

“A PROSPECTIVE STUDY OF COMPARISON BETWEEN FUNCTIONAL OUTCOME OF MULTIDIRECTIONAL INTERLOCKING INTRAMEDULLARY NAILING & LOCKING COMPRESSION PLATING IN EXTRA-ARTICULAR PROXIMAL TIBIA SHAFT FRACTURES”

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Aims and objective: To study the functional outcome and duration of union of metaphyseal-diaphyseal fractures of tibia treated with Multidirectional Interlocking Intramedullary Nailing (ETN: Expert Tibia Nail) and Locking Compression Plating and achieve Restoration of axis, length, and rotation of the lower leg ;Sufficient primary stability of the osteosynthesis for early functional aftercare to maintain joint mobility

Methodology: We conducted a prospective study to know which definitive surgical treatment option (nailing or plating) is better for extra-articular proximal tibia fracture. Subjects who have sustained proximal tibia extra-articular fracture and who are admitted in Raja Rajeswari Medical College and Hospital, Bangalore were the sources. The Sample Size is 30. With 15 in each group (group A Plating and group B Nailing) .The functional outcome was assessed using Klemm Borner Knee Scoring system during clinical follow up at 6 weeks, 3 months and at 6 months post surgery.

Results: Both Groups showed no significant difference in functional outcome assessed using Klemm Borner score, Klemm borner score in both groups initially at 6 weeks showed 26.7 % good results in plating group and 33.3 % good results in nailing group which progressed to give 60% excellent results in both groups and 26.7% good results in plating group and 33.3% in nailing group there were two complications encountered in our study patients post surgery which are osteomyelitis of tibia and non-union of proximal tibia fracture which were treated successfully accordingly.

Conclusion:: Considering lesser time for union, early weight bearing, lower chances of infection and lesser surgical duration, nailing seems to be more promising for extra articular proximal tibia fractures but Locking Compression Plating provides stable reduction in fractures like (AO41A2.2- simple metaphyseal oblique fracture in sagittal plane) where as the reduction using nailing system in these fractures is cumbersome due to working length for a nail is shorter to control angulation n rotational deformity in these fractures ; But overall in our study there is no significant difference between two mode of treatment as far as early postoperative mobilization, intra operative blood loss, Hospital stay, klemm borner score and complication . It can be concluded that both the technique were equally effective and choice of methods for extra- articular proximal tibia fractures fixation depends on the surgeons own experience .

KEYWORDS: ETN, locking compression plating, extra-articular proximal tibia fracture

INTRODUCTION : Extra-articular proximal tibial fractures account for 5–11 % of all tibial shaft fractures (2, 3) and often result from high-velocity trauma. They lead to complex tissue injuries involving bone and surrounding soft tissues . (2)

Treatment of proximal tibial fractures is challenging because of limited soft tissue cover and less vascularity. There are various treatment options for these fractures starting from closed reduction and casting to open reduction and internal fixation with plate. (4)

Increased incidence of associated complications have made these fractures particularly problematic. Both conservative and operative management options are available for these fractures but conservative management have resulted in complications like non-union, malunion, stiffness of joints or rotational instability. So operative management is preferred over conservative management in these patients. The optimal method of surgical treatment for fractures of proximal third tibial shaft remains debatable. (5) Options include intramedullary implant, half-pin external fixation, hybrid or thin-wire external fixation, plate fixation, or a combination of these techniques (6, 7). In recent years, closed reduction with minimally invasive plating and locked intramedullary nailing have both become widely used treatment modalities for proximal and distal tibial metaphyseal fractures (8,9), despite the absence of any conclusive proof of the superiority of one modality over the other.

Extraarticular fractures of the proximal third of the tibial shaft are somewhat uncommon, Intramedullary nailing has become the standard of care for most displaced tibial diaphyseal fractures but proximal tibial fractures can be much more difficult to treat with intramedullary nailing than other tibial shaft fractures. These fractures frequently result in malunion with apex anterior and valgus deformities. Treatment of tibial fracture with intramedullary devices is considered ideal because this method spares the extra articular blood supply without opening the fracture site and thus reduces the chance of infection. In recent years minimally invasive plating with locking plates for fixation of closed extraarticular proximal tibial fracture has gained popularity. (10) In recent years, closed reduction with minimally invasive plating and locked intramedullary nailing have both become widely used treatment modalities for proximal and distal tibial metaphyseal fractures, despite the absence of any conclusive proof of the superiority of one modality over the other. (12)

Recent design changes to intramedullary nails (IMNs) and adjunctive fixation techniques like Expert Tibia Nail with Multidirectional Interlocking facility have definitely increased the popularity of IMN for the treatment of this fracture as this nail provides rotational and angular stability because of this multidirectional locking mode . Similarly the development of percutaneous biological plating has allowed surgeons to treat these complex fractures without the need for large incisions or fear of soft-tissue stripping with subsequent failure due to infection and non-union. In most instances, intramedullary nailing has become the method of choice for the fixation of diaphyseal tibial fractures and has been extended to the treatment of proximal fractures. Minimally invasive plate osteosynthesis techniques have recently been applied to fractures of proximal tibia. Recently, the use of plate fixation utilizing minimally invasive techniques has been put forward as one way maintaining alignment in proximal tibial fractures. (13)

AIMS AND OBJECTIVE :

AIM: To study the functional outcome and duration of union of metaphyseal-diaphyseal fractures of tibia treated with Multidirectional Interlocking Intramedullary Nailing and Locking Compression Plating .

