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Functional and radiological outcomes of suprapatellar intramedullary nailing for tibia diaphyseal fracture-an observational study

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Abstract
Background: For tibial shaft fractures, intramedullary nailing (IMN) is considered the preferred treatment because it has a high fracture union rate, allows early mobilization, reduces complications such as infection, malunion, non-union or implant failure, and provides early stabilization, which decreases morbidity and mortality.
Methods: The purpose of this study is to evaluate the functional and radiological outcomes of tibia diaphyseal fractures treated with intramedullary nailing through a suprapatellar approach from 2019 to 2021. Lower Extremity Functional Score (LEFS) was used to measure subjective functional outcomes, and knee range of motion (ROM) was used to measure objective functional outcomes, Radiological outcome was determined by the time of union of the fracture, pain scores were assessed by visual analogue scale (VAS) and fluoroscopy time, blood loss and complications were recorded.
Results: Among 33 cases, all fractures healed completely without any secondary procedures. No patient had malunion, nonunion, or implant failure. The mean LEFS and knee ROM score at the end of 6 months was 66.27±6.00, and 125.15±7.95 degrees for the affected extremity, the average time of union of fracture was 13.58±1.86 weeks. Average blood loss during surgery was 82.58±12.06 ml and the average radiation time was 84.18±6.77 seconds. 1 (3%) patient had anterior knee pain. Outcomes based on observations are Excellent in 33.3%, good in 48.5%, fair in 18.2%, and Poor in 0%.
Conclusion: A tibia diaphyseal fracture treated by IMN through SP leads to better subjective functional outcomes and excellent objective functional outcomes like knee ROM after 6 months.

Keywords: Tibia-diaphyseal fractures, intramedullary nailing, LEFS, Knee ROM

Introduction
The tibia shaft fracture is one of the most common long bone fractures and a common consequence of high energy trauma with 2% of all fractures in adults [1-3]. Due to the increase in the number of vehicles in India, complex trauma cases caused by road traffic accidents (RTA) have increased progressively. In orthopaedic practice, the tibia is the most commonly fractured bone due to its subcutaneous location. Open fractures are more common because one third of its surface is subcutaneous throughout most of its length and the blood supply to the tibia is more precarious than that of bones enclosed by heavy muscles. Due to the presence of hinge joints in the knee and ankle, there is no adjustment for rotatory deformities after fractures. Delayed union, non-union, and infection are the common complications, especially after open fractures of the shaft of the tibia. So special care and expertise are required to treat such fractures.
Several treatment methods are present for tibial shaft fractures, such as open reduction and internal fixation with plates, external fixation, and intramedullary nailing (IMN) [4]. The IMN has been proven to be reliable and efficient in the treatment of tibia shaft fractures with increasing application [5]. Today IMN is the preferred choice of treatment for tibia shaft fracture due to its superior advantages with fewer complications and re-operation [6-8]. However, IMN insertion through the infrapatellar (IP) approach is technically challenging due to proximal fracture fragment displacement with knee flexion induced by quadriceps and extensor complex as well as the multiple adjustment made during imaging [9].

Besides anterior knee pain was a common and perhaps the most frequent complication after IMN insertion through the IP approach, with the reported incidence varying from 10-80% [10, 11]. The SP approach was developed as an alternative to avoid these potential drawbacks. By splitting the quadriceps tendon, the SP pouch and retro-patellar space can be accessed through an incision 2.5 cm from the patella. A cannula system is then used for the standard insertion of the tibia nail. The full or near full extension position of the leg assists in neutralizing the deforming forces of the quadriceps muscle and 4 helps to maintain proper alignment of the proximal tibia, it also helps to align comminute shaft fractures or highly unstable distal third fractures, cases in which maintaining reduction against gravity in the flexed or hyper-flexed position can be extremely difficult. Also, the extended position of the lower limb allows for easier fluoroscopic imaging [12]. The potential drawback of this approach is the chance of articular injury. Therefore this prospective study aims to evaluate the functional and radiological outcomes of tibial shaft fractures using Intramedullary Nailing through Suprapatellar approach.

