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Evaluation of outcome, safety, and efficacy of diaphyseal fracture of femur and tibia in children - treated by Titanium Elastic Nailing System (TENS)

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ABSTRACT:
The importance of this biological and minimally invasive fracture treatment is to achieve anatomical reduction and stabilization, which is not expected by conservative methods. The biological principle of the elastic nail is based on symmetrical bracing action of two elastic nails inserted into the metaphysis across the fracture site, each of which bears against the inner bone surface at 3 points. Diaphyseal fractures of the femur and tibia accounts for 10-15% of all paediatric fractures. This novel technique of elastic stable intramedullary nailing (ESIN) has dramatically changed the treatment of pediatric fractures. The objective of current study was evaluate the outcome, safety and efficacy of diaphysis fracture of femur and tibia in children - treated by Titanium Elastic Nailing System (TENS). This observational, interventional study was conducted in 30 patients in the age group of 6-12 years old children, with fractures of long bones with Inclusion criteria: 6-12 years of age, Diaphyseal fractures, closed fractures, Ipsilateral fractures, Fractures with head injury and exclusion criteria: of Metaphyseal fractures, Compound fractures, Pathological fractures, Age group below 6 years and above 12 years. TENS technique was used to stabilize these fractures. Patients were followed-up clinically as well as radio-logically at 3,6,12 and 24 weeks and evaluated by Flynn criteria. The current study had shown excellent results in 17 fractures (77.3%), good in 3 fractures (13.6%) and 2 cases has shown (9%) poor in femur fractures. Tibia results were excellent in 5 fractures (62.5%) and good in 3 fractures (37.5%) with no poor results.
Conclusion: This study concludes that Titanium Elastic Nail System (TENS) technique is an ideal treatment method for treatment of pediatric Diaphyseal fractures of lower limb bones.
Keywords: Diaphyseal fractures, Titanium Elastic Nail System, femur.

INTRODUCTION

The diaphyseal fractures of the femur and tibia accounts for 10-15% of all paediatrics fractures. Long bone fractures in children are usually the result of trauma [1,2]. Femoraldiaphyseal fractures are 2nd most common and diaphyseal fractures of tibia are third most common. These fractures havesex ratio of 2:1[3].The conservative methods ofHip Spica in femur and closed reduction with casting in tibia is the acceptable standard of care for young children (<6 years), but in older children complications such as mal-union, shortening, angulation[6]joint stiffness, angulation, shortening, delay in functional recovery are not uncommon. Moreover conservative treatment results in prolonged hospitalization causing moresocio-economic burden to the family [7]. There is a growing trend towards surgical management which includes external fixation, compression plating and intramedullary nailing either with rigid or flexible nails.[8] The new technique of

elastic stable intramedullary nailing (ESIN) using titanium, which was developed by Metaizeau and team from Nancy, France in 1982.[9]has dramatically changed the treatment of pediatric fractures.

In general, fractures fall into three categories:

- Without deviation
- Oblique or spiral
- Transverse and comminuted with deviation

The rotational deformities do not undergo remodeling and angular deformities could correct to certain limit depending upon age of child.The external rotation deformity is better tolerated than in internal rotation.[10]However,immature bones, open physis, available parental care, and growth potential should be considered in treatment planning plan in children.[11,12]

TREATMENT MODALITIES FOR LONG BONE FRACTURES

Femoral shaft fracture is an incapacitating pediatric injury.[13,14]Majority, treatment options vary according to the surgeon's preferences,[15] but near skeletal maturity, treatment with intramedullary nails is well establishedfor accurate reduction and to prevent angular deformity, which is not correctable by growth.[16]

ESIN or titanium elastic nail system (TENS) is a recent load sharing implant, which allows stable closed reduction, maintenance of reduction and early mobilization[17], leading to develop early bridging callus with rapid restoration of bone continuity.[9] TENS is advantageous over other surgical methods because it is closed and simple that doesn't violate open physis and there is no stripping of periosteum as well as there is no disturbance of fracture hematoma, hence lessens the risk of infection. [18] Micro-motion conferred by the elasticity of the fixation and limiting stress shielding promotes faster external bridging callus formation. Titanium also has excellent biocompatibility.[19]

The aim of this biological, minimally invasive fracture treatment is to achieve anatomical reduction and fracture stabilization. The biological principle of the elastic nail is based on symmetrical bracing action of two elastic nails inserted into the metaphysis, each of which bears against the inner bone surface at 3 points. This produces the following four properties, which are required for optimal results: flexural stability, axial stability, rotational stability and translational stability.[20]

AIMS AND OBJECTIVES

Present study was conducted in Department of Orthopaedics, Government Medical College Patiala, to evaluate the outcome, safety and efficacy of diaphysis fracture of femur and tibia in children - treated by Titanium Elastic Nailing System (TENS).

