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Comparison of 2 Different Fixation Implants for Operative Treatment of Mid-Shaft Clavicle Fractures: A Retrospective Study

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Manuscript Preparation E
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Background: This retrospective analysis was designed to compare the outcomes of mid-shaft clavicle fracture operative treatment using bridge combined fixation system (BCFS) versus clavicular locking plate (CLP).

Material/Methods: Operative surgeries performed between January 2016 and July 2018 were included in the analysis. The surgical internal fixation implants were chosen according to surgeon preference and the choice of patients between the BCFS and CLP. Functional outcomes, fracture union, complications, pain, and patient satisfaction post-operation were assessed at a follow-up of 12 to 24 months.

Results: Two hundred and seventeen (217) patients, aged 21-79 years, were operated, 87 using BCFS and 130 using CLP. The operation time of the BCFS group was significantly less than the CLP group ($P < 0.01$). We also found that BCFS group had higher degree of satisfaction (100% vs. 97%, $P < 0.03$) and less VAS scale (0.25 ± 0.18 vs. 0.35 ± 0.21 , $P < 0.001$) compared with the CLP group, but the significance could only be obtained during the follow-up at 3 months after surgery. No significant differences were observed between the 2 groups when compared for fracture unions, functional scores, or complications.

Conclusions: BCFS significantly reduced the operation time when compared with CLP. No significant differences were observed for functional outcomes, including fracture union and complications, and there was less pain and higher patient satisfaction. Both methods appeared to be safe in terms of complications. However, the effectiveness and safety of BCFS in treating comminuted multi-fragmentary mid-shaft clavicle fractures (AO/OTA 15-2C classification) need further confirmation.

MeSH Keywords: **Bone Plates • Bridged Compounds • Clavicle**

Abbreviations: **BCFS** – bridge combined fixation system; **CLP** – clavicular locking plate; **LISS** – less invasive stabilization system; **MIPO** – minimally invasive plate osteosynthesis; **DCP** – dynamic compression; **VAS** – visual analog scale; **ASES** – American shoulder and elbow surgeons score; **DASH** – disabilities of the arm, shoulder and hand score; **SD** – standard deviations; **RR** – rate ratio; **CI** – confidence interval; **MD** – mean difference

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Background

Clavicle fracture forms 2.5% of all fractures in adults and thus is considered the tenth most common fracture. It is especially common in young active people. In departments of trauma or orthopedics or emergency departments, clavicle fracture is one of the most common injuries, accounting for 35–44% of shoulder girdle injuries and 2.6–10% of all fractures [1]. The most common causes of fracture were traffic accidents and sports injuries. Clavicle fractures can be categorized according to the region affected: middle third, medial third, and lateral third. Middle third fractures account for 69–82% of all clavicle fractures [2]. The majority of middle third clavicle fractures can be satisfactorily fixed with non-surgical treatment [3]. However, some patients need fixation, especially those with fractures in the distal third or with gross displacement of fragments, deviation or shortening greater than 1.5–2.0 cm between the bone fragments, exposed fractures or at risk of exposure, neurovascular injury, floating shoulder, and polytraumatized patients [3]. Operative treatment and fixation are usually carried out using plates and screws.

Plate osteosynthesis and intramedullary nail fixation are the 2 most commonly used techniques for the operative treatment of displaced mid-shaft fractures. Equivalent effectiveness and long-term functional outcomes were previously observed for treatments using intramedullary nailing or plates [4,5]. Plate osteosynthesis can be minimally invasive (less invasive stabilization system [LISS] or minimally invasive plate osteosynthesis [MIPO]), using a standard, dynamic compression (DCP) or anatomic plate, locked or not [6]. The clavicle is constructed around 2 inverse curves, enabling it to absorb stress [7]. Most of the commercially available anatomic plates are designed according to these curves using statistical software. However, normalization of these curves may fail to allow for “mismatches” between individual anatomy and plate design. Wand et al. [8] recently reported a new bridge combined fixation system (BCFS), with the advantages of locking plate, external fixator, and interlocking intramedullary nails. The new BCFS can minimize both surface contact with the bone and disruption of periosteal perfusion simultaneously, and it can also provide multi-angle fixation and reduce the probability of needing to reshape the steel plate. This new BCFS also theoretically provides similar bone-holding strength, and a better anatomical restoration, compared with use of a locking compression plate.

