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RESEARCH ARTICLE

A PROSPECTIVE STUDY OF SURGICAL MANAGEMENT OF DIAPHYSEAL FRACTURES OF TIBIA IN CHILDREN AGED BETWEEN 5 TO 16 YEARS USING ELASTIC STABLE INTRA MEDULLARY NAILING

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Abstract:
Elastic stable intramedullary nailing for the treatment of Pediatric Femur diaphyseal fractures was introduced by Pr´evot and colleagues in 1979. The technique offers several advantages, including better reduction, dynamic axial stabilization, shorter hospitalization with early rehabilitation and low rate of complications. OBJECTIVES: To study the union rates and functional outcome of closed reduction and internal fixation of pediatric diaphyseal fractures of tibia with TENS. DESIGN: PROSPECTIVE STUDY. SETTING: AT SAPTHAGIRI HOSPITAL AND RESEARCH CENTER ,BANGALORE. METHODS: 30 children between ages 5 to 16 years admitted to the Department of Orthopedics at SAPTHAGIRI INSTITUTE OF MEDICAL SCIENCE AND RESEARCH CENTER,BANGALORE with diaphyseal fractures of femur during the period from NOVEMBER 2013 to FEBRUARY 2015 are selected. All patients were followed up for an average of 6 months. Outcome was assessed using TENS SCORING SYSTEM USED BY FLYNN et al. RESULTS: The selected patients evaluated thoroughly clinically and radiologically. The fractures were treated BY CLOSED REDUCTION AND INTERNAL FIXATION WITH ELASTIC STABLE INTRAMEDULLARY NAILING. Results of the entire patients were followed up for an average of 6 months. Our series consisted of 30 patients, 24 male and only 6 female. Most common fracture pattern of tibia was spiral. 23 fractures healed within an average duration of 10 to 12 weeks following surgery. There was superficial infection in 1 case, 2 cases had LLD <2cm & 1 tibia case had nail backing out proximally which was treated with second surgery for implant removal after complete union of fracture.2 cases had varus angulation & 1 case had valgus angulation. All patients had full range of knee and ankle motion in the present study and 4 (13.33%) patients had mild restriction in knee flexion at 12 weeks. CONCLUSION: Based on our experience and results, we conclude that ELASTIC STABLE INTRAMEDULLARY NAILING technique is an ideal method for treatment of pediatric tibial diaphyseal fractures. It gives elastic mobility promoting rapid union at fractures site and stability which is ideal for early mobilization. It gives lower complication rate, good outcome when compared with other methods of treatment.
KEYWORDS: Diaphyseal tibia, , Elastic Stable Intramedullary Nailing,Titanium Elastic Nailing System.

INTRODUCTION:

Treatment of pediatric fractures dramatically changed in 1982, when Métaizeau and the team from Nancy, France, developed the technique of flexible stable intramedullary pinning (FSIMP) using titanium pins[1, 2]. In the last two decades there was an increased interest in the operative treatment of pediatric fractures, although debate persisted over its indications[3].

For the vast majority of tibial shaft fractures in the children, closed reduction and casting is an effective form of treatment and remains the gold standard of care. Occasionally, reduction cannot be maintained due to excessive shortening, angulation, or malrotation at the fracture site, making operative intervention necessary . In other cases, surgical treatment is warranted because of open fracture, polytrauma, compartment syndrome, or severe soft tissue compromise [4].

Historically, external fixation and plate and screw fixation were the treatment options available for those unstable tibial shaft fractures that required operative fixation. Complications associated with these techniques include infection, overgrowth, and refracture [5,6,7]. Reamed locked intramedullary nails, while shown to be effective in the skeletally mature, pose unnecessary risk to the proximal tibial growth plate, and have limited indications in those children with open physes.

In the past seven years fixation with flexible intramedullary nails have become popular technique, for stabilizing tibial fracture in school aged children[8,9]. ESIN fixation system is a simple, effective and minimally invasive technique. It gives stable fixation with rapid healing and prompt return of child to normal activity. This study was intended to assess the results following treatment of tibia shaft of femur by flexible intra medullary nail or elastic stable intramedullary technique[10].

Elastic stable intramedullary nailing of long bone fractures in the skeletally immature has gained widespread popularity because of its clinical effectiveness and low risk of complications. Many studies have supported the use of this technique in the tibia, citing advantages that include closed insertion, preservation of the fracture hematoma, and a physeal-sparing entry point[9,11].The purpose of this study was to present our results following fixation of tibial shaft fractures with ESIN.

MATERIALS AND METHODS

All children and adolescent patients between 5-16 years of age with diaphyseal fractures of tibia admitted at SAPTHAGIRI hospital, Bangalore - meeting the inclusion and the exclusion criteria (as given below) during the study period were the subjects for the study.

Inclusion criteria: Children and adolescent patients from 5 to 16 year with diaphyseal tibia fracture. children of both the sexes are included in the study children with closed and type 1 open diaphyseal fractures of tibia.Patient fit for surgery

Exclusion criteria: Patients less than 5 years of age and more than 16 years of age. Patients unfit for surgery. Patients not willing for surgery Patients medically unfit for surgery

As soon as the patient was brought to casualty, patient's airway, breathing and circulation were assessed. Then a complete survey was carried out to rule out other significant injuries. Plain radiographs of AP and lateral views of - the leg including knee and ankle joints to assess the extent of fracture comminution, the geometry and the dimensions of the fracture.

