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A new method to predict refracture risk after locking compression plate removal of clavicle shaft

Shuai Han[1†], Qinghe Wang[1†], Fang Tan[1†], Kun Li[1] and Shuang Li[1*]

Abstract

Background The incidence rate of subsequent refracture after removal of the implant in mid-shaft clavicle fracture patients is relatively high. This can lead to additional medical costs and cause doctor-patient dispute. This study tries to introduce a new method to predict the refracture risk of the clavicle after hardware removal.

Methods A retrospectively review of 244 patients who had undergone ORIF with LCP for mid-shaft clavicle fractures, and had hardware removal surgery after bony union from January 2013 to September 2022 at our hospital was performed. We evaluated basic demographic characteristics, and analyzed the mean gray value of screw holes with the Image J software, which was extensively used in Western-blot analysis.

Results Our study showed that about 2.0% patients suffered refracture after removal of the LCP. For the first time we found obvious differences in remaining bone ratio and the index of remaining Clavicle intensity between the two groups. There was no difference between groups with regards to preoperative characteristics.

Conclusions Surgeons should mention that there is a relatively higher possibility of refracture rate and emphasize a proper immobilization after secondary operation. There are no significant preoperative demographics parameters associated with refracture. The mean gray value of screw holes on immediate postoperative X-ray can be a potential clinical predictor for refracture rate after LCP removal.

Keywords Clavicle, Implant removal, Mid-shaft, Refracture, Risk factor

Introduction

Clavicle fracture is a common fracture accounting for approximately for 3% of all fractures in adults. Of these fractures, 80% occur in the middle third of the clavicle [1, 2]. In the past, clavicle fractures are treated conservatively [3]. However, obviously unrecognized high nonunion rate and decreased shoulder function with nonsurgical management of displaced mid-shaft clavicle fractures are reported in the last two decades. This has led to a paradigm shift towards an increase in operative treatment [4, 5].

Superior locking compression plate (LCP) fixation is one of the commonly used open reduction and internal

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fixation (ORIF) techniques for mid-shaft clavicle [6]. Implant removal(IR) is a major cause for secondary surgeries in patients who have undergone ORIF [7]. The incidence varies between 38% and 50% according to Woltz and Smeeing [8, 9]. Two other studies, however, showed a much higher rate of more than 70% [10, 11]. Although we would remind patients that there is usually no need to remove LCP without specific reasons. Due to China's work-related injury insurance system and cultural customs, patients rather to have the LCP removed after the fracture has healed. The incidence of refracture of clavicle after IR is not common and ranges from 1 to 7%.Refracture after LCP removal often results in months of patient suffering, losing productivity and additional medical expenses, it is also an important source of medical disputes [11–15]. Despite a relatively high incidence, there is minimal literature report and explore how to predict and avoid this condition [15].

In this study, we retrospectively reviewed patients with refracture after LCP removal in our hospital. Unexpectedly, we found that the most refractures occurred in a certain screw hole. Therefore, we measured the mean gray value of screw hole on the postoperative clavicle anteroposterior X-ray after LCP removal and attempted to analyze its value in predicting refracture likelihood after LCP removal in midshaft clavicle fractures after bony union.

Materials and methods

Study population

This single center, observational and retrospective review included data from Shanghai Pudong New Area People's Hospital between January 1, 2013 and September 30, 2022. This retrospective study was approved by the ethical committees and the need for written informed consent was waived.

Patients who underwent LCP fixation for mid-shaft clavicle fractures and removal of plate were included in this study. All patients were followed up for at least one year and confirmed fracture healing by radiographs and clinical signs before IR. The criteria for bony union were (1) a bridging callus formation or complete obliteration of the gap between fracture fragments, (2) no further migration of the fixation construct and no fracture displacement, and (3) affected limb activity was normal and pain free. We excluded patients who had pathologic fractures, fixation methods other than LCP, loosened or broken plates or screws, fracture nonunion, surgical site infection, periprosthetic fracture or further traumatic events that required a second operation.

