ORIGINAL RESEARCH

A randomised trial comparing outcome of expert tibial nailing and plating for distal tibial fractures

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Received: 15 February, 2023 Accepted: 20 March, 2023

ABSTRACT

Background: Treatment of distal tibial fracture can be complicated by contusion, infections, delayed union and non-union; all these may lead to revision surgeries. Distal tibial fracture needs a stable fixation while minimizing damage to the soft tissues by the surgical dissection andimplants. The optimal method of fixation remains debatable. Traditional methods like ORIF have been associated with infections, devitalization of softtissues and hence have poor results. **Aim:** The aim of our study is to compare the functional and radiological outcome of the distal tibial fractures treated by Expert tibia nailing and tibial plating. **Methods:** This study was carried out in Rajendra Institute of Medical Sciences, Ranchi. This is a prospective study, period from November 2021 to October 2022. Patient was randomized using lottery method in both the group by an independent observer. Patients fulfilling the inclusion criteria are randomly selected and operated, 30 with locking compression plate and 30 with expert tibia nailing. **Results:** In ETN, the mean Ankle Score (mean± s.d.) of patients was 85.3333± 6.8145. In Plating, the mean Ankle Score (mean± s.d.) of patients was 85.5000± 5.9234. Distribution of mean Ankle Score with Mx Plan was not statistically significant(p=0.9198). **Conclusions:** Thus, based on the finding from our study we can conclude that both expert tibia nail andplating offer no significant advantage over each other in term of fracture union, delayed union, malunion, non-union, deep infection. But in term of lesser operating time, blood loss and lesser superficial infection Expert tibia nail offers slight more advantage over plating.

INTRODUCTION

Distal tibia fracture account for 1% of all lower extremity fracture and 10% of tibia fracture, bilateral in 0-8 % of cases, which is more common in male, more in age group of 30-50 year and compartment syndrome is seen in 0-5% of cases.

The spectrum of injuries varies from low to high energy. Low energy distal tibia fractures are commonly seen in older age group, mainly because of rotational forces. The spiral fracture with or without intra articular extension is commonly encountered in this mechanism of injuries. Younger age group are commonly involved in high energy distal tibia fracture due to road traffic accident (RTA) and fall from height. Axial loading, compression and torsional forces[1,2]are involved in this mechanism of injury.

The distal tibial fractures are mostly due to road traffic accident, fall from height and twisting of ankle. Distal Tibia Fracture can be difficult to treat because of precarious vascularity, limited soft tissue coverage, subcutaneous location and proximity to the ankle joint.

Treatment of distal tibial fracture can be complicated by contusion, infections, delayed union and non-union; all these may lead to revision surgeries. Distal tibial fracture needs a stable fixation while minimizing damage to the soft tissues by the surgical dissection andimplants. The optimal method of fixation remains debatable.

Traditional methods like ORIF have been associated with infections, devitalization of softtissues and hence have poor results[3].

For distal tibial fractures various modalities of internal fixation have been described. These are anterior plating using T- plates, AO medial plating using medial buttress plate, cloverleaf plate and dynamic compression plates.

The locking compression plates with anatomical contoured version is now available for the distal tibia fracture with lower incidence of wound- dehiscence and deep infectionthan that of standard AO plating.

Minimally invasive techniques were developed to

avoid complications like soft tissue devitalization while providing the stability and alignment with internal fixation. MIPPO techniques reduces these risks.

External fixator is used in emergency management of open fractures but associated with pin site infection, inadequate fixation and poor patient compliance.

Intramedullary nail spares the extraosseous blood supply, avoids soft tissue dissection and help in load sharing and aids in better radiological and clinical outcome[4].

Expert Tibia Nail {ETN} was designed an adaptation for the conventional tibial intramedullary interlocking nail specially designed for the metaphyseal fractures. The ETN provides additional bio-mechanical stability when compared to conventional Intramedullary nail and plate osteosynthesis[5].

There are many studies on fixation of distal tibia fracture but till now it is not clear which is better. The aim of our study is to compare the functional and radiological outcome of the distal tibial fractures treated by Expert tibia nailing and tibial plating. The primary objectives of the study is to analyse the outcome in terms of fracture union by means of clinical and radiological features. The secondary objectives of the study is to analyse the outcome after surgical procedures for complication such as Non - union, osteoarthritis, malunion, restriction of range of movement and infections.