The objective of this retrospective study was to compare the clinical and radiographic outcomes of patients with displaced mid-shaft clavicular fractures treated with clavicular locking plates (CLP) and BCFS. The primary outcomes were shoulder joint function, complications, fracture healing, pain, and patient satisfaction after surgery. Our hypothesis was that there

would be no significant differences in primary outcomes between the 2 groups.

Material and Methods

Clinical data of 217 patients (aged 21–79 years) with only clavicle fractures indicated for open reduction and internal fixation were retrospectively obtained from the Affiliated Changzhou No. 2 People’s Hospital of Nanjing Medical University, between January 2016 and July 2018. Patients having a history of trauma, shoulder pain, limited mobility of the affected limbs, and the diagnosis of mid-shaft clavicle fracture (confirmed by X-ray) were included in the study. Exclusion criteria were open fractures, fracture of the medial or lateral thirds of the clavicle, pathological fracture, unrelated fractures, any pre-operative neurologic deficit or vascular injury, brain injury, or diabetes. All included patients were assigned to 1 of 3 experienced fellowship-trained senior shoulder surgeons in terms of their date of admission. The internal fixation implants were chosen according to surgeon preference between BCFS or CLP. To select suitable cases, 2 independent surgeons firstly applied the inclusion criteria to scan all the cases to confirm that they fulfilled the study criteria. A senior reviewer named Nanwei Xu resolved any disagreement.

The Institutional Ethics Committees of the Affiliated Changzhou No. 2 People’s Hospital of Nanjing Medical University approved the study.

Surgical technique

All patients were given nerve-blocking anaesthesia before operating in the beach chair position. Before the incision, cephalosporin was given intravenously over 30 min for infection prevention. The horizontal incision was performed over the fracture site centrally, and extended laterally and medially for better exposure when necessary. The supraclavicular nerve was firstly identified and protected. A locking plate (Weigao, China or Kanghui, China) was used for the CLP group and was placed in the superior position (Figure 1). A BCFS (Weiman, China) was used for the BCFS group, using the bone block, connecting rod, and locking screws placed in a comfortable position, either superiorly, or anteriorly to the clavicle (Figures 2–5). At least 3 screws were fixed on each of the 2 sides of the fracture. Lag screws were used when the fracture was oblique or when the size of the intermediate fragment was favorable. Both BCFS and CLP allowed axial compression or extension in a simple fracture. Intraoperative fluoroscopy was used routinely in the operating room for every surgical case. Continuous intradermal absorbable suture (Monocryl 3/0, Ethicon, Somerville, NJ, USA) was used to close the skin following each procedure. Implant removal was scheduled at about 1 year after surgery,

