

# Clinical effects of dynamic stabilization with far cortical locking system in the treatment of simple distal-third tibia fractures: A cohort study

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## Research article

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# Abstract

**Background:** Locked plating constructs provided rigid fixation and may suppress callus formation at the fracture site, while far cortical locking (FCL) constructs have been shown to reduce the stiffness, thereby promoting fracture healing. A few publications have demonstrated that FCL construct increased axial dynamization and improved fracture healing. However, it is unclear whether the FCL construct was superior over locked plating construct for treating simple tibia fractures. Thus, we aimed to compare the clinical effect of FCL construct and locked plating construct for these fracture types.

**Methods:** We retrospectively analyzed 18 patients treated with locked plating (control group) and 22 patients treated with the FCL construct (FCL group) from January 2016 to January 2018; the simple distal-third tibia fractures were included (AO/OTA classification: 42A1-A3 or 43A1). Patients were followed up regularly at 1, 2, 3, 6, and 12 months postoperatively, and data from clinical and radiological examinations were obtained. Patients' demographics, operative time, time to radiological fracture union, time to full weight bearing, callus index, radiographic union score in tibia (RUST), and surgery-related complications were analyzed between the two groups.

**Results:** The baseline patients' demographics were similar between the two groups ( $P>0.05$ ). There were no significant differences in of the operative time, time to radiological fracture union, or time to full weight bearing ( $P>0.05$ ). However, the median callus index was 1.15 (IQR=1.08–1.25) in the FCL group and 1.09 (IQR=1.00–1.14) in the control group, showing a significant difference between the two groups ( $Z=-2.35$ ,  $P<0.05$ ), and the RUST was significantly higher at 2 months postoperatively ( $6.50\pm 0.92$  vs  $7.59\pm 1.37$ ,  $P=0.006$ ). Seven out of 18 patients in the control group and 2 out of 22 patients in the FCL group had no callus formation (callus index=1.0). All patients ultimately healed, and the complication rates were similar between the two groups.

**Conclusions :** The FCL construct could promote fracture healing and was superior to locked bridge plating, as it did not lead to more surgery-related complications.

Level of Evidence :  $\square$ , retrospective cohort study

## Background

Distal-third tibia fractures have been noted with a high rate of complication, and its treatment strategy should be carefully planned. As pointed out by some researchers that intramedullary nailing was associated with more malalignment and anterior knee pain [1–4], plating seemed to be a simple and effective method for this fracture. To protect the blood supply and provide durable stabilization, the bridge technique with a locking plate by minimally invasive plate osteosynthesis was extensively adopted. Numerous researches identified the advantage of this plating technique for distal distal-third tibia fractures; however, trials have observed the increased rate of prolonged healing for simple distal tibia fractures [5–6], thereby indicating the limitation of the locking plate for simple distal distal-third tibia fractures. A few studies revealed that locked plating constructs provided overly rigid fixation and inhibited

micromotion at the fracture site, which may suppressed callus formation, resulting in delayed union, nonunion, and fixation failure [7–10]. Increasing the bridging span of the locking plate may be an effective method to decrease the stiffness and increase the interfragmentary micromotion [11]. While this solution still possesses inherent defects, the fracture motion is asymmetric, as the cortex motion underneath the plate is also under the most proper motion range inducing callus formation; additionally, the shear motion increased concomitantly, which also impacts fracture healing [12–13].

Numerous studies have demonstrated that axial dynamization can improve fracture healing by reducing the stiffness and increasing the flexibility of the constructs. Notably, the far cortical locking (FCL) construct, a novel strategy of bridging fixation and for axial dynamization that was shown to reduce the stiffness, may be a solution to this problem. The FCL screw possesses the characteristics of reduced mid-shaft diameter and is threaded only distally, which provides unicortical fixation in the far cortex of the diaphysis to reduce the stiffness of the construct. In biomechanical testing, the FCL significantly reduced the axial stiffness while retaining sufficient construct strength compared with the locked plating constructs [13–14]. In addition, the FCL construct did not raise the shear motion between the fragments [13]. Several clinical studies have revealed the safe and effective benefits of FCL for femur fractures. However, there have been few reports on simple distal-third tibia fracture treated with FCL construct.

