Tibial fracture treated by minimally invasive plating using a novel low-cost, high-technique system

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Received: 22 November 2011 / Accepted: 5 April 2012 / Published online: 3 May 2012
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Abstract

Purpose The less invasive stabilization system (LISS) can effectively treat tibial fractures. However, the LISS is technically demanding, has a long learning curve, and presents a heavy economic burden to patients. The U-grooved locking compression plate (U-LCP), characterized by a U-groove at each end, is designed to treat tibial fractures. This paper reports the outcomes of tibial fractures treated using the U-LCP compared with the LISS.

Methods Seventy-eight patients with unilateral tibial fractures treated with either the U-LCP (group I) or LISS (group II) were enrolled. In group I, a U-LCP was inserted subcutaneously with two Kirschner wires embedded into the U-grooves to temporarily secure the plate. A second identical

plate was placed over the first to guide screw insertion. In group II, the LISS was used to fix the tibial fractures. Patient age, sex, fracture type, severity of soft tissue injury, operative time, fluoroscopic time, complications, and functional recovery of affected limbs were recorded.

Results The two groups were comparable in age, sex, fracture type, and severity of soft tissue injury ($p > 0.05$). The average operation and fluoroscopic times in group I were significantly less than those in group II ($p < 0.05$). At follow-up, all fractures healed. There were no significant differences between both groups in time to bony union, wound complication rate, or functional recovery of injured limbs ($p > 0.05$).

Conclusions The U-LCP can yield good outcomes in the treatment of proximal tibial fractures, with less radiation exposure, a shorter operation time, and a sustainable price compared with the LISS.

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Introduction

Many treatment options exist for tibial fractures, and no one method is appropriate for all types of tibial fractures. Minimally invasive plate osteosynthesis (MIPO) [1] provides an alternative to manage these lesions. In MIPO, the plate is inserted percutaneously through a small incision, providing enough stability and minimizing intra-operative iatrogenic damage to soft tissue. This technique is widely applied in clinics with excellent results [2, 3]. The less invasive stabilization system (LISS) is a good example of a MIPO technique used to treat tibial fractures [4–6]. However, LISS plating is technically demanding and has a longer learning curve [7, 8]. During the operation, the LISS plate should be inserted submuscularly and fixed onto the bone. In some cases, it is difficult to achieve anatomic alignment of the tibia and appropriate plate position. In addition, it is often

difficult to maintain the plate near the cortex of the tibia without continued manual force. In these cases, adjustment of the plate position may be required, which is often difficult, subsequently prolonging the operative time and increasing radiation exposure. The insertion guide, which includes the main components, radiolucent extension, fixation bolt, and stabilization bolt, is essential for percutaneous insertion of the plate and screws. However, the guide components require time and expertise to assemble [7, 8]. Another concern is that the LISS is much more costly than conventional plates, and the increased costs post heavy financial burdens on patients and society, especially in developing countries [9, 10], which may limit its widespread application.

To preserve the advantages of the LISS at a sustainable price, we introduced the U-grooved locking compression plate (U-LCP) and developed a percutaneous plating technique. Theoretically, this plating technique is easy to perform and potentially has a shorter learning curve. We hypothesized that our simplified plating system would result in equal or better fracture healing, fewer complications, and a shorter operative time, but with reduced cost to the health-care system. This paper reports the outcomes of tibial fractures treated using the U-LCP compared with the LISS.

Methods and patients

Features of the U-LCP

The U-LCP (Tianjin Zhengtian Medical Instrument Co., Ltd., Tianjin, China) is characterized by a U-groove at each end of the plate (Fig. 1). The design of the U-groove can also be applied to other types of plates, such as anatomical plates and reconstruction plates. Two Kirschner wires are inserted into the corresponding U-grooves of the same two U-LCPs at the ipsilateral end, which can make one plate lie right above the other with the corresponding holes of both plates aligned vertically (Fig. 2).

Patients

This randomized prospective study included 78 patients with unilateral tibial fractures treated with either the U-LCP or the LISS from September 2009 to March 2010. Each

patient was assigned a random number at administration, and was then included in group I (treated with the U-LCP) or group II (fixed with the LISS) according to the random number table. All patients agreed with the recommended treatment algorithm and provided signed informed consents.

