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Clinical effects and risk factors of far cortical locking system in the treatment of lower limb fractures

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ABSTRACT

Introduction: This study aims to analyze clinical effects between far cortical locking (FCL) system and standard plating techniques in the treatment of lower limb fractures and identify potential preoperative risk factors for complications in patients treated with FCL system.
Method: We retrospectively analyzed 76 patients treated with FCL system (the study group) and 68 patients treated with standard plating techniques (the control group) between January 2014 and January 2017. Patients were followed up for a minimum of one year. Surgery-related complications, fixation features, fracture healing rates, the radiographic union scores, and knee functions (Kolment scores) were analyzed between the two groups in the study. Besides, we analyzed eight preoperative characteristics for surgery-related complications, including age, gender, presence of risk factors affecting bone healing, cause of injury, AO/OTA fracture classifications, facture sites, presence of open fractures, and presence of bone losses.
Results: The distributions of baseline date were similar between the two groups (P=0.05). The average number of FCL screws was 4.5 (range: 3–9) in the study group. The average time to union was 2.8 ± 0.9 months in the study group and 3.6 ± 1.0 months in the control group (P0.001), and average time to whole weight bearing was 2.3 ± 0.8 months and 2.8 ± 1.2 months, respectively (P = 0.004). Regarding radiographic union score, the study group scores were significantly higher than the control group scores at 1 and 3 months after surgery (P0.001), while it becomes insignificant between the two groups at 6 and 12 months after surgery (P = 0.19 and P = 0.15).The working lengths, fracture healing rates, complication rates, and Kolment scores were similar between the two groups (P=0.05). In the multivariate analysis, fracture sites (OR = 5.34; 95% CI, 1.11–25.75; P = 0.03) and presence of open fractures (OR = 6.19; 95% CI, 1.05–36.38; P = 0.04) were significant associated with complications, whereas other variables were not included.
Discussion: FCL system can truly accelerating bone healing and allow earlier whole weight bearing. Fracture healing rates and complication rates were similar between patients treated with FCL implants or conventional plating techniques. Patients with shaft fractures and open fractures trended to have higher complication rates.
Conclusions: FCL system is superior to standard plating technique in terms of early callus formation, but standard plating technique is not inferior to FCL system in terms of final fracture healing, surgery-related complication, and function outcome. Fracture site and presence of open fracture are the independent factors for complications in patients treated with FCL system.

Introduction

The main objective of any plate osteosynthesis is to achieve two seemingly dilemma goals: on the one hand, the plate osteosynthesis should provide durable stabilization for fractures; on the other hand, it shouldn't disturb the natural fracture healing process which is often determined by biological and mechanical factors. Locking plates have been a widely used method to treat femur and tibia fractures, which could provide proper reductions, sufficient stabilities, and blood supplies. However, the stiffness resulted from locking plates was really a problem [1,2]. Patients may not obtain the needed motion to facilitate the adequate callus formation for fracture physiologic healing. Thus, surgery-related complications, such as fixation failure, implant breakage, infection, delayed nonunion, and nonunion, may occurred mainly because of stiffness stability [3].

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Notably, far cortical locking (FCL) system, a novel bridge-plating technique, was developed to solve this problem in 2005. As compared with locking plating or conventional plating, FCL provides more flexible fixation [4]. Increased flexibility of FCL constructs is considered to better stimulate secondary osteosynthesis and result in better fracture healing. The core diameter of MotionLoc screw (Zimmer, Warsaw, IN) is smaller at the near cortex, which differs from traditional locked screws by not engaging the cortex closest to the plate, and thus that can provide increased motion at the near cortex. Biomechanical studies have confirmed the effects of FCL technique on long fractures. It had the advantages of reducing axial stiffness and providing nearly parallel interfragmentary micro-motion [4–7]. Several clinical studies have reported the benefits of FCL technique for fractures, and this method was thought to be safe and effective [8–10]. However, above-mentioned studies only contained small sample size, and, to our knowledge, there was few clinical reports addressing the comparison between FCL system and conventional plating technique.

Therefore, the purpose of this study was to compare the clinical effects of lower limb fractures treated with FCL system or standard plating techniques. The fracture healing rates, surgery-related complications, fixation features, radiographic union scores, and knee functions were systematically analyzed in the study. Besides, we analyzed eight preoperative characteristics for surgery-related complications, including age, gender, presence of risk factors affecting bone healing, cause of injury, AO fracture classifications, facture sites, presence of open fracture, and presence of bone losses.

