PJ, Ahktar MA, Read EO, Foster CJ, Clark K, Brooksbank AJ, Arthur A, Crowther MA, Packham I, Chesser TJ. Open reduction and plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a multicenter, randomized, controlled trial. J Bone Jt Surg Am 2013 Sep 4;95(17):1576–84.
[4] Woltz S, Stegeman SA, Krijnen P, van Dijkman BA, van Thiel TP, Schep NW, de Rijcke PA, Frölke JP, Schipper IB. Plate fixation compared with nonoperative treatment for displaced midshaft clavicular fractures: a multicenter randomized controlled trial. J Bone Jt Surg Am 2017 Jan 18;99(2):106–12.
[5] Hill JM, McGuire MH, Crosby LA. Closed treatment of displaced middle-third fractures of the clavicle gives poor results. J Bone Jt Surg Br 1997 Jul;79(4):537–9.
[6] Robertson C, Celestre P, Mahar A, Schwartz A. Reconstruction plates for stabilization of midshaft clavicle fractures: differences between nonlocking and locking plates in two different positions. J Shoulder Elbow Surg 2009 Mar-Apr;18(2):204–9.
[7] Robinson CM, Cairns DA. Primary nonoperative treatment of displaced lateral fractures of the clavicle. J Bone Jt Surg Am 2004 Apr;86(4):778–82.
[8] Woltz S, Duijff JW, Hoogendoorn JM, Rhemrev SJ, Breederveld RS, Schipper IB, Beeres FJ. Reconstruction plates for midshaft clavicular fractures: a retrospective cohort study. Orthop Traumatol Surg Res 2016 Feb;102(1):25–9.
[9] Celestre P, Roberston C, Mahar A, Oka R, Meunier M, Schwartz A. Biomechanical evaluation of clavicle fracture plating techniques: does a locking plate provide improved stability? J Orthop Trauma 2008 Apr;22(4):241–7.
[10] Smekal V, Oberladstaetter J, Struve P, Krappinger D. Shaft fractures of the clavicle: current concepts. Arch Orthop Trauma Surg 2009 Jun;129(6):807–15.
[11] Xu B, Lin Y, Wang Z, Cao J, Yang Y, Xia H, Zhang Y. Is intramedullary fixation of displaced midshaft clavicle fracture superior to plate fixation? Evidence from a systematic review of discordant meta-analyses. Int J Surg 2017 Jul;43:155–62.
[12] Gehrmann SV, Windolf J, Kaufmann RA. Distal radius fracture management in elderly patients: a literature review. J Hand Surg Am 2008 Mar;33(3):421–9.
[13] Bjorkenheim JM, Pajarinen J, Savolainen V. Internal fixation of proximal humeral fractures with a locking compression plate: a retrospective evaluation of 72 patients followed for a minimum of 1 year. Acta Orthop Scand 2004 Dec;75(6):741–5.
[14] World Medical Association. WMA Declaration of Helsinki: ethical principles for medical research involving human subjects. Available at: http://dl.med.or.jp/dl-med/wma/helsinki2013e.pdf. [Accessed January 2020].
[15] Sahara W, Sugamoto K, Murai M, Yoshikawa H. Three-dimensional clavicular and acromioclavicular rotations during arm abduction using vertically open MRI. J Orthop Res 2007 Sep;25(9):1243–9.
[16] Constant CR, Gerber C, Emery RJ, Søjbjerg JO, Gohlke F, Boileau P. A review of the Constant score: modifications and guidelines for its use. J Shoulder Elbow Surg 2008 Mar-Apr;17(2):355–61.
[17] Mckee MD, Wild LM, Schemitsch EH. Midshaft malunions of the clavicle. J Bone Jt Surg Am 2003 May;85(5):790–7.
[18] Robinson CM. Fractures of the clavicle in the adult. Epidemiology and classification. J Bone Jt Surg Br 1998 May;80(3):476–84.
[19] Houwert RM, Smeeing DP, Ahmed Ali U, Hietbrink F, Kruyt MC, van der Meijden OA. Plate fixation or intramedullary fixation for midshaft clavicle fractures: a systematic review and meta-analysis of randomized controlled trials and observational studies. J Shoulder Elbow Surg 2016 Jul;25(7):1195–203.
[20] van der Meijden OA, Houwert RM, Hulsmans M, Wijdicks FJ, Dijkgraaf MG, Meylaerts SA, Hammacher ER, Verhofstad MH, Verleisdonk EJ. Operative treatment of dislocated midshaft clavicular fractures: plate or intramedullary nail fixation? A randomized controlled trial. J Bone Jt Surg Am 2015 Apr 15;97(8):613–9.
[21] Kabak S, Halici M, Tuncel M, Avsarogullari L, Karaoglu S. Treatment of midclavicular non-union: comparison of dynamic compression plating and low-contact dynamic compression plating techniques. J Shoulder Elbow Surg 2004 Jul-Aug;13(4):396–403.
[22] Mullaji AB, Jupiter JB. Low-contact dynamic compression plating of clavicle. Injury 1994 Jan;25(1):41–5.

[23] Wijdicks FJ, Van der Meijden OA, Millett PJ, Verleisdonk EJ, Houwert RM. Systematic review of the complications of plate fixation of clavicle fractures. Arch Orthop Trauma Surg 2012 May;132(5):617–25.
[24] Haidukewych GJ. Innovations in locking plate technology. J Am Acad Orthop Surg 2004 Jul-Aug;12(4):205–12.
[25] Perren SM. Evolution and rationale of locking internal fixator technology. Introd Remarks Injury 2001 Sep;32(Suppl 2):3–9.
[26] Jiang H, Qu W. Operative treatment of clavicle midshaft fractures using a locking compression plate: comparison between mini-invasive plate osteosynthesis (MIPPO) technique and conventional open reduction. Orthop Traumatol Surg Res 2012 Sep 19;98(6):666–71.
[27] Canadian Orthopaedic Trauma Society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. A multicenter, randomized clinical trial. J Bone Jt Surg Am 2007 Jan 4;89(1):1–10.
[28] Altamimi SA, McKee MD, Canadian Orthopaedic Trauma Society. Nonoperative treatment compared with plate fixation of displaced midshaft clavicular fractures. Surgical technique. J Bone Jt Surg Am 2008 Mar 20;90(Suppl 2):1–8.
[29] Lee YS, Lin CC, Huang CR, Chen CN, Liao WY. Operative treatment of midclavicular fractures in 62 elderly patients: knowles pin versus plate. Orthopedics 2007 Nov 21;30(11):959–64.