MATERIALS AND METHODS

This observational, interventionalstudy includes 30 patients in the age group of 6-12years, with fractures of long bones of lower extremity.

Inclusion criteria: 6-12 years of age, Diaphyseal fractures, Simple fractures,ipsilateral fractures, Fractures with head injury

Exclusion criteria: Metaphyseal fractures, Compound fractures, Pathological fractures, Age group below 6 years and above 12 years.

After informed consent was taken, thedetailed history taking with clinical examination and relevant investigations including x-ray and blood was done. PAC (pre-anesthetic check- up) was done for fitness for surgery.

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Method / Technique

With patient in free supine position or on a fracture table with a traction boot. Fracture reduction was done manually under image intensifier,which was kept on the lateral side of the affected femur for AP and lateral views of the leg and allowing easy access to surgeon on bothaspects of the limb. After preparation and draping of injured leg. A 2.5cm incision is made distally on both medial and lateral sides and 3cm away from the physis. The bone was opened with drill bits on the both sites at the same level. Selected titanium elastic nail were prebent, according to fracture pattern and was inserted, crossing the fracture site and proximally embedded in proximal metaphysis. Another nail from opposite cortex was inserted in the same manner.Distal ends of nails were cut 1.5cm distal to the entry level points and was embedded in soft tissues and skin closed with 2 or 3 stitches and antiseptic dressing.

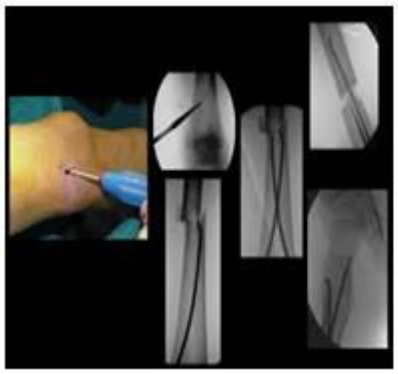
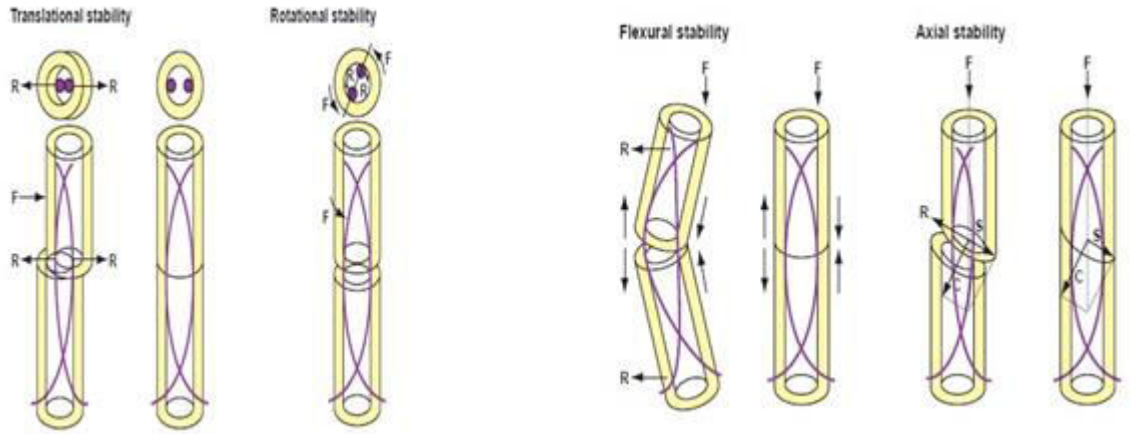


Fig 1&2 : Intra-op picture of nail entry

Fig 3: Cut nail ends



F= force acting on the bone; R= restoring force of the nail; S= shear force; C= compressive force

Flynn criteria was used forevaluating the outcome of these patients.Post-operativelylimb exercises was allowed in bed from 2nd day and continued till 2 weeks. Partial weight bearing was started at 3 weeks and full weight bearing by 6-8 weeks depending on the fracture configuration, callus response and associated injuries. Nails were removed after 4 months.