On admission to ward, a detailed history was taken, relating to the age, sex, and occupation, mode of injury, past and associated medical illness. Routine investigations were done for all patients. Patients were operated as early as possible once the general condition of the patient was stable andpatient was fit for surgery.

After prior informed consent, a pre-operative anesthetic evaluation is done. Pre-op planning of fixation is made.

PREOPERATIVE PLANNING:

Nail Size

Nail width: The diameter of the individual nail is selected as per

1) Flynn et al's formula.

Diameter of nail= width of the narrowest point of the medullary canal on AP and LATERAL view X 0.4mm

2) Intra operative assessment

Nail length: Lay one of the selected nails over the leg, and determine that it is of the appropriate length by fluoroscopy. The nail for tibia should extend from the level of the 3cm distal to proximal tibial physis to a point approximately 2 cm proximal to the distal tibial physis.

Preoperative preparation of patients:

Patients were kept fasting over night before surgery.

Adequate amount of compatible blood was kept ready for any eventuality.

The whole of the extremity below the umbilicus, including the genitalia was prepared when required

A systemic antibiotic, usually a 3rd generation cephalosporin was administered 1 hour before surgery.

Under anesthesia, closed reduction and internal fixation with TENS nails done under c-arm guidance.

PROCEDURE FOR TENS NAILING OF DIAPHYSEAL FRACTURE OF TIBIA ANTEGRADE FIXATION

General / Spinal anesthesia is administered, and patient is placed in supine on a radiolucent table. The operative extremity is then prepped and draped free. Under fluoroscopy, the fracture site and proximal tibial physis are marked. The starting point for nail insertion is 1.5–2.0 cm distal to the physis, sufficiently posterior in the sagittal plane to avoid injury to the tibial tubercle apophysis. A longitudinal 2 cm incision is made on both the lateral and medial side of the tibia metaphysis just proximal to the desired bony entry point. Using a hemostat, the soft tissues are bluntly dissected down to bone. Based on preoperative measurements, an appropriately sized implant is selected so that the nail diameter is 40% of the diameter of the narrowest portion of the medullary canal. A drill roughly 0.5 cm larger than the selected nail is then used to open the cortex at the nail entry site; angling the drill distally down the shaft facilitates nail entry. Both nails are then inserted through the entry holes and advanced to the level of the fracture site.

Under fluoroscopic guidance, the fracture is reduced in both the coronal and sagittal planes, and the first nail is advanced past the fracture site. If proper intramedullary position of the nail distal to the fracture site is confirmed on anteroposterior and lateral views, then the second nail is tapped across the fracture site. Both nails are advanced until the tips lie just proximal to the distal tibial physis. Fluoroscopy is again used to confirm proper fracture reduction as well as nail position.

To minimize soft tissue irritation, the nails are backed out a few centimeters and cut along proximal tibial metaphysis. A tamp is used to re-advance the implants until <1 cm of nail lies outside of bone. Care is taken not to bend the nails away from the bone to facilitate cutting, as we have found that this increases nail prominence and subsequent skin irritation. The two incisions for nail entry are closed in a layered fashion, and the wounds are well padded with gauze.

Postoperative Care:

Patients were kept nil orally 4 to 6 hours post operatively

IV fluids/blood transfusions were given as needed

Analgesics were given according to the needs of the patient

The limb was kept elevated over a pillow.

IV antibiotics were continued for 5 days and switched over to oral antibiotics on the 5th day and continued till the 12th day.

Sutures were removed on the 12th postoperative day and patients were discharged.

Post-operatively, patients are immobilized with above knee POP cast for tibia fracture for 6 weeks and such immobilization was continued for another 2-3 weeks based on radiological assessment.

The period of immobilization was followed by active hip and knee/knee and ankle mobilization with non-weight bearing crutch walking

Full weight bearing is started by 8 - 12 weeks depending on the fracture configuration and callus response.

FOLLOW UP:

Assessment done at 6, 12 and 24 weeks.

At each follow up patients are assessed clinically, radiologically and the complications are noted.

RESULTS

Age incidence: In the present study 16(53.3%) of the patients were 5-8 years, 7 (23.3%)were 9 to 12 years and 7(23.3%) were 13 to 16 years age group with the average age being 9.03 years.

Sex incidence: There were 6(20%) girls and 24 (80%) boys in the present study. The sex incidence is comparable to other studies in the literature.

Mode of Injury: In the present study RTA was the most common mode of injury accounting for 18 (60.0%) cases, self-fall accounted for 10 (33.3%) cases and fall from height accounted for 2 (6.66%) of the cases.

Pattern of Facture: In our study, transverse fractures accounted for 11(36.6%) cases, oblique fractures - 9(30.0%), spiral fractures . 10(33.3%) and there were no segmental fractures

Level of Fracture: Fractures involving the middle 1/3rd accounted for 15 (50%) cases, proximal 1/3rd . 10(33.3%) and there are 5(16.66) distal 1/3rd fractures in our study.

Time interval between trauma and surgery: In the present series, 16 (53.3%) patients underwent surgery within 2 days after trauma, 8(26.6%) in 3 . 4 days, 4(13.3%) in 5 . 7 days and 2(6.6%) patients after 7 days.

Duration of surgery in minutes: In the present study, duration of surgery was < 30 mins in 5(16.6%) case, 30-60 mins in 16 (53.3%) cases, 61-90 mins in another 7 (23.3%) cases and 91-120 mins in 2 (6.7%) of the cases.