Data collection and measurement of radiological parameters

Standard clavicle anteroposterior projection was used for serial radiographic assessment. Plain X-rays taken immediately after the surgery were reviewed to measure postoperative "mean gray value of screw hole". Image J software was used for image analysis. Based on initial analyses, we used the following settings to make the screw holes in the images clearer. First, X-rays images were exported as JPEG and converted to 8bit gray scale. Then background was subtracted using the "Subtract Background" plugin with a rolling ball radius of 40 pixels, sliding paraboloid enabled and smoothing disabled. Next, mean gray value of screw holes were measured by "straight or freehand line" measurements. The marginal normal bone tissue was using as the normal control. Band of osteosclerosis besides the screw hole should be avoided. If images of rib and clavicle were overlapped, make sure the proportion between screw hole and normal control is approximately equal. We used propensity score matching to control for confounding factors. For each patient with re-fracture, we selected 5 samples from those without re-fracture, based on clinical factors such as gender, age, height, weight, BMI, etc., to find the closest overall scores for matching. This is a statistical measure often used when the sample size of the experimental group is too small. This process can be easily implemented using SPSS or R. Five controls that did not show refracture after IR were selected for every case to yield a matching ratio of 5:1. (Fig. 1)

Statistical analysis

For statistical analyses, we calculated remaining bone ratio (RBR) as the ratio of gray value of screw hole to its control and intensity. We also defined the index of remaining Clavicle intensity (IRCI) which was calculated by multiplying RBR by length of the segment. Statistical comparisons were performed by two-tailed Student's t-test. Data are given as mean±SEM. Significance was established when $P<0.05$.

Results

The demographics of the included patients are shown in Table 1. There was no significant difference in the general clinical data between no fracture group and refracture group in terms of gender, height, weight, BMI, and mean interval time between plate fixation and removal. The mean patients' age in refracture group seemed younger but there was no significant difference ($P=0.0573$).

The refracture group included 2 men and 3 women. After the plate was removed, none of these patients had experienced additional trauma events (e.g. a fall, a direct blow) but felt sudden pain and disability during activities