OBJECTIVES:

- Restoration of axis, length, and rotation of the lower leg.
- Sufficient primary stability of the osteosynthesis for functional aftercare.

- Early functional aftercare to maintain joint mobility.

STUDY DURATION

October 2019 to August 2021 in Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India.

MATERIAL AND METHODS :

This is a prospective study comparing the functional outcome of Patients with Extra-articular proximal tibia fracture who were admitted in Rajarajeswari Medical College and Hospitals, Bengaluru and operated in two groups ; Group I by Open Reduction and Internal Fixation with Locking Compression Plate and Group II by Closed reduction and Internal Fixation with Multidirectional Interlocking Intra medullary nail (Expert Tibia Nail) . Total of 30 patients were taken into study based on previous statistical data of incidence of the fracture of proximal tibia admitted in our hospital and these patients divided into two groups of treatment mentioned as above. These patients were followed up at 1.5months, 3 months and 6 months and assessed by clinically and radiologically using the KLEM BORNER score.

INCLUSION CRITERIA:

- ❖ The patient with fractures of proximal Tibia according to AO classification
 - 41 A1: AVULSION TYPE
 - 41 A2: METAPHYSEAL SIMPLE
 - 41 A3: METAPHYSEAL MULTIFRAGMENTARY
- ❖ Age limit: 18 years onwards
- ❖ Both gender
- ❖ skeletally mature patients with:
 - i.) Metaphyseo-diaphyseal fractures of proximal tibia
 - ii.) Segmental fractures of tibia or combination of these one of which fracture lies in the proximal one third of tibia.

Exclusion criteria:

- ❖ Patients with pathological fractures.
- ❖ Patients with intraarticular Extension of fractures
- ❖ Skeletally immature patients
- ❖ Gustillo Anderson Grade IIIB and III C open fractures

STATISTICAL ANALYSIS

SPSS (Statistical Package For Social Sciences) version 20. (IBM SPASS statistics [IBM corp. released 2011] was used to perform the statistical analysis

- Data was entered in the excel spread sheet.
- Descriptive statistics of the explanatory and outcome variables were calculated by mean, standard deviation for quantitative variables, frequency and proportions for qualitative variables.
- Inferential statistics like
 - Chi-square test was applied for qualitative variables to find the association with groups.
 - Independent sample t test was applied to compare the quantitative variables (age, TLC, duration of hospital stay, Time for union, length of incision, duration of surgery, blood loss, VAS score on POD 1) between the groups.
- The level of significance is set at 5%

RESULTS :**TABLE 1: DISTRIBUTION OF THE SUBJECTS BASED ON AGE GROUPS**

Age groups		Groups		Total
		LCP	ETN	
19 to 25 yrs	Count	2	1	3
	%	13.3%	6.7%	10.0%
26 to 35 yrs	Count	4	8	12
	%	26.7%	53.3%	40.0%
36 to 45 yrs	Count	5	3	8
	%	33.3%	20.0%	26.7%
> 45 yrs	Count	4	3	7
	%	26.7%	20.0%	23.3%
Total	Count	15	15	30
	%	100.0%	100.0%	100.0%
Chi-square value-2.3				
p value-0.51				

