This study was to compare the relative strength of fixation and clinical outcomes of single lateral plate and double plating of comminuted supracondylar femoral fractures.

Eight matched pairs of embalmed cadaveric femurs were selected. A gap osteotomy was created to stimulate an AO/OTA A3 comminuted distal femoral fracture. One femur of each pair was fixed with a locking plate; the other, with a locking plate and a medial plate. Nondestructive axial compression and maximum load to failure test were performed. A total of 32 patients with comminuted supracondylar femoral fractures were identified and divided into single lateral plate group (SPG) and double plating group (DPG) randomly. Operative time, blood loss, time to union and complications were recorded. Visual analog score (VAS), range of motion (ROM) and Neer knee score were reviewed at one, three, 6, and 12 months postoperatively.

Significantly greater axial displacement occurred with the SPG than with the DPG. In load-to-failure testing, the peak load was 2568 ± 452 N, and 3822 ± 567 N, respectively. The follow-ups lasted twelve months at least. The operative time was significantly lower in the SPG. However, there was no significant difference between the SPG and the DPG in terms of blood loss, time to union, complication rate, VAS, ROM and Neer knee score.

Double plating proved stronger than single lateral plate in biomechanical testing; however, double plating was not superior to traditional lateral plating in clinical outcomes. Therefore, we do not recommend double plating as a routine fixation of comminuted supracondylar femoral fractures.

**Keywords** : supracondylar femoral fractures ; lateral locking plate ; double plating ; biomechanical study.

**INTRODUCTION**

Comminuted distal femoral fractures occur commonly among young patients involved in high-energy injuries, and elderly population with severe osteoporosis, resulting from low-energy trauma (20). Surgical management for these fractures has become the standard, promoting early motion of the joint and preventing joint stiffness (7,32); demonstrating better outcomes than nonsurgical treatment (14,28,29). Locking plates, with fixed-angle screws, have improved fixation strength of plate constructs compared with conventional plates.

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**No benefits or funds were received in support of this study. The authors report no conflict of interests.**
(12,25,34). Locking devices rely on the principle of bridge plating, thus working best in comminuted metaphyseal fractures (i.e., AO/OTA 33A2-, 33A3-, 33C2-, 33C3-type fractures), and providing fixed angle stabilization in comminuted and osteoporotic fractures (34). For these fractures, locking plates have been rapidly adopted as an alternative to condylar buttress plates, dynamic condylar screws and intramedullary nails (5,21,35). Unfortunately, such complications as loss of alignment, delayed/non-unions, and implant failure are not less observed in the literature (2,9,18). Some reports, focused on comminuted C-type fractures, suggest that double plating may lead to better recovery (13,33). However, there is little literature pertaining to the outcome comparison in comminuted A- or C-type fractures between single lateral plate and double plating.

The purpose of this study was to compare the strength of fixation and clinical outcomes of single lateral locking plate and double plating (lateral locking plate combined with medial plate) of comminuted supracondylar femoral fractures. We hypothesized that double plating was superior to single lateral plate with regard to strength of fixation, time to union, knee function and complication rate.

MATERIALS AND METHODS

Biomechanical test

Eight matched pairs of embalmed human femoral cadaveric specimens were selected for the biomechanical study. Donor demographics, including the sex, age at time of death were recorded on all specimens. Standard radiographs were performed to exclude prior surgery or pathologic bone lesions. DEXA (dual energy X-ray absorptiometry; GE, Lunar, Madison, WI) was used to evaluate bone density of the cadaveric specimens. The specimens were prepared by removing all skin and remaining musculature, and the proximal femur was removed just below the level of the lesser trochanter. Specimens were wrapped in fluid-soaked towels to ensure moisture content.

All specimen pairs were randomly assigned to have the left specimen receive single lateral plate or double plating (Trauson Medical Instrument Co. Ltd., China). The contralateral femur received the remaining implant. An oscillating band saw was used to create a transverse 1-cm osteotomy gap 7 cm proximal to the distal articular surface of the femur to simulate an AO/OTA 33A3-type distal femoral fracture with comminution (8,11,16). The specimens of single lateral plate were fixed with a distal femoral locking compression plate on the lateral side by using the standard technique described in the AO Manual of Internal Fixation (23). The plate was placed internally to match the slope of the femoral condyle region, ensuring central placement of the proximal diaphysis screws. Five 5.0-mm locking screws were placed in the distal fragment, and four bicortical standard 5.0-mm screws were inserted in the proximal fragment. The specimens of double plating were fixed with a same locking compression plate on the lateral side, and a dynamic compression plate on the medial side, with three 6.5-mm cancellous screws placed distally and four bicortical standard 4.5-mm screws used proximally (Fig.1).

