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A study on the outcome of open tibial fractures managed definitively by external fixator

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Abstract
Introduction: High energy tibial diaphyseal open fractures are a common occurrence in modern times. In a resource strapped country like India, AO unilateral external fixator is a cheap, technically easier method for the definitive management of the same. The aim of the paper is to present the results of the treatment of 33 patients with open tibia fractures, as well as the complications that accompany the treatment of these fractures.
Method: An observational prospective study was undertaken including all open diaphyseal tibia fractures with Gustilo Anderson classification Type II, IIIA, IIIB and Ganga hospital open injury severity score of 6-12. Patients underwent debridement, definitive fixation with exfix, and later Patellar Tendon Bearing Cast after removal. Outcome was measured by the Association for the Study and Application of the Method of Ilizarov Group score.
Results: In 81.8% cases the mechanism of injury was road traffic accident. Mean time for complete weight bearing was 19.33 weeks, mean time for union was 26.18 months. ASAMI Radiological outcome was Excellent in 45.5%, Good in 30.3%, Fair in 9.1% and Poor in 15.2% cases. ASAMI Functional outcome was Excellent in 33.3%, Good in 51.5%, Poor in 15.2% cases. Pin tract infection was found in 39.4% and malunion in 24.2%. The mean time for union (p=0.0004), incidence of non-union (p=0.014) was found to be statistically significant to the severity of initial injury.
Conclusion: Thus by this study it can be expressed that external fixator is a feasible implant in the definitive management of open tibia fractures.

Keywords: Open fracture, tibia, external fixator, patellar tendon bearing cast, exfix

Introduction
The curse of an advancing civilization is the road traffic accident, which very often leads to open fractures of the long bones. The annual incidence of open fractures of long bones has been assessed to be 11.5 per 100,000 persons [1] with 40% occurring in the lower limb, most commonly at the tibial diaphysis [1-3]. But the incidence could be much higher in developing countries. Open long bone fractures are a therapeutic challenge to both Orthopaedic and Plastic Surgeons. Not only are they difficult to treat, but the cost of inadequate treatment is high both in financial terms and in continuing patient disability [1]. High energy tibial diaphyseal fractures are most commonly associated with vehicular trauma. Road traffic accident leads to open tibia fractures, in which pedestrians being struck are the most common modes, while the next most common mode is when the motorcycle driver is affected. But distinctively when open tibia fractures occur, they are more commonly type IIIB requiring flap coverage than for other sites of open fractures [4]. Due to its location, structural anatomy and scanty anterior soft tissue coverage, the tibia is on the whole predisposed to being converted into an open fracture. Also due to its subcutaneous nature, open tibia fractures are commonly accounted for in a trauma centre [5]. Open tibia fractures carry poorer prognosis than their closed counterparts including longer time to union, longer hospital stay, higher re-operation rate, and higher incidence of infection [4-6]. There is universal agreement that open fractures require emergency treatment, including adequate debridement and irrigation of the wound. Prevention of wound sepsis remains the prime objective in the management of open fracture. Open injuries of the limb are classified according to the Gustilo and Anderson classification [7], which classifies the open fractures in to three groups of increasing severity, based on the size of the open wound, the degree of its contamination and the extent of soft-tissue injury and neuro vascular damage (Table 1).

Gustilo *et al*. came to the conclusion that, Primary closure was indicated for Type I & II fracture whereas in Type III delayed wound closure is advocated with plastic surgery interventions. Internal fixation is not recommended but External fixation is. Antibiotics should be administered before and during surgery, antibiotic of choice being cephalosporins [7]. A revised version has come in to effect later on by Gustilo, as the type III category initially described included a wide variety of open fractures with variable prognosis. In contrast to Type I and Type II open fracture, infection in Type III open fractures is a major problem. Thus, Type III fractures were further classified according to the injury to the covering tissues (skin and fascia), functional tissues (muscles, tendons and nerves), and skeleton (bones and joints) of the limb in order of worsening prognosis [8] (Table 1). Since none of these fractures are ideal for internal fixation, emergency external fixation is the advocated way. In a resource scarce country like India, it was sought to leave the emergency external fixation as a definitive procedure and then evaluate the outcome. So this study was conducted with the objective of evaluating the outcome of open tibial fractures treated definitively by AO unilateral external fixator.

