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# Randomized controlled trial comparing outcome of hybrid Ilizarov versus distal tibial metaphyseal locking plate (P) for treatment of distal tibial fractures in adults

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## ABSTRACT

**Background:** Distal tibia fractures include extra-articular fractures of the metaphysis and the more severe intra-articular tibial plafond or pilon fractures. Several treatment methods have been recommended for the treatment of these injuries, with a recent emphasis on minimally invasive techniques and Ilizarov technique also. Several studies regarding distal tibial fracture treatment are available. Few of them are only randomized controlled trial. So, we conducted this research comparing distal tibial plating (P) versus hybrid Ilizarov (HI) for treatment of distal tibial fractures.

**Methods:** The randomized controlled trial was conducted in B.P. Koirala Institute of Health Sciences, a tertiary care hospital in Eastern Nepal, over a period of fifteen months from June 2015 to August 2016. Patient in group A underwent HI fixation, and group B underwent P.

**Results:** Gender ratio for male: female was 2.63 in HI, 1.35 in P group. Mean age was 47.03±15.93 and 42.1±12.788 for HI and P respectively. Most fractures in both group belonged to AO A3 type. Most surgeries were done at interval of 1 day to 1 week. Mean hospital stay was 6.43±4.545 and 4.93±4.676 for HI and P respectively. Mean Lower extremity functional score (LEFS) was 66.55 in HI and 67.15 in P group. Mean Percentage of maximal function (LEFS/80 *100) was 83.56. Three cases among 40 cases in P had infection but no infection in HI group was seen at the end of 12$^{th}$ week follow up.

**Conclusions:** Our study showed that there is no significant difference in terms of LEFS criteria, union, fracture alignment, ROM (knee, ankle), infection and other outcome measures between HI fixation and P in the treatment of distal tibia fracture in adults.

**Keywords:** Distal tibia, Fracture, Functional outcome, Hybrid Ilizarov, Plating

## INTRODUCTION

Distal tibia fractures include extra-articular fracture and intra-articular fractures also known as Pilon's or plafond fractures. Incidence reported is from 3 per 10,000 per year among 30 to 34-year-old women to 28 per 10,000 per year among 15 to 19 year old boys. These fractures constitutes 3% to 10% of all tibia fractures and less than 1% of lower extremity fractures.[1-4] These are high energy injuries caused by falls from heights or motor vehicle accidents. They are often open fractures and are frequently associated with additional trauma in other areas of the body.[2,3] They are usually associated with severe soft tissue compromise.[5,6] The limited soft tissue, subcutaneous location and poor vascularity makes the treatment more difficult.[7,8] The distal tibial fracture management is considered to be quite challenging because of the possible complications associated with

it.[9,10] Several treatment methods have been recommended for the treatment of these injuries, including, varieties of external fixation, intramedullary nailing, and plate fixation with a recent emphasis on minimally invasive techniques. These treatment options have their own benefits and complications.[9,11] Wound infection is the most common complications of distal tibial fracture management. Deep infection is considered to be a major problem among patients who would undergo external fixation or plating. It is believed that infection could range from 0 to 15%. The development of infection may result from soft tissue that is compromised, immune system's inability to ward off potential infection, colonization of virulent microorganisms.[12,13] Several studies regarding distal tibial fracture treatment are available. They are mainly prospective and retrospective studies with variable results. Few of them are only randomized controlled trial. So, we conducted this study comparing the above two methods for treatment of distal tibial fractures.

## METHODS

### *Setting*

The study was conducted in the Department of Orthopaedics, B.P. Koirala. Institute of Health Sciences (BPKIHS), a tertiary care hospital in Eastern Nepal, over a period of fifteen months from June 2015 to August 2016. Ethical clearance was obtained from Institutional Review Committee (IRC).

### *Inclusion criteria*

All patients aged more than 18 years with closed/Gustilo and Anderson Grade I traumatic extra-articular/intra-articular distal tibia fractures presenting to Emergency/OPD in Department of Orthopaedics, BPKIHS, in the 15 day timeframe post injury giving written informed and understood consent for the trial.

### *Exclusion criteria*

Exclusion criteria were patients with compartment syndrome; patients with generalized bone or joint disease; patients with pathological fracture; patients not fit for anesthesia; patients with comorbidities like uncontrolled diabetes, peripheral vascular disease; patients associated with other major injuries/polytrauma; previous surgery.

### *Sample size calculation*

Malunion is being considered as the single most important criteria in this study.