Therefore, we performed a retrospective case-control study to compare the clinical effect of FCL construct and locked plating construct for simple distal-third tibia fractures. We hypothesized that the FCL construct could accelerate callus formation and promote fracture healing for simple tibia fractures.

## Methods

### Inclusion and exclusion criteria

From January 2016 to January 2018, patients with tibia fractures treated via minimally invasive plate osteosynthesis (MIPO) and bridging fixation with a locking plate (control group) or with an FCL construct (study group) were retrospectively analyzed in our hospital. The inclusion criteria were as follows: (1) age > 18 years; (2) simple distal third fracture, AO/OTA classification of types 42A1-A3 or 43A1; and (3) bridging fixation by locked bridge plating or FCL construct. The exclusion criteria were as follows: (1) pathological fracture; (2) old fracture; (3) open fracture of Gustilo-Anderson II-III; (4) ipsilateral limb fracture; and (5) follow-up of < 1 year. The study was retrospectively registered and approved by the Medical Research Ethics Board of the Chongqing General Hospital, University of Chinese Academy of Science.

### Surgical procedures

The fractures were fixed with biological bridging plate techniques by MIPO. Briefly, all procedures were performed in the supine position on a radiolucent table. Although we recognized the controversy surrounding fibula fixation associated with distal tibia shaft fractures [15], in this study, the fibula fracture was fixed first if it was within 6 cm of the tibiotalar joint to provide a template for tibia restoration. The

tibia fracture was then indirectly reduced by manual traction and temporarily fixed by percutaneous clamps or Kirschner wire, which was performed under fluoroscopic guidance. If the fracture could not be reduced by using the indirect method, an approximately 3-4-cm incision was made at the fracture site for minimal open reduction. A small incision was made over the medial malleolus; then, the plate was inserted extraperiosteally, and adhered to the principle of long plate and low density of screw [16]. For metaphyseal fixation, a minimum of 5 standard locking screws were placed in all patients. In the study group, shaft fixation was stabilized with only FCL screws (5.0-mm FCL screws) to generate a dynamic fixation construct (Fig. 1), and at least 4 FCL screws were recommended. In the control group, at least 4 standard locking screws were utilized for shaft fixation.

## **Rehabilitation, radiographic analysis, follow-up, and data analysis**

Limb elevation and ankle movements were performed during the first week after surgery. Partial weight bearing of no more than 15 kg was encouraged from 2 weeks to 6 weeks postoperatively and gradually transformed to full weight bearing. All patients were followed up regularly at 1, 2, 3, 6, and 12 months postoperatively, and X-rays were obtained to monitor the fracture healing. For patients with delayed union or nonunion, increasing the number of follow-up visits may have been required according to the specific condition. Data from clinical and radiological examinations were obtained and analyzed.

The operative time, time to radiological fracture union, time to full weight bearing, maximum callus index, radiographic union score in tibial (RUST), and the surgery-related complications (infection, delayed union, nonunion, fixation failure, and malalignment  $> 5^\circ$  in the anteroposterior view or  $10^\circ$  in the lateral view) were analyzed. All measurements were done by an independent examiner to decrease the possibility of bias. Radiological fracture union was defined as a bridging bone or disappearance of the fracture line on a minimum of three out of the four cortices on the plain radiographs for patients who are able to bear full weight. Fracture cases in the process of union that did not achieve union at 6 months were regarded as delayed union, whereas fractures that did not heal within a year were considered nonunion. Full weight bearing was defined as the ability to walk pain free without aids. The callus index was defined as the ratio of the maximum callus diameter to the bone diameter at the same level as the callus, which has been verified as a potentially useful measurement for quantifying fracture healing [17]. According to the RUST reported previously, each cortex of the anteroposterior and lateral radiographs was assessed, which was based on the following scale for each cortex: 1 = fracture line without visible callus; 2 = fracture line with visible callus, and 3 = bridging callus without a fracture line [18–19].