METHODOLOGY

This study was carried out in Rajendra Institute of Medical Sciences, Ranchi. This is a prospective study, period from November 2021 to October 2022. Patient was randomized using lottery method in both the group by an independent observer. Patients fulfilling the inclusion criteria are randomly selected and operated, 30 with locking compression plate and 30 with expert tibia nailing. Surgical incisions and approaches to reduce and fix fractures of distal third tibia have been modified to decrease the incidence of wound complications. In our study surgery was done through medial approach and anterolateral approach. Postoperative results with respect to clinical, radiological and functional assessment was done 6wk, 12wk, 24wk.

INCLUSION CRITERIA

1. Adult patients of Age more than 20 years and less than 70 years of age
2. Closed fracture and grade I compound fracture of distal tibial fractures(43-A1, 43- A2, 43-A3 of AO type) without intra articular extensions.
3. Patients who give consent.

EXCLUSION CRITERIA

1. Grade II and III open fracture of distal tibia.
2. Fracture with intra articular extensions.
3. Patient with terminal illness or not fit for surgery
4. Patient with neurological involvement like leprosy, tabes dorsalis
5. Patient with burger disease

RESULTS

The statistical analysis of data was performed using the computer program, statistical package for social sciences (SPSS for windows, version 20.0 Chicago, SPSS Inc.) And Microsoft Excel 2010. In ETN, 5 (16.7%) patients were ≤30 years of age, 15 (50.0%) patients were 31 – 40 years of age, 5 (16.7%) patient were 41-50 years of age and 5 (16.7%) patients were ≥51 years of age. In Plating, 2 (6.7%) patients were ≤30 years of age, 14 (46.7%) patients were 31 – 40 yearsof age, 3 (10.0%) patient were 41-50 years of age and 11 (36.7%) patients were ≥51 yearsof age.In ETN, 12 (40.0%) patients were Female and 18 (60.0%) patients were Male.In Plating, 12 (40.0%) patient were Female and 18 (60.0%) patients were Male. Association of Sex with MX Plan was not statistically significant (p=1.0000). In ETN, 3 (10.0%) patients had fall from height, 24 (80.0%) patients had RTA, 2 (6.7%)patients had Self Fall and 1 (3.3%) patient had Twisting Injury. In Plating, 3 (10.0%) patients had fall from height, 22 (66.7%) patients had RTA, 5 (16.7%) patients had Self Fall and 2 (6.7%) patient had Twisting Injury. Association of MOI with MX Plan was not statistically significant (p=0.5760). In ETN, 3 (10.0%) patients had Infection all were superficial infection. In Plating, 12 (40%) patients had Infection in which 10 were superficial infection, and 2 deep infection in which one lead to implant failure which eventually lead to non-union. Association of Infection with MX Plan was **statistically significant** (p=0.00729). In ETN, 21 (70.0%) patients had Full ROM Ankle, 4 (13.3%) patients had Mid-Range ROM Ankle and 5 (16.7%) patients had Near Normal ROM Ankle. In Plating, 20 (66.7%) patients had Full ROM Ankle, 2(6.7%) patients had Mid-Range ROM Ankle and 8 (26.7%) patients had Near Normal ROM Ankle. Association of ROM Ankle with MX Plan was not statistically significant (p=0.5007). In PLATING, 2 (6.67%) patients had Malunion, 10 (33.33%) patients had Superficial Infection, 5 (16.67%) patients had Delayed Union, 1 (3.33%) patient had Wound Dehiscence and 1 (3.33%) patient had Plate Exposed, Implant Failure, and Non-Union. In EXPERT TIBIA NAIL, 5 (16.67%) patients had Malunion, 3 (10.00%) patients had Superficial Infection and 3 (10.00%) patients had Delayed Union. Association of Malunion with MX Plan was statistically not significant (p=0.2269). Association of Superficial Infection with MX Plan was **statistically significant** (p=0.028266). Association of Delayed Union with MX Plan was statistically not significant (p=0.4463). Association of Wound Dehiscence with MX Plan was statistically not significant (p=0.3125). Association of Plate Exposed, Implant Failure, Non-Union with MX Plan was statistically not significant