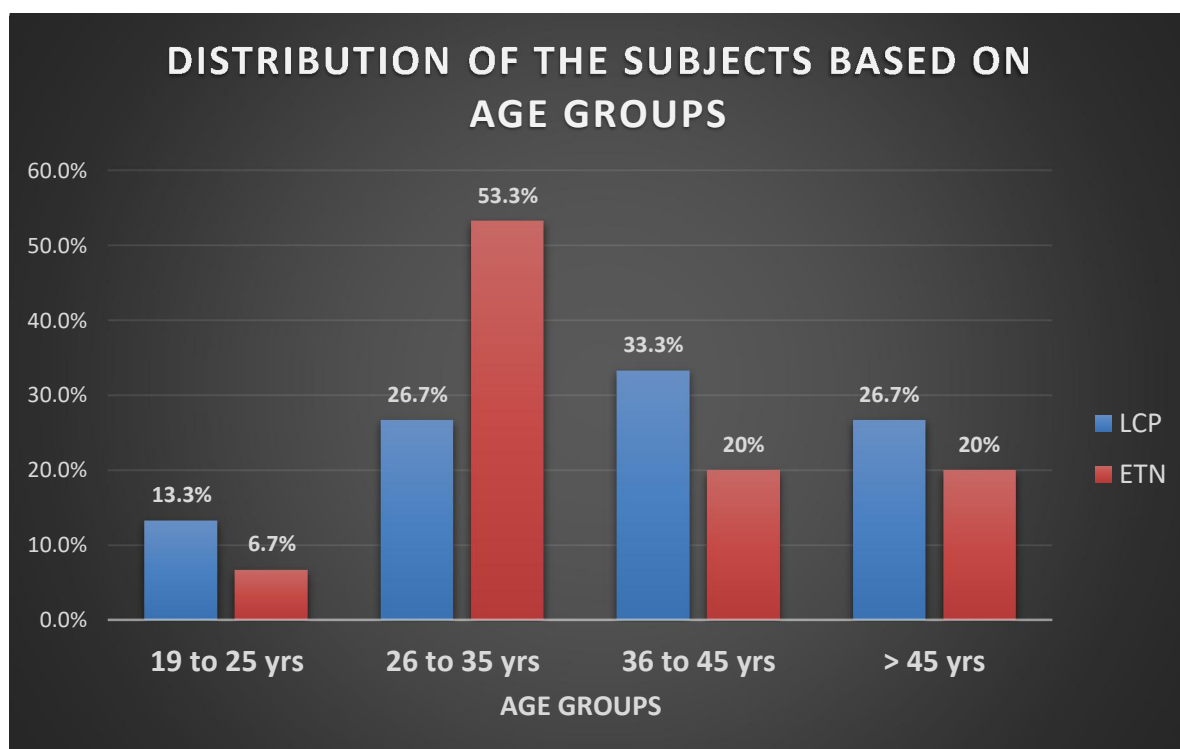


TABLE 2: DISTRIBUTION OF THE SUBJECTS BASED ON GENDER

Gender		Groups		Total
		LCP	ETN	
Females	Count	3	2	5
	%	20.0%	13.3%	16.7%
Males	Count	12	13	25
	%	80.0%	86.7%	83.3%
Total	Count	15	15	30
	%	100.0%	100.0%	100.0%
Chi-square value- 0.24				
p value-0.62				

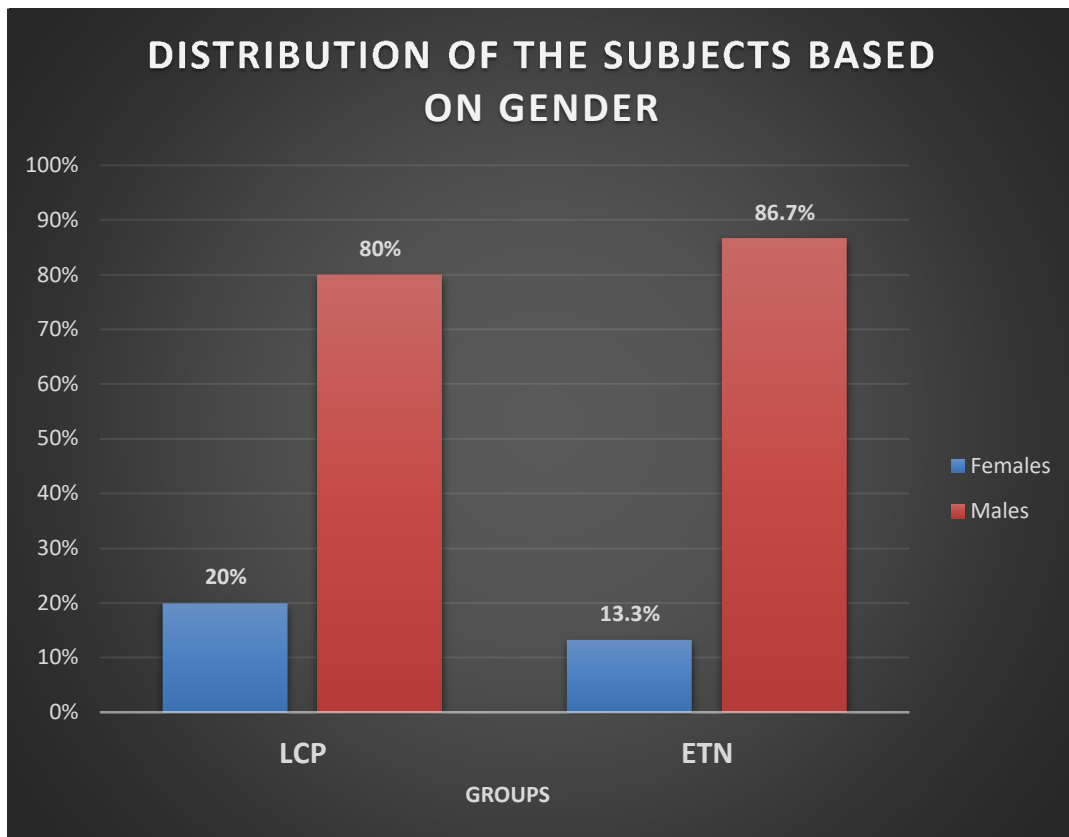


TABLE 3: DISTRIBUTION OF THE SUBJECTS BASED ON FRACTURE:

Fracture		Groups	Total
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classification		LCP	ETN	
41A2.1	Count	4	5	9
	%	26.66%	33.33%	30%
41A2.2	Count	3	1	4
	%	20.0%	6.6%	13.3%
41A2.3	Count	2	3	5
	%	13.3%	20.0%	16.7%
41A3.1	Count	3	3	6
	%	20%	20%	20%
41A3.2	Count	2	2	4
	%	13.33%	13.33%	13.3%
41A3.3	Count	1	1	2
	%	6.7%	6.7%	6.7%
Total	Count	15	15	30
	%	100.0%	100.0%	100.0%
Chi-square value- 11.31				
p value-0.046*				