## **Statistical methods**

The data were analyzed by the IBM SPSS version 20.0. Descriptive analysis and Pearson's Chi-square test were carried out to analyze preoperative baseline characteristics between the two groups. For continuous nonparametric data, the median and interquartile percentiles were calculated, and the Wilcoxon rank-sum test was utilized. For continuous parametric data, the mean and standard deviation were calculated, and t-tests were used to analyze the data. A P-value  $\leq 0.05$  was considered statistically significant.

# Results

## *Patient demographics*

Fifty-one patients were retrospectively analyzed. The following 11 patients were excluded: 6 patients were followed for <1 year, 3 patients had open fractures of Gustilo-Anderson II classification, and 2 had ipsilateral limb fractures. Consequently, 40 patients with 40 tibia fractures were enrolled. The mean follow-up period was 14 months, ranging from 12 to 18 months. The baseline demographics were comparable between the two groups (Table 1).

## *Operative time*

The average operative time was  $78.70 \pm 15.92$  min in the FCL group and  $72.78 \pm 13.29$  min in the control group. There was no significant difference between the two groups ( $t=1.268$ ,  $P>0.05$ ).

## *Time to radiological fracture union and time to full weight bearing*

The average time to radiological fracture union and average time to full weight bearing were comparable between the two groups ( $t=0.803$ ,  $P>0.05$ ;  $t=0.891$ ,  $P>0.05$ ), and there was no significant difference (Table 2).

## *Callus index and radiographic union scores*

The median callus index was 1.15 (IQR=1.08–1.25) in the FCL group and 1.09 (IQR=1.00–1.14) in the control group. There was a significant difference between the two groups ( $Z=-2.35$ ,  $P<0.05$ ). There were seven patients in the control group and two patients in the FCL group with no significant callus formation (callus index=1.0) (Figures 2 and 3).

The radiographic union scores were measured at 1, 2, 3, and 6 months postoperatively, with a slightly increasing average score in the FCL group at 1 month and significantly higher score at 2 months postoperatively ( $6.50 \pm 0.92$  vs  $7.59 \pm 1.37$ ,  $P=0.006$ ), although these became comparable between the two groups at 3 and 6 months postoperatively ( $P \geq 0.05$ ).

## *Complications*

There were no cases of nonunion, malalignment, or deep infection, but there was 1 case of delayed union in each group. Additionally, there was 1 case of superficial infection in the control group and 2 in the FCL group, which did not require debridement and were cured by intravenous antibiotic and local treatment. There was no significant difference in the complications between the two groups.

## Discussion

Currently, numerous studies have confirmed the priority of bridging plate fixation by MIPO [6–20–21]. However, the stiffness and stress shielding resulting from the locking plate may inhibit callus formation and lead to delayed union or nonunion. Some studies noted that the stiff construct did not facilitate adequate callus formation because of inadequate motion [9]. Moreover, some other reports revealed that bridging fixation by a locking plate for simple tibia fracture can lead to delayed union and suggested fixation of absolute stability [5–6]. Wenger and his colleagues [22] compared absolute stability with relative stability for simple distal tibia fracture by MIPO, and found that the median time to radiological union was 19 weeks in the absolute fixation group and 27 weeks in the bridge plating group. However, whether the satisfactory reduction was achieved was not reported, which may be an interference factor for fracture healing. In this research, all of the fractures were fixed by relative stability, but we did not note prolonged healing time, with  $4.06 \pm 1.20$  months in LCP group and  $4.43 \pm 1.66$  months in the FCL group for radiological union. This may be attributed to the overall satisfactory reduction, as excellent reduction can accelerate fracture healing. Moreover, Plecko and his colleagues [23] also did not encounter prolonged healing when bridge plating was applied for simple fracture with satisfactory reduction.