According to Ramos et al, malunion rate for P done for distal tibial fractures was 1/34(0.97).[14]

According to Vidyadhara et al, malunion rate for HI fixation for distal tibial fractures was 1/21 (0.95).[15]

Now using the difference between two proportion formula for a RCT study as below

$$n = \frac{\left(\left(\frac{\frac{Z\alpha}{2}}{\sqrt{2pq}}\right) + Z\beta\sqrt{p1q1 + p2q2}\right)^2}{p1 - p2}$$

Where

n= number of sample
Zα/2=1.96 at 95% confidence interval (C.I)
Zβ=0.842 at 80% power (P)

According to literature review, 95% CI and 80% power has been used for sample size estimation

p=1/2(p1+p2); q=1-p; p1= the malunion rate of HI; p2= malunion rate of P; q1=1-p1; q2=1-p2.

Using the corrected sample size formula which is recommended by WHO, CDC Atlanta (EPI info 2007 software)

$$Corrected\ sample\ size = \frac{Calculated\ sample\ size}{1 + \frac{Calculated\ sample\ size}{\text{Estimated population}}}$$

$$Corrected\ sample\ size = \frac{1500}{1 + \frac{1500}{86}} = 80$$

After using appropriate formula, sample of 80 was calculated, 40 samples were taken in each groups, which were allocated using www.randomization.com into two blocks.

### *Intervention*

Patients were admitted in Orthopaedic ward on analgesics and splinting of limb was done. In cases of open fractures, wound was debrided and sutured, and iv/oral antibiotics was administered in all Gustilo Grade I fractures. In patients with poor skin conditions, if haemorrhagic blister was there, it was aspirated and limb was elevated with two pillows underneath the leg until wrinkle sign was observed. He/she underwent full investigations pertaining to pre-anaesthetic check-up. Following fitness for anaesthesia, these patients were taken up for elective surgery.

***Group A:*** These patients underwent hybrid ilizarov (HI) fixation. Lower limb tourniquet and C-arm image intensifier was used. All patients received 2 gm. Ceftriaxone 1 hour preoperatively and was repeated if operation time exceeded 3 hours. Similar preparation was done for Group B patient.

*Operative procedure*

Position-supine with affected leg elevated on a pillow/sand bag. Compound wounds were thoroughly debrided. If there was a fracture of the distal fibula involving syndesmosis or below it, this was treated first by a classic open reduction and internal plate and screw fixation through a lateral approach. Fibula fixation was same for Group B.