Materials and Methods

An observational prospective study was undertaken at R.G. Kar Medical College, Kolkata, India, during the study period May 2020 to June 2022. The final sample size was 33, after 2 patients were lost to follow-up. The sample size was selected based on previous literature [9-12]. This is a time bound single centre study with no financial funding. As a result, a non-random convenience sampling technique was chosen. Samples were selected from the patients admitted in the inpatient and visiting the outpatient department of the Department of Orthopaedics, R.G. Kar Medical College. Inclusion Criteria was all patients with open diaphyseal tibia fractures with Gustilo Anderson classification Type II, IIIA, IIIB [7] and Ganga hospital open injury severity score of 6-12 [13]. Patients with open tibia fractures with Gustilo Anderson classification Type I, IIIC, fractures with Ganga hospital open injury severity score of 0-5 and more than 12, intra articular fractures, patients unfit for surgery were excluded from the study. After admission, hemodynamic stabilization was done and the patient's injuries were assessed according to ATLS protocol. The wounds were examined, the initial contaminants were removed immediately sterile normal saline, and classified according to the Gustilo Anderson classification and the Ganga Hospital Open Injury Severity Score (Table 1, 2). Then in the emergency room itself the fracture was reduced with traction, to as much as feasible and splintage with plaster of paris slab was given. After that the patient was sent for X-rays of the tibia in antero-posterior and lateral views, including the knee and ankle joint. All open tibia fracture patients who came to the emergency room/Trauma Care Unit and were enrolled for this study were managed universally by a unilateral longitudinal tubular AO External fixator was used with large threaded half pins for bony fixation. Limb Reconstruction System (Orthofix) and Ilizarov's ring fixator were not used, neither were bilateral trans fixation frames. The open tibia fractures were planned to be shifted to the emergency OT as soon as a slot was available after taking written informed consent. Pins were always wrapped with povidone iodine-soaked gauze. All fractures with a GHOIS skin score of 2 or less, most GA II, IIIA fractures were sutured primarily with tension free [14-18]. Primary closure was done after the theory that infections caused were not due to the initial contamination but due to nosocomial bacteria from the hospital [19-21]. The rest were either given Vacuum Assisted Closure therapy or were referred for plastic surgery management. Active and passive movements of the ankle and knee joint along with quadriceps strengthening exercises were started immediately the day following surgery to the feasible extent. Immediate weight-bearing was not encouraged as that goes against the bio-mechanics of the frame but if the fracture pattern allowed under exceptional circumstances the same was done. Post-operative pin care was done by the nursing personnel but soon was taken over by the patient. If the wounds started healing and the laboratory results were normal, patients were discharged and referred to the department of plastic surgery for any late reconstructive procedures. Plastic surgical interventions were given to the patients who needed the same for early wound closure especially the GA IIIB patients. The time for complete skin closure was noted in subsequent follow-ups. At least 3 follow-ups were requested of the patients and the minimum time of follow-up was 9 months. Patients were encouraged to come for follow-up every 1 month after the initial 2-week post-operative follow-up. Patients were encouraged to do tip toe weight bearing from 4 weeks, partial or guarded weight bearing at 6 weeks, and complete weight bearing was given once there were clinical signs of union, consolidation i.e. no tenderness at fracture site, after Patellar Tendon Bearing Cast or Splint (in more compliant patients). This prevented any pin stress fracture from taking place. PTB Cast was kept in situ for at least 3 weeks. At 24 weeks of follow-up routinely x-rays were done to determine delayed union, which was when no or less callus was seen after 6 months of injury also if the patient was unable to bear full weight at that time with tenderness at fracture site. At 36 weeks of follow-up routine x-rays were done to determine non-union, which was when pre-anaesthetic check-up was advised to allow management of the same. Delayed union is defined as union in between 24 – 36 weeks of injury, where healing has not advanced at the expected average rate. Non-union is defined as absence of union after 36 weeks of injury. The actual definition according to Brinker is when a fracture that, in the opinion of the treating physician has no possibility of healing without further intervention [22]. Mal-union is defined as varus or valgus misalignment of 5ºor more, anterior or posterior angulation of 10º or more, shortening of 1.5 cm or more, or rotational malalignment of 10º or more as compared with the contralateral leg according to Trafton's recommendation [23] with no tenderness at the fracture site. Complete wound closure is defined as 100% epithelialization without drainage or dressing requirements confirmed at two consecutive study visits 2 weeks apart [24]. The post-operative functional and radiological outcome was then assessed for both types of management after complete union by the Association for the Study and Application of the Methods of Illizarov (ASAMI) score [25]. When it came to radiological outcome Excellent is defined as Union with no infection and deformity less than 7° and limb length discrepancy of less than 2.5 cm. Good is defined as Union with any two of the above three criteria. Fair is defined as union with any one of the above three criteria, while Poor is when none of the four criteria are met. Functional outcome is defined as Excellent when the patient is active with no limp and minimum stiffness and no reflex sympathetic dystrophy and insignificant pain. Good is defined as active with 1 or 2 of the following: Limp, Stiffness, Reflex Sympathetic Dystrophy, Significant pain while Fair is when 3