Patients and methods

Inclusion and exclusion criteria

The entire cohort of 76 patients treated with open reduction and internal fixation with FCL (the study group) and 68 patients treated with standard plating techniques (the control group) was retrospectively analyzed in the study at the Changhai Hospital of Military Medical University, Shanghai, between January 2014 and January 2017. Inclusion criteria: (1) age more than 17 years old; (2) lower limb fractures; (3) AO/OTA classifications of types 33, 32, 41, and 42; (4) a minimum follow-up of one year. Exclusion criteria: (1) pathological fracture; (2) revision of previous surgery; (3) periprosthetic fracture; (4) pregnant patients; (5) lost to follow-up.

This study was approved by the Medical Research Ethics Board of the Changhai Hospital of Military Medical University, which waived the need for written informed consent due to the retrospective nature of the study.

Surgical procedures

Study group

Fractures were stabilized with the non-contact bridging (NCB) plate and Motionloc screw system (Zimmer, Warsaw, IN) according to the manufacturer's suggested technique (Fig. 1). For shaft fixation, FCL screws (5.0 mm NCB MotionLoc screws) were performed to generate a dynamic fixation construct. A minimum of four FCL screws were recommended in each patient, and only FCL screws were used in the shaft. For metaphyseal fixation, a standard technique, 5.0 mm NCB cancellous screws with locking cap screws, was performed. Biological bridge plating techniques were used to preserve soft tissue and achieve functional reduction in all surgeries.

Control group

Fractures were stabilized with standard plating techniques (Fig. 2). This plate technique would be taken the stability at fracture site using the concept of absolute stability.

Radiographic analysis and follow-up

All patients were followed up for a minimum of one year with radiographic assessments obtained at postoperative 1, 2, 3, 6 and 12 months in the two groups. Patient's general characteristics, AO/OTA fracture classifications (type 32 vs. type 33 vs. type 41 vs. type 42), presence of open fractures [11] (open vs. closed), and presence of bone losses (yes vs. no) were recorded preoperatively in both groups. Bone loss was defined that discrepancy of the length with the limb contralateral difference was less than 4 cm. And the length of bone defects was ranged from 0 to 4 cm. Above-mentioned information was added in the manuscript. Besides, surgery-related complications, fixation features, fracture healing rates and knee functions were assessed postoperatively in both groups.

Patient's general characteristics included patients' age, gender, risk factors affecting fracture healing (such as smoking and diabetes et al.), and cause of injury. Surgery-related complications