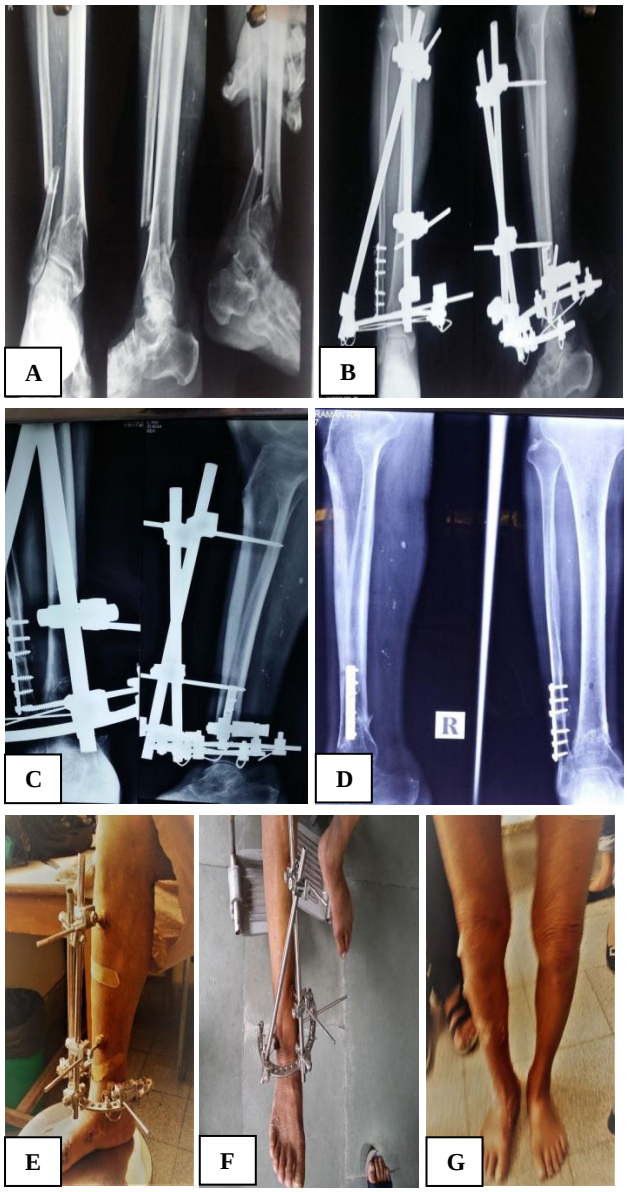


**Figure 1: Hybrid Ilizarov fixation. A=X-ray at time of presentation; B=postoperative X-ray; C=6 weeks follow up case of patient treated with HI; D=12 weeks follow up case of patient treated with HI; E and F=assessing range of motion (ROM) during follow up of patient who underwent HI; G=patient after implant removal.**

*Securing articular fragments*: After reduction of the peri-articular fragment, it was secured using two- three Ilizarov wires. The wires were pushed manually until it hit the cortex, then drilled across both the cortices and hammered out through the opposite soft tissue. Nerves and vessels were avoided based on the safe corridor for pin insertion in the leg. Olive wires were used in cases where compression of the longitudinal split was needed. The first wire was passed parallel to the joint in a lateral to medial direction under fluoroscopic control. It was fixed to an appropriate size ilizarov ring so as to leave at least 2 cms between the leg and the ring on all sides. One wire each from posterolateral to anteromedial and posteromedial to anterolateral under fluoroscopic control keeping an angle of 30 to 60 degrees between the wires was inserted. The axial plane of the wires was about 5 mm from the joint and as parallel to it as possible. The wires were fixed to the rings using slotted wire connecting bolts and tensioned using a dynamometric tensioner. Additional stability was achieved using extra Schanz pin / wire parallel to the articular surface with posts fixed on distal ring (drop wire technique).The syndesmosis or malleolar fragments were stabilized using wires fixed with distal ring through posts. Skin traction by the wires, if any, were released using minimal incisions on the side of the skin stretching.

*Securing the diaphyseal fragment*: Two/ Three 4.5 mm/5.5 mm Schanz pins were placed 3 - 4 cm apart on the antero-medial surface of tibia perpendicular to its longitudinal axis. The pins were connected to the connecting rods with the pin clamps. *Fracture reduction* and *frame assembly*- Fracture reduction was obtained using longitudinal traction (Ligamentotaxis) under the image intensifier. The pin fixator assembly was connected to the ring assembly using a connecting clamp. All nuts and bolts were tightened. One or two connecting rods were connected diagonally from the Schanz pins to ring frame for extra stability (Figure 1).

***Group B*:** These patients underwent closed reduction/ORIF/MIPO with medial distal metaphyseal locking plate (P).

*Operative procedure*

These patients were positioned supine on the operating table with fractured leg on fracture table. A vertical or curvilinear incision was made at the level of medial malleolus with the utmost care not to injure great saphenous vein and saphenous nerve. Sub cutaneous plane was made with haemostat without stripping periosteum and disturbance to fracture haematoma. Fracture was reduced under C- arm control. Where reduction was difficult despite of repeated attempt, we made a small incision and used a Kirschner wire (3 mm) as a joystick to aid in fracture reduction and towel clip or reduction clamp to hold reduction. Even after this attempt, if reduction was not achieved then open reduction via anterolateral approach was done. Pre contoured plate was tunnelled into subcutaneous plane and its position was reconfirmed with C- arm.