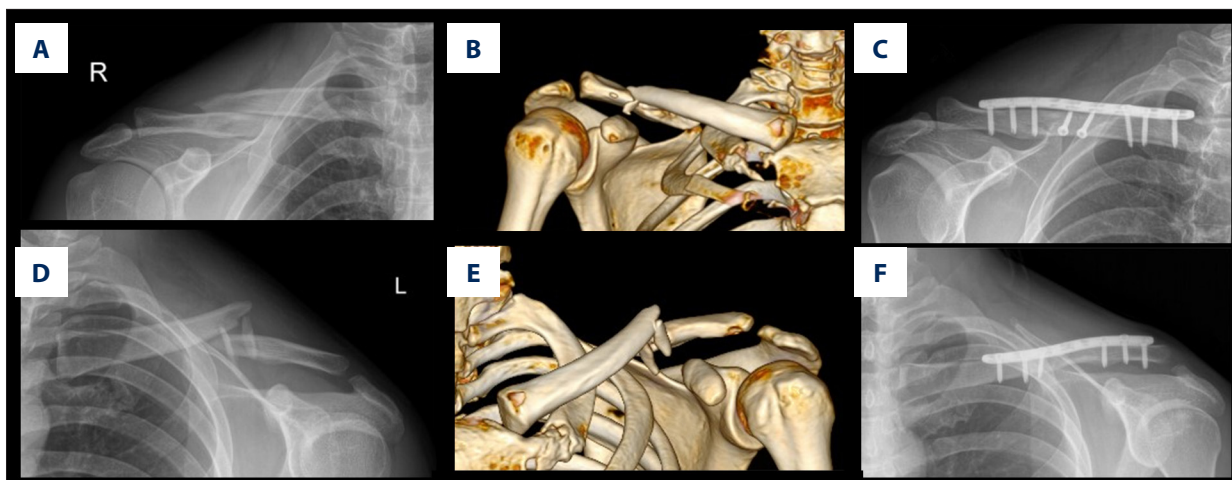


Figure 1. AO/OTA 15.2B fracture in 43-year-old male patient, pre-operative X-ray (A) and CT scan (B) of right mid-shaft clavicle fracture, and which had been treated by operative treatment and internal fixation with plate (C). AO/OTA 15.2C fracture in 48-year-old male patient, pre-operative X-ray (D) and CT scan (E) of left mid-shaft clavicle fracture, and which had been treated by operative treatment and internal fixation with plate (F).

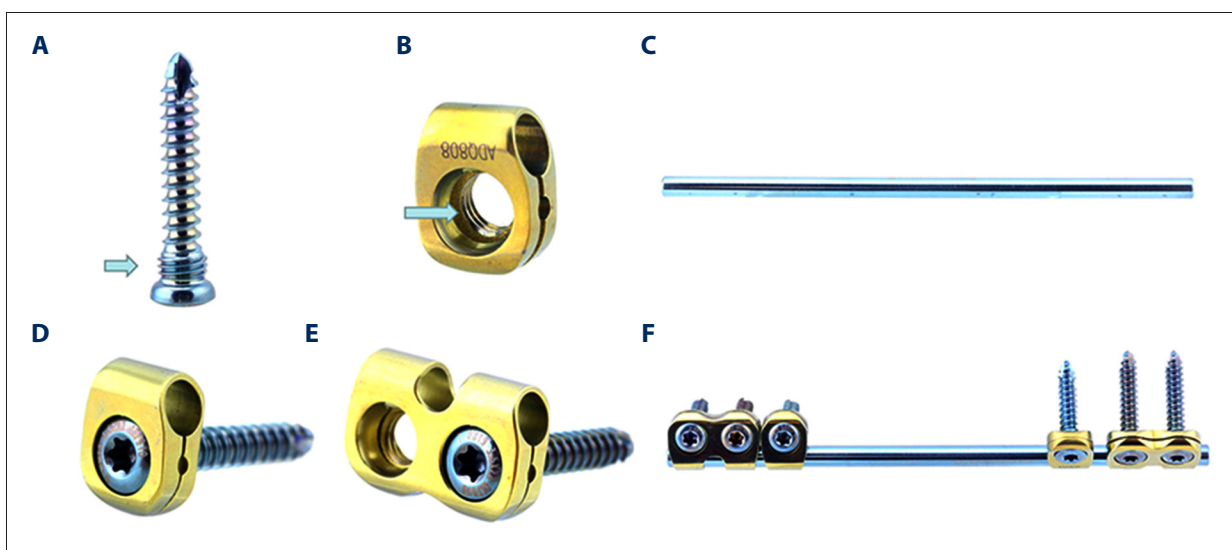


Figure 2. BCFS, which is composed of locking screw (A) and bone block (B), and connecting rod (C). The bone block could be locked with 1-2 screws (D-E). Locking screws and bone blocks of BCFS could be fixed in multiple directions (F). The arrows show the locking threads.

after complete fracture union, and ideally not earlier than 6 months for both groups. The postoperative rehabilitation protocol for both groups consisted of sling immobilization for 4 weeks and active range of motion with physiotherapy starting at 2 weeks. Pendulum movements were encouraged at 2 weeks after surgery, but not to abduct the arm by more than 90° or transmit load until 6 weeks after surgery. Weight lifting and return to full activities were allowed only after complete fracture healing.

