Locking versus non-locking neutralization plates for treatment of lateral malleolar fractures: a randomized controlled trial

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Received: 1 August 2013 / Accepted: 6 September 2013 / Published online: 28 September 2013
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Abstract

Purpose The reduction of periosteal compression through the use of a locking plate may minimize disturbances of bone blood supply and may improve the rate of bone union. A single-centre, assessor blinded randomized controlled trial was conducted to compare the clinical effectiveness of a locking plate and a non-locking plate.

Methods A total of 52 patients with AO/OTA 44B lateral malleolar fractures were included in this study. All patients underwent surgical fixation using a lag screw and neutralization plate. An identical treatment protocol was used in all patients, with exception of plate selection. The rate of radiographic bone union, defined as the complete disappearance of fracture lines confirmed through anteroposterior, lateral, and internal oblique views was compared at three, six, and 12 months following surgery. In addition, the Medical Outcomes 36-Item Short-Form Health Survey (SF-36) score, the time required for resolution of tenderness at the fracture site and the complication rate were evaluated.

Results Twenty-three patients were randomly assigned to undergo fixation using a locking plate, and 29 patients were assigned to undergo fixation using a non-locking plate. Intention-to-treat analysis showed no difference in the radiographic bone union rate of fibula, SF-36 score, the time for resolution of tenderness at the fracture site and complication rates.

Conclusion No differences were observed in patients with AO/OTA 44B lateral malleolar fractures undergoing fixation with a locking versus non-locking neutralization plate.

Keywords Locked plate · Ankle fracture · Bone adhesion · SF-36 · Randomized control trial

Introduction

Less compression of the periosteum is an advantage of a locking plate [1–3]. A non-locking conventional plate obtains the fixation stability by the frictional force between the plate and bone [1]. This compression could cause disturbances in blood supply to the bone and introduce an unfavourable condition for bone union. Therefore, the reduction of periosteal compression may improve the rate of bone union. Although many types of plates were developed, which do not interfere with the cortical blood flow, no clinical effectiveness of these plates has been clearly proven [4–6].

The locking plate can be used in various ways; it may serve as a bridging plate, a compression plate, a tension band plate or a neutralization plate [7–11]. The use of a locking plate as a neutralization device for lag screw fracture fixation is one of the most important techniques for locking plate [7]. Most displaced fractures of the lateral malleolus of ankle must be treated by anatomical reduction with absolute stability, and the fixation using a lag screw and neutralization plate is frequently performed.

We conducted a randomized controlled trial to compare the rate of bone union of the locking plate versus the non-locking plate in lateral malleolar fractures using a neutralization plate technique. The hypothesis of this study was that the rate of bone union is higher in the fracture treated with a locking plate than with a non-locking plate.

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Materials and methods

This study was a single-centre, assessor-blinded randomized controlled trial. The protocol of the study was approved by the institutional review board.

In this study, participants were eligible if they had the AO/OTA 44B malleolar fracture and were medically fit to undergo surgery [12]. We excluded patients from the study if they had an open fracture or if they declined to participate in the trial.

Patients were recruited between November 2010 and March 2012. Eligible patients signed an informed-consent document that clearly stated the aim and protocol of study, which included that the patients would be randomly allocated to groups and they would not know which plate was being used until 12-month follow-up.

Randomized numbers were generated in the range from 0 to 99 by the computer software (Excel 2010, Microsoft, Redmond, WA). Each time the patients participated in the trial, the generated randomized number was assigned accordingly. The patients obtaining an even number were allocated under treatment with the locking plate, and the patients obtaining an odd number were allocated under treatment with the non-locking plate.

Operative technique and postoperative treatment

All procedures were performed with the patient under lumbar anaesthesia using a pneumatic tourniquet.

The lateral malleolar fracture was reduced by direct open reduction. In both groups, the amount of periosteal elevation was maintained to the minimum required for anatomical reduction. After fracture reduction and insertion of a lag screw, the elevated periosteal was repaired as well as possible with absorbable surgical sutures followed by the locking or non-locking neutralization plate placed on periosteal of the lateral aspect of lateral malleolus.

The locking plate used in this study was a straight titanium alloy plate (LCP Metaphysical plate, Synthes Japan, Tokyo, Japan). The contact surface of the plate was designed to be pruned to reduce the area of bone contact (Fig. 1). The plate has two holes to insert screws for the distal fragment (Fig. 2a). We only used locking head screws to fix the locking plate to fibula. To avoid compression of the periosteum, the conventional screws were not used to fix the locking plate to fibula during the study period.

