SHORT-TERM OUTCOMES OF GUSTILO GRADE 3A OPEN TIBIA DIAPHYSEAL FRACTURES: INTRAMEDULLARY NAIL VERSUS EXTERNAL FIXATION

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ABSTRACT

Background: Open tibial fractures pose a major therapeutic challenge due to the high incidence of postoperative complications. Although Locked Intramedullary (IM) nail and uniplanar External Fixation (EF) are the most common treatment modalities, the superior mode of management remains controversial.
Objective: The purpose of this study was to prospectively compare short-term outcomes of patients with Gustilo 3A open tibia shaft fractures treated with IM nail compared to uniplanar EF.
Methodology: In this prospective cohort study, adult patients (≥18 years-old) with Gustilo 3A open tibia shaft fractures treated by either intramedullary nail or EF were included. This study was conducted at Muhimbili Orthopaedic Institute, Dar es Salaam, Tanzania for a period of twelve months from March 2013 to February 2014. After enrollment, patients were followed-up at 2, 6, 10, 14, and 18 weeks postoperatively. At these visits, rate of callus formation at fracture site and surgical complications (e.g. infection, limb length discrepancy, malalignment) were assessed.
Results: Out of 50 patients enrolled in the study, 26 were treated by IM nail and 24 by external fixation. Twenty-four patients (92.3%) in the IM nail group and 6 (25%) in the external fixation group had callus formation by the 10th week. The mean times to callus formation in the IM nail group and external fixation group were 8.2±2.6 weeks and 14.7±3.3 weeks, respectively (p=0.000). Two (7.7%) patients in the IM nail group and 3 (12.5%) in the external fixation group developed infection (p=0.661). No IM nail patients developed limb length discrepancy. In contrast, to 2 (8.3%) external fixation patients developed limb shortening between 2-3cm. No patients had limb length shortening of >3cm. No malalignment was observed in IM nail patients, but 3 (12.5%) external fixation patients developed malalignment and required reoperation.
Conclusion: Interlocking intramedullary nail appears to be a better option for the treatment of Gustilo 3A open tibia shaft fractures as compared to uniplanar external fixation. Advantages of the IM nail include faster rate of callus formation and lower rates of limb length discrepancy and malalignment.

Key words: Open tibia fractures, Orthopaedic surgery, Tanzania, Intramedullary nail, External fixation

INTRODUCTION

Musculoskeletal injuries are on the rise in many developing countries including Tanzania (1-3). Presently, road traffic injury is the most common cause of open fractures, which are fractures that communicate with the external environment due to skin breakage (4-7). The shaft of the tibia is the most common long bone to sustain an open fracture, which is significant given the precarious superficial position of its blood supply (4-7). Open tibia shaft fractures occur most commonly in young, working men, leading to a societal burden as well (8). In Tanzania, open tibial shaft fractures account for over 50% of fractures seen at referral centers, such as the Muhimbili Orthopaedic Institute, with complication rates as high as 30% (9). Management of these open fractures is a common problem in trauma centers of developing countries like Tanzania. Although there is no dispute that soft-tissue management is the most important factor in determining the outcome of open tibial fractures, the optimal method of fixation is still debated. Sufficient stability of the fracture fragments and soft tissues usually can be obtained only by locked intramedullary nail or external fixation

(10). External fixation has been popular because of the relative ease of application and the limited effect on the blood supply of the tibia, but these advantages have been outweighed by the high incidence of pin-track infection, difficulties relating to soft-tissue management and the potential for malunion, delayed union and non-union (11,12). Currently, many traumatologists prefer intramedullary nailing for Gustilo Grade I, type II and grade IIIA open fractures, although equipment for nailing in resource-limited environments may make it difficult to perform (8). Thus, the current recommended treatment for grade IIIA open tibia shaft fracture can be either; surgical debridement and fixation by interlocking intramedullary nail or surgical debridement and fixation by external fixation.