Follow-up and data collection

Patients were followed for 12–24 months. We collected information on age, sex, smoking history, left or right, mechanism of injury, AO/OTA classification, the distance between the fracture displacement and shortening, time to surgery, time of operation and discharge, visual analog scale (VAS), functional outcomes, time of fracture union, and complications date. A visual analog scale for pain was administered on the first day, first week, first month, and third month after the operation. Satisfaction with the treatment was assessed using a binary parameter (1 for satisfied and 0 for unsatisfied) at the



Figure 3. The process of axial compression or and safety for BCFS. Locking screw A (A) and bone block had been locked with connecting rod, and the locking screw B (B) had not been locked (A). Axial compression was performed with pressurized pliers, using screw A, screw B and bone block (B). Axial extension was performed with pressurized pliers, using screw A, screw B and bone block (C). Locking screw B and bone block had been locked with connecting rod after axial compression or extension (D). Retractor (E) and Pressurized pliers (F).

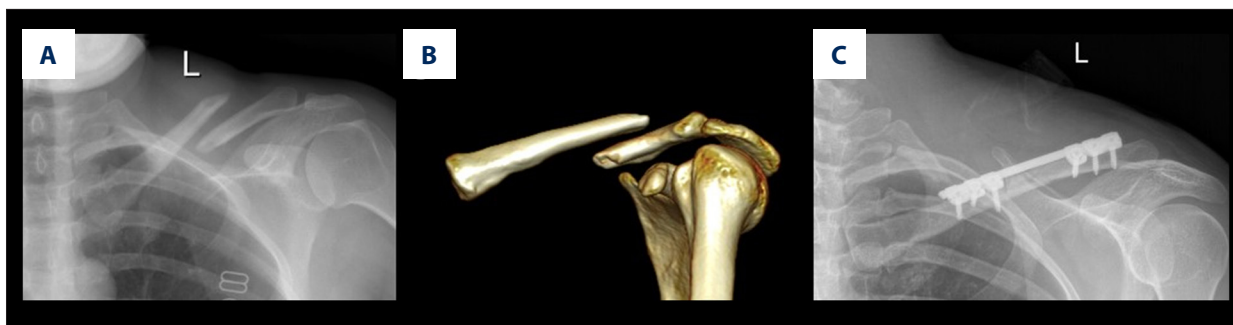


Figure 4. AO/OTA 15.2A fracture in a 22-year-old female patient, Pre-operative X-ray (A) and CT scan (B) of left mid-shaft clavicle fracture, and which had been treated by operative treatment and internal fixation with BCFS (C).



Figure 5. Intraoperative images in conventional operative treatment and internal fixation with BCFS. Figure also shows supraclavicular nerve in the middle third of the clavicle.

first, third, and sixth months. American Shoulder and Elbow Surgeons score (ASES) and Disabilities of the Arm, Shoulder and Hand score (DASH) were used to evaluate the functional outcomes [9,10] at 3-, 6-, and 12-month follow-ups after surgery. Fracture union was assessed radiographically and clinically. All of the complications were recorded during follow-ups, including minor and major complications. Minor complications included acromioclavicular pain, sternoclavicular pain, implant-related pain, implant bending (deformation of $>10^\circ$), incision paresthesia, partial implant migration (with no fixation loss), superficial infection, and hematoma. Major complications included deep infection, shoulder elevation deficit (after complete fracture union), nonunion (fracture not healed at 6 months), re-operation (secondary to a complication), total implant failure, total implant migration (with fixation loss), and permanent neurological deficits.