Post-operative immobilization/mobilization: In our study, 24 (80%) cases were immobilized for 2 weeks and such immobilization was for 4 weeks in rest of the 6 (20%) of the cases with associated injuries.

The period of immobilization was followed by active hip and knee/knee and ankle mobilization with non-weight crutch walking. The advantage of the present study was early mobilization of the patients.

Duration of stay in the hospital: The duration of stay in the hospital . 7 days for 21 (70%) patients, 8-10 days for 3 (10%), 11-15 days for 4 (13.3%) and 2 (6.6%) patients stayed for more than 15 days with associated injuries. The average duration of hospital stay in the present study is 6.6 days.

Time for union: In our study union was achieved in <3 months in 23 (76.6%) of the patients and 3 . 4.5 months in 5 (16.6%) and 4.5- 6 months in 2(6.6%). Average time to union was 10.2 weeks.

Time of full weight bearing. In the present study, unsupported full weight bearing walking was started in <12 weeks for 23 (76.6%) of the patients, between 12 and 18 weeks in 5 (16.6%) and at 20 weeks in 2 (6.6%) patient. The average time of full weight bearing was 12.06 weeks.

COMPLICATIONS:

Pain at the site of nail insertion: In the present study, 4(13.3%) patients had developed pain at site of nail insertion during initial follow up evaluation which resolved completely in all of them by the end of 16 weeks.

Infection: Superficial infection was seen in 1(3.3%) case in our study which was controlled by antibiotics.

Range of motion: All patients had full range of knee and ankle motion in the present study and 4 (13.33%) patients had mild restriction in knee flexion at 12 weeks, but normal range of knee flexion was achieved at 6 months.

Limb length discrepancy: No patient in our study had major limb length discrepancy (i.e. > 2cm).

MALALLIGNMENT: Some degree of angular deformity is frequent after femoral shaft fractures in children, but this usually remodels after growth.

Varus/valgus malalignment: 2 (6.7%) patients presented with varus (80 and 60) angulation, 1(3.3%) patient presented with valgus (60) angulation.

Other complications: Bursa over tip of the nail was noticed in 3 cases in our study; Implant removal is done in all the 3 cases.

Assessment of Outcome: In the present study, the final outcome was excellent in 20 (66.66%) cases, satisfactory in10 (33.33%) cases and there were no poor outcome cases based on FLYNN CRITERION.

TENS outcome score (Flynn et al) [12]

RESULTS VARIABLES at 24 weeks	Excellent	Satisfactory	Poor
Limb-length inequality	< 1.0 cm	< 2.0 cm	> 2.0 cm
Malallignment	5 degrees	10 degrees	>10 degrees
Unresolved pain	absent	Absent	present

Other complications None Minor and resolved Major and lasting morbidity

Statistical Analysis: Descriptive statistics like numbers, percentages, average, standard deviations, were used. Data was presented in the form of tables and graphs wherever necessary.

DISCUSSION

Diaphyseal fractures of the tibia are common injuries in children. However, very few require surgical stabilization[13,14].Surgical stabilization may be indicated for children in whom acceptable positioning is not maintained after closed reduction; those who are ten years of age and older[15]; those who have selected open fractures; those who have an associated compartment syndrome; those who have spasticity due to head injury or cerebral palsy; those who have multiple long-bone fractures or multiple-system injuries; and those who have concomitant severe soft-tissue injuries[15-19].

Tibial fractures requiring surgical stabilization are treated differently in children than in adults. Locked intramedullary rods are not used in children because of the risk of physeal injury. Treatment options include external fixation[16,20,21], elastic stable intramedullary nailing, and transfixation pins and casts.

The development of the TENs fixation method has put an end to criticism of the surgical treatment of pediatric long bone fractures, as it avoids any growth disturbance by preserving the epiphyseal growth plate, it avoids bone damage or weakening through the elasticity of the construct, which provides a load sharing, biocompatible internal splint, and finally it entails a minimal risk of bone infection. The low incidence of complications reported in this study especially for malunion and limb-length discrepancy may be related to meticulous adhesion to all technical requirements of the technique, and the use of postoperative immobilization in cases with concern about stability.

WUDBHAV N. SANKAR et al between 1998 and 2005 studied 19 consecutive patients between 7.2 and 16 years of age treated with elastic stable intramedullary nailing for unstable tibial shaft fractures.

All patients achieved complete healing at a mean of 11.0 weeks (range 6–18 weeks). At final follow-up, mean angulation was 2° (range 0°–6°) in the sagittal plane and 3° in the coronal plane (range 0°–9°). Five patients (26%) complained of irritation at the nail entry site; there were no leg length discrepancies or physeal arrests as a result of treatment. Two patients required remanipulation after the index procedure to maintain adequate alignment. According to the Flynn classification, we had 12 excellent, 6 satisfactory, and 1 poor result

Conclusion: Elastic stable intrameddulary nailing is an effective surgical technique which allows rapid healing of tibial shaft fractures with an acceptable rate of complications.[22,23,24,25]

TODD O'BRIEN, DAVID S. WEISMAN, PETER RONCHETTI et al, over a 5-year period treated 16 unstable tibia fractures in 14 patients with flexible titanium intramedullary nails. The average age was 10 years 4 months. There were three open fractures. All fractures healed. Closed injuries obtained union by an average of 8 weeks, open fractures by an average of 15 weeks. There were no malunions. The average follow-up was 1 year 5 months. There were no instances of growth arrest, remanipulations, or refracture.

