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A Prospective Study to Compare the Outcome of Surgical Treatment of Compound Tibia Fractures by Staged Intramedullary Nailing After Preliminary External Fixation versus Primary Intramedullary Nail

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Abstract: ***Compound tibia diaphysis fractures that have extensive soft 7 tissue loss/destruction because of high energy trauma are a challenging problem (1). 8 Among all tibial fractures about 23% fractures are open and most of these are Gustilo 9 Anderson grade III (2) and most of them are due to the road traffic accident (51) Various modalities of 11 treatment were used in the past for the management of compound fracture of tibia and 12 these includes application of POP cast with window for dressing, use of external fixator 13 as definitive management till union. Material and methods- In this observational study, we stabilized compound leg fractures with external fixators, followed by interlocking nail procedures, comparing outcomes with primary interlocking nailing in 60 patients and were randomly divided into two groups of 30 each, with follow-up assessments at 1, 3, 6, and 9 months, evaluating functional outcomes based on the modified Johner Wruh's score. Result- In primary nailing, the average healing time was 19.30 weeks, with a non-union rate of 3.3%, and 33% excellent and 47% good results. In staged nailing, the average healing time was 20.87 weeks, with a non-union rate of 6.6%, and 10% excellent and 30% good results post-external fixator. Conclusion- Primary nailing facilitates early radiological union, enabling prompt weight bearing, minimal morbidity, and swift patient mobilization, offering robust fixation and rotational stability, leading to the quickest return to functional status compared to staged nailing.***

Keywords: Compound fractures, Tibia, External fixator, interlocking intramedullary nailing, staged intramedullary nailing

1. Introduction

With the rising trend in high-speed motor vehicle accidents, the occurrence of compound fractures has been escalating rapidly. A compound fracture is characterized by a break in the bone that penetrates the skin, often involving soft tissue damage and exposure of the fracture or its hematoma. Among the various types of compound fractures, those affecting the tibia are the most frequently observed. Tibial diaphyseal fractures, particularly those involving significant soft tissue damage due to high-energy impacts, pose a considerable challenge in medical treatment.[1] Approximately 23% of all tibial fractures are open fractures, with the majority classified as Gustilo-Anderson grade III. The majority of these fractures result from road traffic accidents, followed by falls, sports activities, assaults, gunshot wounds, and less common causes such as blast injuries. [2] Open tibial fractures exhibit contamination levels twice as high as other open fractures. With improved understanding of the importance of repeated wound debridement and early soft tissue coverage, outcomes have significantly improved. However, the subcutaneous nature of the tibia complicates secondary reconstructive procedures, leading to high rates of non-union and presenting a significant health resource challenge due to the associated high care costs. These costs are mainly due to the poor recovery of functional independence in many patients following conventional fracture care. Nonetheless, advancements in free flap techniques and microvascular procedures have provided reliable solutions for covering traumatic musculocutaneous defects. Ensuring union and preventing infection in compound leg fractures remains a major challenge for orthopaedic surgeons.

Treatment strategies for open tibial fractures depend on factors such as the fracture's characteristics, the patient's age and overall health, the condition of the surrounding soft tissues, and circulatory properties. The preferred method should allow for maximum functional restoration of the limb, optimal bone alignment, and length. Key factors that positively influence prognosis in compound tibial fractures include early treatment, ensuring proper circulation and soft tissue coverage, infection prevention, optimal surgical fixation techniques, and an effective rehabilitation program.

Recent advancements have greatly improved the management of open tibial fractures. Historically, treatments have included the application of a plaster of Paris (POP) cast with a window for dressing, the use of external fixators as a definitive management until union, the Ilizarov technique, and primary interlocking nailing, each with varying results.

In our current study, we stabilized compound leg fractures using external fixators after thorough debridement. Patients were then prepared for definitive management with interlocking nails. This approach was compared to primary interlocking nailing, considering factors such as cosmetic outcomes, frequent pin issues, the risk of fractures through pin tracts, risks of malunion, delayed union, non-union, and patient non-compliance in pin tract care, all of which can affect the durability of the fixator.

