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Primary (Immediate) versus Secondary (Delayed) Nailing in the Management of Gustillo-Anderson Type 3A Open Tibial Fractures – A Comparative Study

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ABSTRACT

Objective: To compare the outcomes of open tibial fractures managed with immediate versus delayed intramedullary nailing in adults. **Study Design:** Prospective Cohort study. **Settings:** Department of orthopedic surgery, Mayo hospital, Lahore Pakistan. **Duration:** January to December 2023. **Methods:** 60 patients (30 in each cohort) were observed. In primary (one-staged) nail group, intramedullary nailing was performed after debridement. In secondary (two-staged) nail group, initial debridement and external fixation were done, followed by conversion to intramedullary nailing after one week. Bone and soft tissue infection, radiological union, and functional outcome were observed after surgery. **Results:** Of the 60 patients, 48 (80%) were males and 12 (20%) were females. Mean age was 32.24 ± 10.76 years, ranging from 17 to 60 years. The right tibia was involved in 42 (70%) patients while left in 18 (30%). Road Traffic Accident (RTA) caused 46 (76.6%) cases, followed by firearm injuries 7 (11.6%) and falls 4 (6.6%). Mean union time in single-staged nail group was 12.67 ± 5.36 weeks compared to 13.18 ± 3.61 weeks in two-staged group. There was no significant difference in union time between the groups (p=0.226). No correlation existed between age and union time (p=0.478), while a significant negative association between soft-tissue infection and union time was observed (p < 0.001). Outcomes between groups showed no significant difference (p=0.827). **Conclusion:** Primary nailing can be safely and effectively performed in Gustilo-Anderson type IIIA open tibial-shaft fractures under antibiotic cover and timely debridement.

Keywords: *Tibia, Open fractures, Intramedullary nail, Functional outcome.*

INTRODUCTION

The most prevalently fractured bone is the tibia, with an incidence of 1 in 2000 and about 2% of all fractures.[1] A wide majority of tibial shaft fractures are open,[2] communicate with the external environment because of skin breach and have an incidence of as high as 42.6%[3] due to subcutaneous location with no muscular coverage on its anteromedial aspect. The most common etiology of open fractures of the tibia is road traffic accidents (RTAs)[4] which affect mostly the younger population.[5] The prevalence is reported differently in national and international surveys. An associated fibular fracture is also reported in more than three-fourths of cases.[6] Management of open tibial fractures is significant because of their limited blood supply. If not treated properly, it can result in infection and nonunion with subsequent long hospital stay, multiple hospital admissions, and socioeconomic burden.[7] Treatment is

focused on the prevention of infection and achieving early union and function of the limb.

A variety of treatment methods are established for these fractures, ranging from application of various types of external fixators to intramedullary nailing. But the best treatment option is still debatable.[8] Treatment outcome with immediate nailing (nailing on the day of injury) in comparison to two-staged nailing (initial Applica infection butal fixation and later conversion to intramedullary nailing, when soft tissue conditions improve) has confusion regarding infection and pain control, functional status of the leg, and bone union.[9] Long follow-ups report comparable results of both these treatment modalities, but initial external fixation and debridement followed by its conversion to intramedullary nailing after a week of removal of external fixation is preferred in our setups to minimize intraosseous infection, but still increases the risk of pin track infection.[10,11] The goals of treating open tibial fractures should be bone union, avoidance of superficial and deep infection, and early maximally functional and painless limb.[12]

The selection of a fixation method should be tailored to each patient's condition, considering infection presence, functional recovery needs, and fracture location. Research shows external fixators, alone or with internal fixation, can effectively manage infection and encourage bone healing, with varying functional recovery.[13,14] When comparing internal and external fixation for bone fractures, infection control, pain management, and bone union are important factors. External fixation is common for open fractures or when minimal soft tissue damage is desired. Some patients prefer immediate internal fixation due to dissatisfaction with external fixation, showing positive outcomes in weight-bearing and pain-free limbs. However, certain internal fixations may increase deep sepsis risk.[15] Research shows intramedullary (IM) nailing for open tibial diaphysis fractures (Gustilo-Anderson types I, II, IIIA) has lower malunion and superficial infection rates versus external fixation. However, outcomes are similar with ring external fixators.[16] Some studies suggest unreamed intramedullary nailing may be better than external fixators for severe open fractures.[17] Early conversion (7 to 10 days) from external fixator to IM nailing shows lower infection rates.[18] Pin-site infection during external fixation contraindicates subsequent IM nailing due to infection risks.[19] The choice between primary IM nailing and external fixator followed by IM nail depends on fracture severity, soft tissue conditions, and complications like infection. Although immediate intramedullary interlocking nailing is typically advised for certain open tibial fractures due to its lower complication rates, using an external fixator, particularly followed by IM nailing, remains a feasible alternative in certain cases. The choice should be tailored to the specific circumstances of each patient, with careful consideration of the timing for any transition between treatment methods.[15,18,19] Our study aimed to compare the outcomes of these two treatment approaches, which may assist in determining the preferred surgical method for such patients, especially considering the limited resources and funding in our hospitals.