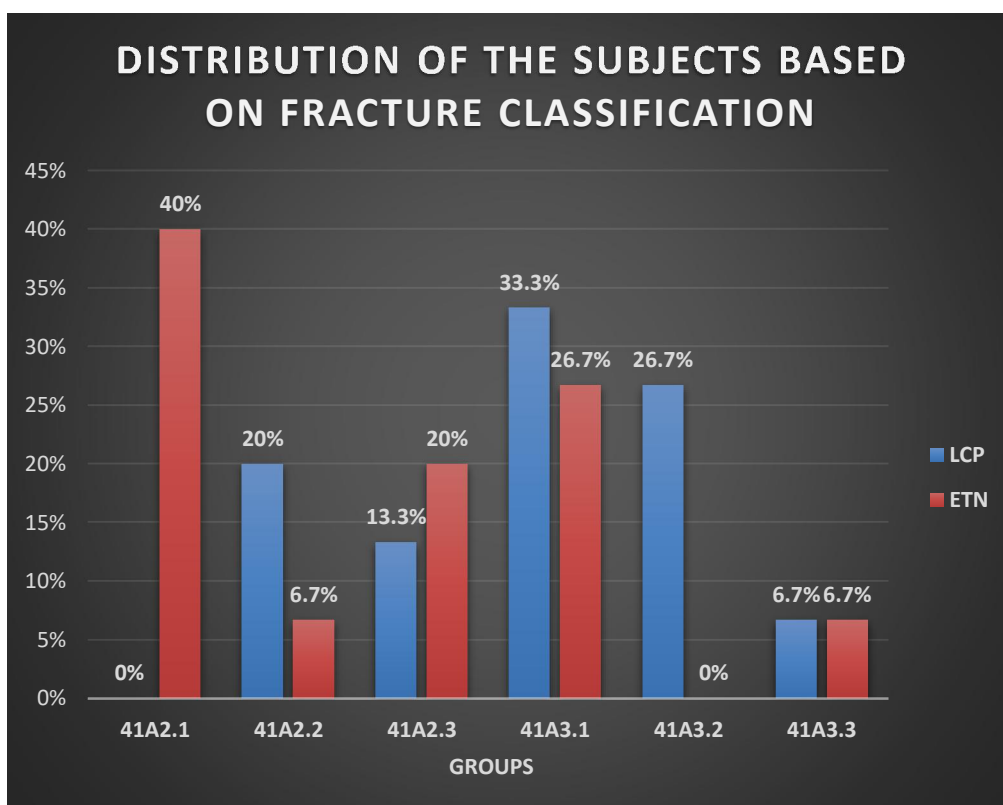


TABLE 4: DISTRIBUTION OF THE SUBJECTS BASED ON COMPLICATIONS :

Complications		Groups		Total
		LCP	ETN	
DELAYED UNION	Count	2	1	3
	%	13.3%	6.7%	10.0%
INFECTION	Count	1	1	2
	%	6.7%	6.7%	6.7%
MALUNION	Count	2	3	5
	%	13.3%	20.0%	16.7%
NIL	Count	9	9	18
	%	60.0%	60.0%	60.0%
WOUND DEHISCENCE	Count	1	1	2
	%	6.7%	6.7%	6.7%
Total	Count	15	15	30
	%	100.0%	100.0%	100.0%
Chi-square value- 0.53				
p value-0.97				