2. Materials & Methods

Study Design**:** This prospective observational study was done after approval of ethicscommittee of the institute. Study Approval: This study was approved by Institutional Ethics Committee. Written, informed and valid consent was obtained from all the patients participating in the study.

Study Population: 60 patients of either sex between age group 18-60 years of age came for the treatment at the Tertiary Care Center. All the cases were fresh fractures and traumatic in nature.

Sample size: Sample size for present study was decided to be 60 patients.

Inclusion Criteria:
Patients presenting with:
- Radiologically and clinically diagnosed Open Tibial fractures.
- Age group 18 and above.
- Consent to participate in the study
- Patient medically fit for surgery

Exclusion Criteria
Patients presenting with
- Gustilo-Anderson Grade I and IIIC* Compound Fractures
- Fractures with features suggestive of compartment syndrome i.e. local blebs, skin discoloration, tense swelling and absent distal pulsations.
- Fractures needing vascular repair.
- Refusal to provide informed consent.
- Patients below 18 years of age.

The study was conducted between the period of August 2020 to July 2022 at tertiary care hospital. Patients age ≥18 years of age with gustillo Anderson type II, IIIA and IIIB of compound tibia fracture who presented within 24 hours of injury were randomized to treatment with primary intramedullary nail or an external fixator and built the patient for definitive management by staged intramedullary nail after few weeks (average 5 week) of external fixator

The total 60 patients were randomly divided into two groups with 30 patients in eachgroup. Group A patients are managed by Primary intramedullary nailing and Group B Patients are managed with Staged intramedullary nailing after preliminary external Fixator. Follow up was taken at 1month, 3 months, 6months and 9 months. The patients were assessed functionally and compared on the basis of modified Johner Wruhs score as excellent, good, fair, poor. (Figure 1)

Johner and Wruhs' Criteria with Modification

Criteria	Excellent	Good	Fair	Poor
Nonunion/ infection	None	None	None	Yes
Neurovascular injury	None	Minimum	Moderate	Severe
Deformity				
Varus/valgus	None	2–5°	6–10°	>10°
Ante/Posterior	0–5°	6–10°	11–20°	>20°
Shortening	0–5 mm	6–10 mm	11–20 mm	>20 mm
Mobility				
Knee	Full	>90%	90–75%	<75%
Ankle	Full	>75%	75–50%	<50%
Pain	None	Occasional	Moderate	Severe
Gait	Normal	Normal	Mild limp	Significant limp

Figure 1: Modified Johner Wruhs score

Procedure details: In the emergency room, management adhered to ATLS guidelines, prioritizing Airway, Breathing, and Circulation (A-B-C). Once vital signs were stabilized and IV fluids administered, the wound was thoroughly cleaned, dressed, and the fractured limb immobilized. Patients underwent a series of radiological and blood tests, including ECG, CBC, liver and kidney function tests, blood typing, chest X-ray, abdominal ultrasound, and X-rays of the affected leg. Other systemic injuries were excluded, and the injured limb was placed in a Thomas splint with static traction.

During the pre-operative and perioperative periods, patients received prophylactic IV antibiotics, such as Ceftriaxone, Amikacin, and Metronidazole. Fractures were categorized using the Gustilo-Anderson classification. Pre-anesthetic evaluations were performed, and informed consent was obtained.

Patients were randomly assigned to receive either primary intramedullary nailing or an external fixator, with definitive management involving staged intramedullary nailing after several weeks.

External fixators were taken out after about five weeks, based on the wound's healing and absence of infection. This was followed by staged intramedullary nailing. Patients were monitored at 1, 3, 6, and 9 months after the procedure.

3. Observations & Results

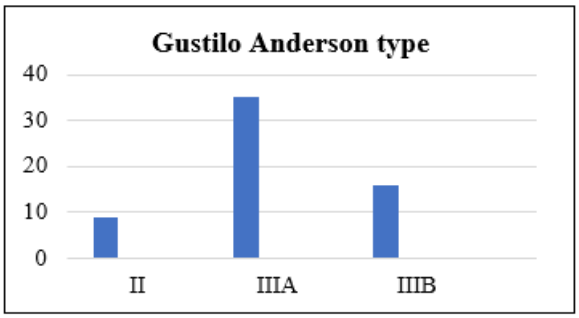
Gender distribution: Predominantly male sex than the female sex. The present study has 73% males (44) and 27% females (16).