Follow-up: Patients were followed at 3,6,12 and 24 weeks and evaluated clinically as well asradio-logically.

TABLE 1: AGE WISE DISTRIBUTION

Age (yrs)	Femur	%age	Tibia	%age	TOTAL	%AGE
6-9	18	81.82%	6	75%	24	80%
10-12	4	18.18%	2	25%	6	20%
TOTAL	22	100%	8	100%	30	100%

In our study, mean age of femur fractures was 8.03 years, having 81.82% (18/22) cases and in tibia having 75% (6/8) fractures. Most common form of injury was RSA occurring in 19 (63.33%) patients out of 30.

TABLE 2:DISTRIBUTION OF BONE INVOLVEMENT

Bone Involved	No of patients (%age)
Femur	22 (73.33%)
Tibia	8 (26.66%)

In this study, femur fracture were more commonly seen than tibia fractures occurring in 22 (73.33%) patients out of 30.

TABLE 3: DISTRIBUTION OF PARTIAL WEIGHT BEARING

PWB(weeks)	Femur	%age	Tibia	%age	Total	%age
3-4	15	68.18%	3	37.5%	18	60%
5-6	7	31.82%	5	62.5%	12	40%
TOTAL	22	100%	8	100%	30	100%

In current study, average duration of partial weight bearing in femur fractures was 4.19 weeks and in tibial fractures it was 4.5 weeks.

TABLE 4: TIME TAKEN FOR FULL WEIGHT BEARING (in weeks)

FWB(weeks)	Femur	%age	Tibia	%age	Total	%age
8-10	19	86.36%	7	87.5%	26	86.67%
11-13	2	9.09%	1	12.5%	3	10%
>13	1	4.5%	0	0	1	3.33%
TOTAL	22	100%	8	100%	30	100%

In our study, average duration of full weight bearing in femur fractures was 9.36 weeks and in tibial fractures was 9.62 weeks.

TABLE 5: DISTRIBUTION OF RADILOGICAL UNION (IN WEEKS)

Radiological Union (weeks)	Femur	%age	Tibia	%age	Total	%age
8-10	20	90.91%	8	100%	28	93.33%
11-13	1	4.5%	0	0	1	3.33%
>13	1	4.5%	0	0	1	3.33%
TOTAL	22	100%	8	100%	30	100%

In our study, the average duration of radiological union in femur fractures was 8.45 weeks and in tibial fractures was 8.75 weeks.

TABLE 6:DISTRIBUTION OF POST OPERATIVE LIMB LENGTH DISCREPENCY

LLD (cm)	Femur	%age	Tibia	%age	Total	%age
Nil	4	18.18%	1	12.5%	5	16.67%
<1	13	59.09%	3	37.5%	16	53.33%

1-2	4	18.18%	4	50%	8	26.67%
>2	1	4.5%	0	0	1	3.33%
TOTAL	22	100%	8	100%	30	100%

In our study, 4 (18.18%) cases out of 22 cases of femur fracture had no limb length discrepancy, 13 (59.09%) cases had a limb length discrepancy of <1 cm, 4 (18.18%) cases had between 1-2 cm and the remaining 1 (4.5%) cases had limb length discrepancy of >2 cm. 1 (12.5%) cases out of 8 cases of tibia fracture had no limb length discrepancy, 3 (37.5%) cases had a limb length discrepancy of <1 cm and the remaining 4 (50%) cases had a limb length discrepancy between 1-2 cm. The average limb length discrepancy in femur fractures was 0.73 cm and in tibial fractures was 0.87 cm.

TABLE 7: SHOWING ANGULAR DEFORMITIES IN FEMUR AND TIBIA

Angulation	Femur	%age	Tibia	%age	Total	%age
$<5^0$	17	77.27%	5	62.5%	22	73.33%
$5\text{-}10^0$	3	13.63%	3	37.5%	6	20%
$>10^0$	2	9.09%	0	0	2	6.66%
TOTAL	22	100%	8	100%	30	100%

In our study, 17 (77.27%) cases out of 22 cases of femur fracture had an angular deformity of <5 degree, 3 (13.63%) cases had an angular deformity between 5-10 degree and the remaining 2 (9.09%) cases had an angular deformity of >10 degree. 5 (62.5%) cases out of 8 cases of tibia fracture had an angular deformity of <5 degree, 3 (37.5%) cases had an angular deformity between 5-10 degree. The average angular deformity in femur fractures was4.45 degree and in tibial fractures was 4.25 degree.