Statistical analysis

SPSS Statistics software (version. 21.0; SPSS Inc., Chicago, IL, USA) was used for analysis. Continuous data are presented as means and standard deviations (SD), and categorical data are presented as absolute numbers and percentages. Continuous variables were analyzed using the *t* test when normally distributed or with the Mann-Whitney U test otherwise. Categorical variables were analyzed using the chi-square test or the Fisher exact test. Rate ratio (RR) and 95% confidence intervals (CIs) were calculated for dichotomous outcomes, and mean differences (MD) and 95% CIs were used for continuous outcomes. The differences were considered statistically significant at $P < 0.05$.

Results

We enrolled 217 patients, including 134 men and 83 women. The mean age was 49 years old (range, 21–79 years), with the mean follow-up time of 15 months. The hospital stays ranged from 4 to 15 days. Smokers accounted for 21.7% of all patients. Most of injury the causes involved an electric-bicycle, bicycle, or car accident. Eighty-seven patients were operated on using BCFS and 130 with CLP. Fracture types were similar in the 2 groups. Mean fracture displacements for the 2 groups were 1.81 ± 0.62 , and 1.74 ± 0.36 cm, while the mean fracture shortening distances were 0.85 and 0.91 cm, respectively. The mean operation time in the BCFS group was significantly less than that in the CLP group (53.87 ± 6.55 versus 57.09 ± 9.43 min, $P < 0.01$) (Table 1).

Most patients from both groups were very satisfied with the treatment. The BCFS group had a higher degree of satisfaction compared with the CLP group, but this difference was only significant at 3-month follow-up (100% versus 97%, $P < 0.03$, Table 2). For VAS, there were no differences in the follow-up of the first day, first week, and first month between the 2 groups. However, the BCFS group had less VAS compared with the CLP group at 3-month follow-up (0.25 ± 0.18 versus 0.35 ± 0.21 , $P < 0.001$, Table 2). No significant differences were

Table 1. Baseline characteristics of included patients according to treatment group.

Characteristic	BCFS group (N=87)	Plate group (N=130)	P value
Age (Mean±SD, range, years)	47.99±12.66, 21–71	49.76±13.04, 21–79	0.32
Sex, Male/Female	50/37	84/46	0.29
Smoking (n,%)	18 (20.69%)	29 (22.31%)	0.78
Left/right shoulder	51/36	75/55	0.89
Mechanism of injury			
Electric-bicycle or bicycle accident	30	51	0.48
Motorcycle accident	5	7	0.91
Car accident	32	38	0.24
Fall	14	26	0.47
Sports	4	5	0.79
Other	2	3	0.99
AO/OTA classification			
15.2A	14	33	0.10
15.2B	68	91	0.18
15.2C	5	6	0.71
Fracture displacement (Mean±SD, cm)	1.81±0.62	1.74±0.36	0.07
Fracture shortening (Mean±SD, cm)	0.85±0.71	0.91±0.65	0.53
Time to surgery (Mean±SD, range, days)	5.04±6.20, 2–7	4.85±5.98, 1–8	0.82
Time of operation (Mean±SD, min)	53.87±6.55	57.09±9.43	0.002
Time of discharge (Mean±SD, range, days)	9.75±3.25, 5–14	10.06±4.21, 4–15	0.54
Follow-up (Mean±SD, range, months)	15.85±3.69, 12–18	16.18±4.65, 12–24	0.56

found between the 2 groups for ASES and DASH scores at 3-, 6-, and 12-month follow-ups (Table 2). Because of the low number of cases in AO/OTA 15-2C classification, the effectiveness and safety of BCFS to treat comminuted multi-fragmentary mid-shaft clavicle fractures need further confirmation.