Objectives

- To assess the Functional outcome using Lower Extremity Functional Score and knee range of motion and radiological outcome by fracture union in radiograph
- To assess post-operative knee pain by visual analogue scale
- To find out Complications like anterior knee pain, non-union, and surgical site infection
- To calculate average blood loss & radiation time during the procedure

Methods

This was a facility-based prospective study conducted in the Asian Joint Reconstruction Institute at SIMS hospitals, the protocol of which was approved by the Institutional Ethical Committee of the medical college and is consistent with all the ethical standards. All patients provided written informed consent. All skeletally mature patients with tibia diaphyseal fractures (Open and closed fractures) undergoing suprapatellar intramedullary nailing and who were fit for surgery medically were included in the study using consecutive sampling techniques from September 2019 to December 2021. Patients with prior fractures to the same bone, pathological fractures, polytrauma, fatigue fracture, and patients with multiple fractures were excluded from the study.

All patients were discharged on 2nd post-operative day and received the same antibiotics and analgesics and the same post-operative protocol. Post-operative physiotherapy initiated as soon as possible-ankle range of motion, static quadriceps strengthening exercise, and active assisted knee range of motion. Weight bearing walking with a walker as tolerated for all patients. Suture removal was done on 14th day. Patients were followed at 2 weeks, 6 weeks, 3 months, and 6 months after surgery. Functional outcome and pain score assessed. AP and lateral X-ray films were taken at follow-up for evaluation of the fracture healing, implant position, and the general condition of the fracture site. Pain assessment was done by visual analogue scale, Subjective assessment of Functional outcome with lower extremity functional score, and objective assessment with clinical evaluation for ipsilateral knee ROM.

All procedures were performed by a single senior orthopaedic trauma surgeon. All patients in the study received SMITH and nephew-trigen meta nail that was inserted using appropriate instruments used in accordance with the manufacturer's operative technique.

Data was entered in MS Excel and analyzed in SPSS version 21.0. Descriptive statistics were carried out by frequency and proportion for categorical variables and mean and standard deviation for quantitative variables. To check the association between the variables chi-square test and Fischer exact test were used P-Value.

Procedure

- The patient is positioned supine on a radiolucent table, and the injured leg is positioned with a roll under the knee joint so that it is flexed to 20 degrees (Fig.1).
- A 4 cm to 5 cm longitudinal incision was made 2 cm superior to the patella. The quadriceps tendon was then split in line with the incision.
- Entry points were just medial to the lateral tibial spine
- Custom-made trocar and protective sleeve were inserted
- A ball tip guide wire was then passed into the tibia, and Measurement of the appropriate length of nail was obtained.
- Serial reaming was done and the appropriate size of the nail was placed.
- Usual Fracture reduction was done and confirmed by fluoroscopy.
- A Proximal screw with custom-made proximal jig was inserted.
- Then the distal screw was inserted by free hand technique under fluoroscopy (Fig 2).
- Wounds were irrigated and closed in a layered fashion and covered by sterile dressings.

Results

A total of 33 patients were included in the study. Table 1 shows the demographic characteristics of the patients. The mean age of the Study participants was 42.8±19.5. The Majority of the patients were Males 27 (81.8%) and the remaining were females 6 (18.2%). among 33 patients, 9 (27.3%) had comorbidities and among the 9 patients 7 (21.2%) had hypertension, 6 (18.2%) had Diabetes and 1 (3%) had coronary artery disease. Road traffic accidents 31 (93.9%) were the most common mode of injury among the patients followed by domestic falls 2 (6.1%). The most common type of injury among the patients was closed fracture 22 (66.7%) and then compound fracture 11 (33.2%). The most common type of fracture was Transverse 12 (36.4%), followed by wedge fracture 9 (27.3%). The most common fracture level was middle 13 (39.4%), followed by distal level 7 (21.1%). The left side of the leg 20 (61%) was the most common side followed by the right of the leg 13 (39%).

Table 2 shows, the mean blood loss of the patients during the surgery. The mean blood loss was 82.58 ml±12.06.