or all of the following is present along with an active patient. Poor is defined as an inactive patient while Failure is defined as a patient who has undergone amputation. All data was collected, compiled and subjected to suitable statistical analysis using appropriate methods. Also, informed consent was undertaken by all the patients participating in the study. The IBM SPSS 25 was used for data analysis and MS Excel 2016 was used for data entry and grand chart creation. Results were discussed on the background of present knowledge & experience of past work.

Results

In this study a total of 33 patients of open tibia fractures were fixed with external fixator definitively and according to the inclusion and exclusion criteria after 2 were lost to follow-up. Among the 33 patients, 2 (6.1%) were female and 31 (93.9%) were male, with the mean age being 33.30 years (SD=12.71). Among the 33 patients, 24 (72.7%) patients were Hindu and 9 (27.3%) were Muslim. 10 (30.3%) had an history of alcohol consumption and 14 (42.4%) were smokers. Mean time to reach the hospital from the time of injury was 148.33 minutes (SD=145.27) with the maximum time being 12 hours. The most common mode of injury was road traffic accident at 27 cases (81.8%), the other modes of injury were fall from height in 3 (9.1%), physical assault at 2 (6.1%) and machine injury at 1 (3.0%). The most common site of injury was mid shaft fractures at 16 (48.5%), distal tibia fractures were 9 (27.3%), proximal tibia fractures were 4 (12.1%) with left sided fractures being the most common at 63.6%. Only 4 (12.1%) cases had a bone loss, and according to the Gustillo Anderson (7) Classification II were 12 (36.4%), IIIA were 12 (36.4%) as well and 9 (27.3%) cases had IIIB injury. According to the GHOIS system score of 6 was given to 2 (6.1%) patients, 7 to 7 (21.2%) patients, 8 to 6 (18.2%), 9 to 6 (18.2%), 10 to 6 (18.2%), 11 to 3 (9.1%) and 12 to 3 (9.1%) patients as well. The mean time to external fixator application from arrival was 6.97 hours (SD=4.71) and among the 33 patients only 7 cases (21.2%) required plastic surgery interventions and these were mainly the GA IIIB injuries. Complete weight-bearing was given once there were clinical signs of union, consolidation i.e. no tenderness at fracture site, after PTB application. The mean time was 19.33 weeks (SD=7.61). The mean hospital stay was 13.36 days (SD=10.13). The mean time for complete skin closure that is after discharge and plastic surgery intervention in some cases to stitch removal was 51.48 days (SD=37.28). The mean time for union was found to be 26.18 weeks (SD=11.16). The radiological outcome according to ASAMI Score (25) was excellent in 15 cases (45.5%), good in 10 (30.3%), fair in 3 (9.1%) and poor in 5 (15.2%) cases. All 5 went into non-union, so the rate of non-union after the open tibia fractures were definitively fixed with external fixator was 15.2%. The ASAMI Functional score (25) was excellent in 11 cases (33.3%), good in 17 cases (51.5%) and poor in those cases of non-union, who were inactive and were unable to pursue any forms of employment that is in 5 cases (15.2%) with chronic osteomyelitis found in 4 cases (12.1%). When it came to other complications, pin tract infection was found in 13 cases (39.4%) while malunion was found in 8 (24.2%) patients, delayed union in 7 (21.2%). The severity of initial injury can affect the outcome and the following complications as well. The mean time of union was compared with the severity of initial injury, and as the outcome variable did not have a normal distribution for each group of the predictor variable (by the Shapiro Wilk test), non-parametric tests were used and the results (Table 3) were statistically significant. The complication of non-union and delayed union was also compared to the severity of initial injury. Using the Pearson's Chi square test, the severity of initial injury (according to the Gustillo Anderson Classification) was found to be statistically significant to incidence of delayed union (DF=2, Test statistic=8.73, p=0.013). Also, the incidence of non-union was found to be statistically significant to the severity of initial injury by the Pearson's Chi square test (DF=2, Test statistic=8.58, p=0.014).