Delayed union was diagnosed in 6 cases – 1 in the BCFS group and 5 in the CLP group. Three of them developed into non-union, and underwent re-operation because of implant failure. All of them were in the CLP group, and achieved fracture union after re-operation. One patient developed a deep infection, and recovered after anti-infection treatment and wound dressing replacement. One patient in each group had shoulder elevation deficit at 6-month follow-up. Hematoma was found in 10 patients (4 in the BCFS group and 6 in the CLP group). Acromioclavicular pain was found in 9 patients (5 in the BCFS group and 4 in the CLP group). Five patients in the BCFS group and 6 patients in the CLP group developed implant-related pain and had their internal fixations removed. Three patients in the BCFS group and 4 patients in the CLP group had incision paresthesia. Superficial infection was found in 8 patients (3 in the BCFS group and 4 in the CLP group), and all of them

recovered after anti-infection treatment and wound dressing replacement (Table 3).

Discussion

Our findings suggested that the operation time for the BCFS group was significantly shorter than in the CLP group, but both yielded similar functional results in patients with mid-shaft clavicular fractures. Additionally, no significant differences were found in terms of time to union, time of discharge, or minor and major complication rates between the 2 groups. The most significant difference was in VAS and patient satisfaction during the third month.

Fractures of the clavicle are common, especially in younger people. Of these fractures, 80% occur in the middle third of the clavicle. Traditionally, most of these fractures were treated non-surgically [11,12]. However, several studies [11,13,14] have recently found a nonunion rate of 15–20% with non-surgical management of displaced mid-shaft clavicle fractures. Also, these authors found that non-surgical management of fractures

Table 2. Outcomes of functional scores, VAS scale for pain, rate of satisfied patients according to treatment groups.

Outcome measurement	BCFS group (N=87)	Plate group (N=130)	RR/MD (95% confidence interval)	P value
VAS scale (Mean±SD)				
First day	5.57±2.21	5.36±3.57	0.21 (-0.56–0.98)	0.59
First week	2.45±1.98	2.85±1.45	-0.40 (-0.89–0.09)	0.11
First month	0.85±0.68	0.76±0.65	0.09 (-0.09–0.27)	0.33
Third month	0.25±0.18	0.35±0.21	-0.10 (-0.15– -0.05)	<0.001
Patient satisfaction (n, %)				
First month	85 (97.7%)	120 (92.3%)	3.54 (0.76–16.58)	0.09
Third month	87 (100%)	123 (94.6%)	1.06 (1.01–1.10)	0.03
Sixth month	87 (100%)	125 (96.2%)	1.04 (1.00–1.08)	0.06
Twelfth month	87 (100%)	125 (96.2%)	1.04 (1.00–1.08)	0.06
ASES score (Mean±SD, range)				
Third month	85.43±5.21, 57–99	84.95±6.67, 50–100	0.48 (-1.11–2.07)	0.55
Sixth month	93.32±6.92, 84–100	92.88±7.07, 80–100	0.44 (-1.46–2.34)	0.65
Twelfth month	94.59±6.42, 88–100	94.38±7.15, 85–100	0.21 (-1.61–2.03)	0.82
DASH score (Mean±SD)				
Third month	8.57±4.21	8.77±3.76	-0.20 (-1.30–0.90)	0.72
Sixth month	6.44±2.51	6.25±3.28	0.19 (-0.58–0.96)	0.63
Twelfth month	5.36±1.38	5.58±1.91	-0.22 (-0.66–0.22)	0.32

Table 3. Outcomes of complications according to treatment groups.

Outcome measurement	BCFS group (N=87)	Plate group (N=130)
Major complications (n)		
Delayed union	1	5
Nonunion	0	3
Deep infection	0	1
Shoulder elevation deficit	1	1
Total implant failure	0	3
Re-operation	0	3
Minor complications (n)		
Hematoma	4	6
Acromioclavicular pain	5	4
Implant-related pain	5	6
Incision paresthesia	3	4
Superficial infection	3	5

