ORIGINAL ARTICLE

A comparison of distal femoral locking plates for distal femur fractures: Long working length versus short working length

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Abstract

Objective: To compare long working length distal femoral locking plates with short working length for treating extra-articular distal femur fractures in terms of union and implant failure.

Method: The randomised controlled trial was conducted at the Lady Reading Hospital, Peshawar, Pakistan, from April 28, 2018, to March 10, 2021, and comprised all adult patients of either gender with extra-articular distal femur fractures who were randomised into two groups. Group A was exposed to long working length, while group B had short working length. Patients in both the groups were followed up regularly for one year for the assessment of fracture union and implant failure. Data was analysed using SPSS 22.

Results: In the group of the 61 patients, 30(49.2%) were in group A; 24(80%) males and 6(20%) females with overall mean age of 37.9±9.6 years. The remaining 31(50.8%) were in group B; 26(83.8%) males and 5(16.1%) females with overall mean age of 37.2±1 years. The mean working length in group A was 75±5mm and in group B it was 35±9mm. In group A 28(93.3%) fractures healed, while in group B 19(61.2%) fractures achieved union (p=0.01). Non-union was noted in 2(6.6%) patients in group A and 7(22.5%) in group B (p=0.08). Plate breakage was noted in 3(9.6%) patients and screw breakage in 2(6.4%) patients in group B and none in group A (p=0.0001).

Conclusion: Long working length titanium locking plates were found to be better than short working length in achieving fracture union and avoiding implant failure.

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http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377657&isReview=true

Keywords: Bone plate, Bony callus, Femoral fractures, Fracture healings, Internal fixation device, Titanium.

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Introduction

The incidence of distal femur fracture is 8.7 per 100 000 persons per year.[1] Younger male patients sustain this fracture due to high-energy trauma, like road traffic accidents (RTAs), while elderly osteoporotic females sustain it due to fall from standing height.[2] Distal femoral locking plate is the implant of choice and the gold standard for the treatment of these fractures and has replaced Blade Plate, Condylar Screw and Intramedullary Nails (IMNs) that were favoured by many orthopaedic surgeons in the past.[3] The treatment of distal femur fractures with locking plate, however, can result in delayed union in 15% cases, non-union in 19% and hardware failure in 20% cases.[4] Factors affecting healing of distal femoral fractures after fixation with locking plates are not entirely and definitely known.[5] Studies have revealed that one of the causes of non-union and fixation failure is the inherent stiffness of the locking plate which prevents micro motion at the fracture site, leading to inhibition of callus formation.[6] The stiffness of a locking plate, however, can be decreased by increasing its working length.[7] The working length is the distance between the first screw in the locking plate on either side of the fracture.[8] Variations in the working length can be achieved by placing screws either closer to the fracture, creating a short working length, or farther from fracture site, creating long working length.[9] Although biomechanical studies have indicated that increasing the working length of locking plate increases the flexibility and improves callus formation,[10] clinical trials comparing long working length with short working length of distal femoral locking plates are lacking.[11] Currently the choice of working length of locking plate is dependent on surgeon's personal experience rather than biomechanical and scientific evidence.[12]

The current study was planned to compare long working length distal femoral locking plates with short working length for treating extra-articular distal femur fractures in terms of union and implant failure.

Patients and Methods

The randomised controlled trial (RCT) was conducted at the Orthopaedic Division of the Lady Reading Hospital (LRH), Peshawar, Pakistan, from April 28, 2018, to March 10, 2021, after approval from the institutional ethics review board, followed by registration with the Australian New Zealand Clinical Trial Registry (ANZCTR).[13] The trial was stopped after the attainment of the required sample size and the

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completion of the follow-up of the last enrolled patient.

The study comprised patients of both gender aged 18 years and above with extra-articular distal femoral fractures having Orthopaedic Trauma Association/ Arbeitsgemeinschaft für Osteosynthesefragen (OTA/AO) classification grade 33 A2, A3[14] who presented within a week of sustaining the fractures and were operated upon for distal femoral locking plates. Patients with spiral fractures grade 33A 2.1, open fractures, pathological fractures, peri-prosthetic fractures, neurovascular injuries, previously surgically-treated fractures and poly-trauma patients with other fractures, like ipsilateral tibia and proximal femur fractures, were excluded.