Discussion

Open fractures of the tibial diaphysis are a relatively common injury due to the high propensity of road traffic accidents nowadays. Tibia being a sub-cutaneous bone, chances of an open injury are high and due to the same reason the vasculature is easily compromised. Thus management if not done at the earliest can result in a myriad of complications, with non-union and deep infection being the most common. The ideal method for closed tibial shaft fractures are closed reduction and internal fixation with intramedullary inter-locking nails. But the management of open tibial fractures continues to be a controversial topic.

The management of open tibial fractures is thus done on an emergency basis with external fixation as the most viable option, as a deficient skin cover ruling out the possibility of an internal fixation. The patient is first hemodynamically stabilized and then removal of the contamination is done by a thorough lavage, and external fixator is applied at the earliest. The AO unilateral fixator has the advantage of being technically easy to apply and at the same time is economical. A bilateral fixator on the other hand provides a too rigid of a frame to allow any kind of callus formation by secondary osteogenesis. The AO external fixator can also be dynamized as need be or converted into a simpler frame according to the needs of the patient, thus proving its ergonomic nature. In 1974, Smith [26] in a series of 470 tibial shaft fractures came to the summary that, the immediate internal fixation of compound fractures was followed by so high an incidence of serious complications that the use of this method is not recommended. The immediate internal fixation of fresh closed fractures was also followed by many complications. In 1976, Gustillo and Anderson [7] conducted a study in which they treated open fractures. Wherever primary internal fixation was used, they had an infection rate of 19% versus where no primary internal fixation was done 5%. Accordingly, they came to the conclusion that internal fixation by plates or intramedullary nails should not be used. External skeletal fixation by skeletal traction, pins above and below the fracture site incorporated in a plaster cast is recommended. A number of studies [27-30] advocate the conversion of the external fixator frame into an intra-medullary nail once the soft tissue cover has healed but these studies also reported a significant association of development of chronic osteomyelitis due to conversion to an intra-medullary device. But in 2015, Neto *et al.* [31] conducted a meta-analysis by comparing intramedullary nailing, external fixation and external fixation followed by intramedullary nailing as management for open fractures of the tibial shaft. They found that cases managed by external fixator alone had the shortest healing time. External fixator followed by nailing has the highest rate of non-union. Primary nailing on the other hand caused delayed union. In a developing country like India, where the patient burden is huge and man power is scarce, external fixator followed by Patellar Tendon Bearing cast is a viable option for the management of open tibial fractures. The present study was