An anatomically pre-shaped titanium alloy plate (distal fibula plate, Stryker Japan, Tokyo, Japan) was used as the non-locking neutralization plate (Fig. 1). The plate has four holes to insert screws for the distal fragment (Fig. 2b). We selected this plate on the basis of the study results by Kim et al. which revealed that internal fixation of the lateral malleolus using three to four conventional screws were equivalent to

Fig. 1 Bone contact surface of the locking and non-locking plate used in the study

using two locking screws [13]. Bending of the plate was not required when using this anatomically pre-shaped plate.

The indication for fixation of posterior and medial malleoli was identical during the study period. The posterior malleolar fragment was fixed if the fragment involved more than 20 % of the weight-bearing surface. Although posterior malleolar fragment reduction was conducted according to the surgeon's preference, almost all reductions were performed through a posterolateral approach. One or two 5.0-mm or 4.0-mm cannulated cancellous screws (ACE cannulated cancellous screw, Japan Medical Dynamic Marketing, Tokyo, Japan) were used for fixation of posterior malleolar fragment. In cases involving the medial malleolar fracture, internal fixation was routinely performed using two 5.0-mm cannulated cancellous screws for fixation. For small fragments, one 5.0- and one 4.0-mm screw or two 4.0-mm screws were used.

Fig. 2 The postoperative X-rays. **a** The locking neutralization plate with two screw holes to fix the distal fragment. The plate was routinely bent to fit the shape of the lateral part of fibula, and fixed only by locking head screw. **b** The non-locking neutralization plate with four screw holes to fix the distal fragment. In this case, three cancellous screws were inserted to the distal fragment

After internal fixation of all malleoli, Cotton's test was performed under fluoroscopy or X-ray with a bone hook [14]. A lateral force was applied to the distal fibula by using the bone hook, and the degree of syndesmosis diastases was assessed. A widening more than 2 mm syndesmosis was considered pathological. A temporary syndesmotic fixation screw was quadricortically inserted with the foot in 10° of dorsiflexion.

Anteroposterior and lateral X-rays were taken before wound closure to confirm anatomical reduction of the fracture site. If acceptable reduction was not obtained, all implants were removed and reduction and internal fixation were repeated.

Identical postoperative care was provided to both groups. Postoperatively, patients remained non-weight-bearing for three weeks. Full weight-bearing was allowed six weeks postoperatively. Unless the surgeon particularly advised otherwise, an external fixation was not performed. However, if the surgeon confirmed that the external fixation was suitable, a splint or cast was used from one to two weeks.

First-generation cephalosporin antibiotics were intravenously administered every eight hours for two days postoperatively.

After confirmation of wound healing, routine follow-up was undertaken at three, six, and 12 months postoperatively. At each follow-up visit, all study patients were clinically and radiographically evaluated. The type of plate used was disclosed to each patient after the 12-month follow-up.

Outcome measurements

Primary outcome

The primary outcome was the radiographic confirmation of lateral malleolar fracture union. Radiographic union was defined as the complete disappearance of fracture lines in the anteroposterior, lateral, and internal oblique views. Radiographic bone union was determined by a single radiologist (AY) who was blinded to the aim and protocol of this study. The rate of radiographic union was compared postoperatively between the two groups at three, six, and 12 months.

Secondary outcomes

Data was collected for three secondary outcomes. The first secondary outcome involved obtaining subjective outcome data from patients through administration of the Medical Outcomes 36-Item Short-Form Health Survey (SF-36). In the SF-36, one item is designed to assess perceived change in health status, and each of the remaining 35 items contributes to a score on one of eight scales: physical functioning, role-physical, bodily pain, general health perception, vitality, social functioning, role-emotional and mental health. The norm-based scoring, which was based on the national average, was applied for scoring. The score at three, six and 12 months post operation was compared between the two groups. The

Japanese versions of the SF-36 have been previously validated for use in Japan [15, 16].

The clinical confirmation of bone union was also determined as a secondary outcome. Clinical bone union was defined as no tenderness on palpation of the lateral malleolus [17]. Clinical bone union was determined by operating surgeon; therefore, this assessment was not assessor-blinded.

Finally, any complications occurring during the course of the trial were recorded with particular emphasis on wound complications.