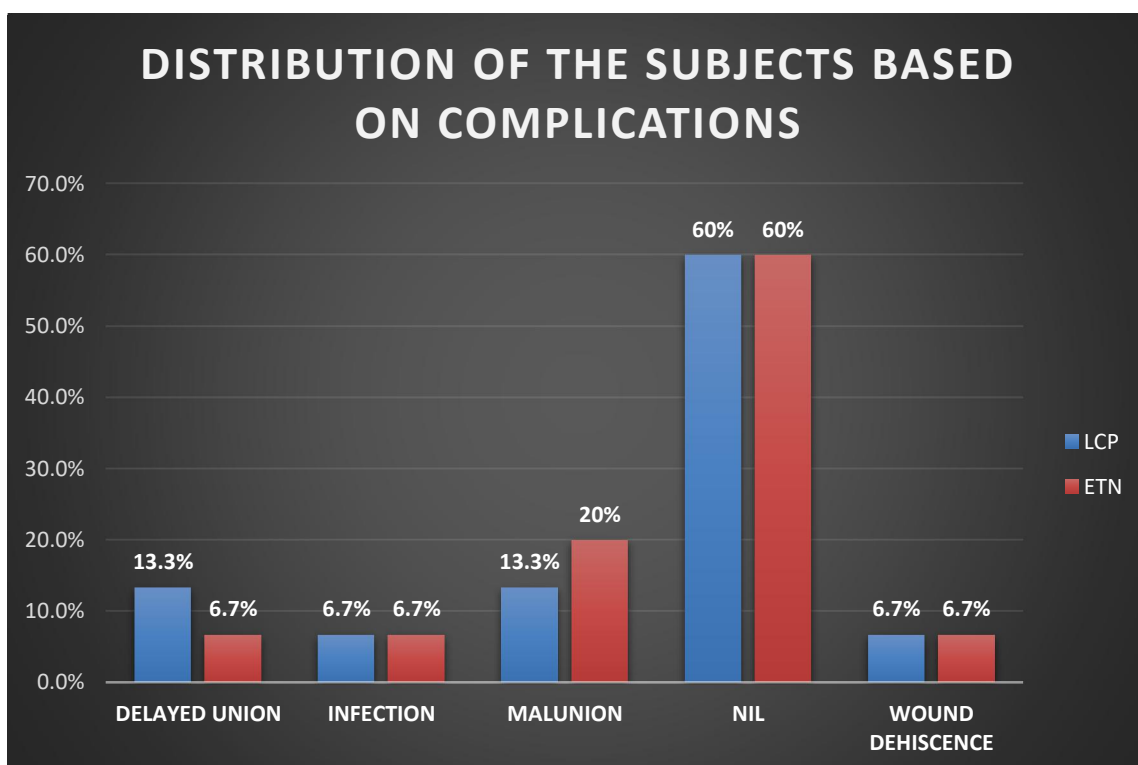
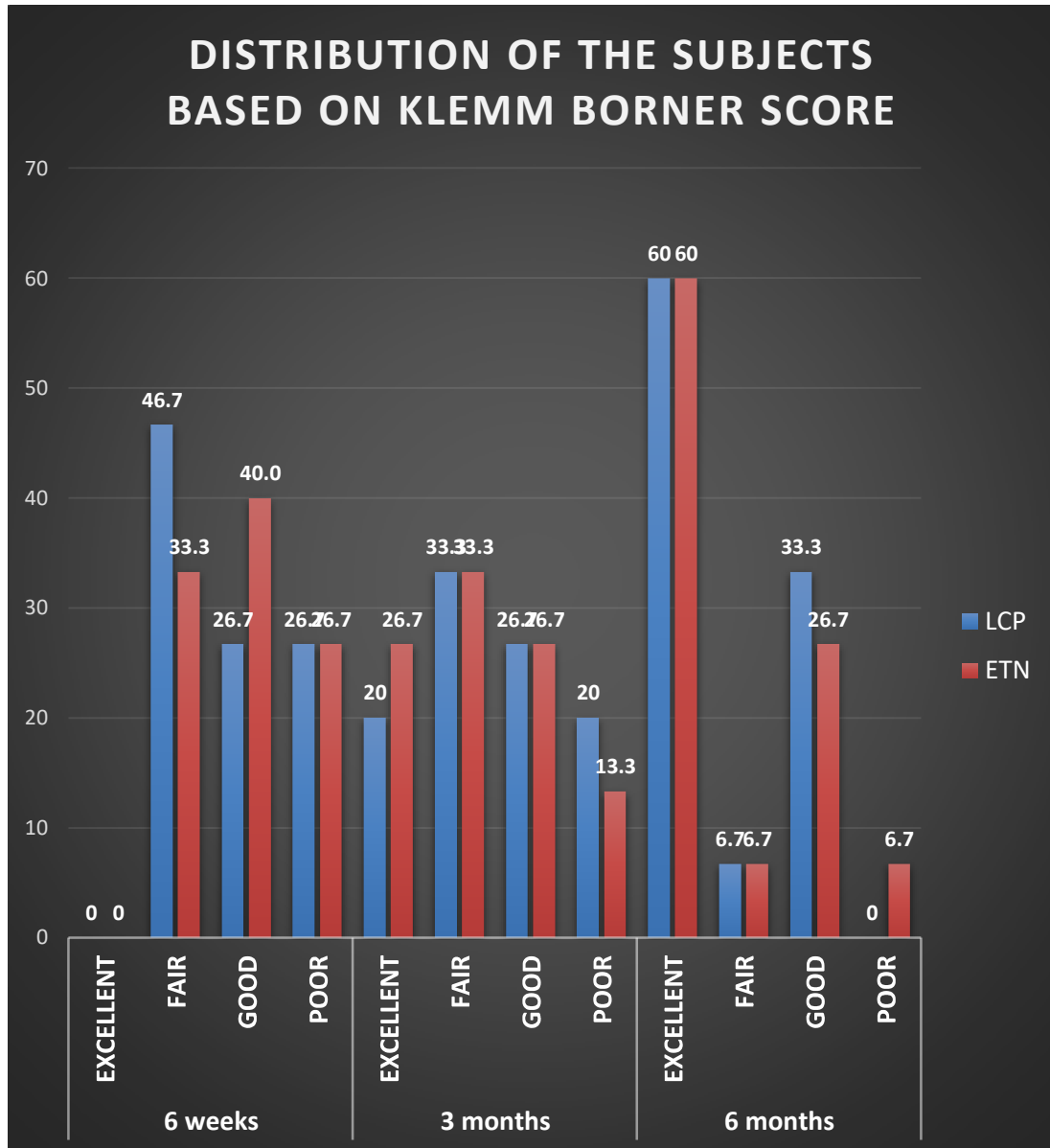


TABLE 5: DISTRIBUTION OF THE SUBJECTS BASED ON KLEMM BORNER SCORE

KLEMM BORNER SCORE			Groups		Total	Chi-square value	p value
			LCP	ETN			
6 WEEKS	FAIR	Count	7	5	12	0.73	0.69
		%	46.7%	33.3%	40.0%		
	GOOD	Count	4	6	10		
		%	26.7%	40.0%	33.3%		
	POOR	Count	4	4	8		
		%	26.7%	26.7%	26.7%		
3 months	EXCELLENT	Count	3	4	7	0.34	0.95
		%	20.0%	26.7%	23.3%		
	FAIR	Count	5	5	10		
		%	33.3%	33.3%	33.3%		
	GOOD	Count	4	4	8		
		%	26.7%	26.7%	26.7%		
	POOR	Count	3	2	5		
		%	20.0%	13.3%	16.7%		
6 months	EXCELLENT	Count	9	9	18	1.11	0.77
		%	60.0%	60.0%	60.0%		
	FAIR	Count	1	1	2		
		%	6.7%	6.7%	6.7%		
	GOOD	Count	5	4	9		
		%	33.3%	26.7%	30.0%		
	POOR	Count	0	1	1		
		%	0.0%	6.7%	3.3%		



CLINICAL ILLUSTRATION :
GROUP 1 : ORIF with Locking Compression Plate :
Intra op Pictures :



APPROACH : KANDEMIR and MACLEAN
INCISION: curvilinear incision extending from 2-3cm above proximal to joint line till Tibial tuberosity connecting Gerdy's Tubercle .