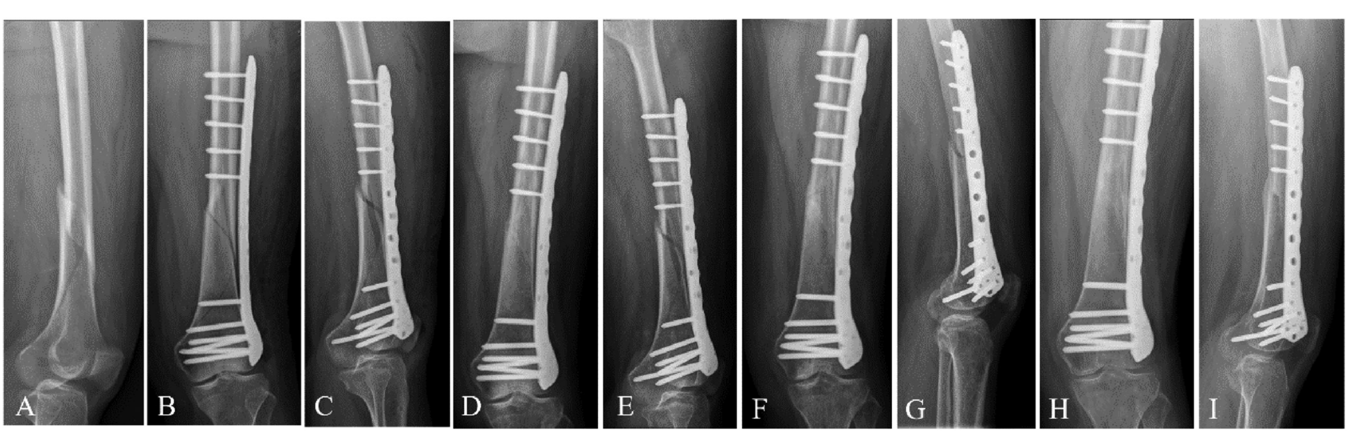

Fig. 1. A 57-year-old female was diagnosed with 32A2 fracture (AO/OTA fracture classifications) due to fall down injury. The fracture was stabilized with the non-contact bridging (NCB) plate and Motionloc screw system (Zimmer, Warsaw, IN). For shaft fixation, five FCL screws were performed to generate a dynamic fixation construct. (A) Preoperative lateral radiograph confirmed fracture; (B and C) Anteroposterior and lateral radiograph of fracture at 1 months postoperatively; (D and E) Anteroposterior and lateral radiograph of fracture at 3 months postoperatively; (F and G) Anteroposterior and lateral radiograph of fracture at 6 months postoperatively; (H and I) Anteroposterior and lateral radiograph of fracture at 12 months postoperatively.

Fig. 2. A 48-year-old male was diagnosed with 33C2 fracture (AO/OTA fracture classifications) due to vehicle accident. The fracture was stabilized with standard plating techniques. (A) Preoperative lateral radiograph confirmed fracture; (B) Anteroposterior radiograph of fracture at 1 months postoperatively; (C) Anteroposterior radiograph of fracture at 3 months postoperatively; (D) Anteroposterior radiograph of fracture at 6 months postoperatively; (E) Anteroposterior radiograph of fracture at 12 months postoperatively.

were defined by fixation failure, implant breakage, infection, or nonunion. Working length and number of screws of both groups were also assessed to evaluate fixation features. Fracture healing was defined by resolution of pain at the fracture site and cortical bridging on biplanar radiographs. Fracture healing was finally measured at 12 months postoperatively. The radiographic union scores were measured by previous research reported by Whelan et al. [12] At postoperative 1, 3, 6, and 12 months, and callus formation at each cortex was evaluated based on the following scale: 1=fracture line without visible callus; 2=fracture line with visible callus; and 3=bridging callus with no fracture line. Final union was defined as bridging callus present on 3 of 4 cortices, translating to a numerical value of at least 9. The minimum of the score of each patient is 4 and the maximum of the score is 12. The function of involved knee was assessed according to the criteria by Kolment et al. [13] at 12 months postoperatively.

Risk factor analysis

Eight preoperative characteristics for surgery-related complications were analyzed in the study group. The eight characteristics included age, gender (female vs. male), presence of risk factors affecting bone healing (yes vs. no), cause of injury (traffic injury vs. fall down injury vs. high falling injury), AO/OTA fracture classifications (type 32 vs. type 33 vs. type 41 vs. type 42), facture sites (shaft fracture vs. none shaft fracture), presence of open fractures (open vs. closed), and presence of bone losses (yes vs. no).

Statistical methods

Observations are reported as mean ± one standard deviation, if applicable. Wilcoxon rank test and Chi-square tests were performed to analyze preoperative baseline date between the two groups. Repeated measures the correlated variance model across each time points, supplemented by Wilcoxon rank-sum test, was performed to analyze radiographic union scores. Simple and multiple logistic regression were used to analyze risk factors for surgery-related complications. A P value of 0.05 or less was considered statistically significant. Statistical analysis was performed using SAS 9.2 software.

Results

Patient characteristics

Seventy-six patients treated with open reduction and internal fixation with FCL (the study group) and sixty-eight patients treated with standard plating techniques (the control group) were included in this study. The average age was 55.0 ± 15.7 years old in the study group and 52.6 ± 18.9 years old in the control group. 34 patients (44.7%) were female in the study group and 32 patients (47.1%) were female in the control group. 32 patients (42.1%) had risk factors that affecting fracture healing in the study group and 25 patients (37.8%) in the control group. The main cause of injury was fall down injury in the both groups (44.7% vs. 52.9%). All fractures were classified by AO/OTA fracture classifications, and there were 20 patients (25.6%) with type 32, 38 patients (48.7%) with type 33, 14 patients (17.9%) with type 41, and 6 patients (7.7%) with type 42 in the study group. Two patients had type 33 and 41 fractures at the same time. In the control group, there were 16 patients (23.2%) with type 32, 25 patients (36.2%) with type 33, 19 patents (27.5%) with type 41, and 9 patients (13.0%) with type 42. One patient had type 33 and type 32 at the same time. 9 patients (11.8%) had open fracture in the study group and 8 patients (11.7%) had open fracture according to Gustilo-Anderson open fracture classification. Bone loss was found in 6 patients in the study group and 5 patients in the control group. The baseline date of both groups was shown in Table 1, which demonstrated that patients in the distribution of each characteristic were similar in the two groups.