Conclusion : In the unstable pediatric tibia fracture, flexible titanium nails are an effective treatment to obtain and maintain alignment and stability.[26,27]

ERIK N. KUBIAK, KENNETH A. EGOL, DAVID SCHER, BRADLEY WASSERMAN et al retrospectively reviewed the operative records and trauma registries of three institutions within their hospital system and identified thirty-one patients with open physes who had undergone operative treatment of a tibial fracture between April 1997 and June 2004, sixteen had been managed with elastic stable intramedullary nails and fifteen had been managed with unilateral external fixation. The clinical and radiographic outcomes were compared. The functional outcomes were compared with use of the Pediatric Outcomes Data Collection Instrument. Complications related to treatment, such as malunion, delayed union, nonunion, infection, and the need for subsequent surgical treatment also were compared.

The mean time to union for the intramedullary nailing group (seven weeks) was significantly shorter than that for the external fixation group (eighteen weeks) ($p < 0.01$). The functional outcomes for the intramedullary nailing group were significantly better than those for the external fixation group in the categories of pain, happiness, sports, and global function (the mean of the mean scores of the first four categories) ($p < 0.01$ for these comparisons).

Conclusion: When surgical stabilization of tibial fractures in children is indicated, we believe that the preferred method of fixation is with elastic stable intramedullary nailing.[28]

CONCLUSION:

Based on our experience and results, we conclude that ELASTIC STABLE INTRAMEDULLARY NAILING technique is an ideal method for treatment of pediatric femoral diaphyseal fractures. It gives elastic mobility promoting rapid union at fractures site and stability which is ideal for early mobilization. It gives lower complication rate, good outcome when compared with other methods of treatment.

Is a simple, easy, rapid, reliable and effective method for management of pediatric femoral and tibial fractures between the age of 5 to 16 years, with shorter operative time, lesser blood less, lesser radiation exposure, shorter hospital stay, and reasonable time to bone healing.

Because of early weight bearing, rapid healing and minimal disturbance of bone growth, ESIN may be considered to be a physiological method of treatment.

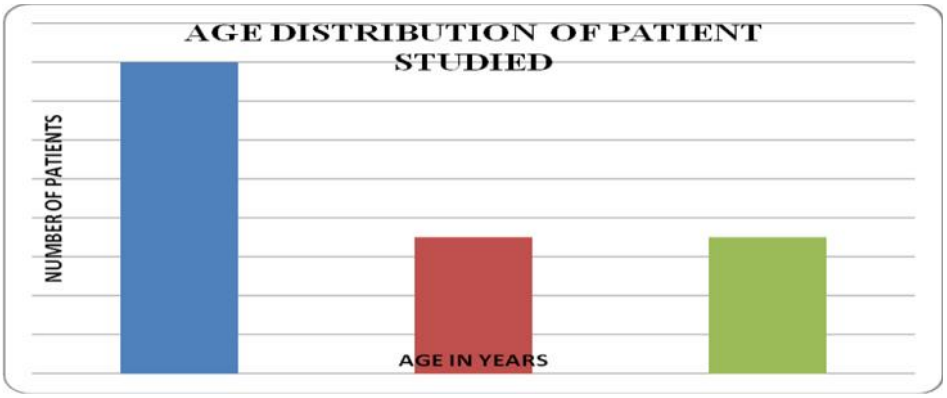
Use of ESINs for definitive stabilization of femoral and tibial shaft fractures in children is a reliable, minimally invasive, and physeal-protective treatment method. Our study results provide new evidence that expands the inclusion criteria for this treatment and shows that ESINs can be successfully used regardless of fracture location and fracture pattern.

OBSERVATIONS AND RESULTS

Study design: An outcome surgical study with 30 patients with Diaphyseal fractures is undertaken to study the outcome of Titalnium elastic nails fixation in tibia.

Table 1: Age distribution of patients studied

Age in years	Number of patients	%
5-8	16	53.3
9-12	7	23.3
13-16	7	23.3
Total	**30**	**100.0**