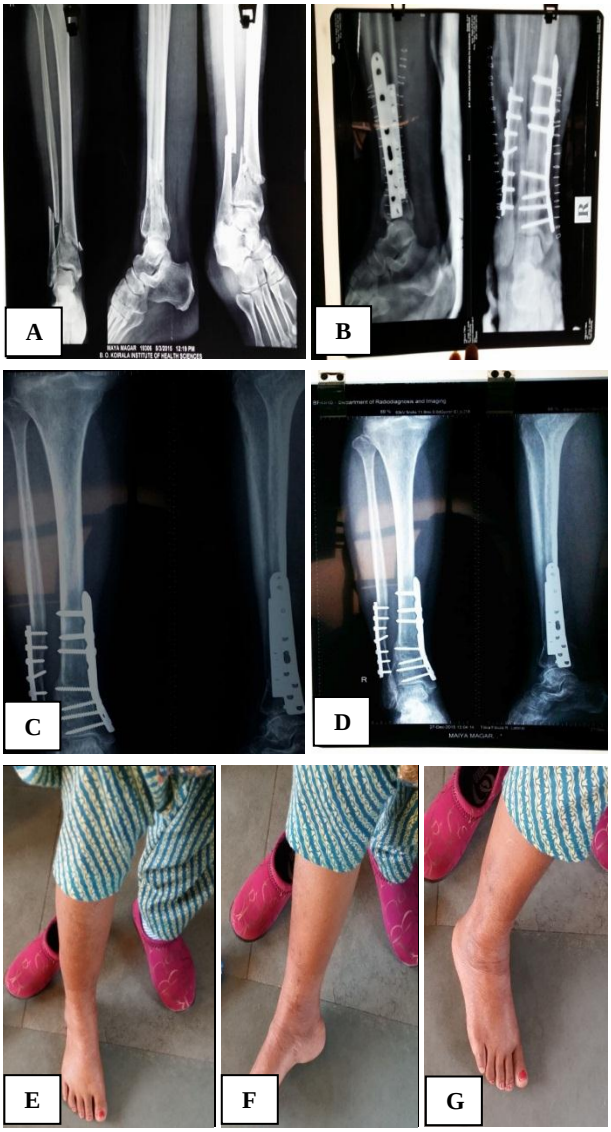


**Figure 2: Distal tibial plating. A=X-ray at time of presentation; B=post-operative X-ray in a patient who underwent P; C=6 weeks follow up in a patient who underwent P; D=12 weeks follow up in a patient who underwent P; E-G=Assessing Range of motion (ROM) and functional status in a patient who underwent P.**

Before fixing the plates with screws, shagging of distal fragment was prevented by putting towel roll under the fracture site. Provisional non-locking screw was applied to bring the plate on the bone. If necessary, interfragmentary compression was achieved by a screw through the plate or outside the plate. Compression osteosynthesis was achieved in simple fracture by using non-locking screw on proximal to fracture site as a hybrid fixation. With separate stab incision, locking screws were applied on the either side of fracture. Malleolar fracture if present were reduced and fixed with screws or tension band wiring before tibia fracture reduction and fixation. Skin was closed with non-absorbable sutures and limb was splinted with below knee posterior back slab (Figure 2).

Any intraoperative or early postoperative complications were noted. X-rays of the leg in AP & lateral views were evaluated for accuracy of reduction and fracture alignment. Measurements were performed for coronal (varus and valgus) and sagittal (procurvatum and recurvatum) plane deformities using the measuring technique described by Milner.[16]

Varus/valgus deformity of upto 5°, procurvatum/ recurvatum of upto 10° was considered aligned.[17] Patients were discharged on 2nd post-operative day if surgical wound was healthy. After discharge patients were reviewed after 2 weeks, 6 weeks and 12 weeks for pain (on VAS), evidence of infection, ROM–Knee, ankle (expressed as percentage with respect to contralateral normal joint), ambulatory status, radiological union, clinical union(fracture site tenderness), fracture alignment (on x-ray), gait. Lower extremity functional score (LEFS) criteria for evaluation of final results was used to evaluate the outcome of the two procedures.[18]

### *Statistical analysis*

Consecutive sampling technique was applied. The data was collected in Microsoft EXCEL 2012. Data analysis was done using SPSS 21.0 for Windows (SPSS Inc., Chicago, Illinois) software. Proportion, measure of central tendency and dispersion of the variables like age, sex, mode of injury, interval between injury and surgery were tested by appropriate parametric and non-parametric statistical technique (e.g. t-test, $X^2$- test etc.) depending upon the nature of the variables in both the groups. The Independent Samples T test and Mann-Whitney U test were used to compare outcome measures with parametric means. The Chi square test, Fisher`s test, were used to compare non parametric means. The level of significance was set at $p \leq 0.05$.

## RESULTS

A total of 190 patients of distal tibia fracture presented to Emergency Room at BPKIHS over a period of 15 months. Out of these patient 80 of these patients who fulfilled the inclusion criteria were taken as the study population, of which 40 were randomized into group A in which patients underwent HI and 40 in group B in which patients underwent P (Figure 3).

In the present study, 65% patients were male and 35% were female in both HI and P, mean age was 44.30 years in HI group and 40.30 years for the P group, the usual mode of injury in both groups was road traffic accidents (45 % cases) followed by fall from height (40 % cases). Nature of fracture (open/closed) was similar in both groups. Most of the patients arrived within interval of 12 hours (Table 1).