With respect to recovery from tibial shaft fractures, the most salient outcomes include callus formation, infection, and malalignment and shortening. Existing literature suggests that IM nailing can lead to bridging callus at the fracture as early as three months, although no study has yet to prospectively compare IM nail and EF patients with respect to callus formation in Tanzania (13). In addition, there have been reports that IM nailing for Grade IIIA open tibia fractures can lead to an infection rate as low as 5.5%, while other reports show that EF infection rate may be as high as 26.4% (14, 15). Finally, open tibia patients are at risk of a shortened and malaligned leg after recovery form tibia fracture, a finding yet to be confirmed prospectively in Tanzania (16).

Given the lack of prospective comparison data on Grade IIIA tibial fractures, the purpose of this study was to compare the short-term outcome of patients treated with IM nail and EF in a tertiary Tanzanian hospital. Based on prior literature, we hypothesize that patients with IM nails would have quicker callus formation times, reduced infection rates and presence of malalignment.

MATERIALS AND METHODS

Study design and location: This study was a prospective cohort study conducted at Muhimbili Orthopaedic Institute (MOI) in Dar es Salaam, Tanzania from March 2013 to February 2014. MOI is a 165 bed national referral center for patients with skeletal trauma. Ethical clearance was obtained from the institutional review board of Muhimbili University of Health and Allied Sciences (MUHAS).

Patients over the age of 18 years who sustained Gustilo Type 3A open tibia diaphyseal fractures and presented to the hospital within 24 hours of injury were invited to enroll in the study. Exclusion criteria included bilateral open tibia fractures, comminuted femur fractures of the contralateral limb, significant comorbidities such as diabetes or known vascular disease, prior ipsilateral lower limb injury, or lower limb deformities.

Study participants were managed with standard hospital procedures upon presentation to the emergency department. Social demographic data was collected and recorded in a questionnaire. Anteroposterior and lateral views radiographs of the fracture site were taken to confirm a diaphyseal shaft fracture of the tibia.

Tetanus immune status was determined and a booster vaccination was provided if necessary. Ceftriaxone (Rocephine) was given during induction of anaesthesia and continued for five days. Intra-operative confirmation of the patient's fracture and wound classification was performed following surgical debridement. Afterwards, patients were treated with either interlocking intramedullary nail or external fixation based on the discretion of the treating surgeon. External fixation was performed using an AO single bar uniplanar device with two proximal and two distal screws. Nailing was performed with the Surgical Implant Generation Network (SIGN) nail and without the use of an image intensifier; two proximal and two distal interlocking screws were used for all nail patients. SIGN nail was chosen because it is designed in treatment of long bone lower extremity injuries, even when no c-arm is available (17).

Postoperative control X-rays were obtained and assessed for alignment and fracture reduction. Additionally, limb length, rotational deformity, and status of the wound were evaluated. Patients were discharged after the wound was satisfactorily clean and their condition was stable. No cast or brace was applied. All patients were instructed to change wound dressing daily. Patients with external fixators were instructed to perform pin care using methylated spirit three times a day.

Wound checks were performed at 2 weeks. Patients with infections in early post-operative stage (2-6 weeks) were treated with high dose antibiotics as long as stability of the fracture was retained and there was no underlying collection of pus. If infection was present beyond 6 weeks and was associated with delayed wound healing, wound necrosis, or discharge from the operative site, patients were taken to the operating room for debridement.

Additional follow-up evaluations occurred at 6, 10, 14, and 18 weeks post-operatively. In these

visits, clinical exam was conducted to evaluate pain, weight bearing status, malalignment, limb rotation deformity, limb length discrepancy, movement at the fracture site, infection, and any other surgical complications. Limb length discrepancy was recorded as present if the difference was greater than 1cm. Malunion was defined as more than 5 degrees of angular deformity in the sagittal or coronal planes. Malrotation was defined as an internal/external rotation deformity greater than 10 degrees of deviation between the femur and tibia. Clinical outcomes were classified using the Thoresen Scoring System (18). Anteroposterior and lateral tibial X-rays were also obtained at follow-up visits and measured using the RUST score to assess the rate of callus formation (19).

Early weight-bearing was recommended if the fixation device was deemed stable. Patients with external fixators who had healed wounds had their fixators removed and were placed in a cast. Cases of delayed union, malalignment requiring correction, and infection were re-operated. The healing of the fracture was considered as complete when both clinical and the radiological criteria of the union were fulfilled to the satisfaction of the researcher and the independent observers.