**XRAYS OF GROUP A PATIENT (Locking Compression Plating) :
PRE OP XRAY :**



POST OPERATIVE X-RAYS :



POST OP XRAY AT 6 WEEKS

POST OP XRAY AT 3MONTHS

POST OP XRAY AT 6 MONTHS

CLINICAL IMAGES OF FOLLOW UP OF GROUP 1 (LCP) PATIENT :





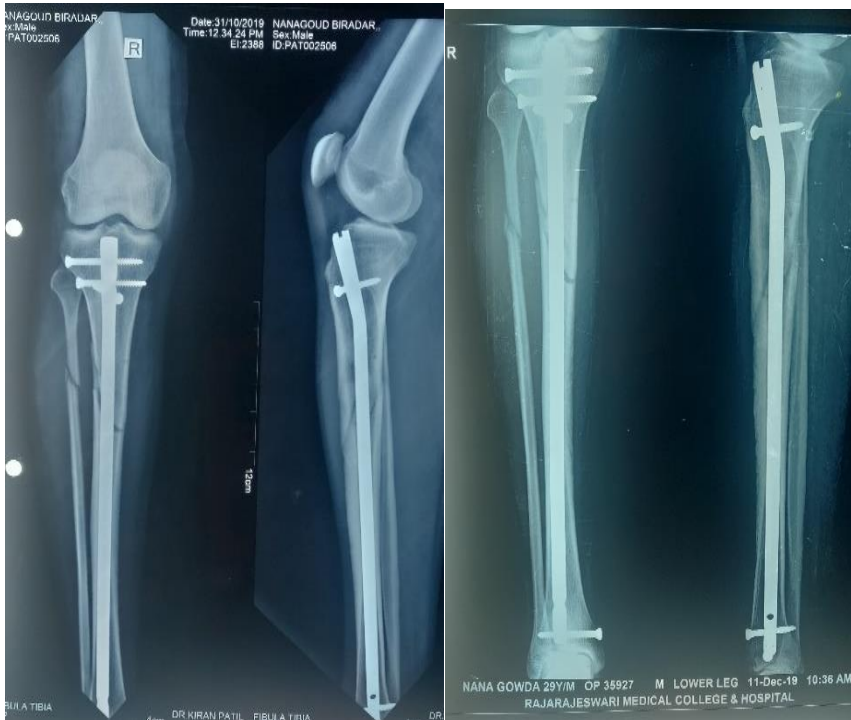
**GROUP 2 : CRIF WITH EXPERT TIBIA NAIL :
INTRA OP PICTURE:**



RADIOLOGICAL STUDY OF GROUP 2 : CRIF with ETN :



Figure 1 PRE-OPERATIVE XRAY : OTA 41A3 EXTRA-ARTICULAR PROXIMAL TIBIA FRACTURE



POS

POST OP XRAY AT 6 WEEKS

POST OP XRAY AT 3 MONTHS

POST OP XRAY AT 6 MONTHS

CLINICAL IMAGES OF PATIENT FROM GROUP 2 NAILING (ETN) :





COMPLICATIONS :

CASE 1 : DELAYED UNION:

A 29yr old male who underwent CRIF with Multidirectional interlocking intramedullary nail (expert tibia nail) for closed Right side extra-articular proximal tibia fracture where patient showed no signs of union radiologically 3 months post surgery for which he was taken up for dynamization and later post Dynamization was followed up for 6 months and showed no radiological signs of union . This time the patient was taken up for autologous bone marrow administration obtained from iliac crest into the fracture site percutaneously .





Radiological union established 3 months autologous bone marrow administration into the fracture site .

DISCUSSION: In our study (Prospective Comparative study) was conducted in Rajarajeswari Medical College and Hospitals, Bengaluru during the period from October 2019 to May 2021 on 30 patients with extra-articular proximal tibia fractures and divided randomly into two groups whom operative line of management was considered in the form of either by CRIF with Multidirectional locking Intra medullary nail or ORIF with anatomical Locking Compression Plating and analysed . Mean age of the 15 patients who were treated with LCP was 38.40 years with minimum age 18 and maximum age 63 yrs and the mean age of 15 patients who underwent fixation with Intramedullary nail was 38.30 years with minimum age 18 and maximum age 78 yrs. The age difference between two groups was not statistically significant ($p > 0.05$). The aim of assessing age is to estimate their ability to comply with rehabilitation protocol. The average age of patients in our series is almost similar to those reported in literature viz. 34.3 (Abdi R(51)), 41.03 yrs (Panse JB(39)). In 2018 Gupta S et al (10) conducted a study and concluded that Age group affected were in the range of 19-59 years. 20 people out of 30 were in the age group of 31-50 years indicating that tibial fractures occur in active people, indicating that now a days, young population is getting these fracture because of increasing incidence of road traffic accident.