(0.3125). In ETN, the mean Age (mean± s.d.) of patients was 38.0333± 9.8172. In Plating, the mean Age (mean± s.d.) of patients was 43.1000± 10.8829. Distribution of mean Age with Mx Plan was not statistically significant (p=0.0633). In ETN, the mean Time Elapsed from Injury to SX (D) (mean± s.d.) of patients was8.3333± 1.4933. In Plating, the mean Time Elapsed from Injury to SX (D) (mean± s.d.) of patients was8.3667± 1.0662. Distribution of mean Time Elapsed from Injury To SX (D) with Mx Plan was notstatistically significant (p=0.9211). In ETN, the mean OP Time (Min) (mean± s.d.) of patients was 75.3333± 6.8195. In Plating, the mean OP Time (Min) (mean± s.d.) of patients was 81.3333± 8.2309. Distribution of mean OP Time (Min) with Mx Plan was **statistically significant** (p=0.0032). In ETN, the mean Blood Loss (ML) (mean± s.d.) of patients was 108.8667± 14.5240. In Plating, the mean Blood Loss (ML) (mean± s.d.) of patients was 135.2000± 18.0467. Distribution of mean Blood Loss (ML) with Mx Plan was **statistically significant** (p<0.0001). In ETN, the mean Hospital Stay after SX (D) (mean± s.d.) of patients was 5.7667± 2.7125. In Plating, the mean Hospital Stay after SX (D) (mean± s.d.) of patients was 6.4667± 3.3910. Distribution of mean Hospital Stay after SX (D)with Mx Plan was not statistically significant (p=0.3809).

Table: Distribution of mean Union (In Months): MX PLAN

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Union (In Months)	ETN	30	5.0333	1.0981	4.0000	8.0000	5.0000	0.1955
	Plating	30	5.5000	1.6135	4.0000	12.0000	5.0000	

In ETN, the mean Union (In Months) (mean± s.d.) of patients was 5.0333± 1.0981. In Plating, the mean Union (In Months) (mean± s.d.) of patients was 5.5000± 1.6135. Distribution of mean Union (In Months) with Mx Plan was not statistically significant(p=0.1955).

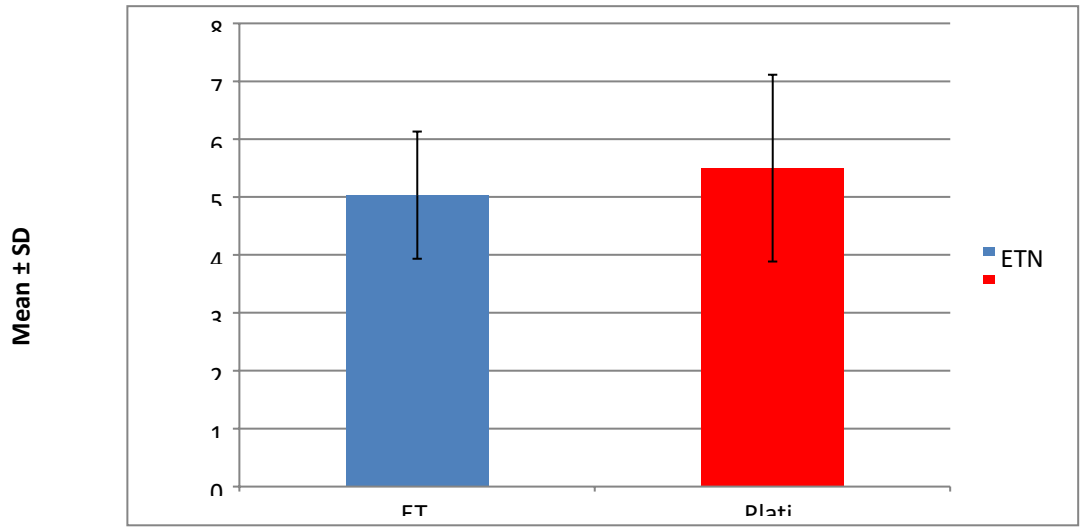
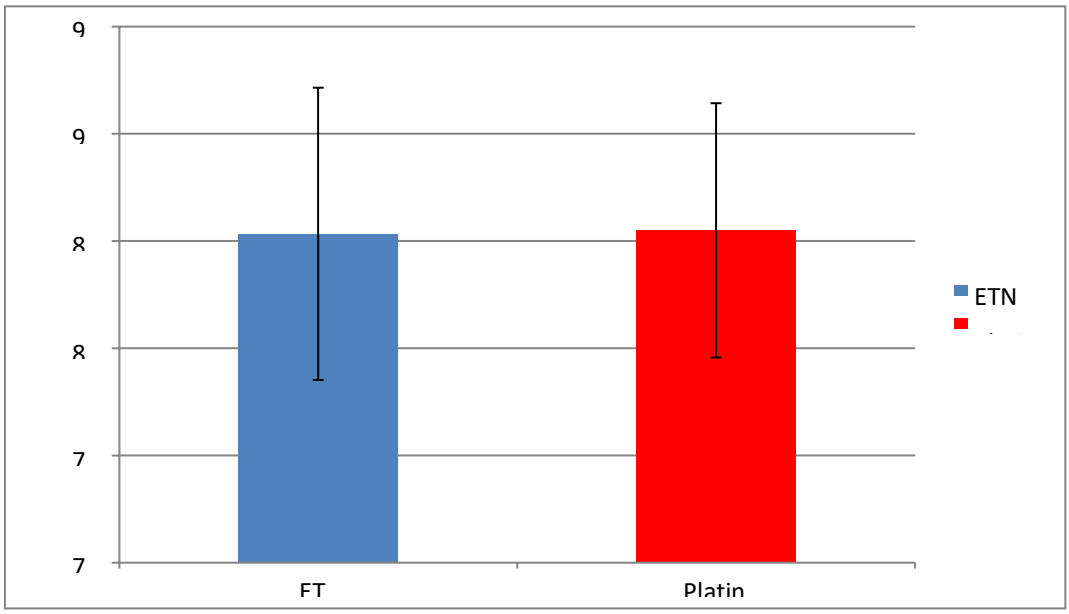