Table 3 shows the Mean LEFS Score of the patients. The mean LEFS score after 6 weeks of surgery was 25.85±4.27, after 3 months was 49.27±5.63, and after 6 months was 66.27±6.00.

Table 4 shows the distribution of patients according to LEFS score, where all 33 (100%) patients had poor LEFS scores at 6 weeks post-surgery. After 6 months 11 (33.3%) had excellent LEFS scores, 16 (48.5%) had good scores and 6 (18.2%) patients had fair LEFS scores. (Fig.3 shows functional outcomes at 6 months).

Table 5, shows the association between LEFS score at 6 months after surgery and its influencing factors. Patients aged

< 20 years and between 21-30 years had excellent scores after 6 months of surgery. Lesser the age, the patients had an excellent LEFS score compared to elderly people. There was a significant relationship between age and LEFS score after 6 months (p<0.05). Males had Excellent (90.9%) scores compared to females (9.1%). Gender, type of injury, type of fracture, and fracture level had no significant relationship with LEFS score at 6 months (p>0.05).

Table 6 shows, the visual analogue scale of patients after surgery. The mean VAS score of patients after 2 weeks of surgery was 6.67±0.69, 4.52±0.62 after 6 months, 2.03±0.85 after 3 months, and 0.55±0.71 at 6 months.

Table 7 shows the Knee ROM of the patients. The mean Knee ROM score after 2 weeks of surgery was 90±7.60, 103.48±7.23 at 6 weeks, 114.24±7.61 at 3 months and 125.15±7.95 at 6 months.

Table 8 shows the Knee ROM of the patients. The Knee ROM after 2 weeks of surgery was < 90 degree for 21 (63.6%) patients and 91-100 degree for 12 (36.4%) patients. After 6 weeks, the knee ROM was < 90 degrees for 3 (9.1%) of the patients and between 91-100 degrees for 12 (36.4%) of the patients and 101-110 degrees for 19 (54.5%) patients. The knee ROM after 3 months of surgery was 3 (9.1%) patients had ROM between 91-100 degrees and 9 (27.3%) had ROM between 101-110 degrees, 18 (54.5%) patients had ROM between 111-120 degrees and 3 (9.1%) patients had ROM more 120 degrees.

Table 9 shows, the association between knee ROM at 6 months after surgery and its influencing factors. There was a significant relationship between age, gender, type of fracture, and fracture level knee ROM after 6 months (p < 0.05).

Table 10 shows, the mean weeks of union of bones after surgery. The mean time of union was 13.58±1.86. (Fig.4 shows the pre and post-operative x-ray at 6 months)

Table 11 shows, the distribution of patients according to complications after surgery. 3% of the patients had Anterior Knee pain on exertion after surgery. The remaining 97% of patients had no complications post-surgery.

Discussion

The suprapatellar approach simplifies nailing proximal and distal tibial fractures. In the present study, the functional outcome didn't show any difference based on the gender of the patient, but age showed a statistically significant relation with functional outcome. The younger the patient better the functional outcome. Various factors influence the postoperative knee ROM, including damage to vascularity and soft tissue. This study showed a lower mean knee ROM at 6 months of 125.15 +/-7.95 degrees which when compared to other studies, Sun *et al.* (13) (130.7±4.09) and Serbest *et al.* [14] (130.3±6.31).

The average time of radiological union was 13.58 weeks±1.86 weeks. In this study, the mean union of time was 95 days, but in studies of Yang *et al.* [32], Wang *et al.* [35], and Huang *et al.* [15], Liu *et al.* [16], Yan *et al.* [17], Fu SP *et al.* [18], it was 105.8, 82.3, 100, 82.63, and 95.6 respectively.

In this study the incidence of anterior knee pain was in 1 patient out of 33 patients, which is relatively less and comparable with other studies, Huang *et al.* [15], Liu *et al.* [16], Yan *et al.* [17], Wang *et al.* [19]. Anterior knee pain is the most common complication of the infrapatellar approach for tibia intramedullary nailing. The etiology remains unclear but it is most consistent with injury to the intraarticular knee structures, longitudinal incision of the patellar tendon during the transtendinous approach, and injury to the infrapatellar nerve [20, 21]. By making the incision proximal to the patella, the suprapatellar approach avoids these potential causes of anterior knee pain. Couterney *et al.* [22] reported that the infrapatellar nerve is well protected in the suprapatellar approach, but cannot make any significant difference in the incidence of pain between the supra and infrapatellar approaches.