Fracture type - Comminuted fractures accounted for 40% of (24 patients) of cases, followed by oblique fractures at 25 (15 patients). Wedge fractures were observed in 15% (9 patients), while transverse fractures and spiral fractures represented 14% (8 patients) and 3% (2 patients) respectively (Table 1).

Table 1: Fracture Type

Fracture type	No. of patients	Percentage
Comminuted	24	40%
Oblique	15	25%
Wedge	9	15%
Transverse	8	14%
Spiral	2	3%
Segmental	2	3%

Gustilo Anderson Injury Classification Type: 9 patients (15%) with Gustillo Anderson Grade II and 35 fractures (58%) were Grade IIIA and 16 patients (27%) were Grade type IIIB. (Graph1)



Graph 1: Gustilo Anderson type

Time period for staged nailing after preliminary external fixation: About 43% (13 patients) and 33% (10 patients) among the Group B were operated between 5-6 weeks and 4-5 weeks respectively with definitive intramedullary nailing after preliminary external fixator. (Table 3)

Table 2: Time period for staged nailing after preliminary external fixation

Period	No. of Patients	Percentage
4-5 weeks	10	33%
5-6 weeks	13	43%
6-7 weeks	7	23%
7-8 weeks	3	10%

Pain intensity at 6 months: At the six-month mark, 16 patients who underwent primary nailing reported no pain, compared to 5 patients who had secondary nailing. Among those with primary nailing, 37% (11 patients) experienced occasional pain, while 10% (3 patients) reported moderate pain. In the secondary nailing group, 7% (2 patients) experienced severe pain, 43% (13 patients) had occasional pain, and 33% (10 patients) reported moderate pain (refer to Table 4).

	No. of patients	
Pain	Primary Nailing	Staged Nailing f/b Ext Fix
Nil	16	5
Occasional pain	11	13
Moderate pain	3	10
Severe pain	0	2

Average time of union/consolidation in weeks: Most fractures in both primary nailing and staged intramedullary nailing patients exhibited consolidation at the fracture site. The average healing time was 19.30 weeks for primary nailing patients and 20.87 weeks for those who had staged nailing. Non-union occurred in 6.6% (2 patients) of the staged nailing group, compared to 3.3% (1 patient) in the primary nailing group. (Table 4)

Table 4: Average time of union/consolidation in weeks

Primary Nailing	19.30 weeks
Staged nailing after preliminary External fixation	20.87 weeks

Radiological union: In primary nailing, 96.66% (29 patients) demonstrated union/consolidation, whereas 93.33% (28 patients) showed union/consolidation on X-ray in staged nailing.

Table 7: Radiological union

	No. of patients	
Radiological union	Primary Nailing	Staged Nailing f/b Ext Fix
Consolidation	29	27
Union	0	1
Non-union	1	2

Complications: The infection rate was 3% in the primary nailing group, while it was 6.6% in the staged nailing group with preliminary external fixators. In the staged nailing group, 40% (12 patients) developed pin tract infections. Non-union occurred in 6.6% (2 patients) of the staged nailing group and in 3.3% (1 patient) of the primary nailing group.

Complications	Primary nailing		Staged nailing	
	No. of patients	%	No. of patients	%
Pin Track infection	0	-	12	40%
Surgical site infection	1	3%	2	6.6%
Nonunion	1	3%	2	6.6%
Anterolateral Knee Pain	2	6.6%	1	3%
Shortening	2	6.6%	5	16%