Most of the fractures belonged to AO.A3 group in both groups. Few cases had comorbid conditions like diabetes mellitus, hypertension, which was controlled in nature, so were included in the study.

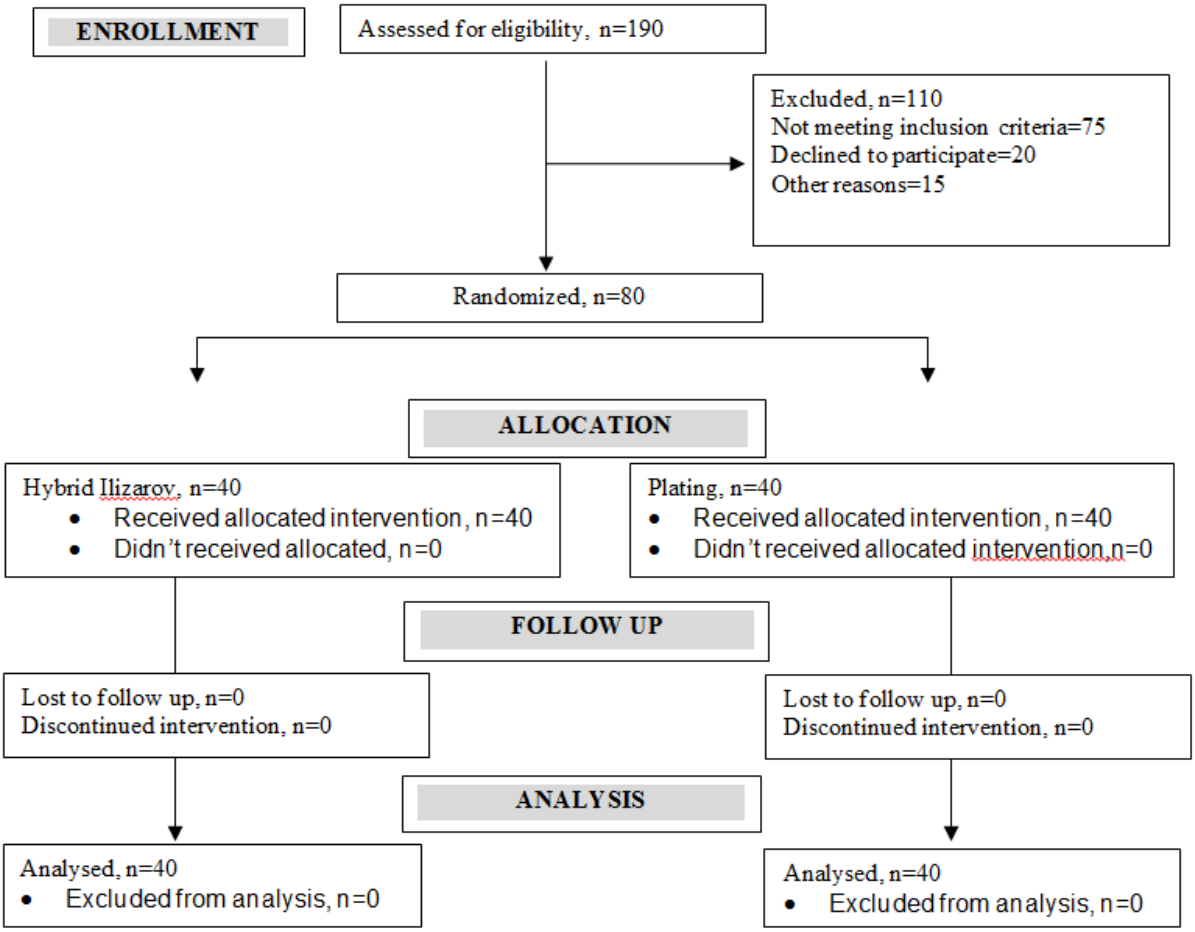


**Figure 3: Consort chart.**

**Table 1: Comparing socio-demographic and clinical parameter in two groups.**

| Characteristic | | Group | | P value |
|---|---|---|---|---|
| | | Hybrid Ilizarov | Plating | |
| **Mean age± SD (yrs.)** | | 47.03±15.93 | 42.1±12.78 | 0.13 |
| **Sex** | Male | 29 | 23 | 0.16 |
| | Female | 11 | 17 | |
| **Nature of fracture** | Closed | 29 | 30 | 0.79 |
| | Open | 11 | 10 | |
| **Mode of injury** | RTA | 20 | 16 | 0.944 |
| | Fall from height | 14 | 18 | |
| | Others/physical assault | 6 | 6 | |
| **Injury and hospital arrival interval** | <12 hrs | 21 | 24 | 0.767 |
| | 12 hr-1 day | 8 | 7 | |
| | >1 day-1 week | 6 | 6 | |
| | >1 week | 5 | 3 | |

Mean hospital stay was more for HI group (6.43 days) as compared to P group (4.93 days). Most of the patients were operated at interval of 1 day to 1 week. Blood loss was slightly more in P group (Table 2).