This study showed a reduced mean VAS score of 0.55±0.71 at 6 months which is comparable to other studies of Serbest *et al.* [14] 1.12±1.5, and Sun *et al.* [13] 0.45±0.502. Daniel S [12] demonstrated that the VAS score in the suprapatellar group was equivalent to the infrapatellar group. Relived [23] reported that 38% of patients who underwent infrapatellar incisions had complications of chronic knee pain and the incidence of knee pain was much higher than the rate in the suprapatellar group in our study, which was thought to be significantly related to iatrogenic damage to the infrapatellar nerve. Gaines's (24) study indicated that the overall incidence of articular structure injury was higher with the infrapatellar approach than the suprapatellar approach through the cadaveric study, but no statistical difference was observed. Those potential causes of pain were theoretically avoided with the suprapatellar approach, which might interpret the lower VAS pain score in the suprapatellar group.

The mean blood loss was 82.58 ml±12.06, which is lower when compared to Liu *et al.* [16] (92.7±8.8), and higher when compared to Huang *et al.* [15] (70±5.2), and Fu SP *et al.* [18] (42.6±7.2). The mean Fluoroscopy time for the procedure was 84.18 seconds±6.77, which is of a little higher exposure duration when compared to Courtney *et al.* [22] (80.8) and Sun *et al.* [13] (80.61).

Table 1: Demographic characteristics of patients

S. No	Variables	Categories	Frequency	Percentage
1	Age	<20	4	12.1
		21-30	8	24.2
		31-40	5	15.2
		41-50	4	12.1
		51-60	3	9.1
		>60	9	27.3
		Total	33	100
2	Gender	Male	27	81.8
		Female	6	18.2
		Total	33	100
3	Co-morbidities	Yes	9	27.3
		No	24	72.7
		Total	33	100
4	Type of Co-morbidity*	Hypertension	7	21.2
		Diabetes	6	18.2

		Coronary Artery Disease	1	3
		Total	14	42.4
5	Mode of injury	Road traffic accidents	31	93.9
		Domestic fall	2	6.1
		Total	33	100
6	Type of injury	Compound	11	33.2
		Closed	22	66.7
		Total	33	100
7	Type of Fracture	Oblique	5	15.2
		Segmental	3	9.1
		Spiral	4	12.1
		Transverse	12	36.4
		Wedge	9	27.3
		Total	33	100
8	Fracture Level	Proximal	4	12.1
		Proximal Middle	1	3
		Middle	13	39.4
		Middle Distal	5	15.2
		Distal	7	21.2
		Proximal Middle + Middle Distal	3	9.1
		Total	33	100
9	Side	Right	13	39.4
		Left	20	60.6
		Total	33	100

Table 2: Mean Blood loss and intra-operative Fluoroscopy Time

S. No	Variables	Mean± SD
1	Blood Loss	82.58±12.06
2	Fluoroscopy	84.18±6.77

Table 3: Mean LEFS Score of the patients

S. No	Variables	Mean ± SD
1	LEFS Score (6 weeks)	25.85±4.27
2	LEFS Score (3 months)	49.27±5.63
3	LEFS Score (6 months)	66.27±6.00

Table 4: Distribution of patients according to LEFS

S. No	Variables	LEFS Score			
		Excellent	Good	Fair	Poor
1	LEFS Score at 6 weeks	0 (0)	0 (0)	0 (0)	33 (100)
2	LEFS Score at 3 months	0 (0)	2 (6.1)	29 (87.9)	2 (6.1)
3	LEFS Score at 6 months	11 (33.3)	16 (48.5)	6 (18.2)	0 (0)