Graph 1: Age distribution of patients studied

Table 2: Gender distribution of patients studied

Gender	Number of patients	%
Male	24	80.0
Female	6	20.0
Total	**30**	**100.0**

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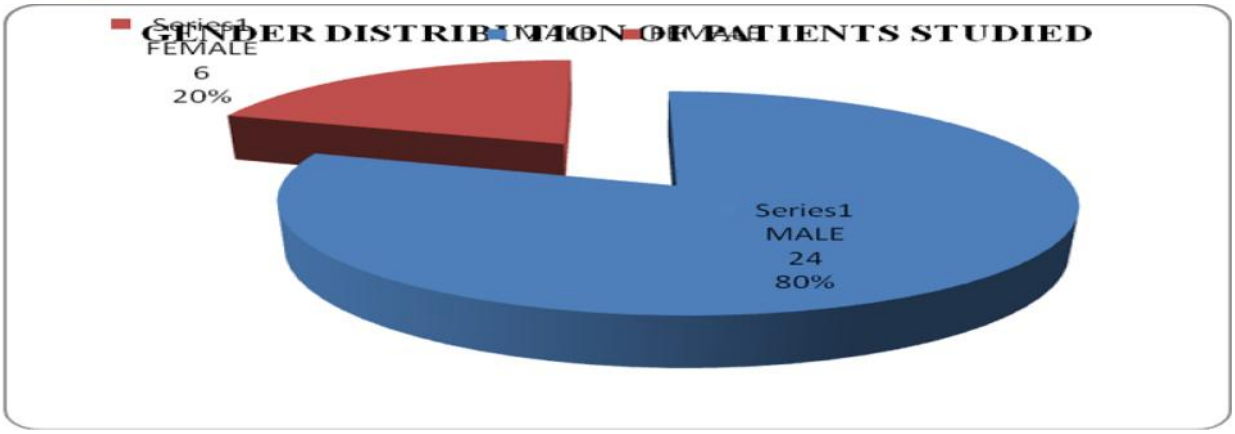
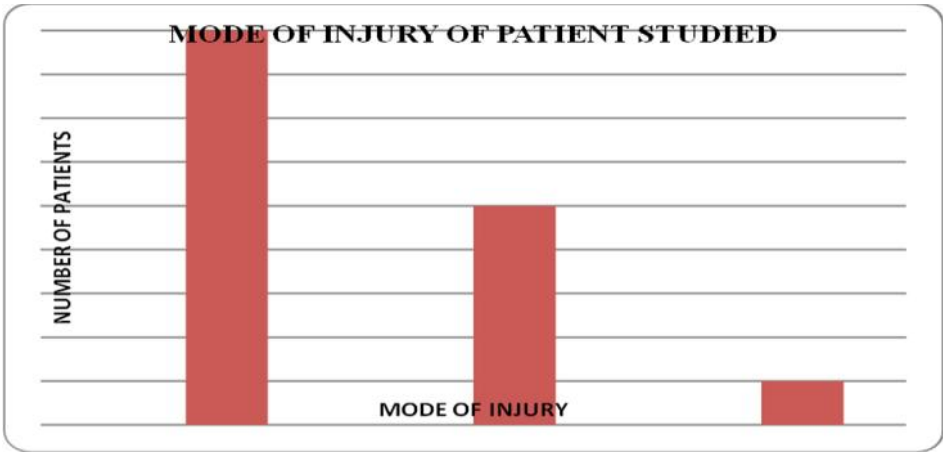


Graph 2: Gender distribution of patients studied

Table 3: Mode of Injury of patients studied

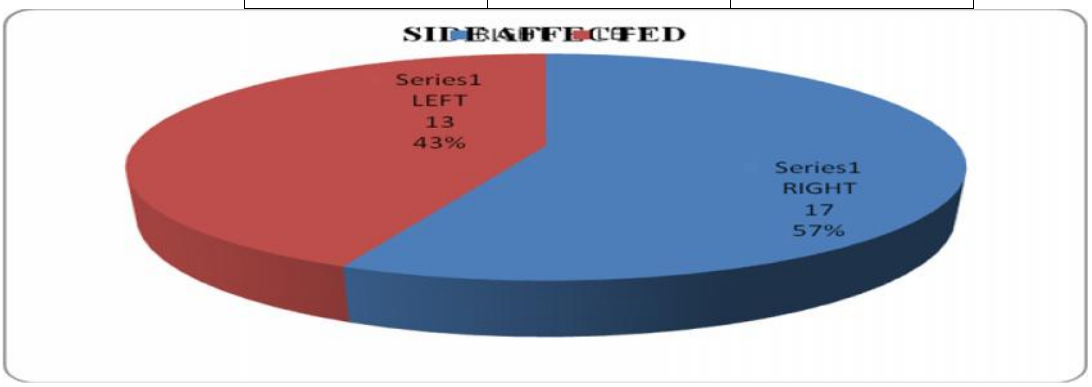
Mode of injury	Number of patients	%
RTA	18	60.0
Self fall	10	33.3
Fall from height	2	6.66
Total	**30**	**100.0**



Graph 3: Mode of Injury of patients studied

Table 4: Side affected

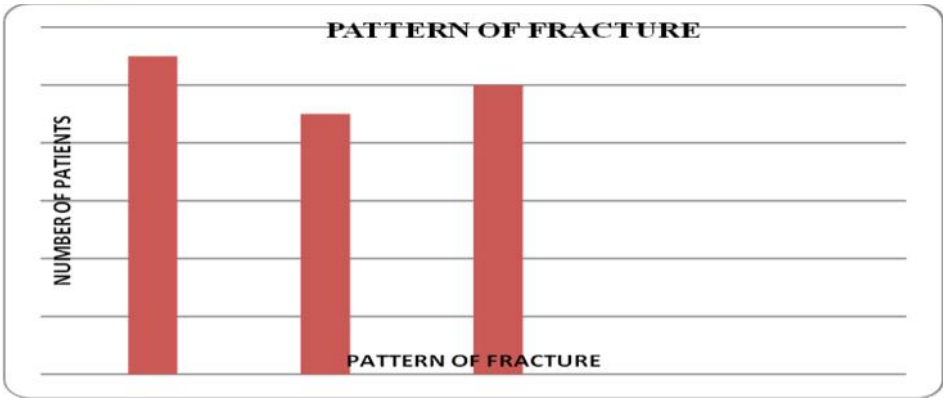
Side affected	Number of patients	%
Right	17	56.6
Left	13	43.3
Total	**30**	**100.0**