Sample size

In our pilot study of 22 patients, the bone union rate was 90 % (nine of ten patients) in the locking plate group and 50 % (six of 12 patients) in the non-locking plate group six months after surgery. In the pilot study, the operating surgeon confirmed bone union. Based on the observed union difference in the pilot study, a type I error rate of 5 %, and a type II error rate of 20 % (80 % power), the sample size of 20 patients per treatment arm was calculated.

Statistical analyses

Statistical analyses were performed using StatView-J 5.0 statistical software (Abacus Concepts, Berkeley, CA). A Student's *t*-test was used for continuous data, and data grouped into distinct categories were evaluated using the chi-squared test. We considered the value of $p < 0.05$ as statistically significant.

Results

A total of 64 patients with AO/OTA 44B fracture were treated during the study period and were eligible for inclusion in the study. All fibula fractures had fracture lines beginning at the level of the ankle mortise and extending proximal, posterior, and lateral in an oblique or spiral orientation. The flow chart presented in Fig. 3 outlines the trial. Nine patients were non-operatively treated, and three patients who declined to take part were excluded. No open fracture was treated during the study period.

The baseline characteristics of the study groups are shown in Table 1. There was no significant difference noted in patient demographics or characteristics in terms of operative side, age, height, weight, body mass index, time from injury to surgery, smoking habits, history of diabetes mellitus, and subgroup of AO/OTA fracture classification.

Primary outcomes

The rate of radiographic bone union is shown in Table 2. The rate of radiographic bone union was determined by a

Fig. 3 Patient flow diagram

radiologist who was blinded to the study protocol, and it was not significantly different between the two groups.

Secondary outcomes

Table 3 shows the postoperative outcomes of SF-36 assessment at three, six, and 12 months, respectively. There were no significant differences between the two groups at three, six, and 12 months for all eight scales.

Table 1 Patient demographics and associated baseline clinical characteristics

Characteristic	Locking plate (n=23)	Non-locking plate (n=29)	P
Side (Right: Left)	13: 10	14: 15	0.55 ^b
Age, year	40.7±14.2	41.7±19.2	0.30 ^a
Sex (F: M)	14: 9	14: 15	0.51 ^b
Height, cm	166±7.9	163±7.7	0.29 ^a
Weight, kg	63.4±9.6	66.5±11.2	0.31 ^a
Body mass index, kg/m ²	23.0±3.1	24.8±3.6	0.07 ^a
Time from injury to surgery, days	7.0±3.2	7.6±3.6	0.49 ^a
Smoking habit (yes: no)	7: 16	8: 21	0.82 ^b
History of diabetes mellitus (yes: no)	0: 23	2: 27	0.20 ^b
AO/OTA classification (44B-11: 12: 13: 21: 22: 23: 31: 32: 33)	12: 2: 0: 0: 3: 0: 2: 4: 0	12: 4: 0: 1: 6: 0: 1: 5: 0	0.78 ^b

Results are expressed as mean ± standard deviation, unless stated otherwise

^a Student's *t*-test

^b χ^2 test

Table 2 Bone union determined by radiologist blinded to the study protocol

Follow up	Locking plate	Non-locking plate	P
3 month (yes: no)	7:15	5:24	0.22 ^a
6 month (yes: no)	12:10	10:18	0.18 ^a
12 month (yes: no)	19:2	23:1	0.47 ^a

Bone union was defined as complete disappearance of the fracture line

^a χ^2 test

Regarding resolution of tenderness at the fracture site, all patients included in the trial achieved clinical bone union. The mean±standard deviation time for resolution of tenderness at the fracture site was 3.9±1.6 weeks in the locking plate group and 4.1±2.4 weeks in the non-locking plate group ($p=0.78$, student's *t*-test).

Table 3 Norm-based score of the medical outcomes 36-item short-form health survey