Second post-operative day infection was 5 % in each group, all were superficial infection managed with dressing and antibiotic coverage. At follow up of 12$^{th}$ week, no patient of HI group had infections, while 3 patient in P group had infection, who underwent debridement with regular dressing under antibiotic coverage (Table 3).

**Table 2: Comparison of injury–surgery interval, hospital stay, and haemoglobin levels in two group.**

| Characteristic | | Group | | P value |
|---|---|---|---|---|
| | | Hybrid Ilizarov | Plating | |
| Injury to surgery interval | Upto 1 day | 7 | 7 | 0.06 |
| | 1 day -1 week | 17 | 26 | |
| | >1 week | 16 | 7 | |
| Mean hospital stay±SD (days) | | 6.43±4.545 | 4.93±4.676 | 0.146 |
| Hb (gm. %) | Preop | 11.07±1.48 | 11.51±2.07 | 0.273 |
| | Postop | 10.19±1.36 | 10.57±2.04 | 0.329 |
| | Difference | 0.88±0.46 | 0.94±0.46 | 0.584 |

**Table 3: Comparison of infection at different stages of follow up in two group.**

| Duration | Infection | Group | | P value |
|---|---|---|---|---|
| | | Hybrid Ilizarov | Plating | |
| 2nd postop day | Present | 2 | 2 | 1.00 |
| | Absent | 38 | 38 | |
| 2nd weeks | Present | 4 | 7 | 0.518 |
| | Absent | 36 | 33 | |
| 6 weeks | Present | 0 | 3 | 0.241 |
| | Absent | 40 | 37 | |
| 12 weeks | Present | 0 | 3 | 0.241 |
| | Absent | 40 | 37 | |

**Table 4: Comparison of alignment in AP and lateral view at different stages of follow up in two groups, i.e. varus/valgus alignment. Alignment was defined as varus/valgus angulation <5 degrees. Alignment was defined as procurvatum/recurvatum angulation <10 degrees.**

| Duration | Alignment (varus/valgus) | Group | | P value |
|---|---|---|---|---|
| | | Hybrid Ilizarov | Plating | |
| Postop day | Present | 34 | 35 | 1.00 |
| | Absent | 6 | 5 | |
| 6 weeks | Present | 35 | 36 | 1.00 |
| | Absent | 5 | 4 | |
| 12 weeks | Present | 35 | 36 | 1.00 |
| | Absent | 5 | 4 | |
| Duration | Alignment (procurvatum/ recurvatum) | Group | | P value |
| | | Hybrid Ilizarov | Plating | |
| Postop day | Present | 33 | 36 | 0.518 |
| | Absent | 7 | 4 | |
| 6 weeks | Present | 33 | 36 | 1.00 |
| | Absent | 7 | 4 | |
| 12 weeks | Present | 37 | 37 | 1.00 |
| | Absent | 3 | 3 | |

**Table 5: ROM knee and ankle between the two groups at different stages of follow up.**

| | Ilizarov | Plating | P value |
|---|---|---|---|
| **ROM knee (Mean±SD)** | | | |
| 2 weeks | 83.15±6.784 | 84.05±5.257 | 0.509 |
| 6 weeks | 83.43±6.957 | 84.68±4.833 | 0.354 |
| 12 weeks | 83.28±7.111 | 85.43±4.888 | 0.119 |
| **ROM ankle (Mean±SD)** | | | |
| 2 weeks | 87.38±6.758 | 89.68±4.817 | 0.84 |
| 6 weeks | 88.08±6.639 | 89.75±4.640 | 0.195 |
| 12 weeks | 88.73±5.444 | 89.63±4.595 | 0.427 |

**Table 6: Lower extremity functional score (LEFS) and percentage of maximum function (POMF) between two groups.**

| Group | LEFS (Mean±SD) | P value |
|---|---|---|
| **Ilizarov** | 66.55± 3.07 | 0.387 |
| **Plating** | 67.55± 2.60 | |
| | **POMF (Mean±SD)** | |
| **Ilizarov** | 83.18±3.83 | 0.349 |
| **Plating** | 83.93±3.26 | |

(POMF) = (LEFS)/80*100.