The sample size was calculated using the World Health Organisation (WHO) calculator[15] with 5% level of significance, 90% power of the test and 0.7%[16] non-union in long working length and 16.6% non-union in short working length titanium locking plate. The sample was raised using non probability convenience sampling technique.

Patients of distal femur fractures presenting at the LRH Accidents and Emergency Department were thoroughly assessed and resuscitated according to the Advanced Trauma Life Support (ATLS) protocol.[17]

Each patient was given parental analgesics and the fracture was splinted with a long leg back slab. X-ray of the knee joint antero-posterior and lateral view, including femur and hip joint, was done. Patients of supracondylar fractures meeting the inclusion criteria were admitted. They were enrolled in the study after obtaining informed written consent for surgery and research publication. Complete history and physical examination was carried out. Three dimensional (3D) computed tomography (CT) scan of the fracture was done in each case to know the exact configuration of fracture fragments, and fractures were classified as per the OTA/AO classification.[14]

All the surgeries were performed by the principal author under general or spinal anaesthesia on a radiolucent table in the supine position with a sandbag under the affected gluteal area and knee joint. Pre-operative dose of intravenous (IV) antibiotic cefuroxime 1.6 gm was administered at the time of induction of anaesthesia before tourniquet inflation. Through a straight lateral distal mid-thigh skin incision and between the vastus lateralis and lateral intermuscular septum, the fracture was exposed. The distal articular area was exposed through lateral parapatellar arthrotomy incision. The fracture zone or gap was measured in millimetres (mm). The fracture fragments were anatomically reduced and provisionally stabilised with k wires, where needed.

All the patients were randomised using computer-generated random allocation sequence with simple random method into long working length (group A) and short working length (group B). To ensure uniform distribution of important baseline demographic and clinical characteristics in both the groups, allocation by minimisation was adopted. The appropriate length of titanium locking plate in either group was chosen according to the fracture comminution and the allocated working length. Locally made pre-contoured (right and left) titanium locking plates (Titanium-6 Aluminium-4 Vanadium [Ti-6Al-4V]® Ortho Tech) of 6mm thickness and 17mm width were used in both the groups. Titanium locking screws of 5mm and cortical screws of 4.5mm of appropriate sizes were used. The distal femoral locking plate was applied with all (maximum) locking screws in the distal expanded condylar portion of the plate inserted in both the groups, while minimum of four bi-cortical screws (mandatory locking screw near the fracture on either side while others locking or hybrid screw construction) were used proximal to the fracture in both the groups. The plate was applied flush on to the bone. The combi screw hole/s overlying the fracture or comminution was/were left empty in both the groups. A perpendicularly directed locking screw in a combi screw hole immediate to the fracture avoiding fracture or comminution and touched the intact bone when not inserted was named the empty or un-occupied screw hole. In group A, one combi screw hole immediate to the fracture was left unoccupied on either of fracture, or two combi holes proximal to the fracture if distal comminution did not allowed intact cortex distally. In group B, no combi screw hole in the intact bone near the fracture was left unoccupied. The working length was measured in mm in both groups and was equivalent to the distance between the two screws immediate to the fracture in the proximal and distal fracture fragment. The wound was closed in layers with radivac suction drain for 24 hours and long backslab for three days in all cases. Check C-ray was done on the first post-op day. IV antibiotic cefuroxime 1.6gm bis in die (BD) was administered for 3 days. Supervised physiotherapy exercises were started on the 3rd day. The first follow-up visit was scheduled two weeks post-operatively and subsequent visits at 4th week for the first three months, and then every three months till one year. Partial weight-bearing was started when radiological signs of callus formation were noticed, usually at 6th to 8th week and full weight-bearing was commenced at 16th to 20th week. In each follow-up visit, fracture union was assessed radiologically and clinically. Failure of progression of callus formation at the fracture site on serial plain X-ray at 16th week was termed delayed union, while at 36th week (along with inability to bear weight on the limb without pain) was taken as non-union[11] by two senior orthopaedic surgeons who were not part of the study. Implant failure, like plate bending, plate pullout, plate breakage, screw pullout and screw breakage, was noted if present. The entire study was planned and executed in accordance with consolidated standards of reporting trials (CONSORT) guidelines.[18]