Table: Distribution of mean Ankle Score: MX PLAN

		Number	Mean	SD	Minimum	Maximum	Median	p-value
Ankle Score	ETN	30	85.3333	6.8145	70.0000	95.0000	85.0000	0.9198
	Plating	30	85.5000	5.9234	70.0000	95.0000	85.0000	

In ETN, the mean Ankle Score (mean± s.d.) of patients was 85.3333± 6.8145. In Plating, the mean Ankle Score (mean± s.d.) of patients was 85.5000± 5.9234. Distribution of mean Ankle Score with Mx Plan was not statistically significant(p=0.9198).



DISCUSSION

In our study, out of 60 patients, most of the patients were [29 out of 60 (48.3%)] was in age group of 31 – 40 years. Chaudhary p et al[6] (2015) A total of 120 patients (75 male and 45 female) were includedin the study. Fifty -five patients were less than 25 years age group followed by 30 patients between 25-40 yrs, 25 patients less than 25 age group and 10 patients more than 55 years. We showed that, Association of Superficial Infection with MX Plan was statistically significant (p=0.028266). Wound Dehiscence with MX Plan was not statistically significant (p=0.3125) and Plate Exposed, Implant Failure, Non-Union with MX Plan was not statistically significant (p=0.3125). Hali h et al[7] (2018) IMN achieved a significantly lower superficial infection incidence [MD=2.41, 95% CI (1.11, 5.23), P=0.03]. There were no significant differences between IMN and plating in deep infection [MD=1.43, 95% CI (0.51, 4.04), P=0.50]. This study was comparable from our study. Hu l et al[8](2019) A significant difference in superficial infection (RR = 0.29, 95%CI 0.13– 0.63, P = 0.002) more in plating. No significant difference was seen in non-union (RR = 2.17,95%CI 0.79–5.99, P = 0.15), deep infection (RR = 0.85, 95%CI 0.35–2.06, P = 0.72). This study was comparable from our study.

Only 5 (16.67%) patients had Malunion in EXPERT TIBIA NAIL and 2(6.67%) in plating it was statistically not significant (p=0.2269). Hali H et al [7](2018) There were no significant differences between IMN and plating in malunion [MD=0.88, 95% CI (0.50, 1.57), P=0.67]. This study was comparable from our study. Hu L et al[8] (2019) A significant difference in malunion (RR = 1.76, 95%CI 1.21–2.57, P = 0.003) noted between the IMN group and Plating group. Malunion was seen more in IMN. This study was not comparable from our study.

In PLATING 5 (16.67%) patients had Delayed Union and In EXPERT TIBIA NAIL, 3 (10.00%) patients had Delayed Union. Delayed Union with MX Plan was not statistically significant (p=0.4463). Hali H et al [7](2018) There were no significant differences between IMN and plating in delayed union [MD=0.69, 95% CI (0.26, 1.85). This study was comparable from our study. Hu L et al [8](2019) No significant difference was seen in delay union (RR = 0.92, 95%CI0.45–1.87, P = 0.82). This study was comparable from our study.