Between the two groups, the patients' demographics were comparable. The similar operative times demonstrated that the use of FCL screws did not increase the difficulty of fixation. The time to radiological fracture union, time to full weight bearing, and complications between the two groups did not show a significant difference, which may be due to the protection of the blood supply that promoted fracture healing and principles of fixation was adhered in both groups. The data resembled the research of Wenger and his colleague, who compared absolute fixation with bridging fixation of simple tibia fractures and found that the median time to full weight bearing was 10 weeks [22]. A previous study reported the rate of malalignment and infection after plating for distal tibia by MIPO was low [24]. The anatomical reduction was achieved during operation and no high-grade open fracture was included in the trial; thus, there was no malalignment and the rate of infection was also very low.

The callus formation and RUST in the FCL group was significantly higher than those of the control group, which may imply that the FCL construct promoted fracture healing. The FCL construct possessed some important features shown to enhance fixation and fracture healing, which are as follows: flexible fixation, progressive stiffening, and parallel interfragmentary motion. Compared with the locked plating construct, biomechanical testing confirmed that the FCL constructs reduced the stiffness by 60–88%, similar to that of an external fixator, which significantly increases the axial interfragmentary motion but not shear motion [13–14–25]. The interfragmentary motion was also controlled in the proper range from 0.2 to 1 mm, which is known to promote callus formation. As callus formation represents the micromotion at the fracture site, the interfragmentary motion in the FCL group was inferred in the proper range for fracture healing. In fracture-healing mode, the FCL group exhibited a symmetric callus formation and had a greater callus volume and stronger fracture healing compared to the locked plating specimens [26]. Conversely, the callus in the control group was insignificant, which may refer to the lack of micromotion and callus formation at the fracture site. Given that this research was a retrospective analysis and CT

was not routinely carried out to assess fracture healing, symmetrical callus formation in the FCL group cannot be revealed directly.

Clinical studies concerning FCL screws are limited, and only a few studies have assessed the clinical effect of the screws on lower limb fracture. Adams et al. reported that the FCL screw construct decreased the nonunion rate and complications for distal femoral fracture, showing that it may be a promising construct for fracture [27]. Galal created the FCL screw construct by near-cortical overdrilling for fixation of distal femur fracture, and the result demonstrated that all patients achieved an average union time of 13.4 weeks and a callus score of 1.8 [28]. Ries and his colleagues followed 18 patients with periprosthetic distal femur fractures who were treated by FCL constructs, and they discovered a high healing rate and that the callus was more robust and uniform compared to their previous experience with locking plate periprosthetic distal fracture [29]. However, Rice and his colleagues retrospectively reviewed 22 tibia fractures treated with the FCL construct or standard plating and found that the FCL implants were not superior [30]. This result may be due to the small cohort size and the diversity of the fracture types included, which decreased the difference between the two groups. Kidiyoor and his colleagues [31] discovered uniform callus formation and minimal complication rates for periarticular fracture treated with FCL screw constructs, and the average time for complete union was 20 weeks in tibial fracture, which was comparable to the results of the present study. Wang and colleagues retrospectively analyzed 76 patients treated with FCL screw constructs and 68 patients treated with plating techniques, and the results revealed that the average union time in the FCL group ( $2.8 \pm 0.9$  months) and RUST were superior to those of the standard plating techniques [32]. The majority of those researches demonstrated the advantage of the FCL construct for fracture healing, which coincides with our study.

However, there are still a few limitations in our study. First, this was a retrospective analysis, which reduced the level of evidence, and potential confounders could influence the outcome. Second, although there was a comparative control group, the cohort size was small, which decreases the statistical power. Third, CT was not routinely performed to assess healing, and callus formation at the fracture site could not be assessed accurately, especially the callus at the near cortex.