with more than 1.5–2 cm of shortening or greater than 100% displacement lead to decreased shoulder function and worse clinical outcomes [11,13,14]. When surgical intervention is undertaken, 2 general options for fixation exist: (1) an intramedullary nail or (2) a plate and screw construct. Both of these opinions have been reported to be equally effective in restoring shoulder function and promoting fracture healing. The periosteum and blood supply are very important for bone regeneration. However, most of the delayed union or nonunion can be dated from stripping or destroying of periosteum and blood supply during plate fixation [15–17]. Besides, long-term stress-shielding from plate fixation or intramedullary nails can prevent the formation of bone, which was also previously reported to induce fracture nonunion [18,19]. The clamp rod internal fixator system had been designed based on the theory of “biological osteosynthesis” by the AO Development Institute [20], to protect and maintain the vitality of soft tissues and maintain the stability of the fracture region. However, the clamp rod internal fixator system was not recommended for long-bone fractures, due to a lack of locking ability between plate and screws [21,22]. At last, BCFS was designed to integrate the advantages of an external fixator, interlocking intramedullary nail, and locking plate, providing a similar function of the built-in external fixation [8]. The possible disadvantage is that the prominent of this rod under the skin over the clavicle has been solved by bending the connecting rod and adjusting

the bone block with 360°, also known as multi-angle fixation. Wang et al. [8] assessed the mechanical properties and stress distribution of the BCFS using the Zwick/Z100 testing machine and finite element analysis. The BCFS was found to have significantly lower bending stiffness compared to the metal locking plate screw system. However, for yield load, bending strength, and maximum force, no significant differences were observed between the 2 groups [8]. In another study, 59 femoral fracture patients undergoing BCFS were followed up to investigate the clinical outcomes; most patients gained bone callus after 3 months, follow by fading and disappearance of the fracture line at 6–to 9 months postoperatively by X-ray; no severe complications, such as wound infection and implant breakage, were observed [8]. In a retrospective study, Niu et al. [23] reported that BCFS has advantages of having fewer complications and faster recovery, and could reduce the incidence of breakage of internal fixation, re-fractures, and osteoporosis after removing the internal fixation for adult mid-shaft clavicle fractures of 28 patients.

To the best of our knowledge, this is the first report comparing BCFS and CLP. We found that the operation time in the BCFS group was significantly shorter than in the CLP group, mostly due to the convenience of shaping and multi-angle fixation. Since this was a retrospective analysis, it was not possible to prospectively define the detailed process and time nodes of clavicle fractures healing, or of functional recovery. Complications showed no statistically significant differences between the 2 groups. Also, no differences were observed in functional outcomes, and this result is consistent with our expectation. Although not statistically significant, there were 5 patients with delayed union of fracture, and 3 of them developed into nonunion; all of these 3 patients had total implant failure and re-operation. Due to lack of a statistically significant difference, we attributed the reasons for these complications to the different number of included patients, with nearly 50% more in the CLP group than in the BCFS group. Excluding these 3 patients, the number of patients who had complications

was similar. These 3 patients considered their function unsatisfactory at 3- and 6-month follow-up, and the difference was statistically significant when compared with the BCFS group in the third month. Therefore, even with the existing statistical differences in VAS and patient satisfaction, it was not possible to adequately demonstrate the clinical importance, despite obtaining significant differences in the current study.

This study has several study limitations. First, this was a retrospective cohort study, which means that the strength of evidence was slightly inferior to that of a randomized controlled trial. Second, the present study just evaluated short-term efficacy. Third, this study was a single-center, retrospective analysis, and it remains unknown if residual confounding factors may have affected the outcomes. Fourth, because there were fewer cases in AO/OTA 15-2C classification, the effectiveness and safety of BCFS to treat comminuted multi-fragmentary mid-shaft clavicle fractures needs further confirmation. Fifth, as a new technique, the stability of BCFS relies on the rod-block connection and the stiffness of the rod, which needs further evaluation, especially when there is an excessive joint motion, so it may not be indicated for use in all types of mid-shaft clavicle fractures.

Conclusions

The BCFS yielded similar functional outcomes, fracture union, and complications, as well as less pain and higher patient satisfaction, when compared with CLP. Both methods appear safe in terms of complications. However, the effectiveness and safety of the BCFS to treat comminuted multi-fragmentary mid-shaft clavicle fractures (AO/OTA 15-2C classification) needs further confirmation in randomized controlled trials of high-quality.

Conflicts of interest

None.

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