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A PROSPECTIVE RANDOMISED CLINICAL TRIAL TO EVALUATE THE EFFECT OF FIBULAR PLATING IN TWO STAGED TREATMENT OF TIBIAL PLAFOND FRACTURES

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ABSTRACT **Introduction:** A single blinded randomized clinical trial of distal plafond fractures , who were treated with primary external fixation with and without fibular plating followed by distal tibial plating .Sincere efforts were made to analyze and compare the results of fibular fixation and staged protocol in tibial plafond fractures. **Materials and Methods:** A prospective study was conducted for 40 cases of tibial plafond fractures who were aged between 18yrs - 65yrs and presented within 2 weeks of injury. Randomization was done to allocate 20 patients each into two treatment models – a)External fixation with fibular plating , b)External fixation without fibular plating. Second stage distal tibial lock plating was done in all cases and follow up was carried out. Results: Statistically significant differences were found in case of operating time, duration of hospital stay in favour of external fixation without fibula plating group, but these may not be clinically significant. Delay in second stage tibial plating was more in fibular plating group. Fibula plating reduces rotational malalignment more significantly than coronal and saggital plane malalignment. There is no significant early union , malunion or nonunion on comparing both groups. Both the procedures gave equally good functional results. **Conclusion:** We recommend two stage protocol for management of plafond fracture to decrease complication rate and fibular fixation is not always necessary in those cases with undisplaced lateral column. Displaced fibular fractures which destabilize the ankle mortise should always be picked up for fibular plating.

KEYWORDS : Plafond fracture, external fixation, distal tibia plating

INTRODUCTION

Destot in 1911 described that ankle fracture that involves the weight bearing articular surface of distal tibia are known as pilon fracture. With the tremendous increase in the vehicular traffic and resultant accidents, the high energy injuries with complex and comminuted fractures are becoming more and more common. Increasing complications due to poor blood supply, poor soft tissue coverage, development of secondary osteoarthritis make the management of tibial plafond fractures not only difficult but also of particular interest to orthopaedic surgeons.

Given the background stated above, we undertook this single blinded randomized clinical trial with distal plafond fractures , who were treated with primary external fixation with and without fibular plating followed by distal tibial plaing .Sincere efforts were made to evaluate the effect of fibular plating in two staged treatment of tibial plafond fractures with regards to treatment outcomes such as complication, union and functional results. This study was treated as a pilot project for a more organized RCT involving a greater number of patients and a longer follow-up.

Purpose of the study was to analyze and compare the results of fibular fixation and staged protocol in tibial plafond fractures to evaluate radiological union, clinical and functional outcome in both groups in terms of early mobilization and weight bearing, complications in both groups in terms of infection, implant failure and nonunion.

MATERIALS AND METHODS

Prospective study for 40 cases of tibial plafond fractures aged between 18yrs - 65yrs attending the OPD and Emergency department of Orthopaedics, Jorhat Medical College & Hospital, Assam with effect from 1st April 2021 to 30th September 2022.

Closed fractures and type I-II compound tibial plafond fracture with closed fibula fracture presenting within 2 weeks, aged between 18 and 65 years and having competent neurological and vascular status of the affected limb were included in the study.

Initial workup was done to evaluate, stabilize and diagnose the patient condition.

Patient were allocated into one of the following two treatment models by randomisation

1. External fixation with fibular plating (Fig 1a)
2. External fixation without fibular plating (Fig 2a)

Followed by second stage distal tibial lock plating in all (Fig 1b, 2b).

Fig 1a- Exfix + fibula plating

Fig 1b - After DTLCP

Fig a- Exfix alone

Fig 2b- After DTLCP

An informed consent was obtained from each patient prior to participation in the study. Clinical and radiological parameters were recorded. CT scan with three dimensional reconstruction were ordered in few cases.

SURGERY

All the cases in our series were operated under spinal anaesthesia. A standard radiolucent operating table and IITV were used in all cases. The patient was positioned supine with padding under the leg to assist lateral imaging.