## Conclusion

Although this study was a retrospective analysis with a small cohort size, our data indicated that the FCL construct promoted callus formation and fracture healing for simple distal-third tibia fractures, without increasing the risk for complications.

## List Of Abbreviations

FCL: far cortical locking; RUST: radiographic union score in tibia; MIPO: minimally invasive plate osteosynthesis

## Declarations

## **Ethics approval and consent to participate**

The study was approved by the Medical Research Ethics Board of the Chongqing General Hospital, University of Chinese Academy of Science (S2016-011). The need for informed consent was waived by the committee.

## **Consent for publication**

Not applicable

## **Competing interests**

We have no competing interests.

## **Availability of data and materials**

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

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## **Authors' contributions**

JP and JF carried out the research and drafted the manuscript. YL and XTL collected the data and helped in drafting the manuscript. SYC performed the statistical analysis. RHH performed the radiographic analysis.

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## Tables

**Table 1. The baseline demographics between the control and FCL groups**

	Control	FCL	$\chi^2$	P value
Sex				
Male	8	13	0.852	$P>0.05$
Female	10	9		
Age (mean±SD)				
18-40	5	6	0.677	$P>0.05$
41-60	7	11		
>60	6	5		
AO/OTA classification				
42A1	6	12	3.444	$P>0.05$
42A2	3	4		
42A3	1	2		
43A1	8	4		
Trauma intensity				
Low	16	20	0.45	$P>0.05$
High	2	2		
Malleolus fixation				
No Fracture	4	6	0.045	$P>0.05$
No fixation	8	9		
Fixation	6	7		
Anterior malleolus fracture				
Yes	5	8	0.333	$P>0.05$
No	13	14		