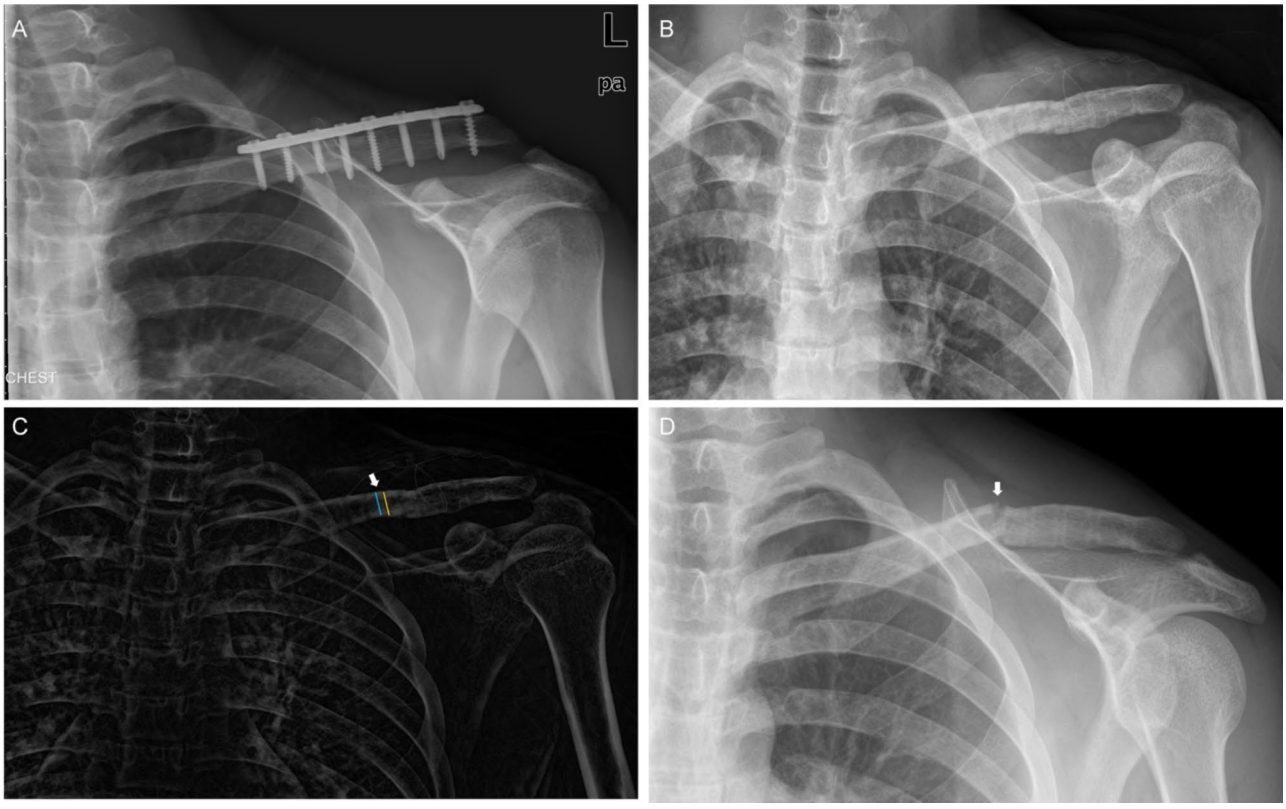

Fig. 1 Measurement method of mean gray value of screw hole. **A**: preoperative X-ray of patient. **B**. postoperative X-ray of patient. **C**: Images were treated using Image J software, mean gray value of screw holes (yellow line) and marginal normal bone tissue (blue line) were measured by "straight or freehand line" measurements. **D**: refracture at the screw hole (white arrow)

Table 1 Patient demographic data

	No fracture (N=239)	Refracture (N=5)	P-value
Sex			
Male	159 (66.5%)	2 (40.0%)	0.446
Female	80 (33.5%)	3 (60.0%)	
Age (years)			
Mean (SD)	46.5 (13.0)	33.0 (11.5)	0.0573
Median [Min, Max]	47.0 [21.0, 76.0]	34.0 [20.0, 47.0]	
Height			
Mean (SD)	168 (7.48)	165 (9.10)	0.485
Median [Min, Max]	167 [149, 189]	168 [150, 173]	
Weight			
Mean (SD)	67.2 (11.0)	63.4 (11.1)	0.492
Median [Min, Max]	65.0 [49.9, 100]	63.0 [50.0, 80.0]	
BMI			
Mean (SD)	23.9 (3.40)	23.3 (2.47)	0.631
Median [Min, Max]	23.4 [15.4, 34.3]	22.2 [22.1, 27.7]	
Time (months)			
Mean (SD)	18.6 (5.22)	17.2 (6.94)	0.674
Median [Min, Max]	18.8 [8.40, 30.4]	15.0 [11.0, 26.0]	

All values are mean ± standard deviation (range) or n (%)

of daily life (e.g. put on clothes, reach out for things, or take a bath).

The detailed clinical information of patients in the refracture group are shown in Table 2. All refractures involved a screw hole in middle third of the clavicle. According to the AO Foundation/ Orthopaedic Trauma Association (AO/OTA), three patients were AO type A fracture, one patient was AO type B fracture and the last patient was type C fracture. Four patients were treated conservatively with a sling or figure-of-8 brace while one patient received re-fixation surgery. All of them achieved solid bony union by the last follow-up visit.

We measured all the screw holes of the patients with refracture and those without fracture for comparison, and divided them into three groups for comparison. The results of radiographic measurements for each group are shown in Table 3. The mean RBR was significantly lower in refracture screw holes (70.59%), than the other screw holes of refracture group (99.5%) and the screw holes of the no-fracture group. (94.19%). The mean IRCI was also significantly lower in refracture screw holes (51.86), than the other screw holes of refracture group (87.60) and the screw holes of the no-fracture group. (90.08). There were no significant differences in RBR or IRCI in no-fracture screw holes between the refracture group and