TABLE 8: DISTRIBUTION OF POST OPERATIVE PAIN

Pain	Femur	%age	Tibia	%age	Total	%age
Absent	21	95.45%	8	100%	29	96.67%
Present	1	4.5%	0	0	1	3.33%
TOTAL	22	100%	8	100	30	100%

In our present study, only 1 (3.33%) patient complained of post-operative pain.

TABLE 9: DISTRIBUTION OF POST OPERATIVE COMPLICATIONS

Complications	Femur group	Tibia group
Soft Tissue infection	2 (9.1%)	0 (0%)
Wound Gaping	0 (0%)	1 (12.5%)
Nail Back-out	1 (4.5%)	0 (0%)
Inflammatory reaction	1 (4.5%)	0 (0%)
Knee Stiffness	0 (0%)	1 (12.5%)
Delayed Union	1 (4.5%)	0 (0%)
No complications	17 (77.2%)	6 (75%)
TOTAL	22(100%)	8(100%)

In our study, 17 (77.2%) cases had no complications and only 2 (9.1%) cases of femur fracture had soft tissue infection, 1 (4.5%) case each had shown nail back-out as well as inflammatory reaction and 1 (4.5%) case had delayed union.Similarly,in tibial fractures 6 (75%) cases had no complications, but only 1 (12.5%) case each had shown wound gaping and knee stiffness.

TABLE 10: DISTRIBUTION OF POST OPERATIVE RESULTS AS PER FLYNNCRITERIA

Results	Femur	%age	Tibia	%age	Total	%age
Excellent	17	77.27%	5	62.5%	22	73.33%
Good	3	13.63%	3	37.5%	6	20%
Poor	2	9.09%	0	0	2	6.67%
TOTAL	22	100%	8	100%	30	100%

In our study, as per Flynn criteria, 77.27% i.e. 17 cases of femur fractures had shown excellent results out of 22 cases,while 03 (13.63%) cases had a good result and the rest 02 (9.09%) cases had a poor results. However, 5 cases out of 8 (62.5%)cases of tibia fractures had an excellent result and the rest 3 (37.5%) cases had a good result as per Flynn criteria. Overall, 28 (93.33%) patients had excellent to good results as per Flynn criteria.

DISCUSSION

The mean age in the present study was found out to be 8.03 years. These results are in concordance withBhaskar A et al [21]in which the mean age was 10 years and Venkataswamy K et al [22] showing mean age 9.8 years. Males were (60.33%) more commonly involved than the females and comparable results are shown by Heybeli M et al[14] in which 57.14% patients were males and Gamal EL et al[23]having 72.7% patients were males. In the present study, RSA was found out to be the most common mode of injury occurring in 63.33% patients, which were comparable with Heybeli M et al [14] and, .Khurram B et al [24] in which 62.5% and 73.17% respectively. Right side was found out to be more commonly involved (60%) in our study.

In the present study, femur (73.33%) was found out to be more commonly involved than the tibia (26.66%). Similar results were found in the study conducted by BASKAR A. et al [21] involving femur in 55%and GAMAL EL et al[23] in which the femur was involved in 72 % patients.

The average time interval between admission and surgery was found out to be 2.06 days while the average duration of hospital stay was found out to be 7.63 days.

In current study, the average duration of partial weight bearing in femur fractures was 4.19 weeks while in tibial fractures it was 4.5 weeks,these results were comparable to study conducted by Saikia KC et al [17]having PWB 3 weeks andFabiano PN et al[25] had shown average time for PWB was 3.3 weeks and 4 weeks in another study by Singh P et al [26].