Authors	Mean Age	
	Intramedullary nail	Plate
Jain S et al (51)	36.02 yrs	40.08 yrs
Meena RC(13)	39 yrs	36 yrs
Pandey A(7)	39 yrs	36 yrs
Patel Z(9)	38 yrs	34 yrs
Our Study	38.30 yrs	38.40 yrs

Sex: In our study sex distribution of male and female was 90 and 10 % respectively showing male preponderance. Other studies done on similar topic also have almost similar findings such as study by **Chaudhary P et al(39)** shows 62.5% male, Study by **Gupta S et al(10)** shows 80% male. The reason could be males being the earning member of the family causing the need to travel more, thereby increasing the chances of accidents. Females usually are at home and travel only for social purposes thereby decreasing the incidence of accidents among them

AUTHORS	TOTAL CASES	MALE (%)	FEMALE (%)
Abdi R et al (40)	33	31 (93.93%)	2 (6.07%)
Jain S (41)	62	56 (90.32%)	6 (9.68%)
Shah S (42)	56	42 (75%)	14 (25%)
Present study	30	25 (83.33%)	5 (16.66%)

Comorbidity:

In our study 57% of study subjects had no comorbidity whereas rest 43% had some comorbidity such as 17% had hypertension, 17% had DM, 7% had hypothyroidism and 2% had epilepsy. Co-morbidity play role in weak bones and may result in increased chances of fracture in cases of fall or low force impact. Mode of trauma and Associated injury Domestic fall like slip and fall, missed step caused fracture of proximal tibia in 10 % of patients, 10% due to assault and 86.6% suffered from RTA and 3.3% fall from height . Similar observation made by Shah S et al who observed 65.2% RTA and 32.1% Domestic fall, **Gupta S et al(10)** observed 70% and 30% patients who sustained RTA and domestic fall respectively. Road traffic accidents are one of the major causes of male population having proximal tibial fracture. In a study by **Chaudhary p et al(39)** they also concluded that Road traffic accident is commonest mode of injury followed by fall from height. Study by **Sharma AK et al(43)** also concluded that in plating group 90% fracture were due to RTA whereas in nailing group 80% fracture were due to RTA. Study by **Pandey A et al (14)** also concluded that 8/21 were RTA, 11/21 fall. This could be because 2 wheeler is maximally used for travelling, being most economical and convenient for the middle class patients, to add to it 2 wheelers are

unstable as compared to four wheeler thereby increasing the chances of accidents amongst them. While riding two wheelers the rider keeps knees and hip in 90 degrees flexion thereby increasing the chances of direct impact on proximal part of tibia during collision, thereby increasing chances of fractures. Fall from height has contributed towards 10% of total injuries where in direct impact of the lower end of femur over tibial plateau results in fracture of upper tibia.

Fracture classification :

Fracture were classified by AO/OTA classification, 41-A2 class was dominating in our study with total 18/30 (60%) patients, and 12 (40%) patients with 41-A3 type, Other similar studies such as **Shah S et al (42)** concluded that In this study ~45% of the patients had AO-A type (Extra-articular) fractures, ~10% of the patients had AO-B type (Partially-articular) fractures while ~45% of the patients had AO-C type (Intra-articular) fractures. Study by **Pandey A et al (14)** noted that 61.9% subjects had 41-A3 whereas 38.1% subjects had 41-A2 type of tibial fracture. Study by **Sharma AK et al (43)** found that total 20 fractures in plating Group out of which most of the fractures (65%) fall into type 41 A2 of AO classification of proximal tibial fractures. In Nail group also most of the fractures (60%) fall into type 41 A2 of AO classification of proximal tibial fractures.

HOSPITAL STAY :

Mean Hospital stay in our study group 1 (Plating) and group 2(nailing) were 8.45 (7-10 days) and 4.75 days (3-5) which is comparable to study done by **Meena RC et al(13)** 5.3 days and 4.1 days, **Pandey A et al(14)** 5.3 and 4.1, Our study had less hospital stay compared to study by **Jain S et al(41)** 19.1 days and 11.3 days. Whereas **Gupta S et al(10)** found mean hospital stay as 7.8 days in plating group whereas 4.1 days in nailing group. In study done by **Patel Z et al (44)** mean hospital stay was 4 days in plating group whereas 2 days in nailing group.

AUTHORS	GROUP1(LCP)	GROUP 2(NAILING)
Meena RC et al (13)	5.3days	4.1 days
Pandey A et al (14)	5.3 days	4.1 days
Jain S et al (41)	19.1 days	11.3 days
Gupta S et al (10)	7.8 days	4.1 days
Patel Z et al (44)	4 days	2 days
Present Study	8.45 (7-10 days)	4.75 (3-5 days)

Intraoperative blood loss :

Mean blood loss in group 1(plating) and group 2 (nailing) were 138.66ml and 128.33 ml respectively. **Jain S et al (41)** 100 -150 ml and 50-100 ml, **Chaudhary P et al (39)** 95 and 105 ml, **Pandey A et al (14)** 100-200 ml and 50-100 ml, had Less blood loss than our study and **Saied A et al (45)** 338±95 ml and 353±92 ml had slightly more blood loss than our study. Less invasiveness of IMN implants causes less blood and less soft tissue handling.