Table 2 Series of five patients in refracture group

Patient no.	Sex	Age at refracture (yr)	AO/OTA classification	Interval fixation to IR (mo)	Refracture time after IR (day)	Refracture site	Refracture treatment	After refracture follow-up (mo)	Final follow-up result
1	F	41	A2	11	9	Screw hole	ORIF	20	Bone union
2	F	34	A2	15	17	Screw hole	Conservative	14	Bone union
3	F	47	C3	23	49	Screw hole	Conservative	8	Bone union
4	M	23	B2	26	48	Screw hole	Conservative	11	Bone union
5	M	21	A2	11	26	Screw hole	Conservative	3	Bone union

AO/OTA: AO Foundation/ Orthopaedic Trauma Association, IR: implant removal, ORIF: open reduction and internal fixation

Table 3 RBR and IRCI in refracture and no fracture group

	Screw hole in no refracture clavice	The other screw holes	Refracture screw hole	*P*-value
RBR(%)	94.19% (92.58-95.81%)	99.50% (91.73%-1.071%)	70.59% (56.91-84.28%)	*P*<0.0001
IRCI	90.08 (86.85-93.58)	87.60 (77.20-98.00)	51.86(44.61-59.11)	*P*=0.0029

RBR: Remaining bone ratio, IRCI: Index of remaining Clavicle intensity

no-fracture group. More excitingly, the refracture screw holes had the lowest, or second lowest RBR and IRCI in each case of refracture group, respectively. (Figure 2)

Discussion

In our study, the overall refracture rate after LCP removal was about 2.0%(5/244), which is consistent but slightly lower than reported previously [12–16]. J. Poigenfürst et al. reported that (in 1992), the refracture rate was about 3.6%(4/110), but one case happened because the plate was removed too soon, five months after ORIF, and another one was produced when the surgeon tried to chisel out an inter-fragmentary screw, so we think the true rate should be 1.8%(2/110). In Ho-Youn Park's study (in 2021), the refracture rate was about 1.99% [16]. But in Shang-Wen Tsai's study (in 2019), the refracture rate was about 7.2% (20/278), we found that 60% (12 cases) of the refracture cases in their study had the plate removal operation within 12 months, which the high rates maybe explained [15]. In our study, all of the plates were removed after ORIF at least 11 months in refracture group, and bony union was confirmed by radiographs and clinical examinations.

Some preliminary correlation studies were done, but no consensus exists on which potential predictive factors are for refracture after plate removal in patients with mid-shaft clavicle fracture. Some scholars believe that female patients and lower BMI were risk factors associated with

