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Evaluation of the comparative results of ender's nailing and AO type external fixator in the management of open fractures of the tibial shaft. (Gustilo type II, type IIIA and type IIIB): A comparative study

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Abstract

Background: Open tibia fracture, due to high energy or low energy trauma classified according to Gustilo-Anderson classification system. There are five keys to successful treatment: antibiotic therapy, radical debridement and pulsed lavage irrigation, stabilization of fracture with minimal further devascularization, early soft tissue coverage and early bone-grafting.

Methods: The study included a total 24 patients of open fracture of tibia shaft type II, IIIA and IIIB (Gustilo) managed in IMCHRC Indore from 01/09/2018 to 01/09/2019. In these study we include pt. of both sex (19 males & 5 females).

Results: Open tibia fractures were mostly in males (79.2%) where 70% were young patients with a mean age of 37 yrs. Among these patients 75% sustained high velocity injury. Mean period of fracture union in ENDERS group were 24.05 weeks (range 22 to 28 weeks) while in external fixator group was 27.08 weeks (range 29 to 30 weeks). Among these 24 cases infection detected in 3 cases (all were treated by external fixator; 06 cases belong to Gustilo-Anderson III group). 33.33% mal-alignment in external fixator group in comparison to 16.6% in patients treated with ENDERS nail.

Conclusion: Open tibia fracture treated with ENDERS nail united earlier than external fixator and total number of secondary surgeries to achieve union in ENDERS nail was significantly lesser than external fixator group. Infection and mal-alignment rate was also high in external fixation cases.

Keywords: Management, Tibial, Comparative, fractures

Introduction

Tibia diaphyseal fractures are the commonest long bone fracture encountered by most of the orthopaedic surgeon. They are approximately 3 times more frequent in male than in female ^[1]. Because one third of the tibial surface is subcutaneous throughout most of its length, open fractures are more in tibia than in any other major long bone. Furthermore, the blood supply of tibia is more precarious than that of bone enclosed by heavy muscles ^[2]. Open tibia fracture are more severe as compared with those in the upper limb because of the degree of soft tissue damage and frequency of associated musculoskeletal injuries. The important factors in prognosis are (1) Amount of initial displacement (2) Degree of comminution (3) Degree of contamination and (4) Severity of soft tissue injury excluding infection ^[2].

Classification of open fracture Soft tissue injuries were classified according to criteria of gustilo *et al.* ^[3-5]. This classification system can be used to guide treatment. Wound infection in patients who have open fractures correlates directly with the extent of soft tissue damage. The system is prone to poor inter-observer reliability, especially with inexperienced surgeon, S ^[6]. Recently it has emerged that injured limbs are appropriately categorised by this system after wound excision ^[7]. Another drawback of the Gustilo classification is the relative lack sophistication in the description of the skeletal injury. Despite these limitation's, this system is simple and has found widespread application.

Clinical features and initial management

Open fracture of the tibia and fibula present as any other fracture, with pain, swelling and deformity following trauma.

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Soft tissue injury of varying degree present over the fracture site. The patient should be approached as any other patient following trauma by the Advanced Trauma Life Support (ATLS) guidelines. A detailed history taken if possible. A history of the cause of the trauma and the velocity aid appreciation of the soft tissue damage. Anteroposterior and lateral X rays of the entire tibia and fibula as well as the knee and ankle joint should be taken. The patient should then be transferred to the operating theatre as soon as possible and Under anaesthetic the limb is fully exposed and through debridement done. Tissue of questionable viability can be left for a second look in 48 hours. Swabs should be taken from the wound site to guide antibiotic therapy in the post-operative period. After primary management of fracture site look for stabilization of fracture. The choice of technique for stabilisation of open tibial fractures has not been analysed. Currently there are 2 major surgical therapies for open tibial fractures. Intra medullary nailing allows earlier extremity weight loading and less stress shielding [8], which can result in better fracture union. External fixation also is popular because of its easy application and economy, while pin site complications such as infection may be major hazards to consider and to prevent [9]. External fixation is usually recommended more for severe open fractures, and it is more successful in superficial bones such as the tibia [10].

External fixation is frequently used within this category because internal fixation methods may need more exposure of the wound site and therefore increase the risk of further contamination. However, with use of systemic antibiotics and better avoidance of bone gap [11] now-a-days also prefer flexible intramedullary nailing, which provides a relatively more stable fixation and better bone union efficacy with less bone cavity exposure and

less bone marrow related complications [12]. We reviewed the results of comparative studies and controlled trials designed to determine the therapeutic effects of the 2 different methods. As the choice of these two methods remained inconsistent, our purpose were to better define their advantages and disadvantages, and thereby enabling better decision making in a tertiary level health facility.