Table 5: Association between LEFS score at 6 months and its influencing factors

S. No	Variables	LEFS Score at 6 months			P-Value
		Excellent	Good	Fair	
1	**Age**				
	< 20	3 (27.3)	1 (6.3)	0 (0)	**0.001**
	21-30	6 (54.5)	2 (12.5)	0 (0)	
	31-40	2 (18.2)	3 (18.8)	0 (0)	
	41-50	0 (0)	4 (25)	0 (0)	
	51-60	0 (0)	3 (18.8)	0 (0)	
	>60	0 (0)	3 (18.8)	6 (100)	
2	**Gender**				
	Male	10 (90.9)	14 (87.5)	3 (50)	0.08
	Female	1 (9.1)	2 (12.5)	3 (50)	
3	**Type of Injury**				
	Compound	5 (45.5)	4 (25)	2 (33.3)	0.541
	Closed	6 (54.5)	12 (75)	4 (66.7)	
4	**Type of Fracture**				
	Oblique	2 (18.2)	2 (12.5)	1 (16.7)	0.142
	Segmental	1 (9.1)	0 (0)	2 (33.3)	
	Spiral	0 (0)	4 (25)	0 (0)	
	Transverse	4 (36.4)	5 (31.3)	3 (50)	
	Wedge	4 (36.4)	5 (31.3)	0 (0)	
5	**Fracture Level**				
	Proximal	1 (9.1)	2 (12.5)	1 (16.7)	0.532

	Proximal Middle	0 (0)	1 (6.3)	0 (0)	
	Middle	4(36.4)	7 (43.8)	2 (33.3)	
	Middle distal	3 (27.3)	2 (12.5)	0 (0)	
	Distal	2 (18.2)	4 (25)	1 (16.7)	
	Proximal middle + Middle distal	1 (9.1)	0 (0)	2 (33.3)	

Table 6: Visual Analogue Scale during follow up

S. No	Variables	Mean + SD
1	VAS Score (2 weeks)	6.67±0.69
2	VAS Score (6 months)	4.52±0.62
3	VAS Score (3 months)	2.03±0.85
4	VAS Score (6 months)	0.55±0.71

Table 7: Mean Knee ROM during follow up

S.no	Variables	Mean + SD
1	Knee ROM Score (2 weeks)	90±7.60
2	Knee ROM Score (6 weeks)	103.48±7.23
3	Knee ROM Score (3 months)	114.24±7.61
4	Knee ROM Score (6 months)	125.15±7.95

Table 8: Distribution of Patients according to the Knee Range of Motion

S. No	Variables	Knee Rom				
		< 90	91-100	101-110	111-120	>120
1	KNEE ROM at 2 weeks	21 (63.6)	12 (36.4)	0 (0)	0 (0)	0 (0)
2	KNEE ROM at 6 weeks	3 (9.1)	12 (36.4)	18 (54.5)	0 (0)	0 (0)
3	KNEE ROM at 3 months	0 (0)	3 (9.1)	9 (27.3)	18 (54.5)	3 (9.1)
4	KNEE ROM at 6 months	0 (0)	0 (0)	3 (9.1)	6 (18.2)	24 (72.7)

Table 9: Association between Knee ROM at 6 months & its influencing factors

S. No	Variables	KNEE ROM at 6 months			P-Value
		101-110	111-120	>120	
1	**Age**				
	< 20	0 (0)	0 (0)	4 (16.7)	< 0.005
	21-30	0 (0)	0 (0)	8 (33.3)	
	31-40	0 (0)	0 (0)	5 (20.8)	
	41-50	0 (0)	1 (16.7)	3 (12.5)	
	51-60	0 (0)	0 (0)	3 (12.5)	
	>60	3 (100)	5 (83.3)	1 (4.2)	
2	**Gender**				
	Male	2 (66.7)	3 (50)	22 (91.7)	0.04
	Female	1 (33.3)	3 (50)	2 (8.3)	
4	**Type of Fracture**				
	Oblique	1 (33.3)	1 (16.7)	3 (12.5)	0.01
	Segmental	2 (66.7)	0 (0)	1 (4.2)	
	Spiral	0 (0)	0 (0)	4 (16.7)	
	Transverse	0 (0)	4 (66.7)	8 (33.3)	
	Wedge	0 (0)	1 (16.7)	8 (33.3)	
5	**Fracture Level**				
	Proximal	0 (0)	1 (16.7)	3 (12.5)	0.05
	Proximal Middle	1 (33.3)	0 (0)	0 (0)	
	Middle	0 (0)	3 (59)	10 (41.7)	
	Middle distal	0 (0)	1 (16.7)	4 (16.7)	
	Distal	0 (0)	1 (16.7)	6 (25)	
	Proximal middle + Middle distal	2 (66.7)	0 (0)	1 (4.2)	