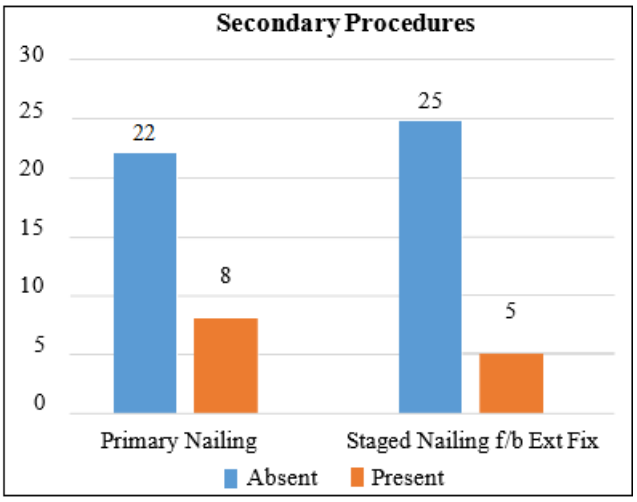
Deformity at 6 months: Valgus deformity was noted in 10% (3 patients) of primary nailing cases and 13% (4 patients) of staged nailing cases. Varus deformity occurred in 10% (3 patients) of the staged nailing group. Anteversion deformity was found in 10% (3 patients) of the primary nailing group and 20% (6 patients) of the staged nailing group. Retroversion deformity appeared in 3% (1 patient) of the staged nailing group. No recurvatum deformity was observed in the primary nailing group.

	No. of patients	
Deformity	Primary Nailing	Staged Nailing f/b Ext Fix
Absent	24	16
Valgus	3	4
Varus	0	3
Anteversion	3	6
Recurvatum	0	1

Type of Gait: Nearly all patients treated with primary nailing had a normal gait (93%, 28 patients), with only 7% (2 patients) experiencing a mild limp. In contrast, patients who underwent staged nailing predominantly exhibited limping: 47% (14 patients) had a mild limp, and 7% (2 patients) had a significant limp.

	No. of patients			
Gait type	Primary Nailing		Staged Nailing f/b Ext Fix	
Normal	28	93%	14	46%
Mild Limp	2	7%	14	47%
Significant Limp	0	0%	2	7%

Secondary procedures: Secondary procedures often linked with severe soft tissue loss such as in compound tibia fractures (Gustillo-Anderson type 3A and 3B), were more commonly associated with primary nailing in this study, with 26.6% (8 patients) requiring secondary procedures like split skin grafting or musculocutaneous flaps. In contrast, 16.6% (5 patients) of the staged nailing group needed secondary procedures.



Graph 2 Secondary procedures

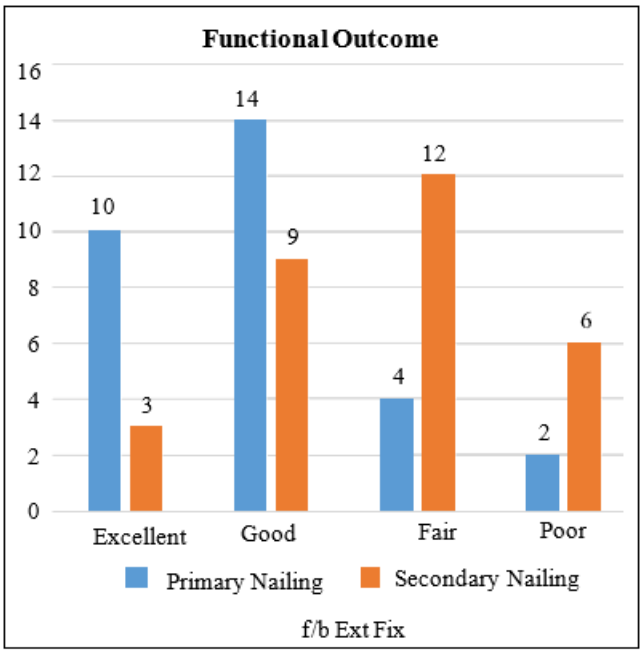
Functional outcome: According to Johner and Wruhs criteria:

In primary nailing:

- Excellent results: 33% (10 patients)
- Good results: 47% (14 patients)
- Fair functional outcome: 13% (4 patients)
- Poor functional outcome: 7% (2 patients)

In staged nailing after preliminary external fixator:

- Excellent results: 10% (3 patients)
- Good results: 30% (9 patients)
- Fair functional outcome: 40% (12 patients)
- Poor functional outcome: 20% (6 patients)



Radiograph and clinical photos:

Figure 7: Primary nailing, Case no 1. a. Wound picture and Preoperative xray **b.**immediate post-op xray (anteroposterior and lateral view) **c.**6 month post-operative xray **d.**Clinical picture at