Material and Methods

Twenty four patients who presented to Department of Orthopaedic Surgery of index medical college hospital and research centre Indore with open fractures of the tibial shaft type II, IIIA, and B (Gustilo) were treated between 01.09.2018 and 01.09.2019 were considered for the trial. In this study we included the patients of both sexes, who are between 20-60 years ago with diaphysal fractures 5cm distal to the tibial tuberosity and at least 5 cm proximal to the tibial plafond, irrespective of fibula fracture and Open fractures type II, IIIA, and IIIB according to Gustilo Anderson classification. We excluded the patients with intraarticular fractures of proximal/distal tibia, closed fractures and Gustilo type IIIC fractures, surgically unfit patient, unwilling patient. After these inclusion and exclusion criteria, twenty-four patients (19 male and 5 female) were randomised on the basis of odd or even medical record number. Other than the method of stabilisation, author followed a standard treatment protocol for both groups. Twelve patients were treated by statically AO external fixator and twelve by ender's nailing.

Observation and Result

Table 1: Age wise distribution

	Treatment					
	Ender's nail			External fixator		
	Mean	Median	Standard deviation	Mean	Median	Standard deviation
Age	36	32	14	38	35	12

Table 1 In present study younger patients were more prone for open fracture because those are more active and outside worker.

Table 2: Sex wise distribution

Sex	Frequency	Percent
Female	5	20.8
Male	19	79.2
Total	24	100.0

Table 2 shows distribution of cases according to their sex amongst total number of cases. The higher incidence of male population is due to the distribution of high energy and heavy work in male population as compare to female population.

Table 3: Distribution according to mode of injury

Road side accident	18	75.0%
Sport injury	00	00.0%
Assault	02	8.3%
Fall from height	04	16.6%
Total	24	100%

Table 3 shows distribution according to mode of injury. More number of road side accident are due to poor road infrastructure and maintenance in these region and included more young active people those outdoor activities is more. And less sport injury due to major is games not played.

Table 4: Distribution according to injured site

Right	12	50.0%
Left	12	50.0%
Total	24	100.0%

Table 5: Distribution according to level of injury

Level of fracture	External fixator (n = 12)	Percent	Ender's nail (n = 12)	Percent
Upper	4	33.33%	3	25.0%
Middle	5	41.66%	7	58.33%
Lower	3	25.0%	2	16.66%
	12	100.00%	12	100.00%

Table 5 show distribution according to level of injury in leg. In present study tibia fractures commonly involved middle level on both groups.

Table 6: Distribution according to type of fracture

	External fixator (n = 12)		Ender's nail (n = 12)	
Transverse	6	50%	9	75%
Oblique	3	25%	2	16.6%
Segmental	0	00	0	00
comminuted	3	25%	1	8.3%

Table 7: Distribution according to treatment

Gustilo classification	Ender's nail		External fixator	
	Count	%	Count	%
II	4	33.3%	2	16.7%
III A	5	41.7%	4	33.3%
III B	3	25.0%	6	50.0%

Table 8: Requirement of secondary surgical procedure

	Ender's nail (n = 12)	External fixator (n = 12)
Muscle flap	1 (8.3%)	3 (25%)
Bone grafting	NA	2 (16.6%)

Table 8 shows more numbers of secondary surgical procedures required in external fixator group because the patients in the external fixation group had more grade IIIB injuries than those in the ender's nailing group (50 percent as compare with 25 percent).

External fixator group

The external fixator group comprised twelve fracture patients. The average age of the patients was 38 years (25 to 60 years). All fractures patients were stabilised by AO external fixator, in all cases were used delta configuration for fixation. Ten fractures (83.3%) were used six schanz pin per case and two patients (16.7%) used seven pin per case. The average time in external fixation was 11 weeks. After removal of fixator eleven fractures patients were treated with a cast, but two patients require second surgery as bone grafting.

Time of union: The time of union averaged 27.08 weeks (26 to 30 weeks); the average time for union was 26 weeks for grade II, 26.75 weeks for grade IIIA, 27.66 weeks for grade IIIB.

Alignment: Two fracture (16.7%) had 7 degree of valgus angulation; two (16.7%) had 7 degree of varus mal-union, three patients had between 7 and 10 degree of recurvatum, two patients present with comminuted fracture healed with shortening of 1 centimetres.

Range of motion: Eight fractures had between 110 and 130 degree knee flexion, four patients had 100 or less knee flexion, two patients had 5 degree of extension deficit. Two patients had major loss of dorsiflexion of the ankle. Two patients had equines contracture.