Clinical outcome analysis

The average number of FCL screws was 4.5 (range: 3–9) in the study group. The working length was 117 ± 27 mm in the study group and 112 ± 20 mm in the control group (P = 0.27, Table 2). Fracture healing rate was 96.1% (73/76) in the study group and 91.2% (62/68) in the control group (P = 0.23). Average time to clinical and radiographic union was 2.8 ± 0.9 months in the study group and 3.6 ± 1.0 months in the control group (P0.001). Besides, Average time to whole weight bearing was 2.3 ± 0.8 months in the study group and 2.8 ± 1.2 months in the control group (P = 0.004).

Table 1
The baseline date of the two groups.

Characteristics	Study group (n = 76)	Control group (n = 68)	P value
Age (mean, years)	55.0 ± 15.7	52.6 ± 18.9	0.23
Gender			
Female	34	32	0.78
Male	42	36	
Presence of risk factors[1]			
Yes	32	25	0.51
No	44	43	
Cause of injury			
Traffic injury	32	25	0.60
Fall down injury	34	36	
High falling injury	10	7	
AO fracture classifications[2]			
Type 32	20	16	0.27
Type 33	38	25	
Type 41	14	19	
Type 42	6	9	
Site of fracture[2]			
Shaft fracture	26	25	0.71
None shaft fracture	52	44	
Presence of open fracture			
Open	9	8	0.98
Closed	67	60	
Presence of bone losses			
Yes	6	5	0.90
No	70	63	

Note: 1 indicates risk factors affecting fracture healing; 2 indicates that two patients with type 33 and 41 in the study group and one patients with type 32 and type 33 in the control group.

Regarding radiographic union score, the study group scores were significantly higher than the control group scores at 1 and 3 months after surgery (P0.001), while it becomes insignificant between the two groups at 6 and 12 months after surgery (P = 0.19 and P = 0.15). The complication rates were 11.8% (9/76) in the study group and 16.2% (11/68) in the control group (P = 0.45, Case report was shown in Fig. 3). The distribution of postoperative Kolment score was similar between the two groups (P = 0.36).

Risk factors for complication in the study group

In the simple logistic regression, complication was associated with fracture sites (OR = 4.70; 95% CI, 1.07–20.68; P = 0.04) and open fracture classifications (OR = 5.08; 95% CI, 1.01–25.69; P = 0.04, Table 3). Age (P = 0.21), gender (P = 0.47), risk factors (P = 0.41), cause of injury (P = 0.09), AO fracture classifications (P = 0.15), and presence of bone losses (P = 0.11) were found to be not significant. In the multiple logistic regression, fracture site (OR = 5.34; 95% CI, 1.11–25.75; P = 0.03) and open fracture classifications (OR = 6.19; 95% CI, 1.05–36.38; P = 0.04) were also significant, whereas other variables were not included in the model. In details, 23.1% of shaft fractures (6/26) had complication while 5.8% of none-shaft fractures (3/52) had complication. 33.3% (3/9) of open fractures had complication while 9.0% (6/67) of closed fractures had complication.

Discussion

To date, locking plates have been a widely used method to treat femur and tibia fractures, which could provide proper reductions, sufficient stabilities, and blood supplies. However, the stiffness resulted from locking plates was really a concern. Recent studies have proved that the high stiffness of standard locked plating constructs can suppress interfragmentary motion to a level that was insufficient to reliably promote secondary fracture healing by callus formation [1,2]. Besides, stiff locked plating constructs can also result in uneven stress distribution that may lead to stress fracture and stress shielding [2]. Thus, surgery-related complications, such as fixation failure, implant breakage, infection, delayed nonunion, and nonunion, may occurred mainly because of stiffness stability [3]. According to reports, fracture nonunion rates after locked plating were up to 4.9%–14.6% [14–16].