The average duration of full weight bearing in femur fractures was 9.36 weeks and in tibial fractures it was 9.625 weeks, which were comparable to study conducted by Wudbhav N et al[27] showing FWB in 8.4 weeks and Saikia KC et al[17 shows FWB for femur was 8.8 weeks. Singh P et al[26] had shown average weight bearing in femoral shaft fractures 8.5 weeks and 8.8 weeks was shown by Fabiano PN et al[25].In the present study, the average duration of radiological union in femur fractures was 8.45 weeks and in tibial fractures it was 8.75 weeks. Similar results were found in study conducted by Heybeli M et al[14]showing average time 7.4 weeks, and Baskar A et al[21] in which average time in radiological union of femur was 12 weeks and of tibia was 11 weeks. Vallamshetla V et al[28] had shown average time for radiological union of tibia was 10 weeks in his study. SAIKIA KC et al[18]and SINGH P et al[26] in which average time for radiological union 8.7 weeks for tibia and was 8 weeks respectively for femur fractures

The average limb length discrepancy in this study in femur fractures was 0.73 cms and in tibial fractures was 0.875 cms and these results were comparable to study conducted by Vallamshetla V et al [28] showing average LLD in tibia fractures was < 1.5 cm. and Gamal EL et al[23] in which average LLD in tibia and femur fractures were 0.7 -1.1 cm. These results were alsocomparable to studies by Fabiano PN et al[25] and Saseendar S et al[29] in which average LLD in femur fractures was 0.66 cmand 1cm respectively. Gupta S et al[30] (2014) and Choudhary P et al[31] had also shown similar comparable results of average LLD <1cm and 0.7 cm respectively.

Present study had shown,an average angular deformity of 4.45 degree in femur fractures and 4.25 degree in tibial fractures. Similar comparable results were found in studies conducted by Saseendar S et al [29] and Ozkul E et al[32] in which mean angular deformity in tibia fractures was 3.2 and 4-5 degrees respectively.In our study 17cases (77.2%) had no complications, while only 2 (9.1%) cases out of 22 cases of femur fracture had soft tissue infection, 1 (4.5%) case had nail back-out, 1 (4.5%) case had an inflammatory reaction, 1 (4.5%) case had delayed union. In tibial fractures, 6 (75%) cases had no complications, but only 1 (12.5%) case out of 8 cases had wound gaping, 1 (12.5%) case developed knee stiffness. Similar study was also conducted by Goodwin RC et al[33] in which 26% patients had complications. Another study conducted by Gupta S et al [30] in which only 30% patients had complications and 70% patients had no complications.In current study, 90.9% patients with femoral fractures had excellent to good results according to the Flynn criteria, whereas all the patients with tibial fractures had excellent to good results. Overall, 93.32% patients had excellent to good results which were comparable to study conducted by Heybeli M et al [14] in which more than 90% patients had excellent to good results, and study by Wudbhav N et al[27]showing 99% excellent results in tibial fractures. Our study had shown comparable results to study by Saikia KC et al[18] in with 86.2% excellent to good results and Saseendar S et al[29] shows excellent results in 82% cases of femur fractures. Similar results of 90% was shown by study conducted by Gupta S et al[30].

SUMMARY

- The present study had shown mean age of about 8.03 years with involvement of males (60.33%) than females and RSA being most common mode of injury in 63.33% patients with more involvement of right side (60%).The involvement of femur (73.33%) was more common than the tibia.
- The average duration of partial weight bearing in femur and tibial fractures were 4.19 weeks and 4.5 week respectively while the average duration of full weight bearing in femur fractures and tibial fractures were 9.36 weeks & 9.625 weeks respectively.
- Radio-logically femur fractures were united at an average of 8.45 weeks and tibial fractures at 8.75 weeks.
- The average limb length discrepancy in femur and tibial fractures was 0.73 cms and 0.875 cms respectively.
- The average angular deformity in femur fractures was 4.45 degree and in tibial fractures was 4.25 degree.
- Uncomplicated union is seen in 77.7% in femur and 75% in tibial fractures. However, fewer complications like soft tissue infection in 2, wound gaping in 1 case, nail back out and knee stiffness in 1 case each were encountered.
- According to the criteria by Flynn et al,excellent results were shown in 17 fractures (77.3%), good in 3 fractures (13.6%) and 2 cases has shown (9%) poor in femur fractures. Tibia results were excellent in 5 fractures (62.5%) and good in 3 fractures (37.5%) with no poor results.

CONCLUSION

Based on our observations and results, we conclude that Titanium Elastic Nail System (TENS) technique is an ideal method for treatment of paediatric diaphyseal fractures of lower limb long bones because, It gives elastic stabilization whichpromotes rapid union and early mobilization. TENS can be considered as a simple, biocompatible, reliable and effective method for management of unstable pediatric fractures of long bones of lower extremity.