AUTHOR	BLOOD LOSS (in mL)	
	GROUP1(LCP)	GROUP 2(NAILING)
Jain S et al (41)	100-150	50-100
Chaudhary P et al (39)	105	95
Pandey A et al (14)	100-200	50-100
Saied A et al (45)	338 \pm 98	353 \pm 92
Present study	138.66	128.33

Duration of surgery :

Operative time in our study group 1(LCP) and 2(IMN) were 131.40min (100-175min) and 95.90min (90-160min) respectively. Mean Operating time in our study is higher than other studies Chaudhary P et al (39) 70 and 60 min, Jain S et al (41) 72.8 and 61.25 min, and Meena RC et al (12) 87.91 and 81.57 min for the Plating and IMN respectively. Pandey A et al (14) in their study for plate 72.8 min and for nailing 61.25 min, Patel Z et al (44) 100 ml for grp 1 and 80 min for grp 2. Gupta S et al need for 82.57 min and 76.70 min for nailing.

AUTHOR	DURATION OF SURGERY (minutes)	
	GROUP1(LCP)	GROUP 2(NAILING)
Chaudhary P et al (39)	70	60
Jain S et al (41)	72.8	61.25
Meena RC et al (12)	87.91	81.57
Present study	128.33	138.67

Post operative weight bearing :

Limb movement started after 3 days when pain subsided. Partial and Full weight bearing Allowed earlier in IMN groups than LCP . 60% Subjects had immediate weight bearing in LCP and 67% in IMN Group . IMN implants have load sharing property which allows early mobilization compared to load bearing extramedullary implants. In our study difference of partial and full weight bearing were statistically not significant between two groups.

Radiological union :

In our study average radiological union time for group 1(LCP) was 18.67 weeks and 16.13 weeks for group 2(nailing), union time of our study is lesser than study by Saied A et al(50) it was found that The average time for union in the plating cohort was 4.30 ± 1.48 months, and in the intramedullary nailing cohort, it was 4.34 ± 1.45 months. The difference between cohorts was not significant ($P = 0.13$). There are many studies which shows union time similar to our studies. **Jain S et al(41)** found Union time (Weeks) 16.2 and 18.1, **Meena RC et al (12)** found Union time (weeks) or time required before full weight-bearing (weeks) 22.84 (16–34) and 18.26 (10–30), **Pandey A et al (14)** noted 22.84 week for 1st grp and 18.26 week in 2nd grp, **Gupta S et al (10)** found 16.7 and 14.2 week, **Patel Z et al (44)** noted 17 and 20 week, **Sharma AK et al (43)** found the average time to union was 20 weeks (16 to 36 weeks) for plating group and 16.55 weeks (15 to 24 weeks) for nailing group.

AUTHOR	RADIOLOGICAL UNION(weeks)	
	GROUP1(LCP)	GROUP 2(NAILING)
Saied A et al	4.58 +/-1.48 month	4.34 ± 1.45 months
Jain S et al	16.3	18.1
Meena RC et al	22.84	18.26
Present study	18.67	16.13

Complication

In our study in group 1 i.e plating group 13.33% study subjects had malunion and 7% had infection, 13.33% subjects had delayed union , whereas in nailing group 20% had malunion, 7% had infection and 7% subjects each had delayed union, implant failure and wound dehiscence were in 5% study subjects each respectively. Plating has higher chances of skin infection and superficial necrosis which could be due to extensive dissection needed in plating and then type of fracture wherein plating is used being high velocity injury. Similar study done by **Sharma AK et al (43)** concluded that, 2 patients in Plating group developed deep infection. They were treated with debridement and IV antibiotics and infection was controlled. One patient had late postoperative infection i.e., at the end of 12 months and was treated with implant removal. In nail group, one patient developed superficial infection which was managed with I.V. antibiotics for 3 weeks with alternate day dressings. In the study by **Pandey A et al (14)** noted that in present study rate of mal union was higher in Group I treated with IMN as compared to the Group II treated with Plating 14.8% (1/7) cases develop malunion in follow up. In study by **Gupta S et al (10)** they found that Surgical site infections were seen in three patients in the group B, which resolved with debridement and antibiotics and no surgical intervention was required. No infection was reported in group A. Delayed union was seen in 3 cases of group A and was managed by dynamization. No patient developed non-union in group A. There was non-union in one patient in the group B; bone grafting was done in that case, which eventually led to fracture healing. In study by **Patel Z et al (44)** concluded that The plating group also had 5 patients of malunion (16%), but the

difference was not statistically significant. An important character of proximal tibia fractures is gross swelling around the fracture site. It is one of the character which was encountered in 90% of the proximal tibia fracture.

CONCLUSION

We concluded from our study that intramedullary nail is superior to minimally invasive plating in terms of brevity of hospital stay and speed of union along with early full weight-bearing, but there was no clear advantage of either technique in terms of operative time, infection rate, range of motion of the knee, and rates of malunion and nonunion. Both implants yielded promising results with extra-articular proximal tibial fractures and provided rigid fixation that prevented secondary fracture collapse.

It is concluded that both the technique were equally effective and choice of methods for Extra-articular proximal tibia fractures fixation depends on the surgeon own experience.

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