Parameter	Locking plate	Non-locking plate	P
Three months after surgery			
Physical functioning	44.1±11.6	40.1±15.4	0.42 ^a
Role-physical	35.8±22.3	35.8±21.5	0.99 ^a
Bodily pain	45.6±5.3	44.1±8.7	0.58 ^a
General health perception	53.0±10.3	53.4±9.9	0.90 ^a
Vitality	52.7±10.7	49.8±10.1	0.46 ^a
Social functioning	39.6±15.7	39.4±13.5	0.98 ^a
Role-emotional	41.5±18.5	40.9±18.8	0.92 ^a
Mental health	48.9±16.3	51.7±10.3	0.57 ^a
Six months after surgery			
Physical functioning	52.1±7.2	42.6±17.2	0.06 ^a
Role-physical	50.1±9.9	46.3±13.7	0.42 ^a
Bodily pain	51.1±6.6	46.7±8.3	0.14 ^a
General health perception	53.0±10.3	53.4±9.9	0.90 ^a
Vitality	50.7±9.5	50.0±11.1	0.86 ^a
Social functioning	47.0±12.9	42.6±16.6	0.47 ^a
Role-emotional	52.0±9.0	48.4±11.2	0.37 ^a
Mental health	51.1±13.3	49.2±11.8	0.72 ^a
Twelve months after surgery			
Physical functioning	52.0±12.0	47.7±11.8	0.43 ^a
Role-physical	51.5±11.1	46.0±12.9	0.32 ^a
Bodily pain	56.2±7.6	49.3±9.8	0.09 ^a
General health perception	52.3±10.5	52.5±10.0	0.97 ^a
Vitality	53.3±10.0	49.9±10.0	0.46 ^a
Social functioning	50.5±14.5	49.2±11.5	0.83 ^a
Role-emotional	51.9±11.1	46.3±15.0	0.09 ^a
Mental health	50.4±12.1	52.0±8.5	0.73 ^a

Results are expressed as mean ± standard deviation

^a Student's *t*-test

In terms of operative complications, no repeated procedures were required because of the complications. Delayed healing of the wound of lateral malleolus was complicated in one patient treated using non-locking plate. The wound healed five weeks after surgery without requiring intervention. There were two superficial infections at the wound of medial malleolus in the non-locking plate group, which was conservatively treated with oral antibiotics only. No wound complication was found in the patients treated using the locking plate. There were no differences in the rate of wound complications between the two groups ($p=0.11$, chi-squared test). No deep infection or thromboembolic complications developed in any patient during this study.

Discussion

Summary of results

No difference was observed in the primary outcome of this study, i.e. the radiographic rate of bone union between the locking and non-locking plate as the neutralization plate for the treatment of AO/OTA 44B malleolar fractures. Moreover, the SF-36 score, time for resolution of tenderness at the fracture site or wound complication rate showed no significant difference.

Comparison with other studies

To our best knowledge, there was only one randomized controlled trial comparing locking and non-locking plates for the treatment of long bone fractures [6]. Koshimune et al. conducted a randomized control trial to compare locking and non-locking plate by investigating the clinical results of unstable radial end fractures. In this study 22 patients treated using a locking plate had similar clinical results to that of 31 patients treated using non-locking plate in terms of bone union rate, palmar tilt, radial length, radial inclination, range of motion and Gartland and Werley score [6]. These results were similar to that of our study; our study could not reveal the clinical advantage of the locking plate.

Takemoto et al. investigated the difference between locking and non-locking neutralization plate in a laboratory biomechanical human cadaveric study [18]. They concluded that there was no advantage in using a locking plate when lag screw could achieve stable fracture fixation. We believe that anatomical reduction and proper lag screw insertion is most important for successful treatment in procedures involving a lag screw and a neutralization plate; therefore, we agree with the suggestion given by Takemoto et al.

Schepers et al. conducted a retrospective clinical study comparing the complication rate in procedures using the locking plate compared with that in procedures using the

non-locking plate [19]. Of the 40 patients using the locking plate, seven had wound complications, and of the 165 patients treated with the non-locking plate, nine had wound complications. The rate of wound complication observed with the use of the locking plate was significantly higher than that with the non-locking plate. These results were convincing because the characteristics of no compression to periosteum could increase the subcutaneous volume of the fracture site. The discrepancy of our results may be explained by the fact that we used an anatomically pre-shaped plate as a non-locking plate, which had larger breadth than that of the straight plate. The routine of bending the straight locking plate in our study may also offer an explanation for this discrepancy.

Strengths and limitations of the study

The strength of the present study was the randomized, controlled design, and the assessor blinded determination of the radiographic bone union, which was the primary outcome.

The main limitation of our study was all subgroups of AO/OTA 44B fracture were included in the study. Although the ratio of subgroups between the locking and non-locking groups was not significantly different, a more rigorous comparison can be achieved with a comparison among each subgroup. The number of cases in our study, however, did not support this analysis.

Conclusion

There were no differences between the use of the locking plate and non-locking plate as neutralization plate for AO/OTA 44B malleolar fractures in terms of radiographic bone union rate, patient-reported clinical scores, the time for resolution of tenderness at the fracture site or wound complications.

Acknowledgments The authors thank Dr. Toshio Maeda for his helpful advice and suggestions.

Conflict of interest All authors declare no conflict of interest and no funding was received for this study.

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