conducted among 33 patients with an overwhelming 93.9% cases being male, a similar result was seen in an epidemiological study by Court-Brown *et al.* [3]. The mechanism of injury it was found that road traffic accidents caused the majority that is 81.8% of the cases, while the next was due to fall from height at 9.1%. A study by Court-Brown and McBirnie *et al.* showed the same result [4]. In 1975, Karlstrom *et al.* [12] conducted a study on 28 open tibia fracture patients managed definitively by external fixation with PTB support and found the mean time of union to be 31.6 weeks but the time to full weight bearing at 19.6 weeks, same was shown by Widenfalk *et al.* [32] at 19.2 weeks. In our study the time of union with external fixation to be much shorter at 26.18 weeks but the time to full weight bearing almost similar at 19.3 weeks. In 1980, the study by Lawyer *et al.* [11] in a study among 34 open tibial fractures with external fixation as a definitive management found that there was no non-union and the time for union was 23.2 weeks on average. But studies conducted by Chan *et al.* [33] in 1984, Kesemenli *et al.* [34] in 2004, Naique *et al.* [35] in 2006, Beltios *et al.* [36] in 2009, Neelakandan *et al.* [9] in 2014, Singh *et al.* [37] in 2017, Hao *et al.* [38] in 2019, Parikh *et al.* [39] in 2020 all found similar results to ours when it came to time of fracture union with external fixation as definitive management that is at 25-28 weeks. Studies by Haider *et al.* [40] in 2019 and Hao *et al.* [38] showed similar results to ours when it came to the rate of non-union by definitive external fixation at 16.7% and 14.1% respectively, ours is 15.2%. But studies by Papaioannou *et al.* [41] and Chan *et al.* had a much higher rate of non-union at 39.7% and 30% respectively. A number of studies have been successful as well when it came to fixation and successful union of open tibia fractures by exfix. Kumar *et al.* [10] in 2017, Schroder *et al.* [42] in 1986, Kesemenli *et al.* [34] in 2004, Kimmel *et al.* [43] in 1982, Edwards *et al.* [44] in1988, Pahore *et al.* [45] in 2010 all had non-union rates as low as 2.7% to 8.9%. The study by Kimmel *et al.*, also had a rate of malunion similar to ours (24.2%) that is 26%. The rate of delayed union in this study was 21.2% which is similar to that of Pahore *et al.* at 21.4%. We found an incidence of 39.4% when it came to pin tract infection, which is similar to what is shown by Pahore *et al.* (33.9%), Schroder *et al.* found an incidence of 36% in their study. However, in studies by Hao *et al.*, Kimmel *et al.* the incidence was found to be as high as 42% to 50%. But the study by Golubovic *et al.* [46] in 2016 found the incidence of pin tract infection to be only 19.1%. Thus, it can be seen that pin tract infection is thus one of the most complications of external fixator application especially in open wounds. The rate of chronic osteomyelitis is quite low in most studies, Rommens *et al.* [47] showed it to be 4.2%, Kumar *et al.* showed it to be 2.7%, Tornetta *et al.* [48] showed it at 7.1%, Beltios *et al.* showed it to be only 1.3%, compared to ours at 12.1%, which is relatively higher. In Kaftandziev *et al.*'s [49] study it was 20%. However, Chan *et al.* found the incidence of chronic osteomyelitis to be about 38%, which led them to conclude that exfix is an appropriate method only for limb salvage rather than fixation. The comparison for the outcomes and complications of definitive fixation by external fixators are given in Table 4. Kumar *et al.* and Haider *et al.* stated that exfix with can be a definitive procedure in the management of open tibia fractures, and a similar inference can be drawn from thus study. It was found in this study that the severity of injury by Gustillo Anderson Classification was significantly related to the mean time of fracture union, and similar findings can be corroborated from Wani *et al.*'s [50] and Parikh *et al.*'s study.

Table 1: Gustilo Anderson Classification

	Wound	**<1cm**
Type I	Level of contamination	Clean
	Soft tissue injury	Simple
	Bone injury	Minimal commination
Type II	Wound	>1 cm
	Level of contamination	Moderately contaminated
	Soft tissue injury	Moderate, some muscle damage
	Bone injury	Moderate comminution
Type IIIA	Wound	>10 cm
	Level of contamination	Highly contaminated
	Soft tissue injury	Severe with crushing
	Bone injury	Usually comminuted but soft tissue coverage of the bone is possible
Type IIIB	Wound	>10 cm
	Level of contamination	Highly contaminated
	Soft tissue injury	Very severe loss of coverage
	Bone injury	Bone coverage is poor, usually requiring soft tissue reconstructive surgery
Type IIIC	Wound	>10 cm
	Level of contamination	Highly contaminated
	Soft tissue injury	Very severe loss of coverage with vascular injury requiring repair
	Bone injury	Bone coverage is poor, usually requiring soft tissue reconstructive surgery

Table 2: Ganga Hospital injury severity score (GHOISS)

