



## RANDOMIZED CONTROLLED TRIAL COMPARING OUTCOME OF HYBRID ILIZAROV VERSUS DISTAL TIBIAL METAPHYSEAL LOCKING PLATE FOR TREATMENT OF DISTAL TIBIAL FRACTURES IN ADULTS

### Orthopaedics

**Dr. Jeevan Kumar Sharma\*** MS Ortho. Department Of Orthopaedics, BPKIHS, Dharan, Nepal. \*Corresponding Author

**Dr. Pashupati Chaudhary** Professor and HOD, Department Of Orthopaedics, BPKIHS, Dharan, Nepal.

**Dr. Raju Rijal** Additional Professor, Department of Orthopaedics, BPKIHS, Dharan, Nepal

**Dr. Bishnu Pokharel** Assistant Professor, Department of Orthopaedics, BPKIHS, Dharan, Nepal

### ABSTRACT

**Background:** Distal tibia fractures include extraarticular fractures of the metaphysis and the more severe intra-articular tibial plafond or pilon fractures. Incidence ranged from a low of 3 per 10,000 per year among 30 to 34-year-old women to a high of 28 per 10,000 per year among 15 to 19-year-old boys. More data are available for pilon fractures. These fractures are estimated to comprise 3% to 10% of all tibia fractures and less than 1% of lower extremity fractures. Several treatment methods have been recommended for the treatment of these injuries, including, varieties of external fixation, intramedullary nailing (with and without reaming), plate fixation with a recent emphasis on minimally invasive techniques and non-operative treatment also. These treatment options have their own benefits and complications. 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 research comparing distal tibial plating (P) versus hybrid ilizarov (HI) for treatment of distal tibial fractures.

**Methods:** The study was conducted in the Department of Orthopaedics, 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. Ethical clearance was obtained from Institutional Review Committee (IRC). Research Design was Randomized Controlled Trial. Patient in group A underwent hybrid Ilizarov fixation, and group B underwent plating.

**Results:** Gender ratio for male: female was 2.63 in hybrid ilizarov, 1.35 in plating 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 plating respectively. Lower extremity functional score (LEFS) ranged from 59 to 73 with mean of 66.55 in HI and 67.15 in plating group. Percentage of maximal function (LEFS/80 \*100) ranged from 73.75 to 91.25 with mean of 83.56. Three cases among 40 cases in Plating had infection but no infection in HI group was seen at the end of 12<sup>th</sup> week follow up.

**Conclusion:** 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 Hybrid ilizarov fixation and plating in the treatment of distal tibia fracture in adults.

### KEYWORDS

distal tibia; fractures; hybrid ilizarov; plating

### INTRODUCTION:

Distal tibia fractures include extraarticular fractures of the metaphysis and the more severe intra-articular tibial plafond or pilon fractures. Incidence ranged from a low of 3 per 10,000 per year among 30 to 34-year-old women to a high of 28 per 10,000 per year among 15 to 19-year-old boys. These fractures are estimated to comprise 3% to 10% of all tibia fractures and less than 1% of lower extremity fractures.<sup>[1-4]</sup>

These high energy injuries are usually caused by falls from heights or motor vehicle accidents. They are often open fractures and they are frequently associated with additional trauma in other areas of the body.<sup>[2,3]</sup>

They are usually associated with severe soft tissue compromise.<sup>[5,6]</sup>

The limited soft tissue, subcutaneous location and poor vascularity renders the distal tibial fractures very challenging.<sup>[7,8]</sup>

The distal tibial fracture management is considered to be quite challenging because of the possible complications associated with it.<sup>[9,10]</sup>

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.<sup>[9,11]</sup>

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%. It is deemed that 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.<sup>[12,13]</sup>

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.

### MATERIALS AND 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 extraarticular / intraarticular 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:

- Patients with compartment syndrome
- Patients with generalized bone or joint disease
- Patients with pathological fracture
- Patients not fit for anesthesia
- 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 T et al (2013)<sup>[16]</sup>: malunion rate for plating

done for distal tibial fractures was 1/34(0.97).

- According Vidyadhara S, Rao SK (2006)<sup>[17]</sup>: malunion rate for hybrid ilizarov fixation for distal tibial fractures was 1/21(0.95)

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

**INTERVENTION:**

Patients were admitted in Orthopaedic ward on analgesics and splinting of limb. In cases of open fractures, wound was debrided and sutured, and iv/oral antibiotics administered in all Gustilo Grade I fractures. He/she underwent full investigations pertaining to pre-anesthetic checkup. Following fitness for anesthesia, 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 hr 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.