Data was analysed using SPSS 22. Descriptive statistics were used to calculate mean and standard deviation (SD) for numerical variables, like age, working length and healing time. Inferential statistics were used to compare categorical variables, and *p*-values were calculated using chi-square test. Quantitative variables were compared with independent samples t-test. Any $p<0.05$ was considered statistically significant.

Results

Of the 105 patients, 64(61%) were enrolled, and, of them, 61(95.3%) completed the study (Figure).

There were 30(49.2%) subjects in group A; 24(80%) males and 6(20%) females with overall mean age 37.9±9.6 years. The remaining 31(50.8%) were in group B; 26(83.8%) males and 5(16.1%) females with overall mean age 37.2±1 years. There were no significant differences between the two groups at baseline (Table).

The mean post operative follow-up period was 56.4±6 weeks. The mean fracture zone or gap was 24±3 mm in group A and 22±7 mm in group B (p=0.5). The mean working length in group A was 75±5 mm and in group B it was 35±9 mm. Fracture union was significantly better (p=0.01) and there was less plate breakage (p=0.0001) in group A compared to group B. In group A 28(93.3%) fractures healed, while in group B 19(61.2%) fractures achieved union (p=0.01). Non-union was noted in 2(6.6%) patients in group A and 7(22.5%) in group B (p=0.08). Plate breakage was noted in 3(9.6%) patients and screw breakage in 2(6.4%) patients in group B and none in group A (p=0.0001). Delayed union was reported in 1(3.3%) patient in group A and 3(9.6%) in group B. Group A patients achieved union slightly earlier 14.3±4weeks than group B 14.5±7 weeks (p>0.5). Post-operative superficial infection was noted in 2(6.6%) patients in group A compared to 1(3.2%) in group B (p=0.8).

OTA/AO 33A3.3 fracture was present in 2(6.4%) patients and 33A3.2 in 1(3.2%) patient who had plate breakage, while 2(6.4%) patients with screw breakage had OTA/AO 33A3.2. Implant failure was noted before fracture healing in these cases and without any significant trauma and required revision surgeries. Patients with OTA/AO 33A3.3 fractures had more non-union in both group A 2(6.6%,) and group B 6(19.3%) than other types of fractures (p=0.001). Obesity, smoking and diabetes had non-significant association with non-union or other complication (p=0.08) in both groups.

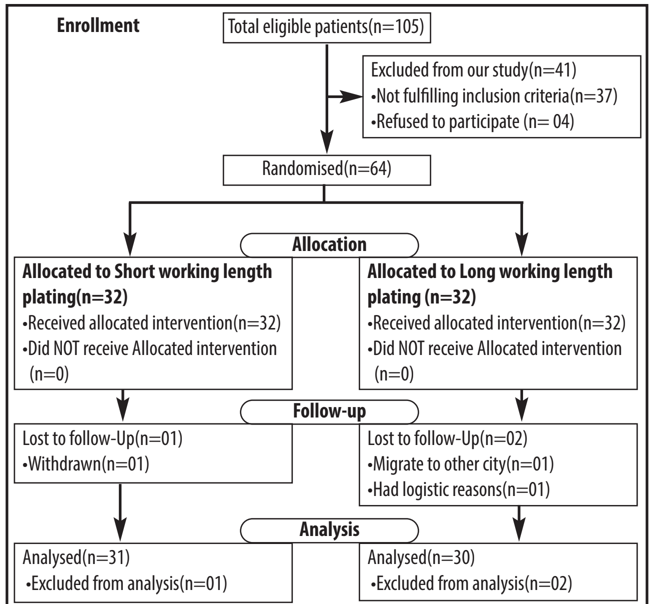

Figure: Consolidated Standards of Reporting Trials (CONSORT) flow-chart.