Implant failure: Three fracture patients (25%) had loosening of schanz pin from insertion site.

Pain: Six patients were associated with mild pain in the leg, and pain usually was exacerbated by activity. No neurovascular complications were associated with the insertion of pins.

Number of operations: The total number of operations averaged 2.3 including debridement, delayed primary closure,

removal of fixator and application of a cast, iliac-crest bone-grafting, split-thickness skin grafting, local or free flap coverage.

Infection: In six patients (50%), a pin track infection developed. Five patients infection cleared after application of betadine pin track dressing and antibiotics but one needed curettage of the infected tract. Two patients (16.6%) grade IIIB developed deep infection (chronic osteomyelitis) with pus discharging sinus and were convert in infected non-union.

Ender's nailing group

The ender's nailing group consisted of twelve fracture patients. The average age of the patients was 36 years (range 20 to 62 years). Eight fractures (66.6%) needed only two enders nail, three fracture (25.0%) were stabilised with three nail, and one (8.3%) had four nails. The average duration of immobilisation, generally with tibia brace, was 2.9 months. The 4.0 mm nail was most commonly used, although the 4.5 mm nail was inserted in young patients who had a large medullary canal.

Time of union: Union was occurred in all patients. The time to union averaged 24.05 week (range 22 to 28 weeks); the average time of union was 22.5 weeks For grade II fractures; 23.6 weeks for grade IIIA; 27.0 weeks for grade IIIB.

Alignment: One fracture (8.3%) had 7 degree of valgus angulation, one fracture (8.3%) had 7 degree of recurvatum.

Range of motion: Ten fracture (83.3%) had 130-degree knee flexion, two patients (16.7%) had 120 or less knee flexion; no one patients had extension deficit; ankle movement of normal in all patients.

Implant failure: In one fracture one nail back out through the skin, no nail broke in the shaft portion but the eye of the nail broke in one patient.

Pain: Two (16.6%) patient were complaint of nail insertion site pain, patients needed removal of nail for relief of pain. Three patients (25%) were associated with mild activity related pain in the leg at the level of fracture.

Number of operations: The total number of operations averaged 1.8 including debridement, delayed primary closure, skin grafting, local or free flap coverage and removal of nail.

Patients 1

A grade IIIA open tibial fracture in a 22-year old female stabilised by enders nail

**Wound photograph**



**Pre-operative
Photograph**

**Immediate post-operative
Photograph**



At 1 month

At 3 month

At 6 month

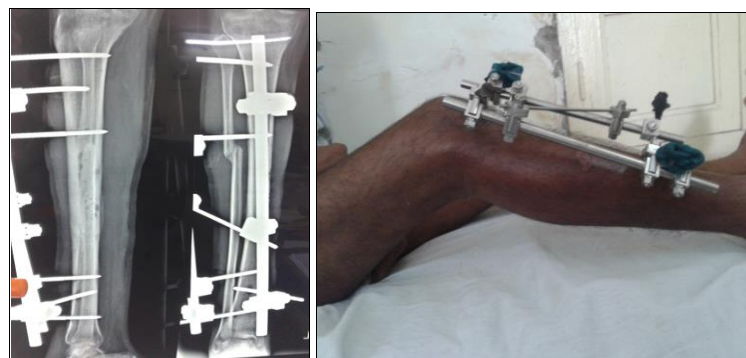
Patients 2

A grade IIIA open tibial fracture in A 32 year-old male stabilised by external fixator



Wound photograph

Pre-operative photograph



At 6 month

Wound healing

Discussion

With all methods of treatment of compound tibia fractures the major problem encountered are infection, non-union, joint stiffness and mal alignment. All these complications prolong the patient's disability.

Mean age in our study was 36 years for Enders nailing group and 38 years for external fixator group which was quite comparable to other studies (Fig - 1). All these studies show that these injuries occur in a younger age group [8, 9, 13-16].