Sample size estimation and sampling technique: A survey conducted at the study center from January 2012 to June 2012 revealed that 3812 patients were attended to at MOI's emergency department during that time (10, 20). Two hundred and thirty eight (6.2%) open tibia shaft fractures were seen. One hundred and nineteen (3.1%) of patients were characterized as having specifically Gustilo Type 3A open fractures. Using a confidence level of 95% (Z Score = 1.96) and a confidence interval of 5% (margin of error = 0.05), we obtained 46 as the required sample size. We accounted for 10% loss to follow-up results in a final sample size of 50 with approximately 25 patients in each treatment arm.

Data collection, management and analysis: A research coordinator was recruited to assist with data collection. Other tools used in data collection were a tape measure for limb length discrepancy and goniometer for rotational and angular malalignment. Data was directly entered into SPSS Version 20. Sample characteristics were analyzed using descriptive statistics. Mean and standard deviation were used for continuous variables and differences between means were examined using Student T-test. For categorical variables, frequencies were calculated. Differences in proportion of various attributes between the two IM nail and external fixator group was examined using chi-square test or Fisher's exact test as appropriate. All analysis was two tailed and significance level was set at 5% level.

RESULTS

A total of 54 patients were included in the study (Table 1). There were 40 (80%) males and 10 (20%) females (male-to-female ratio of 4:1). The age ranged from 18 to 76 years with a mean age of 33.7±11.8 years. Thirty six per cent of patients were between 18-28 years old. Twenty eight patients received IM nail and 26 received external fixation. Loss to follow-up occurred in 4 (7.4%) patients (2 nail and 2 exfix). One patient in the nail group died from causes not related to injury; the remainder were not reachable after discharge. The remaining 50 patients completed a minimum of 18 weeks of follow up after surgery.

Table 1

Patient demographics of open tibia fractures treated by IM nailing vs. external fixation

Variable	IM (n=26)	EF (n=24)	Total
Age group (years)			
18-28	9	9	18
29-38	8	9	17
39-48	7	4	11
49-58	0	2	2
>58	2	0	2
Gender			
Male	20	20	40
Female	6	4	10
Residency			
Dar-es-salaam	25	23	48
Other regions	1	1	2
Location of tibia shaft fracture			
Proximal	3	1	4
Middle	14	17	31
Distal	9	6	15
Time of injury to presentation (hours)			
0-8	20	20	40
9-16	3	3	6
17-24	3	1	4
Time of injury to operation (hours)			
0-8	0	1	1
8-16	16	13	29
17-24	9	10	19
>24	1	0	1

The most common cause of open tibial shaft fracture was motorcycle crash (75.8%). The other causes included motor vehicle crash (20.4%) and fall from height or bicycle crash (3.8%). Sixteen (29.6%) patients sustained associated injuries. Ten had other orthopaedic injuries and 5 (9.3%) had traumatic brain injury. The majority of the patients arrived at the hospital within 8 hours after injury (76.9%). Thirty one (57.3%) patients were operated within 16 hours of arrival to the hospital. Forty (74.1%) were discharged 48 hours post-operatively.

Two (7.7%) patients in the IM nail group and 3 (12.5%) in the external fixation group developed infections. One patient in the IM nail group and two in the external fixation group had to be re-operated due to infection. The modality of fixation had no correlation with rate of wound healing or infection (p=0.661). Pin-tract infection developed in 12 (46.2%) external fixation patients as determined by clinical judgement upon visual inspection of the pin sites and assessment of radiographic findings. In all cases, the infection was successfully managed by oral antibiotics and daily pin-tract care. Two (22.2%) patients had their fixators removed and received a cast by the 6th week.

The rate of callus formation was higher in patients who were treated by intramedullary nail at all follow-up time points as measured by mean RUST scores (p<0.001) (Table 2).