**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. 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.



**Figure1. Hybrid ilizarov fixation instrumentation set**



**Figure 2.X-ray at time of presentation (a) ; Postoperative x-ray (b).**



**Figure 3.6 weeks follow up (a) ;12 weeks follow up (b)**



**Figure 4. Assessing ROM during follow up. (a), (b); After Implant Removal (c)**

**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 hemostat without stripping periosteum and disturbance to fracture hematoma. 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 (3mm) 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 tunneled into subcutaneous plane and its position was reconfirmed with C- arm. 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, at least three 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 5. Distal Tibial Metaphyseal Locking Plate instrument Set



Figure 6. X-ray at time of presentation. (a); Post-operative x-ray. (b)

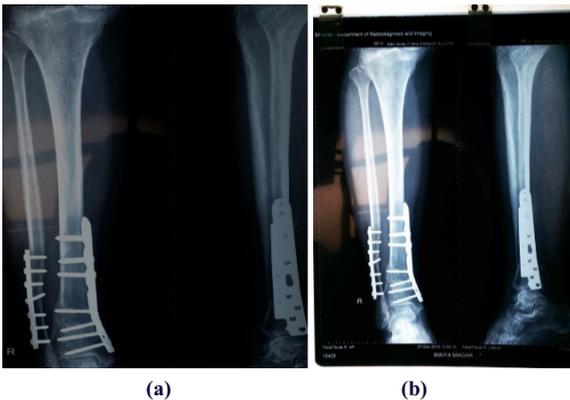


Figure 7. 6 weeks follow up. (a); 12 weeks follow up. (b)



Figure 8. Assessing Range of motion (ROM) and functional status in a patient with plating.

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 & recurvatum) plane deformities using the measuring technique described by Milner.<sup>[14]</sup>

Varus/valgus deformity of upto 5°, Procurvatum/ recurvatum of upto 10° was considered aligned.<sup>[15]</sup>

Patients were discharged on 2nd post op 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 (callus formation), clinical union(fracture site tenderness), fracture alignment(on X-ray), gait. Lower Extremity Functional score (LEFS) criteria<sup>[21]</sup> for evaluation of final results was used to evaluate the outcome of the two procedures.

**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<sup>2</sup>- test etc.) depending upon the nature of the variables in both the groups. The Independent Samples T test & 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≤0.05.

**RESULTS:**

**Table 1: Comparing sociodemographic 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	

Figure 9: AO Classification between the two groups (p value 0.605).

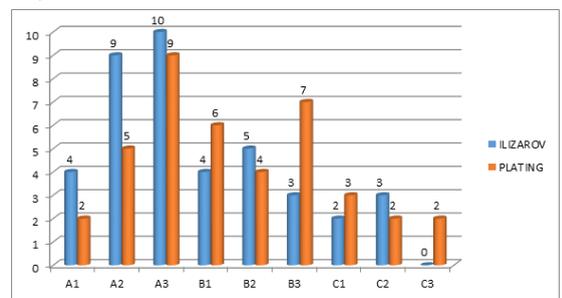
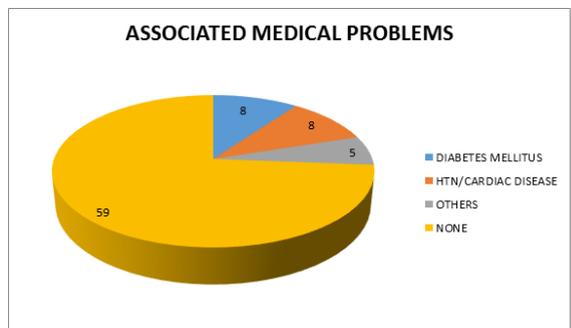


Figure 10: Associated Medical problems. p value 0.193.