METHODS

This prospective study was carried out in the Department of Orthopedic Surgery and Traumatology at Mayo Hospital, King Edward's Medical University, Lahore, Pakistan. Utilizing the World Health Organization (WHO) sample size calculator 7.2b (Hypothesis testing for a population mean, two-sided test) and referencing a previous study,[9] a minimum sample size of thirty individuals per cohort was calculated, with a significance level of 5% and a test power of 95%. Approval was obtained from the Institutional Review Board via letter no 589/RC/KEMU dated 19.09.2024. The study included patients of either gender, aged 17 to 60 years, who sustained Gustilo-Anderson type 3A open fractures of the tibial diaphysis and presented within 12 hours of injury. Exclusion criteria were patients with comorbidities (diabetes mellitus, chronic hepatic diseases, chronic renal disease), pathological fractures, associated neurovascular injury, fracture of the contralateral femur or tibia, floating knee, prior ipsilateral lower limb fracture or deformity, and farm injuries with open fractures.

A total of 60 patients meeting the inclusion criteria were prospectively assessed, in which 30 patients received primary fixation with an intramedullary interlocking nail following wound debridement and closure on the day of injury, while a similar number of patients underwent secondary nailing after an initial period of external fixation and antibiotic coverage for a period of seven to ten days. Informed written consent was obtained from each patient or their representatives. Tetanus immune status was checked, and vaccination was provided if needed. Intravenous (IV) prophylactic antibiotics were empirically administered to all patients for a minimum duration of five days. Movement at the knee and ankle joints was permitted, and patients were mobilized with crutches on the following day of surgery in both study groups. We monitored soft tissue and bone infections, radiological union, infected nonunion, and functional outcomes as primary outcomes. Patients were followed up in the outpatient department up to nine months postoperatively. Soft tissue infection was assessed using the Southampton wound scoring system.[20] Bone union was assessed using the Modified RUST criteria.[21] The functional outcome of the affected limb was evaluated using the American Academy of Orthopedic Surgeons (AAOS) Lower Limb Questionnaire.[22]

The data was gathered, organized, inputted, and analyzed using SPSS version 27. Continuous variables, such as patient age, time to union, and time to bear weight, were expressed as mean ± standard deviation (SD) when they followed a normal distribution. Qualitative variables, like gender and limb side, were shown as frequencies and percentages. The relationship between two variables was assessed using the Pearson Chi-square test for continuous and normally distributed variables (parametric data), while the Spearman correlation test was used for ordinal or non-normally distributed data (nonparametric), with a p-value of less than 0.05 considered statistically significant.

RESULTS

Data from both groups, namely one-staged (primary nail) and two-staged (secondary nail), were analyzed and compared. The average age was 32.24 ± 10.76 years, ranging from 17 to 60 years, and was normally distributed. The mean age in the primary nail group was 31.26 ± 12.61 years, while in the secondary nail group, it was 34.76 ± 15.23 years (Table 1).

Table 1: Age distribution between groups

Variables		Statistic	Std. Error
Age in both groups	Mean	32.24	1.50139
	Std. Deviation	10.76	
	Minimum	17.00	
	Maximum	60.00	
	Range	43.00	
Age in the Primary nail group	Mean	31.2633	2.36409
	Std. Deviation	12.6121	
	Minimum	17.00	
	Maximum	57.00	
	Range	40.00	
Age in the Secondary nail group	Mean	34.6700	2.08042
	Std. Deviation	15.23495	
	Minimum	17.00	
	Maximum	60.00	
	Range	43.00	

Among the 60 patients, 48 (80%) were male and 12 (20%) were female. In the primary nail group, there were 23 (73.3%) males and 7 (26.7%) females. Similarly, the secondary nail group consisted of 25 (83.3%) males and 5 (16.7%) females. The right tibia was fractured in 42 (70%) individuals, while the left was affected in 18 (30%). Road traffic accidents (RTA) were the most common cause of injury, occurring in 46 (76.66%) of the patients. Firearm injuries (FAI) were reported in 7 (11.6%) individuals, falls in 4 (6.6%), and 3 (5%) patients had tibia fractures due to other reasons. Regarding fracture geometry as classified by the AO system, 22 (36.6%) patients had type A fractures, 33 (55%) had type B, and 5 (8.3%) had type C fractures (Table 2).