Graph 4: Side affected

Table 5: Pattern of fracture

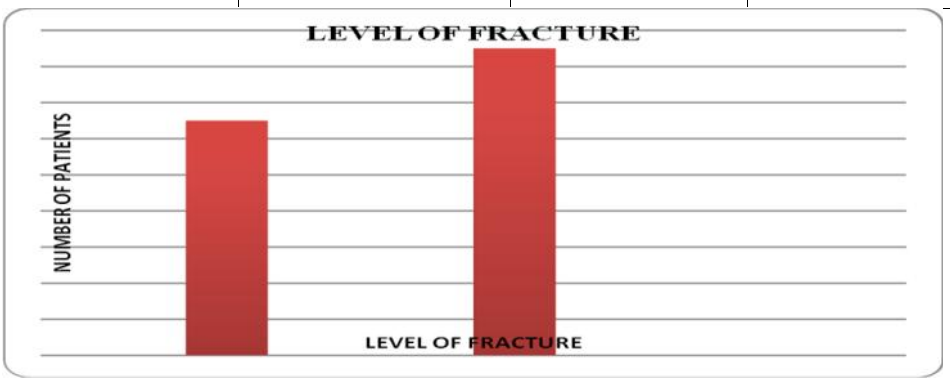
Pattern of fracture	Number of patients	%
Transverse	11	36.6
Oblique	9	30.0
Spiral	10	33.3
Segmental	0	0.0
Communited	0	0.0
Total	**30**	**100.0**



Graph 5: Pattern of fracture

Table 6: Level of fracture

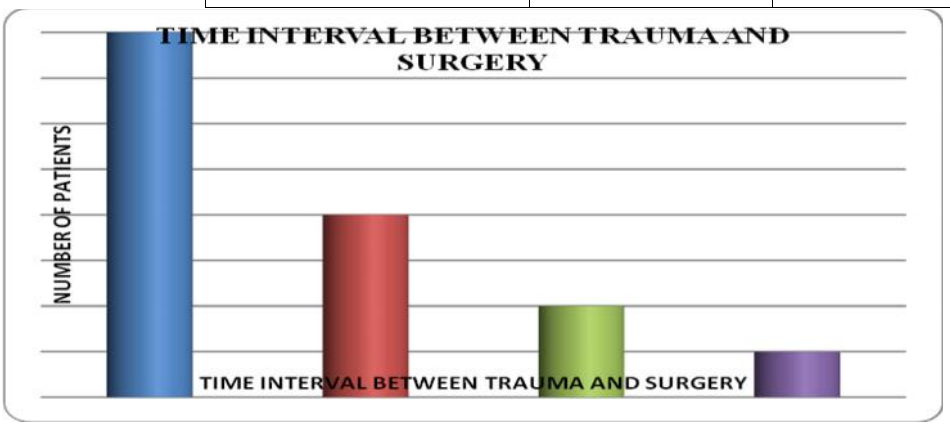
Level of fracture	Number of patients	%
1.Proximal 1/3rd	13	43.3
2.MIDDLE 1/3rd	17	56.6
3.DISTAL 1/3rd	0	0.0
Total	**30**	**100.0**



Graph 6: Level of fracture

Table 7: Time interval between trauma and surgery

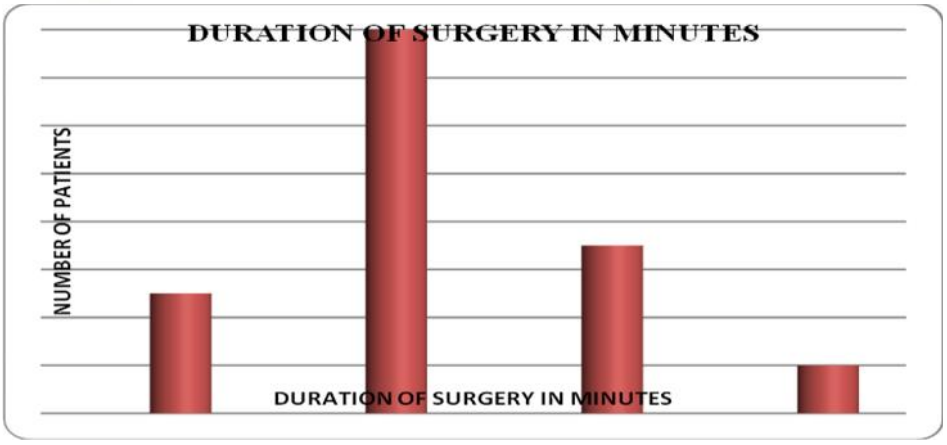
Time of interval between trauma & surgery	Number of patients	%
< 2days	16	53.3
3-4 days	8	26.6
5-7 days	4	13.3
>7 days	2	6.6
Total	**30**	**100.0**



Graph 7: Time interval between trauma and surgery

Table 8: Duration of surgery in minutes

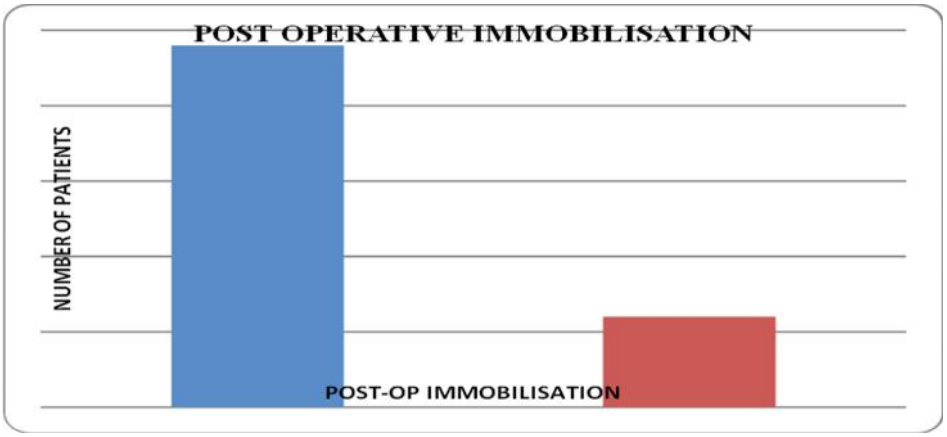
Duration of surgery (min)	Number of patients	%
<30	5	16.6
30-60	16	53.3
61-90	7	23.3
91-120	2	6.7
Total	**30**	**100.0**