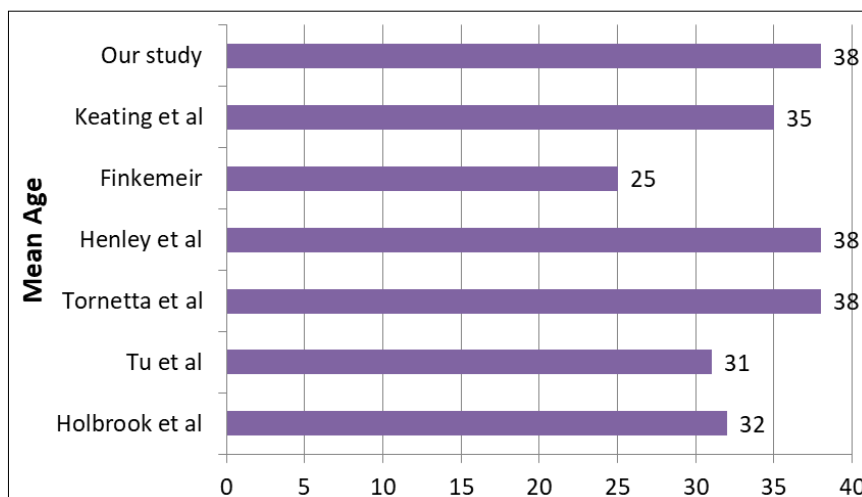


Fig 1: Comparison of mean age of different studies

In present study male involvement was in 79.2% (19 patients) and female involvement was 20.8% (5 patients). Which is almost identical to other studies in the literature. (Fig - 2).

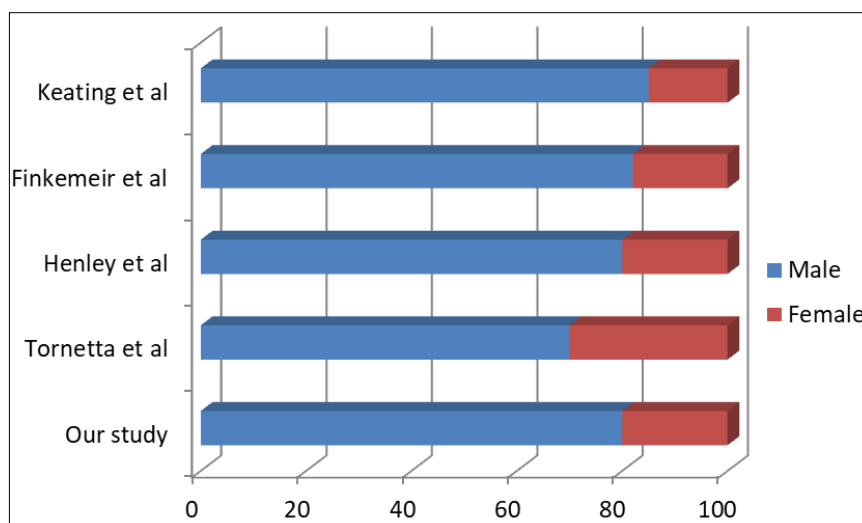


Fig 2: Comparison of male and female involvement in different studies

Several series of patients who were treated only by external fixation have been published. Dr. Muhammedimran *et al.* (2007) [17] conducted study on 25 patients with open fractures of the tibia diaphysis. The end result of the external fixation of 25 tibia shaft fractures; 18 (72%) men and 7 (28%) women with average age of 37.7 years (16-65 years). The union rate was 83%, non-union rate was 12% and mal-union was 5%. Pin track infection rate was 10% and average time of union was 28.5 weeks (15-22 weeks). John and Holbrook *et al.* (1989) [18] conducted study on sixty-three open tibia fractures using external fixation in twenty-eight patients. Average age 25 years, average time of union 26 wks, mal-union in ten patients (36%) non-union was in 3 patients (11%), pin track infection presents in 6 patients (21%). In present study for external fixation mean age was 38 years (25-60). The union rate was 84.4%, non-union rate 16.6% and mal-union was 33.3%. Pin track infection rate was 50%. And average time of union 27.08 weeks (26-30 weeks). A shikali *et al.* (2010) [19] fixation of compound fractures of distal tibia with external fixator mean time of union 24 weeks. Tucker *et al.* [20] and schatzker [21] in separate studies reported union time of 25.6 weeks and 21.9 weeks respectively. Similarly, wheelwright and court brown [22] and Antich *et al.* [23] reported a union rate of 27.5 weeks and 26 weeks respectively. Kaftandzhev [24] in his study

produced union in 71.1% of the patients. Bratislav Stojkovic [25] reported a union rate of 83.68% in his 49 patients. Kimmel [26] reviewed fifteen open tibia fractures that were treated with external fixation noted a 7 percent rate of non-union, a 50 percent rate of pin tract drainage, a 47 percent rate of osteomyelitis, and 26 percent rate of mal-union. In present study rate of osteomyelitis is 16.6%. which is lower than above study. Velazco and Fleming [27] studied on forty open tibial fractures, noted an 80 percent rate of pin tract infection, a 12.5 percent rate of delayed union, and 12.5 percent rate of amputation. Mal-union was not described. Because of the disadvantage of external fixation, interest in nailing without reaming of tibia fractures is increasing. Dobozi *et al.* [28] reported on 192 tibial fractures, including sixty-one open fractures that were treated with flexible intramedullary nailing. They noted a 5 percent of mal-union, a 3 percent rate non-union, and 3 percent of deep infection in the open fracture group.