Table: Comparative analysis of baseline demographics and clinical characteristics.

Demographic/Clinical Characteristic	Group A Long Working Length(n=30) n (%)	Group B Short Working Length(n=31) n (%)	*p*-value
Mean Age (years)	37.9±9.6	37.2±11	
Gender			
Male	24(80)	26(83.8)	0.71∞
Female	06(20)	05((16.1)	0.52
Side of fracture			
Right	20(66.6)	23(74.1)	0.72∞
Left	10(33.3)	07(22.5)	0.10
Mechanism of Fracture			
Motorbike accident	18(60)	21(67.7)	0.22∞
Motor vehicle accident	10(33.3)	09(29.0)	0.08
Fall	02(6.6)	01(3.2)	0.07
Type of fracture			
OTA/AO 33A 2.2*	02(6.6)	03(9.6)	0.32∞
OTA/AO 33A 2.3⊣	05(16.6)	06(19.3)	0.61
OTA/AO 33A 3.2¶	11(36.6)	10(32.2)	0.09
OTA/AO 33A3.3¥	12(40)	12(38.7)	0.53
Obesity(BMI>30)	01(3.3)	02(6.4)	0.07∞
Diabetes Mellitus	03(10)	04(12.9)	0.22
Smokers	02(6.6)	01(3.2)	0.31

* extra-articular oblique ⊣ transverse ¶ fragmentary wedge(lateral) ¥ multifragmentary;
∞ p-value calculated with chi-square test (level of significance <0.05);
OTA/AO: Orthopaedic Trauma Association/Arbeitsgemeinschaft für Osteosynthesefragen classification; BMI: Body mass index.

Discussion

To the best of our knowledge, the current study is the first in Pakistan to investigate the effect of working length of distal femoral locking plate on fracture union. The study tried to resolve the controversy by finding an answer to questions about the appropriate working length of titanium locking plate for extra-articular distal femur fracture. It was found that titanium distal femoral locking plates, when applied in long working length mode for extra-articular femur fracture, had less non-union rates and implant failure than short working length plates. Conflicting opinions, however, can be seen in literature regarding the optimal working length of the distal femoral locking plate. Some[19] preferred short working length fixation, while others[1,5,20] preferred long working length locking plates. Studies[22,23] have demonstrated no significant difference in the outcome between long and short working length distal femoral locking plates. The possible explanation for these differences can be attributed to the disparity between in vitro versus in vivo findings,[12] heterogeneous patient population, different methodologies and outcomes, variable definitions, under-powered studies and lack of RCTs.[8]

In the current study, rate of non-union was noted in short working length (22.5%) than in long working length (6.6%) titanium locking plates. A retrospective review[5] noted an overall non-union rate of 20%.

A study16 treated 127 fractures with distal femoral locking plates. The overall non-unions requiring re surgery was 4(3.1%). Short working length (plate of 12 holes or less with a working length of 3-4 holes) had 3(2.3%) non-unions, while long working length (plate of 13 holes with >4 hole working length) had 1(0.7%) non-union. However, the study noted 3 secondary fractures above the plate after primary fracture union and recommended longer locking plates extending to the subtrochanteric region to avoid this complication. The study documented 12-month mortality rate of 25(22%) and this could be due to the advancing age (mean: 72.8 years) of the patients and associated co-morbidities. Contrary to the study, the current research did not document any mortality in the series and this could be due to the relatively younger age of the patients and no major co-morbidities.

The mean working length in patients in group A was 75±5 mm and in group B 35±9 mm. Translating these measurements into the number of empty screw holes equated to one empty screw hole on either side of the fracture in cases of long working length. Harvin et al.9 compared the outcome of short working length (≥90.5mm) and long (≥90.5 mm) working length while treating 96 distal femur fractures with locking plates. They documented that non-union rate in long working length was 17(40%) while in the short working length it was 17(31.4%) and the difference was not significant (*p*=0.36). They, however, noted that locking plates with all proximal locking screws were 2.9 times more prone to having non-unions than hybrid screw construct (*p*=0.01). Majority of the locking plate construct in the current study consisted of hybrid screw fixation in both groups (21 in group A, 23 in group B) and the latter observation of Harvin et al. could not be verified.