Graph 8: Duration of surgery in minutes

Table 9: Post-operative Immobilization

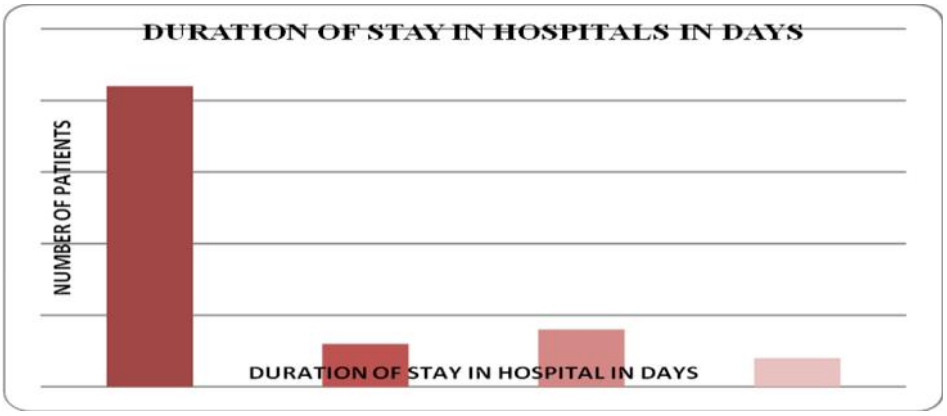
Post-op immobilization	Number of patients	%
6 weeks	24	80.0
9 weeks	6	20.0
Total	**30**	**100.0**



Graph 9: Post-operative Immobilization

Table 10: Duration of stay in hospital in days

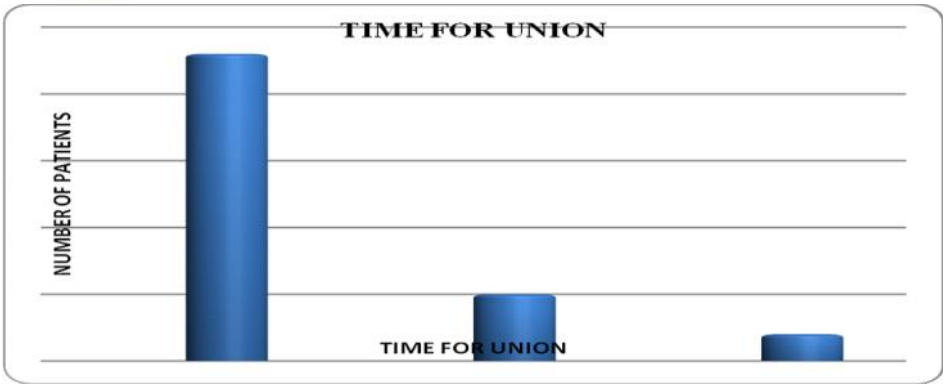
Duration of stay (days)	Number of patients	%
<7	21	70.0
8-10	3	10.0
11-15	4	13.3
>15	2	6.6
Total	**30**	**100.0**



Graph 10: Duration of stay in hospital in days

Table 11: Time for union

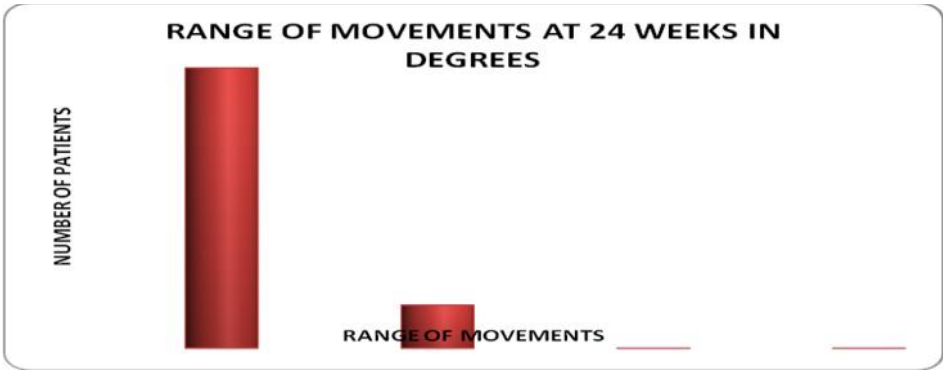
Time for union	Number of patients	%
< / = 12 weeks	23	76.6
>12 – 18 weeks	5	16.6
>18 – 24 weeks	2	6.6
Total	**30**	**100.0**



Graph 11: Time for union

Table 12: Range of movements at 24 weeks(degrees)