John and Holbrook *et al.* (1989) [18] conducted study on sixty three open tibia fractures used enders nailing in twenty-nine patients, average age 28 years, average time of union 24 wks., mal-union in 6 patients (21%) non-union rate was 10%, pain at nail head in 11 patients (38%). In present study results for enders nailing, the mean age is 36 years (20-62 years), mal-

union is 8.3%, pain at nail head rate is 16.6%. And average time of union is 24.05 weeks. Union achieved in all cases. These study result were approximately same to above mentioned studies.

Flexible intramedullary nail offers advantages of Good fixation and control of alignment without periosteal stripping or risk of pin tract infection, early walking with weight-bearing, low incidence of infection, good access for care of the wound and early mobilisation of the joint. Flexible intramedullary nails have some disadvantages also like frequent use of a second surgery for nail removal procedure, the necessity for surgical expertise in closed nailing, less secure fixation in fracture of the distal and proximal one-thirds of the tibia and in comminuted fractures, possibility of loss of reduction, discomfort in the knee joint from prominent nail-heads, the risk of extension of infection throughout the medullary canal.

Table 9: The results of this study allow direct comparison of the results of external fixation and enders nailing

	External fixator (n = 12)	Enders nail (n = 12)
Age mean (year)	38 years	36 years
Union duration	27.08 weeks	24.05 weeks
Union rate (%)	10 (83.33%)	12 (100%)
Mal-union	4 (33.33%)	2 (16.6%)
Non-union	2 (16.66%)	NA
Pain		
▪ Mild activity	6 (50%)	NA
▪ Nail head	NA	2 (16.6%)
No. of surgical procedure	2.3	1.8
Loss of motion		
▪ <100 degree of knee flexion	4 (33.33%)	2 (16.66%)
▪ Restriction of dorsiflexion	2 (16.66%)	NA
Implant failure	3 (25%)	2 (16.66%)
Pin track infection	6 (50%)	NA
Osteomyelitis	2 (16.66%)	NA

The patients in the external fixation group had more grade IIIB injuries than those in the ender's nailing group (50 percent as compare with 25 percent). The predominant influence on rapidity of bone healing was the severity of soft tissue injury, so the rate of non-union is higher in the external fixation group. Limb alignment was better maintained by enders group than by external fixation. Fracture treated with enders nail had fewer infection /inflammations than did those treated with external fixator, as expected the external fixator group was prone to pin tract problems, and these problems contributed to a statistically significant higher incidence of these complications at surgical interfaces for this fixation method. The incidence of osteomyelitis was higher in external fixation group. The patients in the external fixation group needed considerably more operative procedures. In external fixator group three patients required muscle flap surgery for wound closure. Many patients in the external fixation group complained of pain at the fracture site due to mild activity compared with the patients in the enders nailing group. The rate of discomfort in the knee joint due to prominent nail-head was problem in ender nailing group and was similar to that in the other reported series.

Postoperative hospital staying was varied 5-7 days in ender's nail group but in external fixator hospital stay duration more than ender's nail group because patients need proper physiotherapy training and learned self-pin track dressing. In external fixator group were required readmission of two patients

for non-union treatment. Final Functional result on modified Ketenjian criteria of enders nail is excellent (83.3%), good (16.6%) as compared to external fixator is excellent (50%), good (25%), fair (8.3%), and poor (16.6%).

Conclusion

This study of 24 patients of open tibia fractures, treated by using a prospective, systematically allocated protocol, shows that enders nailing is more efficacious than external fixator. Advantages observed are maintaining limb alignment and fewer serious complication, fewer operation needed, and a better range of motion of adjacent joints obtained. It reduces hospital stay of patients and later patient can return early to work, thus minimizes psychological trauma and financial burden. Ender's nailing has easy learning curve. External fixator group had more disability and difficulties in daily routine activity like sleeping, bathing and other social activity. Intramedullary nailing for Gustilo's grade I is established worldwide. Availability of plastic surgery facility, better asepsis and newer broad-spectrum antibiotics are encouraging nailing in grade II also. Dilemma between rigid nailing and external fixator is persisting in grade II, IIIA, IIIB. Authors feel role of ender's nailing is better than external fixator in these fractures.

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