Notably, far cortical locking (FCL) system, a novel bridge-plating technique, was developed to solve the stiffness problem, and this system was first proposed by Bottlang et al. at the 2005 meeting of the Orthopaedic Research Association. As compared with locking plating or conventional plating, FCL provides more flexible fixation, better load distribution, progressive stiffening, and parallel interfragmentary motion [2,4,17]. The core diameter of MotionLoc screw (Zimmer, Warsaw, Indiana) is smaller at the near cortex, and thus that can provide increased motion at the near cortex. Biomechanical studies have confirmed the effects of FCL technique on long fractures. It had the advantages of reducing axial stiffness and providing nearly parallel interfragmentary micro-motion. In details, FCL screws could reduce axial stiffness by 62%–80% in femur fractures [4,7], and it wouldn't lead to shear motion. Increased flexibility of FCL constructs is considered to better stimulate secondary osteosynthesis and result in better fracture healing [5]. In an established ovine tibial osteotomy model, researchers showed that FCL group had a 36% greater callus volume

Table 2
The clinical outcome of the two groups.

Analysis	Study group (n = 76)	Control group (n = 68)	P value
Working length (mm)	117 ± 27	112 ± 20	0.27
Fracture healing			
Yes	73	62	0.23
No	3	6	
Time to union (months)	2.8 ± 0.9	3.6 ± 1.0	0.001
Time to whole weight bearing (months)	2.3 ± 0.8	2.8 ± 1.2	0.004
Radiographic union score			
1 month	4.7 ± 1.9	2.8 ± 1.5	0.001
3 months	7.6 ± 2.7	5.4 ± 2.4	0.001
6 months	8.9 ± 2.8	8.3 ± 3.6	0.19
12 months	10.4 ± 2.6	9.6 ± 3.5	0.15
Complications			
Yes	9	11	0.45
No	67	57	
Kolment score[1]			
Excellent	43	29	0.36
Good	21	22	
Moderate	9	12	
Poor	3	5	

Note: 1 indicates that the score was assessed at postoperative 12 months.

Fig. 3. A 49-year-old female was diagnosed with 42C3 fracture (AO/OTA fracture classifications) due to vehicle accident. The fracture was stabilized with the non-contact bridging (NCB) plate and Motionloc screw system. (A) Preoperative anteroposterior radiograph confirmed fracture; (B and C) Anteroposterior radiograph of fracture at 6 months postoperatively, and it confirmed fixation failure; (D and E) Anteroposterior radiograph of fracture at 6 months postoperatively; (F and G) Anteroposterior radiograph of fracture at 20 months postoperatively; (H and I) Anteroposterior radiograph of fracture at 20 months postoperatively, it showed that the plate was removed and fracture malunion.

and a 44% higher bone mineral content as compared with the locked plating group. Besides, the FCL specimens healed to be 54% stronger in torsion and sustained 156% greater energy to failure in torsion than locked plating specimens.

Furthermore, increasing clinical studies have reported the benefits of FCL system for fractures, and FCL was thought to be safe and effective. In 2014, a series of 29 patients with 31 distal femoral periprosthetic fractures treated with FCL was published by Bottlang et al [8]. In their study, radiography assessments were measured at postoperative weeks 6, 12, and 24, and the primary endpoint was fracture union in absence of complications and secondary interventions. The study obtained satisfactory results which indicate that 30/31 fractures was proceeded to heal without revision. In 2015, Adams et al. [9] retrospectively analyzed 15 patients with distal femur fractures treated with MotionLoc screws. The average time to union was 24 weeks in the entire patients. Bone loss was recorded in 2 patients, and the both healed without intervention. There was only one reoperation due to painful hardware. The authors concluded that FCL may provide the answer to the high nonunion rate associated with distal femur fractures treated with traditional locked constructs. More recently, Madey et al. [10] prospectively enrolled 11 patients with humeral shaft fractures treated with active locking plating without supplemental bone graft or bone morphogenic proteins. 10 of 11 fractures healed at 10.9 ± 5.2 weeks, as evident by bridging callus and pain-free function. The authors concluded that dynamic

Table 3
Analysis of risk factors for complications in the study group.