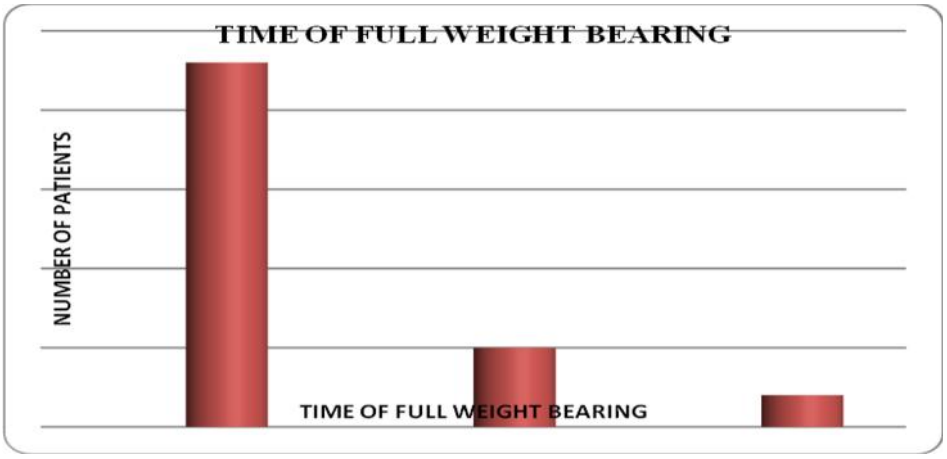
Range of movements(degrees)	**Number of patients**	**%**
Full range	26	86.6
Mild restriction	4	13.3
Moderate restriction	0	0
Severe restriction	0	0
Total	**30**	**100**



Graph 12: Range of movements at 24 weeks (degrees)

Table 13: Time of full weight bearing

Time of full weight bearing	Number of patients (n=30)	%
≤ 12 weeks	23	76.6
>12 – 18 weeks	5	16.6
>18 – 24 weeks	2	6.6



Graph 13: Time of full weight bearing

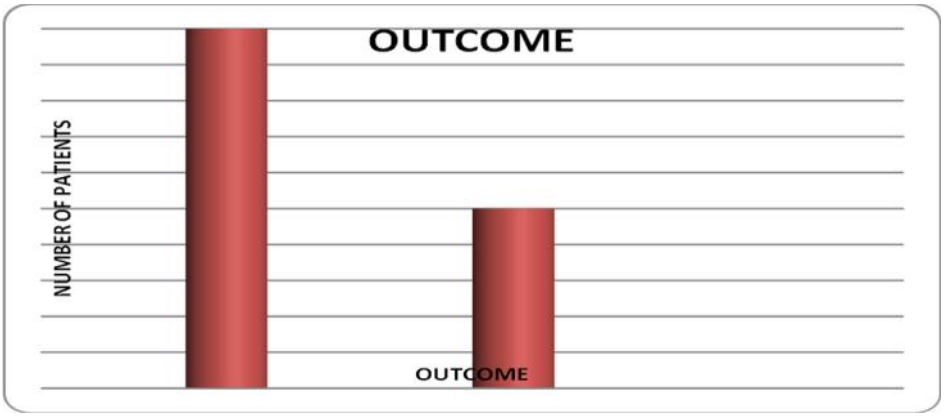
Table 14 : Complications

	Minor	Major	Nil	Total
No.of Patients	10	-	20	100
Percentage	33.33	-	66.66	100

Graph 14 : Complications

Table 15: Outcome

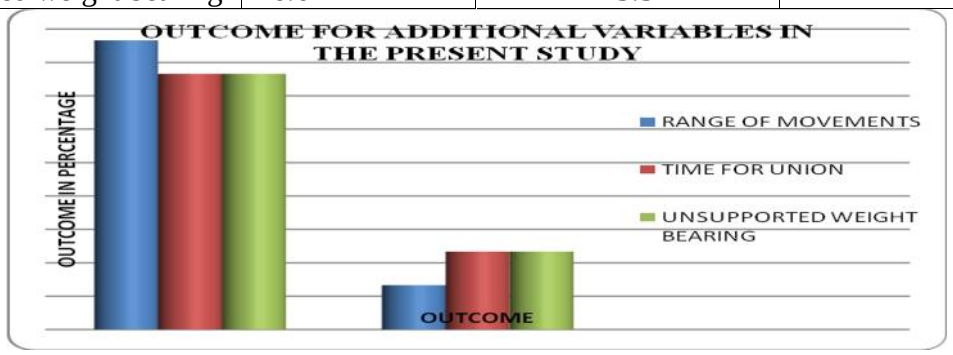
Outcome	Number of patients (n=30)	%
Excellent	20	66.67
Satisfactory	10	33.34
Poor	0	0.0



Graph 16: Outcome

Table 16 : Outcome for additional variables in the present study

OUTCOME / VARIABLES	EXCELLENT (%)	SATISFACTORY (%)	POOR (%)
Range of movements	86.6	13.3	-
Time for union	76.6	23.3	-
Unsupported weight bearing	76.6	23.3	-



Graph 16 : Outcome for additional variables in the present study

CASE NO :1

PRE OP **POST OP 3 WEEKS**

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POST OP 6 WEEKS **POST OP 12 WEEKS**

KNEE EXTENSION **KNEE FLEXION**

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PLANTAR FLEXION **DORSI FLEXION**

CASE NO :2

PRE OP **POST OP 6 WEEKS**

POST OP 12 WEEKS

KNEE FLEXION **KNEE EXTENSION**

PLANTAR FLEXION **DORSI FLEXION**

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