A study[6] treated 33 distal femur fractures with titanium locking plates and 33 with stainless steel. The mean working length was 71±32 (range: 20-157 mm). By measuring the size of callus radiographically at 6th week,12th week and 24th week postoperatively, the study documented excessive callus formation at 6th week in longer working length construct (*p*=0.02) but no association was noted at 12th and 24th weeks post-surgery. Overall, titanium plates were associated with more callus formation than stainless steel at 6th week (*p*=0.04), 12th week (*p*=0.03) and 24th week (*p*=0.09). In a comparative biomechanical study of titanium locking plates versus stainless steel locking plates, a study[13] was able to show that the endurance of titanium locking plate improved by changing the construction from short to long working length. The endurance of stainless steel locking plate, however, was not significantly affected by changing its working length.

The current study was able to achieve long working length by omitting screws in a combi hole on either side of the fracture over intact cortex in majority 19(61.2%) cases, while in 12(38.7%) cases due to excessive distal comminution, two combi holes were left empty proximal to the fracture. Outcome revealed non-union in 5(16.1%) cases in the former and 2(6.4%) in the latter construct (*p*=0.09). One study[7] was of the opinion that leaving one screw hole empty on either side of the fracture in locking plate construct made the construct 60% more flexible in compression and 30% in torsion, and recommended 2-3 screws on either side of the fracture in femur with one or two plate holes left unoccupied in simple fracture (<2 mm gap) and three screws in case of comminuted fracture.

The current RCT demonstrated that patients with OTA/AO 33A3.3 fractures had more non-union in both group A 2(6.6%) and group B 6(19.3%) than other types of fractures (*p*=0.001). Kiyono et al.24 reported a non-union rate of 1(1.4%) in short working length in transverse fracture, 1(1.4%) in long working length in transverse fracture and 5(7%) in long working length in comminuted fractures. A biomechanical study25 revealed that long working length decreases axial stiffness and strain in the distal femur, but not in mid-femur. It was of the opinion that very long working length should be avoided as it increases stress on the screws, and advocated that one or two screw holes on either side of fracture distal femur should be left unoccupied to provide optimal plate flexibility without risking the construct stability. Contrary to earlier findings[7], Weaver et al.[26] in a recent mechanical study compared the stiffness of a 13-hole distal femur locking plate in long working length mode (9.4 cm) and short working length mode (5.4 cm), but could not detect any significant difference in stiffness between the two constructs when axial load was applied. Riedel et al.[27] compared long working length (13.5 cm) supracondylar femur locking plates with short working length (7.5 cm) utilising non-locking screws, locking screws and far cortical locking screws in each construct. When tested for axial load, the axial stiffness and rotational stiffness in short working length with far locking screws were significantly ($p<0.01$) reduced by 23% and 19% respectively than the other screw construct with long and short working length. The study concluded that short working length locking plates with far cortical locking screws construct can provide optimum healing environment for supracondylar femur fracture.[27]

The current study had a few limitations. Firstly, the registration of RCT with ANZCTR was done retrospectively as the patients had already been enrolled before getting the registration process completed. Secondly, although results indicated that long working length titanium locking plates were better and should be preferred, the study was not able to analyse the effects of proximal locking screw density, far cortical locking screw construct, quality of bone, intra-articular fractures, screw size, bi-cortical versus uni-cortical screws construct and post-plate removal complications. It is, therefore, recommended that further well-designed studies should be conducted to address all such limitations so that the current results could be verified.

Conclusion

Long working length titanium locking plates were better than short working length in achieving fracture union and avoiding implant failure. Extra-articular distal femur fractures should preferably be fixed with long working length titanium locking plates. To attain long working length, one screw hole may be left empty on either side of the fracture.

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