We observed that, the mean Time Elapsed from Injury to SX (D) was less [8.3333± 1.4933] in ETN compared to Plating [8.3667± 1.0662] but this was not statistically significant (p=0.9211). The mean OP Time (Min) was less [75.3333± 6.8195] in ETN compared to Plating [81.3333± 8.2309] which was statistically significant (p=0.0032). Vashisht d el at[9] showed better outcome in ILN in term of mean operating time. This study was comparable from our study. Hu L et al [8](2019) No significant difference was seen in the operation time (MD = − 10.46, 95%CI − 21.69–0.77, P = 0.07) in plating and IMN. This study was not comparable from our study.

In our study, the mean Blood Loss (ML) was more [135.2000± 18.0467] in Plating compared to ETN [108.8667± 14.5240] and it was statistically significant (p<0.0001).

It was found that, the mean Union (In Months) was less [5.0333± 1.0981] in ETN compared to Plating [5.5000± 1.6135] but this was not statistically significant (p=0.1955) Kumar Y et al [10] (2016) The average time for union was 16 weeks for nailing group and for plating group it was 18 weeks. Vashisht D et al[9] (2017) average time for union was 20.33 weeks in Interlocking nail group compared to 23.21 weeks in plating group which was significant (p value 0.011). this study was not comparable from our study.

The mean Ankle Score was lower [85.3333± 6.8145] in ETN compared to Plating[85.5000± 5.9234] though it was not statistically significant (p=0.9198) Bleeker nj et al[11] showed no differences were detected with

regard to functional outcomes(WSMD: -0.4, 95%CI -0.9 – 0.1). This study was comparable from our study.

CONCLUSION

Thus, based on the finding from our study we can conclude that both expert tibia nail andplating offer no significant advantage over each other in term of fracture union, delayed union, malunion, non-union, deep infection. But in term of lesser operating time, blood loss and lesser superficial infection Expert tibia nail offers slight more advantage over plating.

LIMITATIONS

As the study was time bound, patients were followed up for a period of only 6 month andlong term effect of these interventions like the difficulty level of removing the implant when required and any long term complications if any have to be assessed in future. Larger sample size, longer duration and multicentric study is recommended to strongly exert our conclusion.

CASE ILLUSTRATIONS

CASE-1

Grade I compound 43 A1 Nail
Number of distal screws :tri planar

PRE-OP
POST-OP

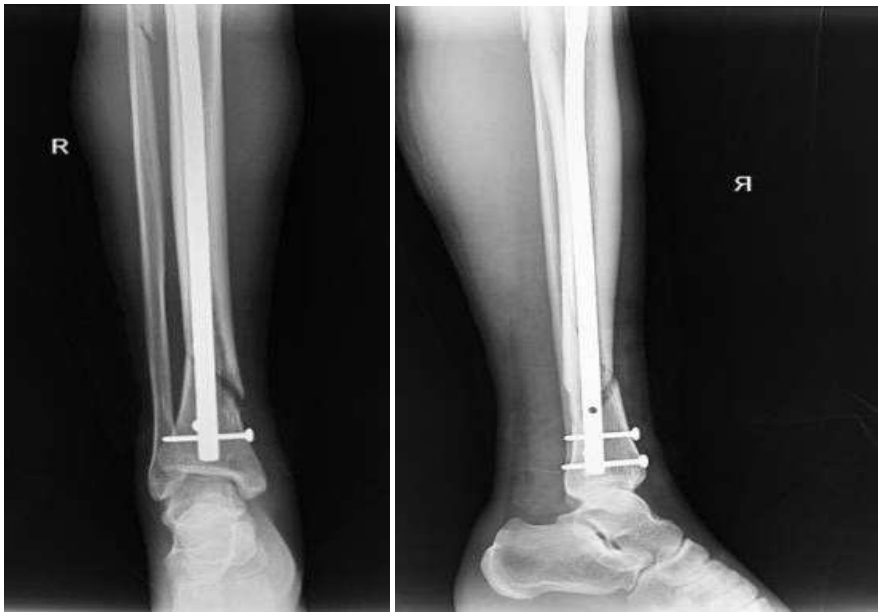
3 months follow up

6 MONTHS FOLLOW UP

CLINICAL OUTCOME

CASE -2
Grade I compound 43 a1
Number of distal screws :tri planar
PRE OP X RAYS

IMMEDIATE POSTOP



3 month follow up x ray

6 month follow up x ray

CLINICAL OUTCOME

Pre operative x-rays

Post operative x-rays

6 months follow up

CLINICAL OUTCOME


CASE -4
Grade I compound 43 A3
Medial approach
PREOP **IMMEDIATE POST OP**

Wound dehiscence – for wound dehiscence we applied negative suction pressure

5 month FOLLOW UP

Clinical pictures showing range of movements

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