For first group fibular fixation with spanning external fixator, fibular plating was done first.

First fibular plating done if required according to randomization plan. Then ligamentotaxis was done via spanning external fixator.

Tibial plating by MIPO technique
It can be done by removing or keeping the fixator in situ. We in our research did it by removing the fixator before hand. After performing the medial approach , the plate was inserted above the epiperiosteal space from distal to proximal on the anteromedial aspect of the tibia. Reduction was confirmed under IITV guidance and plate was fixed by locking screws

Mobilization:
Passive and active range of motion exercises of ankle and knee are then initiated on next post op day and partial weight bearing after 4-8 weeks with 30-50% of body weight after clinical and radiological evaluation of bone healing. Full weight bearing is not permitted until full bony healing is confirmed radiographically, usually by 12-14 weeks.

Follow-up
Follow-up was carried out at 4,6,8,10,12, 16 and 20 weeks and then at 6 monthly intervals.

A superficial soft-tissue infection was diagnosed in the presence of purulent discharge from the wound with positive microbiological speciation. A deep infection was defined if operative exploration with bone debridement was necessary to eradicate the infection.[3]

Angulation was measured on anteroposterior and lateral radiographs. Malunion was defined as >5° of angulation on anteroposterior or lateral radiographs or rotational malalignment >15° or shortening > 1cm. Range of motion was measured in the ankle joint according to the AOFAS.[4]

Union at fracture site was defined as bridging callus in a minimum of three cortices on anteroposterior and lateral radiographs combined with a lack of tenderness at the fracture site or unassisted weight bearing.[5]

Delayed union was defined when the fracture did not show any signs of healing for 4 months along with clinical symptoms like pain and difficulty on bearing weight.[6]

Nonunion was defined when 9 months had passed after the surgery and no progressive signs of union were seen for 3 consecutive months.

Functional results
The functional results were evaluated using American Orthopaedic Foot and Ankle Society (AOFAS) score system.

Statistical analysis
Statistical analysis was done using suitable biostatistical technique on each variable in the same patient and between two treatment groups. Paired t test and other appropriate tests were applied to check for presence of significant difference in outcome variable in two groups. The software Instat Graphpad 3 was used in the analysis. P-value less than 5 % was considered significant.

RESULTS AND OBSERVATIONS
40 patients (18-65years) of tibial plafond fractures were randomly allocated into two groups of treatment.

i. External fixator with fibular plating (n=20)
ii. External fixator only (n=20)

The mean age of the patients was 35.48 years. Of the 20 patients external fixator with fibular plating in group, the age ranged from 18 to 58 years (mean 35.6 years). Of the 20 patients in external fixator without fibular plating group, the age ranged from 24 to 59 years (mean 36.05 years).There were 31 males and 9 females in the study.27 plafond fractures involved right (67.5%) and 13 (32.5%) involved left side of lower extremity. The commonest mode of injury was Road Traffic Accident (77.5%) followed by fall from height and adventurous sports activities. There were 36 closed plafond fractures and 4 open fractures. Majority of the cases (n = 21) were operated within the 24 hours, 9 patients were operated within 48 hours, 7 patient between 3-7 days and the rest of the 4 patients after 7 days. The operating duration in external fixator with fibular plating ranged from 45-90 minutes (mean 74.5 min) while in case of external fixator only, it ranged from 20-45 minutes (mean 35.75 min). Majority of second stage distal tibial lock plate was done within 7-14 days(n=26), 3 cases within 7 days, 9 cases within 14-21 days and rest after 3 weeks. Range was from 5-24 days. Average time of delayed distal tibial plating was 11.58 days. The average delay in second stage distal tibial lock plating in external fixator without fibular fixation was 10.6 days (range 5-18days), whereas in external fixation with fibular plating group was 13.55 days (range 9-24days). The average duration of DTLCP surgery in external fixation with fibular plating group was 57.25 (range 45-85) min and without fibular plating group was 60(range 40-89) min. On statistical analysis p-value was 0.2605, which was not significant. The average duration of hospital stay in both the groups were 14.72 days. The mean duration of hospital stay in the ex-fix group was found to be 13.43 days, (standard deviation 3.7).The mean duration of hospital stay in the ext fix+ fibular plating group was found to be 15.76 days, (SD 4.2). There was no statistical difference in range of motion (dorsiflexion and plantar flexion) on comparing both groups