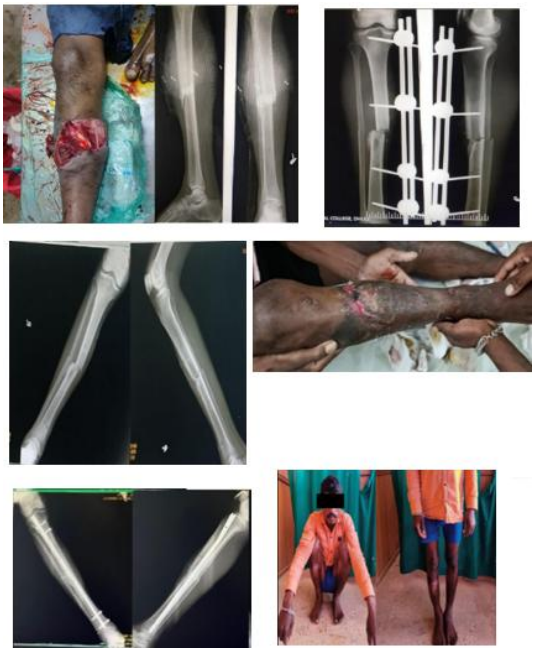


Figure 9: Staged Intramedullary Nailing, Case -1, a.clinical picture and preoperative xray, **b.** immediate post of xray after external fixator application, **c.**xray and clinical picture of wound external fixator removal, **d.** immediate postoperative xray after staged intramedullary nailing, **e.** follow-up xray after 6 months, **f.** clinical pictures after 6 months

Age distribution:
In a study titled 'The Epidemiology of Tibial Fractures' by Court Brown et al. (1995), the average age was reported to be approximately 37 years. Peter Larsen and Rasmus Elsoe (2015) mentioned a mean age of 38.8 years, while David Wennergren et al. (2018) reported a mean age of 47 years.

In our present study, the average age of patients undergoing primary nailing was 32.83 years, ranging from 22 to 55 years. For staged nailing with preliminary external fixation, the average age was 31.67 years, with a range of 20 to 58 years. The overall average age, including both primary nailing and staged nailing patients, was 32.25 years, which aligns with findings from other studies.

Diaphyseal tibia fractures were predominantly observed in younger individuals, likely due to their increased physical activity and participation in various outdoor activities. These injuries were often associated with high-velocity mechanisms, primarily road traffic accidents.

Mode of Injury
In an earlier study by Lawrence B Bone et al. (1968), a 90% incidence of road traffic accidents (RTAs) was reported in tibial shaft fractures. Court Brown et al. (1994) observed a 40.7% incidence of RTAs in their study, while Priyank V Kalaria and Chirag S Kapoor (2018) noted a 72% incidence of RTAs. Sakaki et al. (2007) reported a 91.7% incidence of RTAs in their study.

In our present study, we found that the majority of tibial diaphyseal fractures were due to road traffic accidents, accounting for 85% (51 patients), with falls other than RTAs contributing to 15% (9 patients) of cases. These RTAs predominantly involved motorists, with a smaller proportion involving motor vehicle occupants.

Anatomical location- In Lawrence B Bone et al.'s series (1968), middle-third fractures accounted for 53.5% of cases. Hooper et al. (1991) reported a 48% incidence of middle-third fractures, while Court Brown et al. (1994) found that 44% of fractures occurred in the middle third of the tibia. Vikram Sharma (2019) observed that 57.4% of fractures occurred in the middle third, with 25.5% in the lower third of the tibia.In our present study, fractures were most commonly located in the middle segment of the tibia, including the middle third, junction of proximal & middle third, and junction of middle & lower third, accounting for 54% (32 patients). An equal number of fractures were observed in the proximal and lower third of the tibia shaft, totaling 46% (28 patients).

Middle-third fractures are frequent due to the tibia's anatomical features, including its greater rigidity and subcutaneous nature, which make it more susceptible to injury forces

Type of fracture:
Arne Ekeland et al. (1988) found that 42% of fractures were transverse and oblique. Court Brown et al. (1994) reported 41.6% of proximal tibia fractures as transverse and oblique, followed by distal and middle. Vikram Sharma (2019) observed that the majority of fractures were transverse (68%), with oblique fractures accounting for 21.2%.