The distal part of each femur was potted in dental base acrylic resin powder, while the proximal part was rigidly fixed to the base of a material testing machine (CSS-44010, Changchun Research Institute, China). Each potted femur was placed in the machine for nondestructive axial compression and a load-to-failure test. Axial preload of 100 N was applied proximally to stabilize the construct. Then constructs were loaded in compression at a loading rate of 0.5 mm/min. Testing was stopped when 600 N was reached. The stiffness of the intact bone was measured first to compare the uniformity between two groups. Then, fracture mode was made and axial compression testing was performed. Displacement from the initial position was recorded continuously with a motion sensor. After the nondestructive tests, all of the specimens were loaded at a rate of 10 mm/min from a preload of 100 N until failure. Failure was defined as medial fracture gap closure, or hardware fracture, or acute change in load–displacement curve. The maximum compression load was recorded for each specimen.
Clinical test

This was a prospective randomized study performed at our level I trauma center from December 2011 to January 2016. The study protocol and amendments were approved by the hospital ethics committee. A total of 32 adult patients with comminuted supracondylar femoral fractures were identified in this study. Exclusion criteria: poly-trauma, pathological fracture, malignancy related fracture, periprosthetic fracture. Only fractures classified as AO/OTA 33A2, 33A3 were included. All participants signed informed consent and then randomized to be treated with single lateral plate or double plating. All participants were divided into single lateral plate group (SPG) and double plating group (DPG) in a 1:1 ratio with stratification by means of fracture classification by computerized randomization service. All surgeries were performed by the same experienced orthopedic trauma surgeon.

Under general anesthesia, patients were positioned supine and the affected limb was placed on a bolster to keep the knee in a semi-flexed position and to help with obtaining and maintaining fracture reduction. A lateral approach with minimal soft-tissue dissection was performed as dictated by the fracture pattern. Plates were inserted under the vastus lateralis muscle and placed to bridge the fracture under an image intensifier in the SPG. The reduction of the metaphyseal fracture was achieved indirectly. The distal screws were placed through the lateral approach in the distal fragment while proximal screws were inserted via a small incision. In the DPG, after placing the lateral locking plate, a medial incision with minimal soft-tissue dissection positioned over the distal part of the vastus medialis was made, then a sub-muscular tunnel was created and the medial plate was inserted. Proximal screws were inserted using a small incision at the proximal end of the plate. A final check in anterior-posterior and lateral views was done with the image intensifier (Fig.2).

There was no difference for postoperative rehabilitation between the SPG and the DPG. Operative time, intra-operative blood loss, time to union, delayed/non-unions, and complications in both groups were documented. A continuous passive motion machine was used to facilitate gradual advancement in knee flexion. Weight bearing was implemented for ≥ 12 weeks or until fracture healing was visible radiographically. Standard follow-up procedure including visual analog score (VAS), range of motion (ROM) and Neer knee

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*Fig.1.* — Paired instrumented femurs prepared with a transverse 1-cm osteotomy gap to simulate a metaphyseal fracture with comminution. a. single lateral plate; b. double plating

*Fig.2.* — The postoperative X-rays. a. SPG; b. DPG
score were performed by the treating surgeon and research coordinator at one, three, 6, and 12 months postoperatively. Union was defined as painless weight bearing and radiographic bridging callus on 3 cortices.

**Statistical analysis**

All statistical analyses were performed using the SPSS version 13.0 software in the study. All data are summarized as mean ± standard deviations for continuous variable. The Student t test was applied to compare the difference between the two groups for normally distributed data. For non-normally distributed data, the difference between the two groups was assessed with Mann–Whitney U test. The Fisher exact test was applied to compare the difference in complication rate between different groups. P < 0.05 was regarded as significant difference.

### RESULTS

The mean DEXA value of specimens in the SPG was 0.74 g/cm². The mean DEXA value of the DPG was 0.79 g/cm². The difference was not significant (p = 0.148). In the compression test, there was no significant difference in the mean displacement between the two intact bone groups.

Table I. — Load-displacement between the SPG and the DPG

<table>
<thead>
<tr>
<th>Load (N)</th>
<th>SPG (mm)</th>
<th>DPG (mm)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>0.56±0.12</td>
<td>0.24±0.01</td>
<td>0.000</td>
</tr>
<tr>
<td>200</td>
<td>1.12±0.18</td>
<td>0.44±0.02</td>
<td>0.000</td>
</tr>
<tr>
<td>300</td>
<td>1.62±0.25</td>
<td>0.62±0.06</td>
<td>0.000</td>
</tr>
<tr>
<td>400</td>
<td>2.17±0.38</td>
<td>0.84±0.12</td>
<td>0.000</td>
</tr>
<tr>
<td>500</td>
<td>2.65±0.53</td>
<td>1.11±0.22</td>
<td>0.000</td>
</tr>
<tr>
<td>600</td>
<td>3.17±0.61</td>
<td>1.46±0.35</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Table I shows the mean load-displacement of the two bone-implant constructs. Significant difference was found between the two fixation methods (Fig. 3). The average load to failure of the SPG was 2568 ± 452 N, and the DPG average was 3822± 567 N, the difference between the groups was significant (p = 0.000). No visual loss of fixation or acute change in load–displacement curve was found in either group.