**Table 2: Comparison of injury–surgery interval, hospital stay, and hemoglobin 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	
2 <sup>nd</sup> postop day	Present	2	2	1.00
	Absent	38	38	
2 <sup>nd</sup> 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	

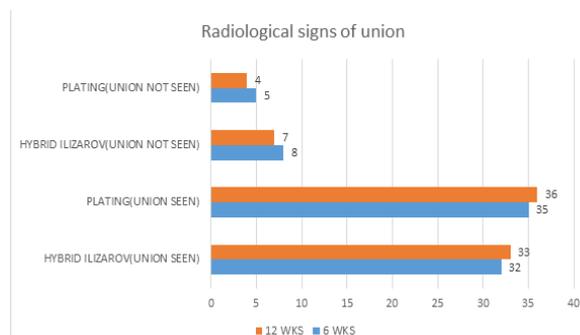
**Table 4: Comparison of alignment in AP view at different stages of follow up in two group. i.e. varus/valgus alignment. Alignment was defined as varus/valgus angulation < 5 degrees.**

Duration	Alignment	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	

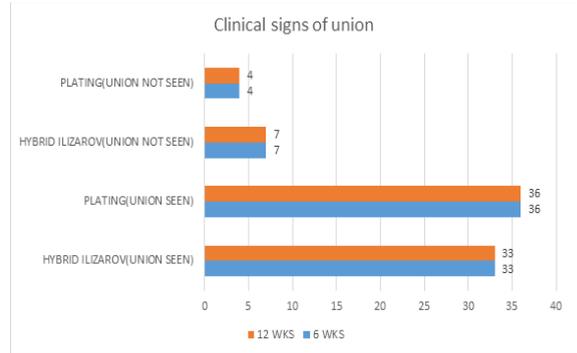
**Table 5: Comparison of alignment in lateral view at different stages of follow up in two group. i.e. procurvatum/recurvatum alignment. Alignment was defined as procurvatum/recurvatum angulation < 10 degrees.**

Duration	Alignment	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	

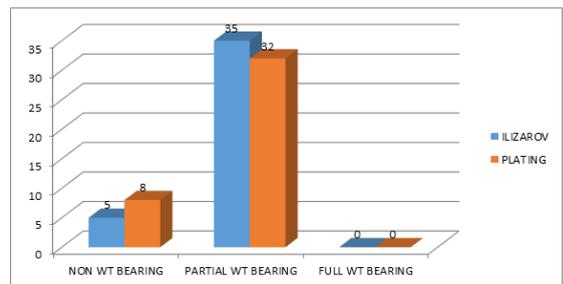
**Figure 11: Radiological signs of union (callus formation) at 6<sup>th</sup> and 12<sup>th</sup> week of follow up (p value at 6<sup>th</sup> week- 0.367,12<sup>th</sup> week- 0.518)**



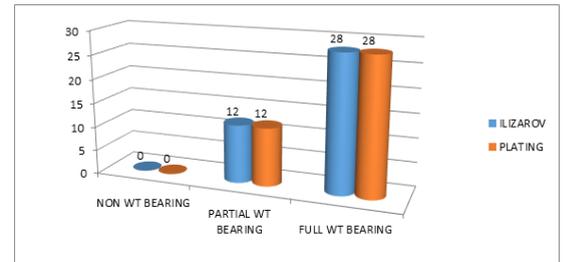
**Figure 12: Clinical signs of union (tenderness) at 6<sup>th</sup> and 12<sup>th</sup> week of follow up (p value at 6<sup>th</sup> week-0.518, 12<sup>th</sup> week-0.518)**



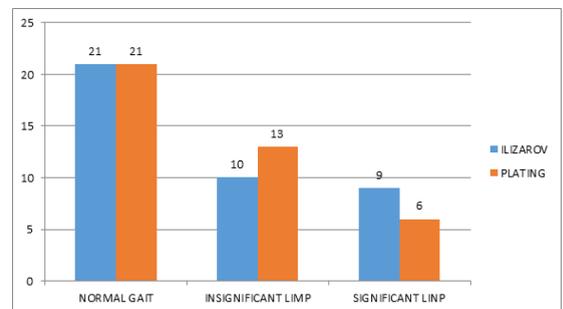
**Figure 13: Ambulatory status amongst patients of the two groups (p value 0.546) at 6 weeks.**