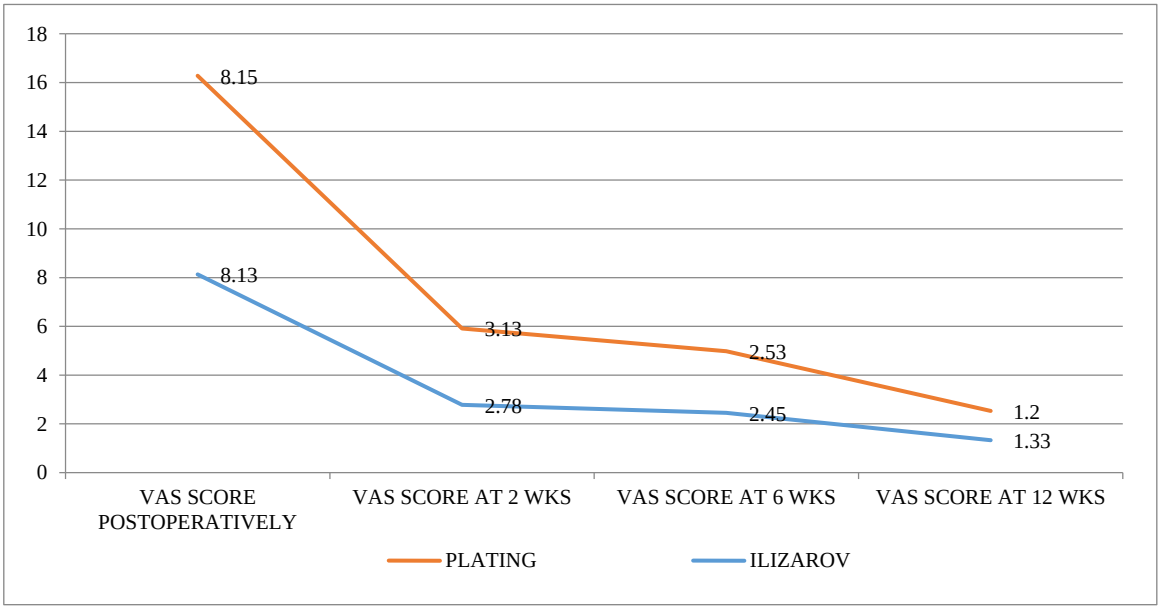


**Figure 4: VAS score between the two groups at different stages of follow-up.**

In the present study, coronal plane deformity (varus /valgus) as seen on X-Ray AP view, >5° mal-alignment was seen in 5/40 patients of HI and 4/40 patients of P group. The mean angulation in coronal plane was 2.55° for HI group and 3.30 for P group at 12 weeks follow-up, there being no significant difference between the two groups. In the sagittal plane deformity (procurvatum/ recurvatum) as seen on x-ray lateral view, >10° malalignment was seen in 3 patients of HI group and 3 patients in P group. The mean post-op angulation in sagittal plane was 4.05° for HI group and 4.63° for P group at 12 weeks follow-up. Both the groups tended towards procurvatum deformity but there was no significant difference between the two groups (Table 4).

In the present study, there was no significant difference between clinical and radiological union at 6 and 12 weeks follow-up. The clinic-radiological union rates at 12 weeks were 82.5 % for HI group and 90 % for P group. Most patient resumed from non-weight bearing to full weight bearing at 12$^{th}$ week, gait being insignificant limp in subsequent follow up. Pain score went down with passage of time in both groups, but it was less in HI group at all stages of follow up (Figure 4). Range of motion of knee and ankle expressed as percentage was almost similar in both groups (Table 5).

In the present study, lower extremity functional score (LEFS) criteria for evaluation of final outcome as well as percentage of maximal function (POMF) was also similar in both groups (Table 6). No patients developed compartment syndrome or deep vein thrombosis.

## DISCUSSION

Distal tibial fractures are one of the most substantial therapeutic challenges that confront the orthopaedic traumatologist. Numerous features are responsible for this, but perhaps none are as difficult as the accompanying soft tissue injury that is frequently present. First described by the French radiologist Destot in 1911, ankle fractures that involve the weight-bearing distal tibial articular surface are known as pilon fractures.[19]

The aim of this study was to find out clinical and functional outcome between HI and P for distal tibia fractures in adults. The HI and P groups were similar with respect to age, sex, mode of injury, nature of fracture, associated medical problems, and injury to

surgery interval, which indicated that the randomization was effective.