Table 2: Frequency of gender, side of limb injured, cause of injury, and type of fracture (AO Classification) in both groups

Variables		Frequency	Percent	Valid %	Cumulative %
Gender	Males	48	80	80	80
	Females	12	20	20	100.0
	Total	60	100.0	100.0	-
Side injured	Right	42	70	70	70
	Left	18	30	30	100.0
	Total	60	100.0	100.0	-
Cause of Injury	RTA	46	76.6	76.6	76.6
	FAI	7	11.6	11.6	88.2
	Fall	4	6.6	6.6	94.8
	Others	3	5.0	5.0	100
	Total	60	100.0	100.0	-
Type of Fracture	42A	22	36.6	36.6	36.6
	42B	33	55	55	91.7
	42C	5	8.3	8.3	100.0
	Total	60	100.0	100.0	-

We compared the treatment results of two groups by examining radiological union, functional outcomes, and complications such as soft tissue infection and infected non-union. The average time to achieve union was 12.6 ± 5.3 weeks for the primary-nail group and 13.1 ± 3.6 weeks for the secondary-nail group. Union was accomplished in 53 patients (88.3%) across both groups, while 7 patients (11.7%) experienced nonunion. In the primary nail group, 90% of patients (n=27) achieved union, compared to 86.6% (n=26) in the secondary nail group by the ninth month post-surgery. Infection leading to nonunion occurred in three individuals from the primary nail group and four from the secondary nail group (Table 3).

Table 3: Comparison of union time between nail and fixator groups

Variables		Statistic	Std. Error
Union time in weeks (Primary Nail group)	Mean	12.6730	.61105
	Std. Deviation	5.3658	
	Minimum	9.00	
	Maximum	22.00	
	Range	13.00	
Union time in weeks (Secondary Nail group)	Mean	13.1865	.72352
	Std. Deviation	3.61563	
	Minimum	11.00	
	Maximum	27.00	
	Range	16.00	

When comparing the union time between the two groups using Spearman's Correlation test, no statistically significant difference was found (p = 0.226), as shown in Table 4. Additionally, there was no significant correlation between patient age and union, with a p-value of 0.478.

Table 4: Spearman correlation test for union time between primary and secondary nail groups

Variables			Union time in weeks (Primary Nail)	Union time in weeks (Secondary Nail)
Spearman's rho	Union time in weeks (Primary Nail)	Correlation Coefficient	1.000	-.435*
		Sig. (2-tailed)	.	.226
		N	27	26
	Union time in weeks (Secondary Nail)	Correlation Coefficient	-.435*	1.000
		Sig. (2-tailed)	.226	.
		N	26	24
*. Correlation is significant at the 0.05 level (2-tailed).				

Soft-tissue infection was noted in 12 patients (20%) of the entire study population. In the primary nail group, 5 patients (16.7%) experienced this complication, while in the secondary nail group, it was observed in 7 patients (23.3%). Of these 12 patients, 5 (2 from the primary nail group and 3 from the secondary nail group) recovered from the infection with culture-specific antibiotics, whereas the remaining 7 (23.3%) developed deep infections resulting in infected nonunion (3 in the primary nail group and 4 in the secondary nail group) (Table 5).

Table 5: Frequency of Soft tissue infections and infected non-unions

Variables		Frequency	Percent	Valid %	Cumulative %
Soft Tissue Infection (Both groups)	Yes	12	20	20	20
	No	48	80	80	100.0
	Total	60	100.0	100.0	
Primary nail group	Yes	5	16.7	16.7	16.7
	No	25	83.3	83.3	100.0
	Total	30	100.0	100.0	
Secondary nail group	Yes	7	23.3	23.3	23.3
	No	23	76.7	76.7	100.0
	Total	30	100.0	100.0	
Frequency of infected nonunion					
Overall	Yes	7	11.6	11.6	11.6
	No	53	88.4	88.4	100.0
	Total	60	100.0	100.0	
Primary nail group	Yes	3	5	5	5
	No	27	95	95	100.0
	Total	30	100.0	100.0	
Secondary nail group	Yes	4	6.6	6.6	6.6
	No	26	93.4	93.4	93.4
	Total	30	100.0	100.0	

A strong negative correlation was identified between the presence of soft tissue infection and union time using the Wilcoxon test ($p < 0.001$) (Table 6).