Overall average union time was 17.31 weeks. The average time of union in the external fixator without fibula plating group was 17.56 weeks (range 12-22 weeks). In the external fixator with fibula plating group, union occurred in an average of 17.06 weeks (range 12-22 weeks). The statistical difference between two groups comes out to be insignificant (p-value 0.2292).

Only 3 cases were complicated by infection, 2 was superficial and 1 was deep infection. Out of 2 in cases treated by external fixator with fibular plating, 1 was superficial and 1 was deep which required implant removal. 1 superficial infection in a case treated with external fixator alone.

There were a total of 4 cases of delayed union (n = 4/40) out of them 2 delayed unions occurred in external fixator without fibular plating group(n = 2/20) while 2 occurred after external fixator with fibular plating (n = 2/20). In analyzing all 40 cases, p-value was 0.5000 which is not significant.

Only 1 case went for non-union(Fig 3) {n = 1/40}, which was treated with external fixator with fibular plating. But this difference cannot be shown to be significant in this study (p-value 1).

Fig 3- Xray showing nonunion

There was one case of varus malalignment (Fig 4) in external fixator group only. No rotational malalignment . But this difference cannot be shown to be significant in this study (p-value 1).

Fig 4 -Xray showing Varus malalignment

There was no case of ankle instability. There was two cases (5%) of ankle stiffness. One case from each group. The functional results, as assessed by Johner and Wruh's criteria, showed that majority (n=20, 60%) of the patients in the study had excellent functional results. These differences between two groups were not found to be statistically significant (p-value 0.3336) on comparing both groups.

DISCUSSION

The age distribution is comparable to the studies by **Sirkin et al**[8], Shikari et al[9], Samir et al[10] and others. The lower mean age in our series was probably due to more exposure of the younger generation to road traffic accidents due to more outdoor activities. Male patients (77%) have exceeded female patients in our study which was comparable and consistent with other studies by Ahmet et al[11], Kienast et al[12] and others. Predominant male involvement was probably due to more outdoor activities and travelling undertaken by males as compared to females in the Indian set up. Right side was involved more (n =27) compared to the left side (n = 13) in our study and was consistent with studies conducted by Gulabi et al.[13]This result is likely to be due to chance than any anatomical or biomechanical factors. In our study there were 36 closed plafond fracture and 4 open fracture, which was comparable to studies by Ruedi et al[14], Roshdy et al[15] and Samir et al[10]. Appropriate timing of surgery after trauma was decided by clinical status of the patient and the soft tissue condition. Majority of fractures were operated as an emergency. Sirkin et al[8] and Patterson and Cole[16] suggested primary external fixation within 24 hours of presentation.Few were prepared and fixed as elective procedure. In our study, the operating time in the external fixator with fibular plating group was more and this difference was statistically significant, p-value <0.0001. It was due to more amount of time consumed in open reduction and internal fixation of fibula. Majority of second stage distal tibial lock plate done within 7-14 days (n=26), Range was from 5-24 days. Average time of delayed distal tibial plating was 11.58 days. It was comparable to study by Shabbir et al[17] on MIPO of distal tibia fractures. The difference average delay in second stage distal tibial lock plating in both groups was statistically significant with p-value 0.0119. This delay in second stage procedure is attributed to time taken for improvement of soft tissue status after added insult to poor soft tissue envelope by more soft tissue dissection for open reduction and internal fixation of fibula. The average duration of DTLCP in external fixation with fibular plating group was 57.25 (range 45-85) min and without fibular plating group wass 60 (range 40-80) min. On statistical analysis p-value is 0.2605, which is not significant. Length of the operative procedure depends upon the learning curve and fracture geometry. *Borg et al*[18] found that average operative time for distal tibial lock plate was 82 minutes. One study by *Shabbir et al*[17] on MIPO of distal tibia fractures the average time was 75 min. Operative time reduced as experience was gained during the study and 1st stage ligamentotaxis helped in maintaining length, alignment and reduction. Tong et al[19] by two stage protocol reported operative time of 58 min in second stage tibial plating . The mean duration of hospital stay in the ex-fix+ fibular plating group was found to be more on comparing the two groups and the *p*-value was found to be 0.0274 (unpaired t test), which was statistically significant. It was due to time allowed for improvement of poor soft tissue envelope after more soft tissue dissection after fibular plating for second stage MIPO. At 8 weeks, patients were allowed partial weight bearing irrespective of callus formation in an effort to load the fracture site. Both groups had same benefits, without any effect on partial weight bearing. Therefore, statistically it can be deduced that fibular plating does not lead to earlier weight bearing.