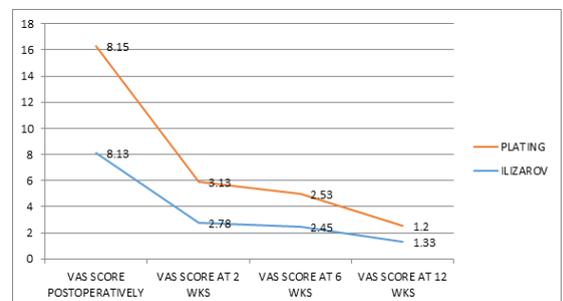
**Figure 14: Ambulatory status amongst patients of the two groups (p value 1.00) at 12 weeks.**



**Figure 15: Gait at 12 weeks between the 2 groups.(p- value 0.60)**



**Figure 16: VAS score between the two groups at different stages of follow-up.**



**Table 6: ROM Knee between the two groups at different stages of follow up:**

ROM KNEE (MEAN+/-SD)	ILIZAROV	PLATING	P VALUE
2 WKS	83.15+/-6.784	84.05+/-5.257	0.509
6 WKS	83.43+/-6.957	84.68+/-4.833	0.354
12 WKS	83.28+/-7.111	85.43+/-4.888	0.119

**Table 7: ROM ankle between the two groups at different stages of follow up:**

ROM ANKLE (MEAN+/-SD)	ILIZAROV	PLATING	P VALUE
2 WKS	87.38+/-6.758	89.68+/-4.817	0.84
6 WKS	88.08+/-6.639	89.75+/-4.640	0.195
12 WKS	88.73+/-5.444	89.63+/-4.595	0.427

**Table 8: Mean value of Varus/valgus angulation.**

DEFORMITY-VARUS/VALGUS (MEAN+/-SD) DEGREES	ILIZAROV	PLATING	P-VALUE
6 WKS	2.58+/-1.567	3.18+/-1.870	0.158
12 WKS	2.55+/-1.632	3.30+/-1.911	0.063

**Table 9: Mean value of Procurvatum/ Recurvatum.**

PROCURVATUM / RECURVATUM (MEAN+/-SD)	ILIZAROV	PLATING	P-VALUE
6 WKS	3.90+/-2.697	3.48+/-2.050	0.430
12 WKS	4.05+/-2.679	3.63+/-2.009	0.425

**Table 10: Lower extremity functional score (LEFS) between two groups.**

GROUP	LEFS (MEAN +/- SD)	P-VALUE
ILIZAROV	66.55+/- 3.07	0.387
PLATING	67.55+/- 2.60	

**Table 11: Percentage of maximum function (POMF) = (LEFS) /80\*100 between two groups.**

GROUP	POMF (MEAN +/- SD)	P-VALUE
ILIZAROV	83.18+/-3.83	0.349
PLATING	83.93+/-3.26	

**DISCUSSION**

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 is effective.

In our study, 65% patients were male and 35% were female in both HI and P. In the study by Cisneros et al,<sup>[18]</sup> 45% were male and 55% were female in HI group, while in the P group, 39% were male and 61% were female.

In our study, mean age was 44.30 years for the HI group and 40.30 years for the P group. The mean age of patients with HI was 43.3 years and 52.6 years for those who underwent P in the study by Cisneros LN et al.<sup>[18]</sup> The mean age of patients with distal tibial fracture was 50 years in the study by Ramos T et al.<sup>[16]</sup> The demographic data in our study and that of Cisneros LN et al. and Ramos T et al. are quite similar.

In our 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 the study by Cisneros LN et al.<sup>[18]</sup>

In our study, Mean hospital stay was more for HI group (6.43 days) as compared to P group (4.93days). Cisneros LN et al<sup>[18]</sup>, in their study had found significantly longer mean hospital stay in plate group (11.61 days) as compared to HI group (5.13 days).

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<sup>[19]</sup>. 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.<sup>[20]</sup>

As far as their knowledge, there is scarce comparative data regarding the rate of infections in cases of tibial plafond fractures managed with an Hybrid external fixation or with a two-stage management with final plate fixation.<sup>[18]</sup>

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 12<sup>th</sup> week, no patient of HI group had infections, while 3 patient in P group had infection.

Pain was evaluated using VAS score. It 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 plate group at different stages of follow-up.

In our 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 plating 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. In the study done by Cisneros LN et al,<sup>[18]</sup> 30%(4/13) cases of HI were not aligned while none in P group.

In our study, average ROM of ankle joint was more for P group with respect to HI group at different follow-up; although it was not significant statistically.

In our 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.

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

To conclude, 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 it has low rate of infection.

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