The follow-up lasted at a minimum of twelve months, a total of 29 patients were available for follow-up until fracture union. One patient in the SPG and two patients in the DPG were lost to follow-up. The patients were still comparable with regard to demographic characteristics with dropouts. There was no significant difference in intra-operative blood loss between the SPG and the DPG. However, the operative time in the SPG was significantly lower than in the DPG (Table II).

There was one case of superficial infection in the SPG. In the DPG, one developed deep vein thrombosis, which was treated with warfarin. One death occurred in the SPG because of pneumonia six months postoperatively. Moreover, one patient in the SPG and one in the DPG complained of pain and implant prominence after they were healed. Nevertheless, comparable VAS pain score was observed between the SPG and the DPG at one, three, 6, and 12 months postoperatively (Table III).

Table II. — Demographic data of patients in the SPG and the DPG

<table>
<thead>
<tr>
<th></th>
<th>SPG</th>
<th>DPG</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males/Females</td>
<td>5/10</td>
<td>5/9</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>57.93±13.60</td>
<td>59.07±14.58</td>
<td>0.829</td>
</tr>
<tr>
<td>Fracture type</td>
<td>A2/A3</td>
<td>6/9</td>
<td>5/9</td>
</tr>
<tr>
<td>Operative time (min)</td>
<td>88.00±13.99</td>
<td>104.29±9.39</td>
<td>0.001</td>
</tr>
<tr>
<td>Blood loss (ml)</td>
<td>220.00±45.51</td>
<td>228.57±50.81</td>
<td>0.636</td>
</tr>
</tbody>
</table>
Of the remaining 29 patients, the mean time to union was 17 weeks for both groups, no significant difference was observed between the SPG and the DPG (p=0.652). There were no significant differences in complication rate between two groups (p =1.000). Postoperative 1-month, 3-month, 6-month and 12-month ROM of injured extremity and Neer knee score showed no statistical significance (Table III).

**DISCUSSION**

Distal femoral fractures with comminution present a challenging problem for orthopedic surgeons (11). Locking plates combined with minimally invasive technology are the preferred implant options for internal fixation of these fractures with advantages of excellent fracture stability, improved biomechanical performance, less damage to vascularity of fracture site and soft tissue (15,30,31). To assess their performance, locking plates are often attached to cadaveric specimens, and biomechanical testing of the implant-bone construct is performed (11,21,24). Our biomechanical study comparing the fixation of single lateral plate to double plating in a cadaveric model of a distal femoral fracture did demonstrate a significant difference in axial compression between the two constructs. The SPG showed greater displacement than the DPG under the same load, and this difference was statistically significant. In load-to-failure testing, the DPG could withstand greater axial load before failure, and this difference was significant. The current study showed that double plating could yield improved strength of fixation compared with single lateral plate. Our experiment did not demonstrate a significant difference in the bone density of the specimens in the two groups studied.

Several biomechanical studies have shown that locking plates are better than classic internal fixation (blade plate, dynamic compression plate, retrograde nailing) (6,34,35). Higgins et al (11) compared locking plate and condylar blade plate in an A3 comminuted distal femur fracture. Cyclic loading and ultimate strength was better with locking plate than with the blade plate. Narsaria et al (24) concluded that the locking plate was better than the dynamic condylar screw (DCS) with increased strength under axial compression and cyclic loading in a simulated A3 comminuted distal femoral fracture. Overall, biomechanical results showed that locking plates are better (4). Muizelaar et al (22) indicated that a double plated construct had greater stabilization in a simulated