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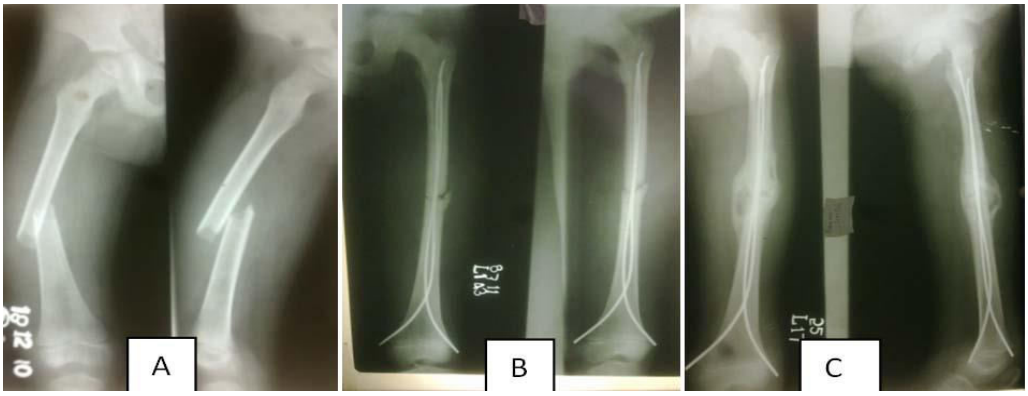


Fig A: Pre-op pictures Fig B: post-op pictures Fig C:Fracture united

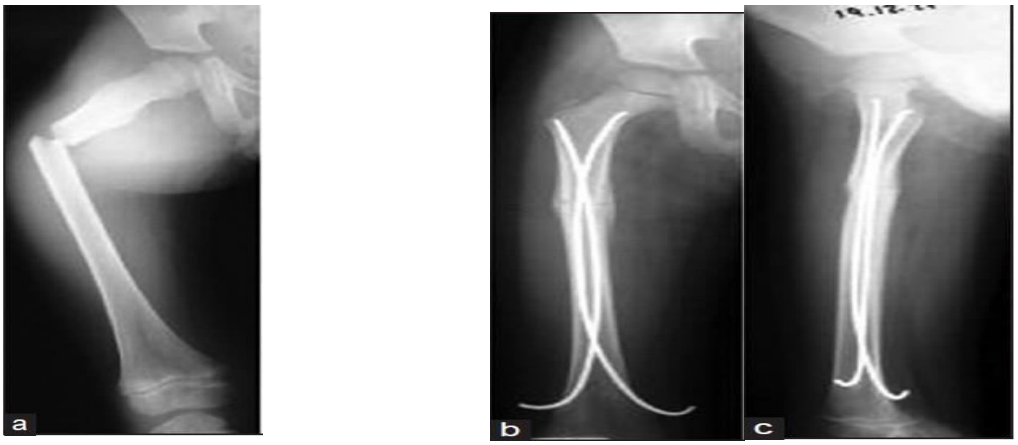
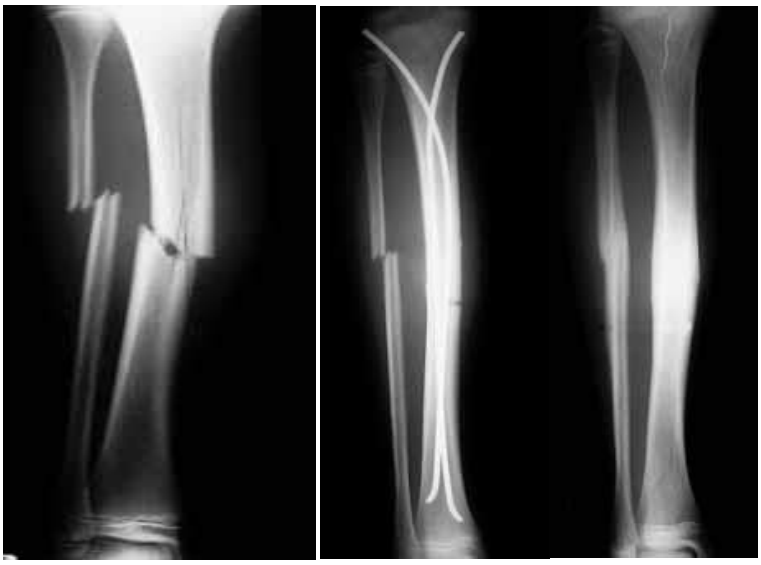
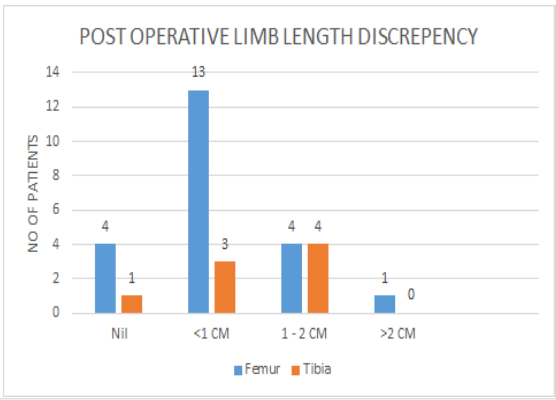
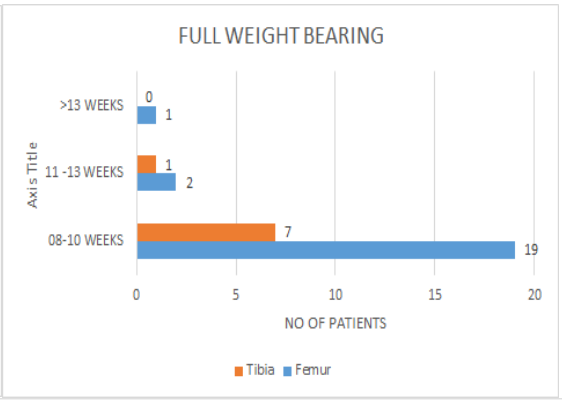