Table 10: Mean weeks of radiological union of fracture

S. No	Variables	Mean ±SD
1	Time of Union	13.58±1.86

Table 11: Distribution of Patients according to complication

S. No	Variables	Frequency	Percentage
1	Anterior Knee pain on exertion	3	9.09
2	No complications	30	90.9
	Total	33	100

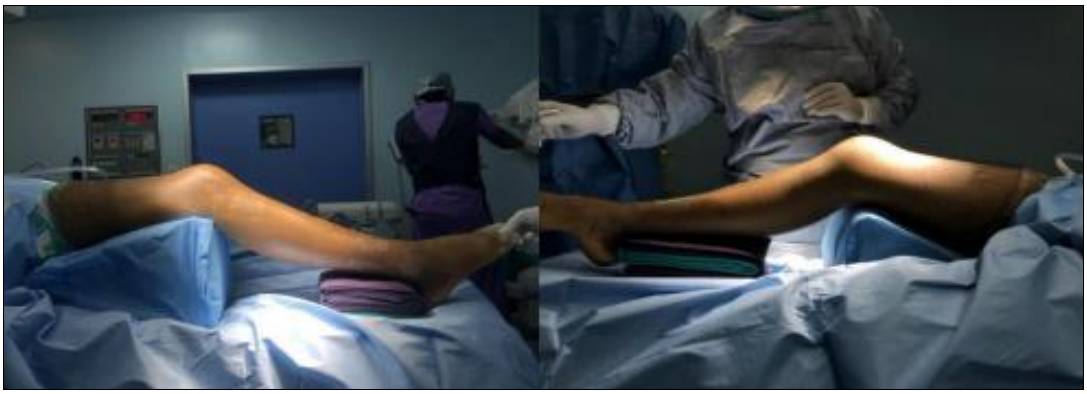

Fig 1: Positioning of Patient

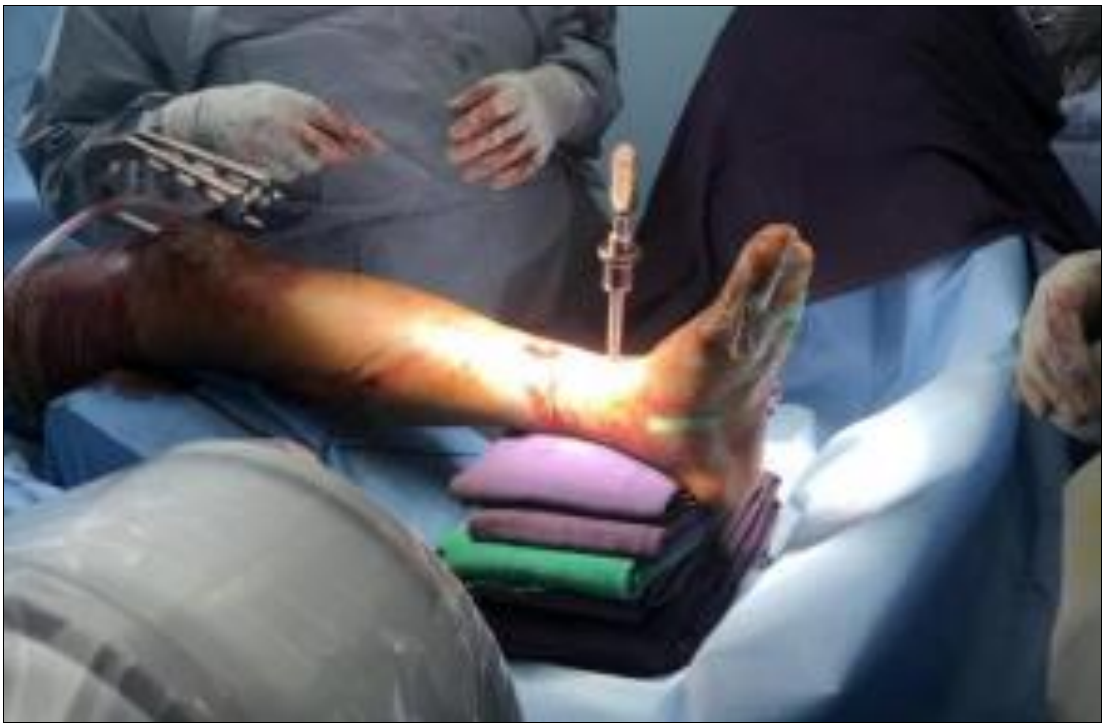

Fig 2: Distal Screw Insertion

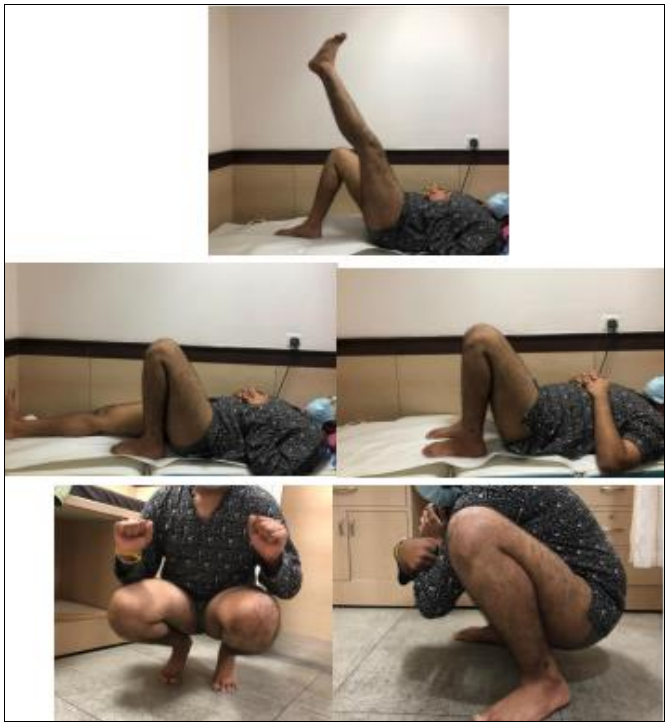

Fig 3: Functional Outcome at 6 Months

Pre-op

Post-op at 6 months

Fig 4: Pre-op & Post-op X-ray

Conclusion

The suprapatellar approach of intramedullary tibial nailing in semi extended position of the knee offers an alternative to the traditional infrapatellar approach for tibia diaphyseal fracture. Specific instrumentation with a cannula system allows for nail insertion in a safe fashion and minimizes the risk of iatrogenic damage to intra-articular structures. In the case of proximal third tibial fractures as well as all diaphyseal tibial fractures, the semi-extended position of the knee facilitates fracture reduction. The suprapatellar approach shows less incidence of anterior knee pain-Suprapatellar approach avoids injury to the patellar tendon and infrapatellar nerve, thus helps in avoiding undesirable postoperative anterior knee pain. It also helping in achieving good functional outcomes with minimal requirements of secondary procedures at lower complication rates in experienced hands provided that proper preoperative planning and patient selection are done. This approach supports achieving a reasonably good knee range of movements and thus helps earlier weight bearing and better functional outcomes at an average of 6 months.

Limitations

- The follow up period of 6 months is not adequate in a sizable number of patients. A longer follow up would be better to evaluate postoperative functional outcomes more accurately.
- It was an observational study with Level 5 evidence. A comparative analysis between the suprapatellar approach and other approaches would have provided a superior level of evidence.

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There was no source of funding in our study.

Conflict of Interest: None

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