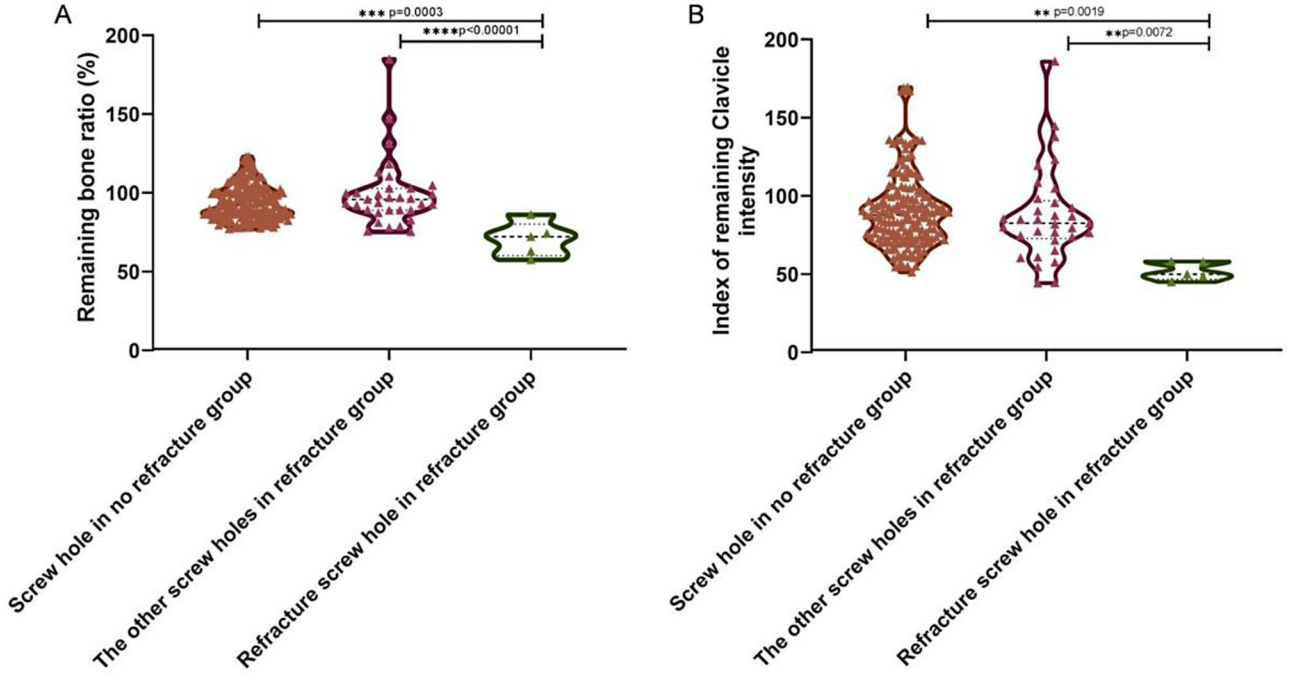

Fig. 2 The grey value analysis of screw holes. **A**: Remaining bone ratio, **B**: Index of remaining Clavicle intensity

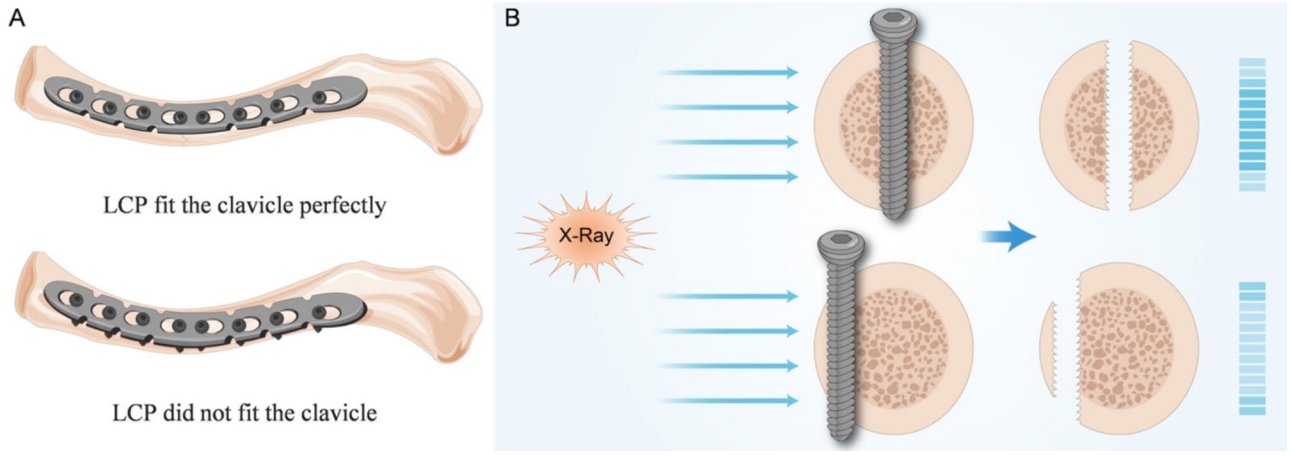

Fig. 3 Schematic representation of the proposed hypothesis

higher refracture rate. Unfortunately, these conclusions were not confirmed by the other researchers [4, 15, 16]. In our results, the demography of preoperative patients did not differ at all between the two groups, despite relatively young age of patients suffered with refracture. One possibility is that young patients always trying to start weight bearing of the affected limb earlier than orthopaedic surgeons recommend.