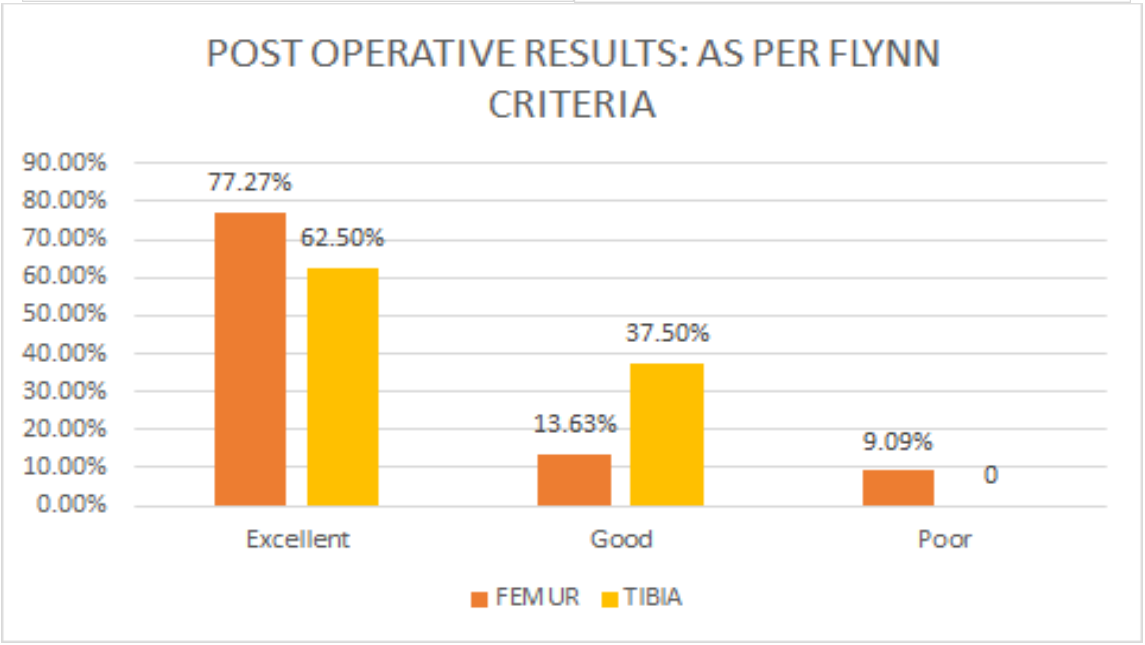
Fig a: Pre-op picture Fig b: Follow-up picture Fig c: Fracture united picture



Pre-op picture **post-op picture** **fracture united picture**







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