Variables		N	Mean Rank	Sum of Ranks
Union time - soft tissue infection	Negative Ranks	0a	.00	.00
	Positive Ranks	53b	26.50	1378.00
	Ties	0c		
	Total	53		
a. Union time < Soft tissue infection				
b. Union time > Soft tissue infection				
c. Union time = Soft tissue infection				
Test Statistics				
	Union time – Soft-tissue infection			
Z	-6.287b			
Asymp. Sig. (2-tailed)	.000			
a. Wilcoxon Signed Ranks Test				
b. Based on negative ranks.				
Wilcoxon Test for the association between soft tissue infection and union time				

Functional outcomes were evaluated at the final follow-up visit nine months after surgery using the American Academy of Orthopedic Surgeons' (AAOS) questionnaire. In the primary nail group, 27 out of 30 patients (95%) achieved union by the ninth postoperative month. Among them, 12 patients (44.4%) had excellent outcomes, 10 patients (37.03%) had good outcomes, 4 patients (14.8%) had fair outcomes, and 1 patient (3.7%) had poor outcomes (Table 25). Conversely, in the secondary nail group, union was achieved in 26 out of 30 patients (93.4%). Of these 26 patients, 10 (38.4%) had excellent outcomes, 12 (46.1%) had good outcomes, 2 (7.6%) had fair outcomes, and 2 (7.6%) had poor outcomes, as detailed in Table 6.

Table 6: Functional outcomes in both groups

Variables		Frequency	Percent	Valid %	Cumulative %
Primary nail group	Excellent (score <11)	12	44.44	44.44	44.44
	Good (score =11 to 22)	10	37.03	37.03	81.47
	Fair (Score = 23 to33)	4	14.81	14.81	96.28
	Poor (score >33)	1	3.70	3.70	100.0
	Total	27	100.0	100.0	
Secondary nail group	Excellent (score <11)	10	38.46	38.46	38.46
	Good (Score = 11 to 22)	12	46.15	46.15	84.61
	Fair (Score = 23 to 33)	2	7.69	7.69	92.30
	Poor (Score >33)	2	7.69	7.69	100.0
	Total	26	100.0	100.0	

Table 7: Spearman correlation test for functional outcome between the two groups using the AAOS questionnaire

Variables			Primary Nail group	Secondary Nail group
Spearman's rho	Primary Nail group	Correlation Coefficient	1.000	.056
		Sig. (2-tailed)	.	.827
		N	30	30
	Secondary Nail group	Correlation Coefficient	.056	1.000
		Sig. (2-tailed)	.827	.
		N	30	30

DISCUSSION

In our research, we found a male-to-female ratio of 4:1. This predominance of males can be attributed to the active lifestyle men lead in our society, as they often bear more responsibilities, particularly in terms of earning a living. The careless behavior of male motorcyclists and drivers, especially among young adults, is another significant factor. This suggests that open tibial fractures are more common in men who are the primary earners for their families, including those with a history of falls. Women who experience high-energy trauma, such as open tibial diaphyseal fractures, are often involved in motorcycle accidents with male drivers. Khattak *et al*.[23] reported a male-to-female ratio of 3:1, which is slightly lower than our findings. A study conducted at Mansoura Emergency Hospital also highlighted male dominance in these types of fractures.[24]

The average age in our study was 32.24 ± 10.76 years, with a range from 17 to 60 years. This indicates that younger individuals are at a higher risk of sustaining open tibial fractures. The primary reasons include workload, reckless behavior, and speeding, which not only increase the number of vehicle collisions but also pedestrian injuries. Firearm injuries are also common in this age group. A significant portion of our population is illiterate, and many engage in risky physical labor, such as construction, where falls from construction sites often lead to multiple open fractures of long bones, including the tibia. Our study's results are similar to those of Khattak *et al*.[23], who found an average age of 37.7 years, close to our study's mean age.