Researchers also have been attempting to identify associations between refracture rate after plate removal and radiographic findings but failed. No differences between the refracture group and non-refracture group were found in fixation device and technique, fracture classification, length, diameter of the clavicula, and callus formation [15]. However, we found that all our five refracture sites contained a screw hole. Therefore, we carefully consulted the literatures of Ho-Youn Park and Shang-Wen Tsa. Ho-Youn Park declared that one of their patients experienced a refracture at the previous site, while the others had refractures at the empty screw hole. But we considered that the "previous site refracture" involved the nearest medial screw hole. Shang-Wen Tsa mentioned that nineteen of their patients had a fracture at the previous fracture site, and one was at a screw hole. But their X-ray radiography presented that their "previous site refracture" was just at the inter-fragmentary screw hole [15, 16]. These observations suggest that refracture most frequently occurs in a certain screw hole.

The grey value analysis of screw holes by means of ImageJ shows that the average RBR and IRCI were significantly decreased in refracture screw holes. The RBR of refracture screw holes were all less than 75%. RBR reflects the amount of residual cortical bone. Vitro mechanistical studies showed that when the ratio of screw diameter to bone diameter is 0.25, the bone strength was decreased to 60% [17, 18]. The IRCI reflects residual bone strength at each screw hole. Our case indicates that although perhaps the RBR of the refracture screw hole was not the lowest, the IRCI was much lower at the refracture screw hole compared with the screw hole with the lowest RBR. Finite element analysis showed that the stress concentrated within in the middle 1/3 part of the clavicle under axial loading, and the stress on the superior surface was twice as high than on the inferior surface [19, 20]. These results are in agreement with our observations. We therefore propose a novel hypothesis: in some situations, the LCP did not fit the fracture site perfectly, this would cause some screws breaching the anterior or posterior cortex. After LCP removal, the residual bone tissue cannot provide sufficient mechanical support. This may explain these discrepant results: female patients, lower BMI and fracture classification are possible factors of mismatch between LCP and clavicle but not determining factors. Moreover, female patients and lower BMI also implies a smaller diameter of clavicle, which means equal sized screw will cause a higher ratio of bone loss. (Fig. 3) Taken together, our studies suggest that the RBR and IRCI of middle 1/3 part of the clavicle can be a clinical predictor for refracture rate after LCP removal. According to the above assumptions, the risk of refracture may be reduced if we use artificial bone rod to fill the screw holes in the middle 1/3 part of the clavicle. Of course, this hypothesis needs further verification. Another interesting finding was that the RBR is not always less than 100%. There may be multiple reasons for this observation. Diverse impact factors mainly include the irregular shape and the medullary-cortical ratio change of clavicle, increased bone turnover mediated by change in mechanical stress and occlusion of the rib.

This study has some limitations. First, since the low incidence of refracture, the number of positive cases was relatively small. Further confirmation in a multicenter setting that includes a larger number of patients would be needed. Second, because of the large 95% confidence

interval, the precise predictive value of RBR and IRCI could not be given. Third, we did not routinely perform CT to assess bony union and screw location before and after plate removal. Despite the preoperative CT might be limited by artifact results from metallic implants that obscure details in the fracture site, the postoperative CT could present a better evaluation of bone defect at the screw holes.

Conclusions

Surgeons should mention that there is a relatively higher possibility of refracture rate and emphasize a proper immobilization after secondary operation. There are no significant preoperative demographics parameters associated with refracture. The mean gray value of screw holes on immediate postoperative X-ray can be a potential clinical predictor for refracture rate after LCP removal.

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Author contributions
All authors reviewed and approved the manuscript.

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Data availability
The datasets used during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This retrospective study was approved by the ethics committee of Shanghai Pudong New Area People's Hospital. (2022-LW-02) and the need for written informed consent was waived by the ethics committee of Shanghai Pudong New Area People's Hospital. (2022-LW-02).

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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References