In our study, comminuted fractures were the most common type, comprising 40% of cases, followed by oblique fractures at 25% and wedge fractures at 15%.

Radiological Union- Previous studies by Lawrence B. Bone et al. (1968), Court Brown et al. (1994), Sakaki et al. (2007), and Arne Ekeland et al. (1988) reported average union times ranging from 16 to 19 weeks. T. Sureshkumar (2014) noted longer union times for Gustillo Anderson type IIIA and IIIB fractures treated with staged nailing after preliminary external fixation, averaging 31 and 47 weeks respectively.

In our study, the average union time for primary nailing was 19.30 weeks, while for staged nailing with preliminary external fixation, it was 20.87 weeks. Primary nailing patients showed earlier union compared to those with staged nailing. Non-union rates were 6.6% in staged nailing and 3.3% in primary nailing. Radiological union was achieved in 96.66% of primary nailing patients and 93.33% of staged nailing patients.

Complications -In previous studies by Lawrence B. Bone et al. (1968), Arne Ekeland et al. (1988), and Blachut PA et al. (1997), infection rates ranged from 1% to 6.25%. In our study, the infection rate was 3% in the primary nailing group and 6.6% in the staged nailing with preliminary external fixator group. Among staged nailing patients, 40% developed pin tract infections, managed according to CHECKETTS-OTTERBURN classification.

Anterolateral knee pain occurred in 1 patient with primary nailing and 2 patients with staged nailing due to nail abutment against soft tissues, similar to findings by Sakaki et al. Limb

shortening was more common in staged nailing (23.3% vs. 6.6% in primary nailing), especially with comminuted fractures, managed with heel raises. Non-union rates were 6.6% in staged nailing and 3.3% in primary nailing.

Deformity assessment - In Arne Ekeland et al.'s (1988) study, valgus deformity of 6-10 degrees was observed in 6 patients and varus deformity in 4 patients among 43 participants. Blachut PA et al. (1997) found valgus deformity of 6-10 degrees in 3 patients and varus deformity in 2 patients among 152 participants.

In our study, valgus deformity was observed in 10% of primary nailing patients and 13% of staged nailing patients, while varus deformity was seen in 10% of staged nailing patients. Anteversion deformity was noted in 10% of primary nailing patients and 20% of staged nailing patients, with retroversion deformity in 3% of staged nailing patients. No recurvatum deformity was observed in primary nailing patients. Our patients generally tolerated these deformities well, and they were not interested in secondary procedures for correction due to satisfactory clinical outcomes.

Functional Outcome

Assessment at 6 months post-surgery in our study utilized Johner and Wruh's criteria, evaluating gait, pain, deformity, joint range of motion, shortening, neurovascular status, activity level, radiological union, and non-union presence. Previous studies by Klemm et al. (1986), Arne Ekeland et al. (1988), Ahmet Aslan et al. (2014), Jagatjit M et al. (2018), and Vikram Sharma (2019) reported varying functional outcomes using similar criteria.

In our study, 33% of primary nailing patients achieved excellent outcomes, with 47% achieving good outcomes, while 13% had fair outcomes and 7% had poor outcomes. In staged nailing after preliminary external fixation, 10% had excellent outcomes, 30% had good outcomes, 40% had fair outcomes, and 20% had poor outcomes, with 2 cases of non-union.

Overall, we attained excellent and good outcomes in 80% of cases, with fewer complications and early functional recovery. The primary nailing group showed better outcomes compared to the staged nailing group, with fewer cases of poor functional outcomes and non-union.

Conclusion-In managing compound tibial diaphyseal fractures of Gustilo Type II, IIIA, and IIIB, Primary Nailing yields a clinically good outcome in over 80% of cases, superior to staged intramedullary nailing after preliminary external fixator, where only 40% achieve excellent or good functional outcomes. Primary nailing allows for early radiological union, weight-bearing, and patient mobilization, with less morbidity. It offers strong fixation and rotational stability, leading to quicker return to function compared to staged nailing. This one-stage procedure with minimal infection rates is recommended for open tibia fractures, particularly beneficial for patients from remote areas seeking treatment in tertiary government centers.

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