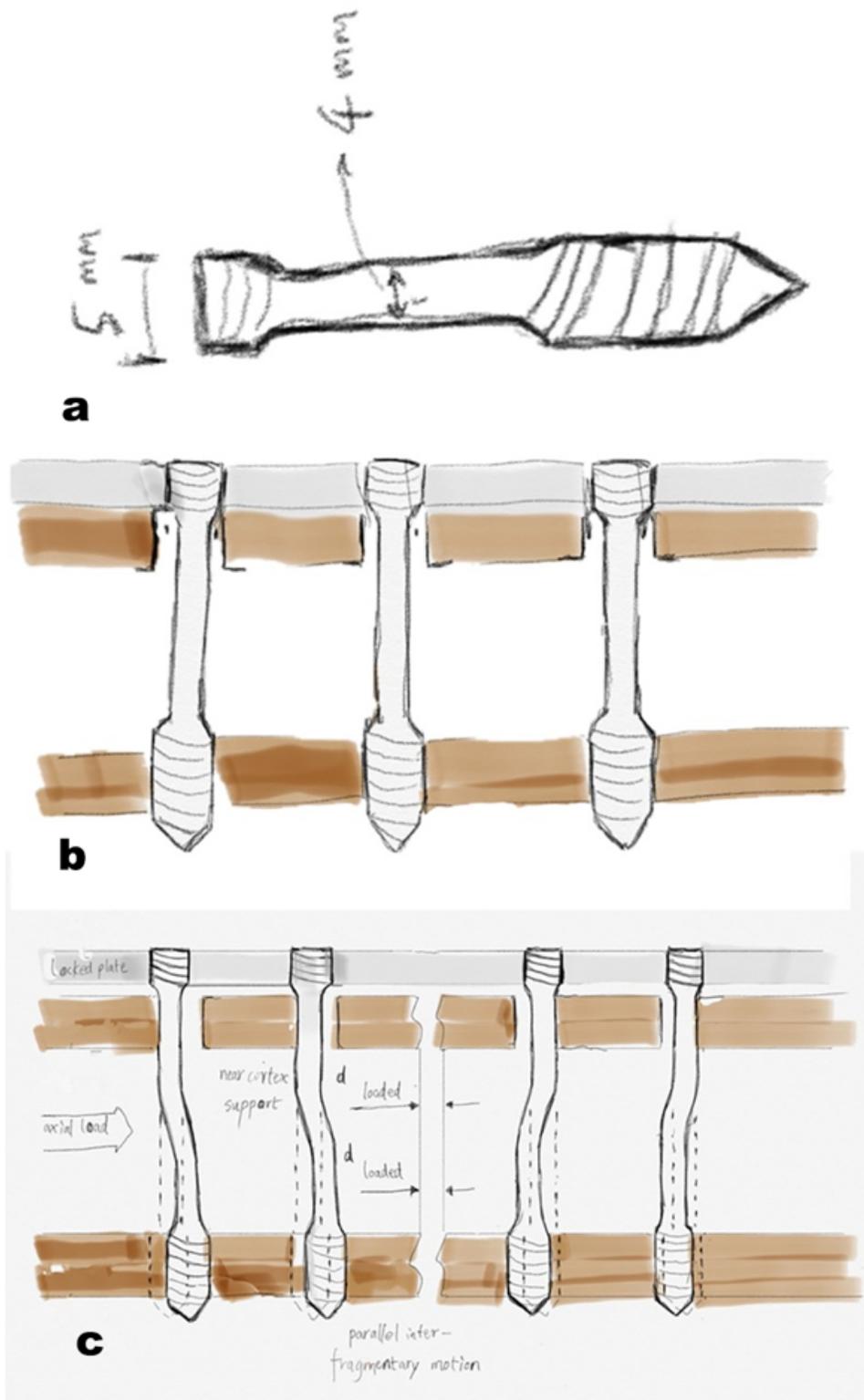
FCL, far cortical locking

**Table 2. Time to radiological fracture union and full weight bearing in the control and FCL groups**

	Control	FCL	P value
Time to radiological union (months)	4.06±1.20	4.43±1.66	<i>P</i> >0.05
Time to full weight bearing (months)	3.33±0.51	3.57±1.02	<i>P</i> >0.05