1. Song HS, Kim H. Current concepts in the treatment of midshaft clavicle fractures in adults. Clin Shoulder Elb. 2021;24:189–98.
2. Frima H, van Heijl M, Michelitsch C, van der Meijden O, Beeres F, Houwert RM, Sommer C. Clavicle fractures in adults; current concepts. Eur J Trauma Emerg Surg. 2020;46:519–29.
3. McKerrow M, North J. Clavicle fracture management: a comparison of a tertiary hospital and rural telehealth sites. J Telemed Telecare. 2017;23:856–60.
4. Napora JK, Grimberg DC, Childs BR, Vallier HA. Results and outcomes after Midshaft Clavicle fracture: matched pair analysis of Operative Versus Nonoperative Management. Orthopedics. 2018;41:e689–94.
5. Dugar N, Hossain E, Bandyopadhyay U, Shaw R. A comparative study of non-operative and operative management in fracture clavicle. J Indian Med Assoc. 2013;111(806):808–9.
6. Sidhu VS, Hermans D, Duckworth DG. The operative outcomes of displaced medial-end clavicle fractures. J Shoulder Elb Surg. 2015;24:1728–34.
7. Wiesel B, Nagda S, Mehta S, Churchill R. Management of Midshaft Clavicle fractures in adults. J Am Acad Orthop Surg. 2018;26:e468–76.
8. Longo UG, Banerjee S, Barber J, Chambler A, Cobiella C, Corbett S, Crowther M, Drew S, Francis A, Lee M, Garlick N, Packham I, Pearse Y, Richards A, Roberts C, Tennent D, Tims E, Ahrens PM. Conservative management versus open reduction and internal fixation for mid-shaft clavicle fractures in adults–the clavicle trial: study protocol for a multicentre randomized controlled trial. Trials. 2011;12:57.
9. Smeeing D, van der Ven D, Hietbrink F, Timmers TK, van Heijl M, Kruyt MC, Groenwold R, van der Meijden O, Houwert RM. Surgical Versus Nonsurgical Treatment for Midshaft Clavicle Fractures in patients aged 16 years and older: a systematic review, Meta-analysis, and comparison of Randomized controlled trials and observational studies. Am J Sports Med. 2017;45:1937–45.
10. Fuglesang H, Flugsrud GB, Randsborg PH, Oord P, Benth JŠ, Utvåg SE. Plate fixation versus intramedullary nailing of completely displaced midshaft fractures of the clavicle: a prospective randomised controlled trial. Bone Joint J. 2017;99–B:1095–101.
11. Hulsmans MH, van Heijl M, Houwert RM, Hammacher ER, Meylaerts SA, Verhofstad MH, Dijkgraaf MG, Verleisdonk EJ. High irritation and removal rates after plate or nail fixation in patients with displaced midshaft clavicle fractures. Clin Orthop Relat Res. 2017;475:532–9.
12. Böstman O, Manninen M, Pihlajamäki H. Complications of plate fixation in fresh displaced midclavicular fractures. J Trauma. 1997;43:778–83.
13. Russo R, Visconti V, Lorini S, Lombardi LV. Displaced comminuted midshaft clavicle fractures: use of Mennen plate fixation system. J Trauma. 2007;63:951–4.
14. VanBeek C, Boselli KJ, Cadet ER, Ahmad CS, Levine WN. Precontoured plating of clavicle fractures: decreased hardware-related complications. Clin Orthop Relat Res. 2011;469:3337–43.
15. Tsai SW, Ma HH, Hsu FW, Chou TA, Chen KH, Chiang CC, Chen WM. Risk factors for refracture after plate removal for midshaft clavicle fracture after bone union. J Orthop Surg Res. 2019;14:457.
16. Park HY, Kim SJ, Sur YJ, Jung JW, Kong CG. Refracture after locking compression plate removal in displaced midshaft clavicle fractures after bony union: a retrospective study. Clin Shoulder Elb. 2021;24:72–9.
17. McBroom RJ, Cheal EJ, Hayes WC. Strength reductions from metastatic cortical defects in long bones. J Orthop Res. 1988;6:369–78.
18. Edgerton BC, An KN, Morrey BF. Torsional strength reduction due to cortical defects in bone. J Orthop Res. 1990;8:851–5.
19. Zhang F, Chen F, Qi Y, Qian Z, Ni S, Zhong Z, Zhang X, Li D, Yu B. Finite element analysis of dual small plate fixation and single plate fixation for treatment of midshaft clavicle fractures. J Orthop Surg Res. 2020;15:148.
20. Lu YC, Untaroiu CD. Statistical shape analysis of clavicular cortical bone with applications to the development of mean and boundary shape models. Comput Methods Programs Biomed. 2013;111:613–28.

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