In group I, 31 patients were treated with the U-LCP (18 men and 13 women; mean age, 47.5 years; range, 27–74 years). Eighteen fractures were caused by motor vehicle crashes, and 13 by falls from a height. According to the AO/OTA classification, fracture patterns included type 41-A in seven patients, type 41-C in 16 patients, type 42-A in two patients, type 42-B in three patients, and type 42-C in three patients (Table 1). Based upon the Gustilo classification [11], six patients had Gustilo type II fractures. According to the Tscherne classification [12], eight patients had type C0, 14 had type C1, and three had type C2 closed fractures (Table 2). Seven patients sustained multiple fractures, including femoral fractures in two patients, fibular fractures in six, and posterior malleolar fractures in two [13]. These fractures were managed appropriately.

In group II, 47 patients were treated with the LISS (30 men and 17 women; mean age, 44.2 years; range, 27–74 years). Twenty-eight fractures were caused by motor vehicle crashes, and 19 by falls from a height. According to the AO/OTA classification, 11 fractures were type 41-A, 24 were type 41-C, five were type 42-A, three were type 42-B, and four were type 42-C (Table 1). Based upon the Gustilo classification [11], 11 fractures were Gustilo type II. According to the Tscherne classification [12], the closed fracture patterns included type C0 in 14 patients, type C1 in 18 patients, and type C2 in four patients (Table 2). Additional fractures were present in 11 patients, including femoral fractures in three, fibular fractures in ten, patellar fracture in one, and posterior malleolar fractures in four [13]. These fractures were also managed appropriately.

The Injury Severity Score (ISS) was used to assess the overall status of the patients in the two groups.

Operative techniques

In group I, the patient was placed supine on the radiolucent operation table. The limb was exsanguinated and the tourniquet was inflated. Fracture reduction was often achieved by longitudinal traction and counter-traction under C-arm guidance, and was maintained by an assistant. Intra-operative fluoroscopy was then applied to assess limb alignment and

Fig. 1 U-grooved locking compression plate, with a U-groove at each end, can be fixed onto the bone with the grooves embedding the Kirschner wires (see arrow)

Fig. 2 Sketch demonstrates that one plate lies subcutaneously and a second plate lies above the skin. Two Kirschner wires are inserted into the corresponding U-grooves of the same two U-LCPs at the ipsilateral end, which results in one plate lying just above the other with the corresponding holes of the two plates aligned vertically

length by comparison with the contralateral unaffected limb. The U-LCPs were laid over the skin of the tibia one by one, and fluoroscopy was used to select the plate with the appropriate length and determine the optimal implant position [10]. A Kirschner wire was drilled through the distal U-groove (Fig. 3). The plate was then inserted subcutaneously across the fracture line via a 2- to 3-cm incision until the distal U-groove embedding the Kirschner wire under fluoroscopic control, leaving the proximal U-groove exposed in the incision. A second Kirschner wire was drilled through the proximal U-groove, and the two Kirschner-wires were temporarily secured to bone in the subcutaneous plate (Fig. 4). A second plate was placed directly above the first one, with its U-grooves embedding the two Kirschner wires. Thus, the holes and U-grooves of the second plate were aligned with the corresponding holes and U-grooves of the subcutaneous plate. The holes of the second plate were marked with a skin pen. Minimal incisions were then made to expose the holes of the subcutaneous plate. Screws of appropriate lengths were inserted percutaneously to fixate the fracture (Fig. 5).

In group II (LISS), the LISS plating technique, which has been described in detail in a previous publication [4], was applied to treat the tibial fractures.

Patients with open fractures received tetanus prophylaxis and intravenous antibiotics, and underwent surgical debridement within 8 h after injury. The patients were managed

with transcalcaneal skeletal traction to allow for compromised soft tissue healing before definitive fixation.

The duration between initial injury and operation, operative time, fluoroscopic time, and blood loss were recorded in both groups.

Postoperative management and follow-up

Rehabilitation was started on the second postoperative day under professional supervision. Non-weight-bearing was encouraged two weeks after operation. Patients were recommended to begin partial weight-bearing approximately four to six weeks after surgery. Full-weight bearing was permitted depending on the radiographic assessment of fracture healing, generally at three months postoperatively. Monthly clinical and radiological follow-up was performed until fracture healing was evident. Fracture healing was clinically defined as the absence of pain and tenderness, as well as the ability to ambulate independently; radiographically, it was defined as bridging callus formation on both anteroposterior and lateral views [14, 15]. The range of motion and angulation of the fracture were measured with a goniometer. The functional score, assessed with the method proposed by Johner and Wruhs [16], was recorded. Clinical examinations and manual tests were performed by an independent surgeon who had not been involved in the treatment of the patients.