Covering Structures: Skin and Fascia	**Score**
Wound not over the bone. No skin loss	1
Wound not over the bone with skin loss	2
Wound over the bone No skin loss	3
Wound over the bone with skin loss/Friction burns / De-gloving over the bone	4
Circumferential wound with bone circumferentially exposed	5
Functional Tissues: Musculo-tendinous & Nerve units	**Score**
Exposed musculo-tendinous (MT) units without injury	1
Repairable injury to MT units	2

Crushing with loss / Irreparable injury to MT units/ Repairable nerve injuries	3
Loss of one compartment of MT units / Irreparable nerve injuries	4
Loss of two or more compartments / Subtotal amputation	5
Skeletal Structures: Bone and Joints	**Score**
Transverse / oblique fracture with periosteal stripping	1
Butterfly fragment/Uni-cortical comminution Segmental fracture without bone loss	2
Peri-articular comminution with joint disorganization	3
Circumferential comminution/Bone loss <4cm	4
Comminuted/Segmental fracture with bone loss>4 cm	5
Co-morbid Conditions:	**Score**
Open Injury > 12 Hrs.	2
Sewage or organic contamination / farmyard injuries	2
Age > 65 yrs.	2
Debilitating diseases (DM, COPD, IHD etc.)	2
Fat embolism	2
Associated systemic injuries	2
Another major injury to the same limb/ Compartment syndrome	2

Table 3: Comparison of the Outcome to the Severity of Initial Injury

Gustillo Anderson	N	Mean time of Union (Weeks)	Kruskal Wallis H Statistic (DF)	P value	Remarks
II	12	22.83 (SD=7.60)	15.23	0.00049	Post-hoc analysis with Bonferroni corrections shows significant difference between GAII and GAIIIB injuries (P = 0.003) and between GAIIIA and GAIIIB injuries (P = 0.001). No statistically significant difference was found between GA II and GAIIIA injurie
IIIA	12	21.33 (SD=4.69)			
IIIB	9	37.11 (SD=14.22)			

Table 4: Comparison of outcomes and complications

Study on exfix as definitive	Sample Size	Non union	Time for union (weeks)	Delayed Union	Mal-union	Pin tract infection	Chronic Osteomyelitis
Golubovic *et al*. 2016 [46]	68	14.7%	22		2.9%	19.1%	5.9%
Neelakandan *et al*. 2014 [9]	22		28				
Singh *et al*. 2017 [37]	68	22%	24			26.4%	
Beltios *et al*. 2009 [36]	139	8%	25	9.4%	1.8%	26%	1.3%
Kumar *et al*. 2017 [10]	37	2.7%				21.6%	2.7%
Kimmel *et al*. 1982 [43]	15	6.6%	39	46.7%	26%	50%	
Tornetta *et al*. 1994 [48]	29		28.3	14.2%	14.2%	21.4%	7.1%
Kesemenli *et al*. 2004 [34]	20	5%	28	5%			
Kaftandziev *et al*. 2006 [49]	48	13.3%	38.4		16.6%	23.3%	20%
Naique *et al*. 2006 [35]	9		26				
Rommens *et al*. 1988 [47]	95	23.2%				20%	4.2%
Lawyer Jr *et al*. 1980 [11]	34	0%	23.2				
Chan *et al*. 1984 [33]	17	30%	28	60%	40%		38%
Haider *et al*. 2019 [40]	114	16.7%			2.6%		
Hao *et al*. 2019 [38]	85	14.1%	27.64	40%	34.1%	42.4%	5.9%
Papaioannou *et al*. 2001 [41]	141	39.7%					
Parikh *et al*. 2020 [39]	182		28				
Schroder *et al* 1986 [42]	96	4.1%			13.5%	36%	7.2%
Karlstrom *et al* 1975 [12]	28		31.6				
Pahore *et al* 2010 [45]	56	8.9%	21	21.4%	3.5%	33.9%	8.9%
Edwards CC *et al* 1988 [44]	202	7%			9%		
This study	33	15.2%	26.18	21.2%	24.2%	32.3%	12.1%

Conclusion

High velocity trauma causing open tibial fractures are a common incidence in a population dense country like India. At the same time keeping in mind the scarcity of man power available and the lack of resources available in most set ups, it can be inferred that external fixation can be done as a definitive procedure in the management of open tibial fractures.

Conflict of Interest

Not available

Financial Support

Not available

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