In the present study, mean age was 44.30 years for the HI group and 40.30 years for the P group. The mean age of patients undergoing surgery for distal tibia fractures belonged to 4th-5th decade of life similar to some of the previous studies.[14,15,20]

In the present study, the usual mode of injury in both groups was road traffic accidents (45 % cases) followed by fall from height (40 % cases) which was similar to previous studies.[14,15,20] Most of the injuries attributed to male with injury due to fall from height can be explained with the nature of work they are into like going to field, climbing trees to get fodder for their cattle. Road traffic accidents are the booming cause of all kind of traumatic injury is a well-known fact.

In the present study, Mean hospital stay was more for HI group (6.43 days) as compared to P group (4.93 days). Previous study had found significantly longer mean hospital stay in P group (11.61 days) as compared to HI group (5.13 days).[20]

In the present study, second post-operative day infection was 5 % in each group.

Lower rates of infections have been reported when hybrid thin wire external fixation methods were used for the management of articular fractures.[21] It has been also reported that the soft tissue affection of ORIF methods could predispose to high rate of infections as the skin vascularity might be compromised by the surgical approach.[22] There is scarce comparative data regarding the rate of infections in cases of tibial plafond fractures managed with an HI or with a two-stage management with final plate fixation.[20] Although the differences in our study are not statistically significant, the second day postoperative infection was similar (5%) in both groups. At follow up of 12th week, no patient of HI group had infections, while 3 out of patient in P group had infection. In some of the previous study the overall rate of infection was 6.7% (two of 32), early wound infection of 15% in P group. [23,24]

Pain score gradually decreased over a passage of time after operation. There was no significant difference in pain in both the groups at any stage of follow up although it was slightly more in the P group at different stages of follow-up. This can be explained with the much more dissection being done in P group, as well as implant prominence being common in P group.

In the present study, coronal plane deformity (varus /valgus) as seen on x-ray AP view, >5° mal-alignment was seen in 5/40 patients of HI and 4/40 patients of P group. The mean angulation in coronal plane was 2.55° for HI group and 3.30 for P group at 12 weeks follow-up, with no significant difference between the two groups. In the sagittal plane deformity (procurvatum/recurvatum) as seen on x-ray lateral view, >10° malalignment was seen in 3 patients of HI group and 3 patients in P group. The mean post-op angulation in sagittal plane was 4.05° for HI group and 4.63° for P group at 12 weeks follow-up. Both the groups tended towards procurvatum deformity but there was no significant difference between the two groups. In one the previous study 30% (4/13) cases of HI were not aligned while none in P group.[20] This can be explained with the expertise in Ilizarov fixation, which is quite good in this tertiary level hospital where study has been done.

In the present study, there was no significant difference between clinical and radiological union at 6 and 12 weeks follow-up. The clinico-radiological union rates at 12 weeks were 82.5 % for HI group and 90 % for P group. Previous study has shown average healing time to be 12-15 weeks in P.[23,25] While some studies have shown average union time in P to be 19 weeks and for HI to be 21 weeks. [20] Previous studies have reported satisfactory union rates when using the external fixation strategy as a definitive method of treatment in cases of tibial plafond fractures.[26] Hybrid external fixation systems in cases of tibial plafond fractures allow early mobilization and weight bearing. The use of circular frames is considered to allow better indirect reduction, progressive correction of deformities and offer improved results.[27,28] The dynamization effect of the fracture that is obtained with the hybrid fixation is considered to promote healing and union.

In the present study, lower extremity functional score (LEFS) criteria for evaluation of final outcome was quite similar for both groups, HI having mean score of 66.55 and 67.15 for P group. No significant difference was noted between the two groups as regard to final functional outcome.

The results of the follow-up observed in this study might differ in the future in terms of functional outcome. Marsh et al claimed that, although tibial plafond fractures have a negative effect on ankle function and pain, at a minimum of five years after the injury, few patients required secondary reconstructive procedures because these symptoms tend to decrease during a long time period after the acute injury.[29]

In one of the previous study it was recommended that because of the increased incidence of bony and soft tissue complications when treating open or closed Type C fractures, use of limited exposures and stabilization with small wire circular external fixators should be done.[30]

To conclude: In the present study, infection rate was slightly higher in P group, union rate was higher in P group, malunion was slightly higher in HI group, but the results were not statistically significant. In cases with soft tissue compromise, we recommend HI, as there is low rate of infection.

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