Statistical analysis

The data were analysed with SPSS 13.0 for Windows (SPSS Inc., Chicago, IL, USA). Categorical variables were

Table 1 Fracture types according to AO/OTA classification for tibial fractures

AO/OTA classification	Group I (n)	Group II (n)
Type 41-A	7	11
Type 41-C	16	24
Type 42-A	2	5
Type 42-B	3	3
Type 42-C	3	4
Total	31	47

Table 2 Soft tissue injury according to Tscherne classification

Tscherne classification	Group I (n)	Group II (n)
C0	8	14
C1	14	18
C2	3	4
Total	25	36

Fig. 3 Demonstrates that a U-LCP was laid over the skin of the tibia, and fluoroscopy was performed to select the appropriate plate and determine the optimal plate location. One Kirschner wire was drilled through the distal U-groove

recorded as numbers and percentiles with frequency tables, which were analyzed with chi-square tests. Continuous variables were recorded as mean, minimum and maximum values. The Mann–Whitney *U* test was applied to analyse continuous variables with non-normal distribution. The non-paired *t*-test was used to compare variables with normal distribution. A *p*-value less than 0.05 was considered statistically significant.

Results

The two groups were comparable in terms of patient age, sex distribution, fracture type according to the AO/OTA classification, open fracture type based upon the Gustilo classification, and severity of soft tissue injury according to the Tscherne classification ($p > 0.05$). The operative information is summarized in Table 3. The average ISS scores were 7.6 (range, five–14) in group I and 8.2 (range, five–19) in group II, and no significant difference was found between both groups ($p > 0.05$). The duration from initial injury to operation was 5.7 days (range, two to eight days) in group I and 6.2 days (range, one to nine days) in group II ($p > 0.05$). The average operative duration was 59.0 min (range, 30–110 min) in group I and 79.7 min (range, 40–130 min) in group II ($p < 0.05$). The fluoroscopic time was 21 s (range, 15–31 s) in group I and 39 s (range, 23–56 s) in group II ($p < 0.05$).

Fig. 4 Plate was inserted subcutaneously across the fracture line until the distal U-groove embedded the Kirschner wire under fluoroscopic control. A second Kirschner wire was drilled through the proximal U-groove, and the two Kirschner wires temporarily secured the subcutaneous plate to the bone

The average blood loss was 47 mL (range, 10–100 mL) in group I and 50 mL (range, 20–100 mL) in group II ($p > 0.05$).

At a mean 16-month follow-up (range, 12–18 months) all tibial fractures had united. The average time to bony union was 11.9 weeks (range, nine to 16 weeks) in group I and 12 weeks (range, ten–15 weeks) in group II ($p > 0.05$). There were four superficial infections (12.9 %) in group I and six superficial infections (12.8 %) in group II ($p > 0.05$). No other wound complications were reported in the two groups. According to the Johner–Wruhs score, the functional outcome was excellent in 18 patients, good in ten patients, and fair in three patients in group I. The functional outcome was excellent in 26 patients, good in 19 patients, and fair in two patients in group II. The cost for each U-LCP was 4500 RMB in group I, much lower than the 10,000 RMB for each LISS in group II ($p < 0.05$).

Discussion

In the present study, patients in both groups were comparable in age, sex distribution, fracture type, severity of soft tissue injuries of the affected lower extremities, and ISS scores. The clinical outcomes of tibial fractures treated with either the U-LCP or the LISS were satisfactory, with more than 90 % of patients achieving excellent or good functional recovery according to the Johner–Wruhs score [16]. There

Fig. 5 Anteroposterior (a) and lateral (b) radiographs of the proximal tibia demonstrate nearly anatomical reduction and rigid internal fixation

were no significant differences in blood loss, duration of fracture healing, complication rates, or postoperative function between the two groups. However, the operative duration and fluoroscopic time were both significantly less in the U-LCP group than in the LISS group, and the cost for the U-LCP was significantly less than that for the LISS.