Risk factors	Patients (n)	Simple logistic regression		Multiple logistic regression	
		OR (95%CI)	P	OR (95%CI)	P
Age (years)	76	2.84(0.55–14.68)	0.21	Not included	
Gender					
Female	34	1.72(0.40–7.47)	0.47	Not included	
Male	42				
Presence of risk factors[1]					
Yes	32	1.81(0.44–7.35)	0.41	Not included	
No	44				
Cause of injury					
Traffic injury	32	3.07(0.83–11.29)	0.09	Not included	
Fall down injury	34				
High falling injury	10				
AO fracture classifications[2]					
Type 32	20	0.48(0.18–1.30)	0.15	Not included	
Type 33	38				
Type 41	14				
Type 42	6				
Fracture site[2]					
Shaft fracture	26	4.70(1.07–20.68)	0.04	5.34(1.11–25.75)	
None shaft fracture	52				
Presence of open fracture					
Open	9	5.08(1.01–25.69)	0.04	6.19(1.05–36.38)	
Closed	67				
Presence of bone losses					
Yes	6	4.50(0.70–29.15)	0.11	Not included	
No	70				

Note: 1 indicates risk factors affecting fracture healing; 2 indicates that two patients with type 33 and 41 in the study group.

fixation with active locking plates may promote increased fracture healing over standard locked plating due to early callus bridging and excellent functional outcome.

Above all, above-mentioned studies only contained small sample size, and, to our knowledge, there was few studies addressing the clinical effects comparisons between FCL system and other locking plates in the treatment of fractures. Therefore, the systematic comparison between the FCL system and the conventional locking or unlocking technique is really warranted clinically. In the present study, fracture healing rates, surgery-related complications, and fixation features were systematically assessed.

In the present study, we found that the average time to union was 2.8 ± 0.9 months in the study group and 3.6 ± 1.0 months in the control group (P0.001), and the average times to whole weight bearing were 2.3 ± 0.8 months and 2.8 ± 1.2 months, respectively (P = 0.004). Biomechanical studies have confirmed that FCL system could reduce axial stiffness, and thus increased flexibility of FCL constructs is considered to better stimulate secondary osteosynthesis. Our date demonstrated that FCL system can truly accelerating bone healing and allow earlier whole weight bearing. Regarding radiographic union score, the study group scores were significantly higher than the control group scores at 1 and 3 months after surgery (P0.001), while it becomes insignificant between the two groups at 6 and 12 months after surgery (P = 0.19 and P = 0.15). We speculated that FCL system can effectively promote early callus formation due to increased flexibility. Thus, the time to union was significantly shorter in the study group than in the control group. But the long-term effects were similar between the two groups. Fracture healing was assessed 1 year postoperatively, and we found that fracture healing rate was higher in the study group than in the control group (96.1% vs. 91.2%), but it didn't reach the significance. There was 88.9%–96.8% (fracture healing rates) reported in other studies [8,18,19]. The complication rates were 11.8% (9/76) in the study group and 16.2% (11/68) in the control group (P = 0.45). 6.9%–9.0% (complication rates) was reported in other studies [8,10]. The distribution of postoperative Kolment score was similar between the two groups (P = 0.36). Rice et al. [18] also showed that the fracture healing rates and complication rates were similar between patients treated with FCL implants or conventional plating techniques. The author concluded that FCL implants were not inferior to conventional plating techniques.

In the multivariate analysis, fracture site (OR = 5.34; 95% CI, 1.11–25.75; P = 0.03) and presence of open fracture (OR = 6.19; 95% CI, 1.05–36.38; P = 0.04) were significant associated with surgery-related complications, whereas other variables were not included. To our knowledge, this was the first article finding that fracture sites and presence of open fractures were the independent factors for complications in patients treated with FCL system. Patients with shaft fractures and open fractures trended to have higher complication rates. Thus, the use of FCL system in those patients needs further investigations.

However, our study had some limitations. First, this was a retrospective analysis of data collected from patient's files, thus a hidden selection bias cannot be excluded. Second, although there was a comparative control group, the statistical analysis didn't include a relatively larger number of patients. Third, it would be more interesting and relevant to only compare homogenous groups of patients suffering from 'junctional' distal or proximal metaphyseal-shaft fractures of either the femur or the tibia only. And fourth, detail fracture situation was not analyzed in the study due to the emphases on analysis of fracture locations for complications. Therefore, a larger prospective comparative study is still warranted.

In summary, FCL system is superior to standard plating technique in terms of early callus formation, but standard plating technique is not inferior to FCL system in terms of final fracture healing, surgery-related complication, and function outcome. Fracture sites and presence of open fractures are the independent factors for surgery-related complications in patients treated with FCL system. Thus, we may not recommend the FCL system in the treatment of patients with limb shaft fractures or open fractures. Still, further investigation is truly required.

Conflict of interest

The authors declare that they have no conflict of interest.

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