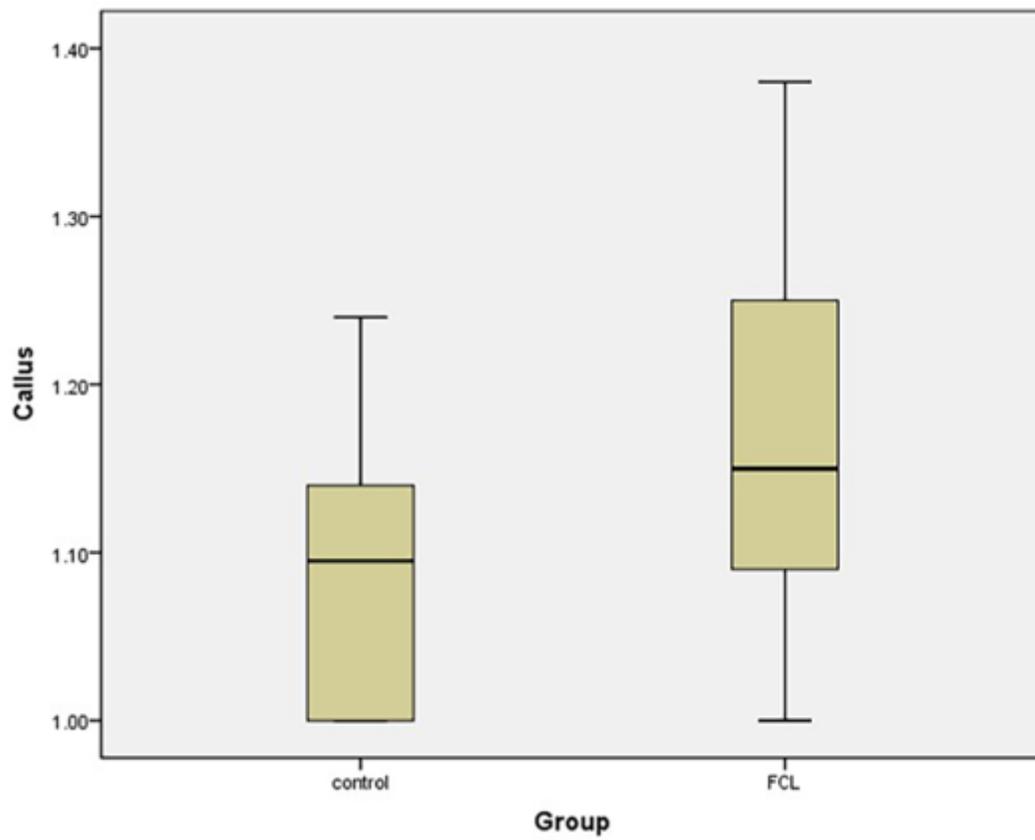
FCL, far cortical locking

## Figures



**Figure 2**

Schematic drawing of the far cortical locking (FCL) screw and the fixation construct. a. The size of the FCL screw. b. The FCL screws locked into the plate and the far cortex with a motion envelope in the near cortex. c. The construct of the FCL system enables controlled and nearly parallel interfragmentary motion under load.



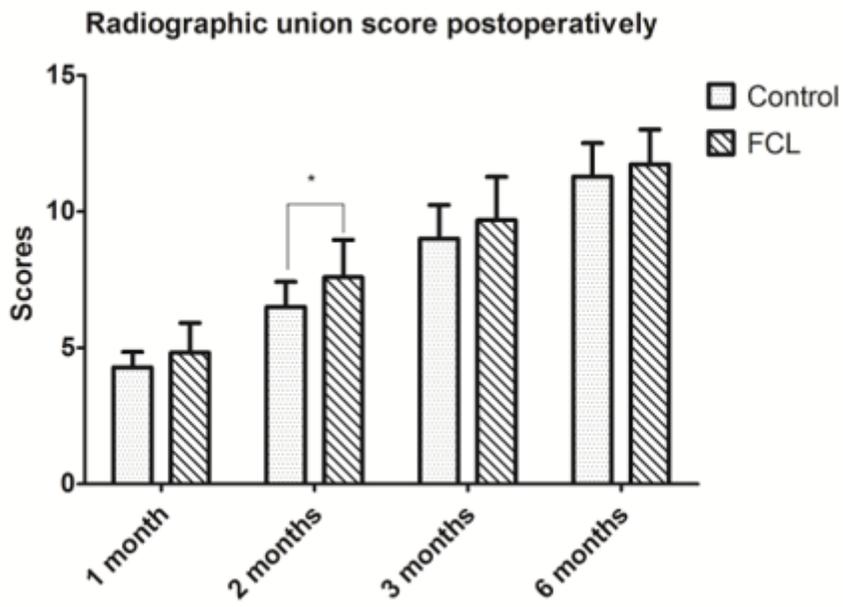
**Figure 4**

The callus index between the control and far cortical locking groups



**Figure 5**

A 54-year-old female patient who suffered a distal tibial shaft spiral fracture (AO/OTA type 42A1) underwent indirect reduction and internal fixation. a-b. X-ray before operation. c. Three-dimensional computed tomography before operation. d. Indirect reduction and fixation by a bridging plate and far cortical locking screw system. e-f. X-ray at 2 days postoperatively. g-h. X-ray at 3 months postoperatively with a significant callus formation at the fracture site. i-j. X-ray at 1 year postoperatively.



**Figure 8**

The radiographic union score at 1, 2, 3, and 6 months after surgery. There was no significant difference at 1, 3, and 6 months, whereas the scores of the far cortical locking (FCL) group at 2 months were significantly higher (\* $P \leq 0.05$ )