In the MIPO technique, plate size and position are determined by a C-arm intensifier [17]. Reduction in radiation

exposure time can benefit both surgeons and patients. During the operation, the U-LCP can be accurately placed in a previously designated position by inserting two Kirschner wires embedded into the U-grooves at each end of the plate. After the plate is well placed, a second identical plate serves as a guide to locate the holes of the subcutaneous plate. The special insertion guide used in the LISS is not necessary. The U-LCP technique is simple and easy to perform, reducing the operation time and radiation exposure and shortening the learning curve for orthopaedic surgeons. The operative and fluoroscopic times were 59.0 min and 21 seconds, respectively, in the U-LCP group. The average fluoroscopic time was reportedly 3.0–5.4 min (range, 0.5–30.0 min) in the management of proximal tibial fractures and distal femoral fractures using the LISS plates [18, 19]. The operation and fluoroscopy times in group II were much longer than those in group I, which may be partially attributed to the need to assemble the components of the LISS insertion guide. In the LISS plating technique, restoration of anatomic alignment of the tibia and appropriate plate position are not always easy procedures. Furthermore, optimal position of the plate is of particular significance [20]. However, the LISS may become displaced from the previously designated position after percutaneous insertion. Adjustment of a malpositioned or displaced plate is often unavoidable, is commonly difficult to conduct, and increases both the radiation exposure and operation time, even in expert hands. Therefore, LISS plating is technically demanding and has a longer learning curve [7, 8]. Specialized training in the use of LISS is often needed before its application in clinics.

Another difference between the two percutaneous plating techniques is the screw hole. The screw holes are all locking holes in the LISS and locking compression

Table 3 Operative information about patients treated in groups I and II

Operative information	Group I (n=31)	Group II (n=47)
Age in years, mean (range)	47.5 (27–74)	44.2 (27–74)
Sex, n (%)		
Male	18 (58.1)	30 (63.8)
Female	13 (41.9)	17 (36.2)
ISS score, mean (range)	7.6 (5–14)	8.2 (5–19)
Duration from initial injury to operation in days, mean (range)	5.7 (2–8)	6.2 (1–9)
Operative time in minutes, mean (range)	59.0 (30–110)	79.7 (40–130) ^a
Fluoroscopic time in seconds, mean (range)	21 (15–31)	39 (23–56) ^a
Blood loss in mL, mean (range)	47 (10–100)	50 (20–100)
Time of bony union in weeks, mean (range)	11.9 (9–16)	12 (10–15)
Wound complications (%)	12.9	12.8
Excellent and good results (%)	90.3	95.7

^aCompared with group I $p < 0.05$

holes in the U-LCP. The locking holes can provide angle stabilization, especially for some difficult periarticular fractures [21]. The compression holes can achieve interfragmentary compression, which is helpful for fracture healing [20]. During application of the U-LCP technique, conventional screws can be replaced by locking screws after compression is achieved.

The scarcity of soft tissue coverage and the subcutaneous nature of the tibia make this fracture more prone to soft tissue complications [22]. The number and size of incisions reportedly have an effect on the incidence of soft tissue complications in the surgical management of tibial fractures [23]. In this series, wound complications were found in four patients in group I and six patients in group II, and these patients sustained open fractures or Tscherne C2 injury. No deep infections, skin necrosis, or wound breakdown developed in either group. In both groups, plate and screw insertions were performed following the MIPO technique, which can effectively minimize the incision size, reduce iatrogenic injury, and accordingly reduce the risk of wound complications.

Cost is a major concern during selection of internal fixators for surgical management of tibial fractures. Both developing and developed countries wish to use the most updated implants with the best outcomes, but all have noticed the increased costs associated with innovative and high-quality implants [9, 24]. Many attempts have been made to reduce the costs. The U-LCP can provide functional outcomes as good as those yielded by the LISS in the treatment of tibial fractures, but at half the cost of the LISS. The economically friendly feature of the U-LCP is of great benefit to both patients and society.

Conclusion

The U-LCP can yield clinical outcomes as good as those yielded by the LISS in the treatment of proximal tibial fractures, with less radiation exposure, a shorter operation time, and a sustainable price. Taking into consideration the simplicity of the U-LCP technique, economically friendly feature, minimally invasive properties, and satisfactory clinical outcome, the U-LCP is a feasible and worthwhile alternative treatment of choice for patients with tibial fractures.

Acknowledgments The assistance of Dr. Zhiyong Hou and Dr. Zhenqing Jiao is acknowledged.

Conflict of interest This study was supported by a grant from the National High Technology Research and Development Program of China (863 Program) (No. 2011AA030101). We have full control of all primary data and agree to allow the journal to review these data if requested.

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