<table>
<thead>
<tr>
<th>Items</th>
<th>SPG</th>
<th>DPG</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td>1M VAS</td>
<td>1.83±0.56</td>
<td>2.11±0.66</td>
<td>0.235</td>
</tr>
<tr>
<td>ROM</td>
<td>94.67±19.22</td>
<td>91.07±11.96</td>
<td>0.548</td>
</tr>
<tr>
<td>Neer score</td>
<td>63.87±4.14</td>
<td>61.21±4.76</td>
<td>0.121</td>
</tr>
<tr>
<td>6M VAS</td>
<td>0.98±0.43</td>
<td>1.21±0.43</td>
<td>0.084</td>
</tr>
<tr>
<td>ROM</td>
<td>115.67±13.35</td>
<td>111.43±13.51</td>
<td>0.403</td>
</tr>
<tr>
<td>Neer score</td>
<td>72.80±3.53</td>
<td>70.43±4.29</td>
<td>0.115</td>
</tr>
<tr>
<td>12M VAS</td>
<td>0.27±0.37</td>
<td>0.32±0.37</td>
<td>0.695</td>
</tr>
<tr>
<td>ROM</td>
<td>119.33±10.50</td>
<td>117.86±11.39</td>
<td>0.719</td>
</tr>
<tr>
<td>Neer score</td>
<td>82.27±3.96</td>
<td>80.79±4.06</td>
<td>0.329</td>
</tr>
</tbody>
</table>

Table III. — The measurement items between the SPG and the DPG
periprosthetic fracture model of the distal femur when compared to a single lateral plate. To our knowledge, no biomechanical and clinical studies have been performed to compare single lateral plate and double plating in comminuted supracondylar femoral fractures. Our results support the hypothesis that double plating could provide stronger fixation for comminuted supracondylar femoral fractures than single lateral plate.

Some studies made recommendations based on the assumption that greater strength of fixation would yield better outcomes (11,24,34,35). We should specify that the greater stiffness was achieved through single lateral plate, not double plating. However, Clinical trials of lateral locking plates have demonstrated multiple failures (2,9,18). Recently, Canadian Orthopaedic Trauma Society (3) published a prospective multicenter randomized controlled study on 52 distal femur fractures treated with the locked Less Invasive Stabilization System (LISS) and DCS. No significant difference was found between the LISS and the DCS in terms of the number of fractures healed, time to union, or functional scores. Complications and revisions were more common in the LISS group. Only 52% of the LISS group healed without intervention by 12 months compared with 91% in the DCS group. Lujan et al. (18) retrospectively reviewed 64 distal femur fractures treated by locked plating. The stiff stainless steel plates had significantly less callus than more flexible titanium plates. This suggests that increased stiffness may, in fact, hinder callus formation.

Recent research pays more attention to the flexible fixation of locking plate. Near cortical slotted holes or far cortical locking were applied to reduce the stiffness and create controlled interfragmentary motion for enhance fracture healing. Linn et al. (17) reported that dynamic plating, an overdrilling technique of the near cortex, had improved callus compared with standard locking plate. The mean callus score for the dynamic group was significantly greater than the control group. Bottlang et al. (1) reported on their results using far cortical locking screws in 33 distal femur fractures. Of the 31 fractures, 30 healed at an average of 15.6 weeks. Evaluation of callus distribution on CT transverse cross-sections demonstrated that 23 fractures (74%) formed periosteal callus that extended to the lateral cortex under the plate.

In the current study, there was no statistically significant difference between single lateral plate and double plating in the terms of time to union, VAS, ROM, Neer knee score, and complication rate. Our results do not support the hypothesis that double plating was superior to single lateral plate with regard to time to union, knee function and complication rate.

Rodriguez et al (27) concluded that obesity, open fracture, occurrence of infection, and the use of stainless steel were prognostic risk factors of nonunion in distal femoral fractures treated with lateral locking plating. Ricci et al (26) found that open fracture, diabetes, smoking, increased body mass index, and shorter plate length were the identified risk factors for reoperation to promote union and complications. Most factors are out of surgeon control but are useful when considering prognosis. Many authors (10,12,19) emphasize that high quality results are more dependent upon the surgical technique than the choice of implant.

Possible limitations of this study lie in the study design. Only axial compression and load-to-failure tests were performed. Other tests, such as torsional loading, media/lateral and flexion/extension bending, and cyclic loading were not tested. Secondly, the cadaveric nature of this study is also a limitation. There is no accounting for the soft-tissue envelope, which is difficult to examine in the in vitro model. Thirdly, the fixation pattern was not blinded to patients, but the patients were not completely informed with the study content and it could not influence the results largely. Finally, a long-term prospective randomized study with a larger scale is needed to further evaluate the efficiency of the fixation pattern.

In conclusion, double plating proved stronger than single lateral plate in axial compression and ultimate strength in biomechanical testing; however, double plating was not superior to traditional lateral plating with regard to time to union, VAS, ROM, Neer knee score and complication rate. Therefore, we do not recommend double plating as a routine fixation of comminuted supracondylar femoral fractures.
Acknowledgements: This study was funded by Shanghai Pudong New Area Commission of Health and Family Planning (PWRq2015-14,PWZb2017-32, to Jun Zhang).

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Informed consent was obtained from all individual participants included in the study.

REFERENCES