In our study, overall average union time was 17.31 weeks. The statistical difference between two groups comes out to be insignificant (p-value 0.2292). Bahari et al.[20] in his study on MIPO distal tibial fractures reported union time of 22.4 weeks, while Mahajan et al[21] reported 12 weeks and Gulabi et al.[13] reported 16 weeks. Roshdy et al.[15] in his study reported average union time of 17.9 weeks via staged protocol, which was comparable to our study.

In our study there were no cases of compartment syndrome, fat embolism, venous thrombosis or iatrogenic fractures. We believe that careful selection of cases prevented these complications in our study. Infection rate in our study (7.5%) correlate well with the studies conducted by Sirkin et al[8] and Kienast et al.[12] There was no case of screw and plate breakage or loosening in lock plate or external fixator. There were two cases (5%) of ankle stiffness, may be due to varying degrees of posttraumatic fibrosis and arthrosis. Anatomic reduction and stable fixation of the fracture allows early range of motion, which may help minimize stiffness. Tornetta et al[22] and Anglen et al[23]in their studies reported that posttraumatic stiffness after tibial pilon fracture was a relatively common complication. Malalignment occurred in 1case, all following distal tibial plating in a external fixator without fibular plating group. It had <10 degrees of varus angulation. No rotatory deformity or shortening was seen. The patient also did not have any objective discomfort and the malunion was not intervent. Only 1 case went for non-union (n = 1/40,2.5%), which was treated with external fixator with fibular plating. But this difference cannot be shown to be significant in this study (p-value 1).

In the present study clinical results were evaluated according to the AOFAS score chronologically and at union. The mean AOFAS Score of our study (91.2) were comparable to studies conducted by Roshdy et al.[15]

We acknowledge that with more number of cases in this study the results and observations would have been more accurate and statistically significant. We propose to continue this study in future to achieve better conclusive evidence. A Randomized Controlled Trial, possibly triple blinded or at least double blinded in nature, involving a large number of patients with long term follow-up is clearly needed to bring the differences between the two techniques.

CONCLUSION

Gradually the focus has been shifted from the mechanical aspect of fracture treatment of anatomic reduction and rigid stabilization to biological fixation technique with least disruption of soft tissue envelops which was the base of this study. For the best outcome, operative treatment of these injuries should be tailored to the fracture pattern, degree of soft tissue injury, patient's demands and expectations, and the surgeon's experience and training. Our study shows that staged protocol can aid in faster fracture healing with minimum complication and fibula fixation is not mandatory.

We recommend two staged protocol for management of plafond fracture to decrease complication rate and fibular fixation is not always necessary in those cases with undisplaced lateral column. Displaced fibular fractures which destabilize the ankle mortise should always picked up for fibular plating.

On behalf of all authors, corresponding author states that there is no conflict of interest.

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