Our study revealed that over three-quarters (n=46, 76.6%) of open tibial fractures were due to RTAs, with the majority being motorcycle-related injuries. Firearm injuries were the second leading cause (n=7, 11.6%), followed by falls (n=4, 6.6%). The high number of traffic accidents is due to the dense urban population, where many people commute to work using economical and fuel-efficient motorcycles. Notably, younger males, particularly teenage boys, are more affected. Many do not adhere to traffic rules, engage in stunts like one-wheeling, and a few possess driving licenses. Khushwaha *et al*.[25] also found that RTAs are the leading cause of open diaphyseal tibial fractures.

We noted that the right tibia was affected in more than two-thirds, or 70% (n=42), of patients, while the left tibia was fractured in less than one-third, or 30% (n=18), of patients. In about one-third of the cases (n=22, 36.6%), the fracture type based on AO classification was 42A, with more than half (n=33, 55%) having 42B type fractures, and only 5 patients (18.3%) had AO type 42C fractures. Tekin *et al*.[26] found AO type 42A to be the most common tibial fracture.

The average time to achieve union in the primary nail group was 12.6 ± 5.3 weeks, while in the secondary nail group, it was 13.1 ± 3.6 weeks. Out of 60 patients in both groups, 53 (86.7%) achieved union. 27 patients (90%) in the primary nail group, while 26 (88.3%) in the secondary nail group achieved union (modified RUST score of 12 or more at 9th month after surgery). Nonunion occurred in 7 patients (11.7%) across both groups (3 in the primary nail group and 4 in the secondary nail group). All 7 patients experienced infected nonunion and underwent secondary procedures, including sequestrectomy, debridement, and external fixation. The Spearman correlation test revealed no statistically significant difference in union time between the two groups, with a p-value of 0.226. Similarly, when examining the correlation between age and union time, the p-value was 0.478, indicating that age has no significant association with bone union. A study by Haonga *et al*[4] found union at 10 weeks, aligning with our findings. Tian *et al*[27] found age to be a significant factor in union time, differing from our study. The confounding factor may be the mean age in our study population being around 34 years, with few participants over 50 and no children, resulting in equally metabolically active bones in adults with neither osteoporotic nor very active bones. Additionally, patients with comorbidities affecting bone union were excluded from our study.

We also monitored soft tissue infections in both groups. In the primary nail group, 5 patients (16.7%) developed superficial wound infections, whereas in the secondary nail group, 7 patients (23.3%) experienced soft tissue infections. As previously mentioned, infected nonunion occurred in 3 patients from the primary nail group and 4 from the secondary nail group. Wilcoxon tests showed that soft tissue significantly affected union time, with p-values of < 0.001. This indicates that the presence of infection adversely affects the union and mostly results in an infected nonunion. Al-Hourani *et al*[28] discovered a negative association between infection and union.

We evaluated functional outcomes using the American Association of Orthopedic Surgeons (AAOS) questionnaire, which assesses activities, pain, range of motion, and swelling of the affected limb over the past week. This questionnaire has a maximum score of 44, where a higher score indicates a worse functional outcome. A score below 11 is deemed an excellent outcome, 11 to 22 is considered a good outcome, 23 to 33 is fair, and above 33 is poor. In the primary nail group, we found excellent outcomes in 12 (44.44%) patients, good in 10 (37.03%) patients, fair in 4 (14.81%) patients, and poor outcomes in 1 (3.70%) patient. Conversely, in the secondary nail group, the outcomes were 10 (38.46%), 12 (46.15%), 2 (7.69%), and 2 (7.69%), respectively. To compare the functional outcomes between the two groups, we utilized the Spearman correlation test, as the functional outcome was an ordinal variable, and the p-value observed in our study was 0.827. Our study revealed no statistical difference in functional outcomes between the two groups. Our findings align with those of Cortez *et al.*[9], who also found no difference in clinical outcomes between the two groups.

CONCLUSION

We concluded that immediate or primary (one-staged) intramedullary interlocking nailing in open tibial diaphyseal fractures (Gustilo-Anderson type IIIA) bears no additional risk for infection and nonunion and is a better option in managing these fractures, provided the wound is timely debrided under good antibiotic prophylaxis and the patient presents within the first 24 hours of injury. External fixation can be safely and effectively avoided in these fractures, reducing the number of surgeries and risks of anesthesia improving functional outcome.

LIMITATIONS

1. Single-centered study
2. Non-randomization

SUGGESTIONS / RECOMMENDATIONS

We suggest randomized control trials with a larger sample size to support our results.

CONFLICT OF INTEREST / DISCLOSURE

All the authors of this research work disclose that there were no conflicts of interest.

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