Table 2

Rate of callus formation using mean RUST scores

Follow-up (Weeks)	IM nail (n=26)	External fixation (n=24)	P-value
6	6.58	5.13	<0.001
10	7.62	6.04	<0.001
14	8.62	6.63	<0.001
18	9.35	7.21	<0.001

The mean time to callus formation in the IM nail and external fixation group was 8.2±2.6 and 14.7±3.3 weeks, respectively (p<0.001). Twenty four (92.3%) patients in the IM nail group had callus formation by the 10th week. Only 6 (25%) in the external fixation had callus formation by the same time point week only six (25%) had notable callus, mean duration to callus formation in external fixation group was 14.67±3.3 weeks. Patients who were treated by intramedullary nail attained full weight bearing earlier than those treated by external fixation. At 10 weeks, 88.5% of IM nail patients were on full weight bearing status which is twice as much as those in the EF group (Table 3).

Table 3

Weight bearing status between IM nail compared with external fixation

	None		Partial		Full		p-value
Follow-up (Weeks)	IM n(%)	EF n (%)	IM n (%)	EF n (%)	IM nail n (%)	EF n (%)	
6	2 (7.7)	12 (50.0)	7 (26.9)	11(45.8)	17 (65.4)	1 (4.2)	0.000
10	0 (0.0)	2 (8.3)	3 (11.5)	12 (50.0)	23 (88.5)	10 (41.7)	0.001
14	0 (0.0)	1 (4.2)	2 (7.7)	8 (33.3)	24 (92.3)	15 (62.5)	0.021
18	0 (0.0)	2 (8.3)	0 (0.0)	6 (25.0)	26 (100.0)	16 (66.7)	0.001

There were no IM nail patients who developed limb length discrepancy. This is in contrast to 4 (16.6%) of patients who had limb shortening in the EF group (Table 4). Patients treated with IM nail also had better outcome as measured by the Thoresen Scoring System compared to those treated with EF (p=0.046) (Table 5).

Table 4

Comparison of limb lengths at 18 weeks (p=0.046)

		Limb shortening	
	Normal n (%)	1-2cm n (%)	2-3cm n (%)
IM	26 (100.0)	0 (0.0)	0 (0.0)
EF	20 (83.4)	2 (8.3)	2 (8.3)

Table 5

Comparison of IM and EF groups using Thoresen scoring system

Variable	IM n (%)	EF n (%)	P-value
Varus/Valgus			
Excellent (5°)	26 (100.0)	17 (70.8)	0.003
Good (>5°)	0 (0.0)	4 (16.7)	
Fair (10°)	0 (0.0)	3 (12.5)	
Poor (>10°)	0 (0.0)	0 (0.0)	
Procurvatum/Recurvatum			
Excellent (5°)	26 (100.0)	21 (87.4)	0.103
Good (>5°)	0 (0.0)	3 (12.6)	
Fair (10°)	0 (0.0)	0 (0.0)	
Poor (>10°)	0 (0.0)	0 (0.0	
Limb rotation			
Excellent (5°)	26 (100.0)	22 (91.6)	0.225
Good (>5°)	0 (0.0)	2 (8.4)	
Fair (10°)	0 (0.0)	0 (0.0)	
Poor (>10°)	0 (0.0	0 (0.0)	

The IM nail demonstrated statistically significant better outcomes in limb alignment. Three (12.5%) EF patients who had "Fair" alignment required

reoperation. Malalignment in these patients was most likely due to either inadequate reduction at the time of initial fixation and/or the loss of reduction after removal of the device.

DISCUSSION

Compared to external fixation in the treatment of Gustilo Grade IIIA open tibia fractures, IM nailing leads to earlier fracture callus and weight bearing status, fewer malalignments and no difference in infection rates.

With respect to fracture union, the study found that union was approximately 6 weeks faster in the IM nail group than the external fixation group. The rates of union in IM nail and EF were similar to those of Court-Brown *et al* (12) and Kakar *et al* (21) respectively. However, Henley *et al* (22) reported no statistically significant difference. Unfortunately, there is no similar study conducted in Africa that we are aware of to provide comparisons. While there is more evidence in the literature to suggest that the IM nail results in faster healing times, additional studies should be conducted to definitively substantiate this claim.

Moreover, postoperative infection rates are an important indicator of the viability of a particular surgical modality. In this series, the rate of infection that we measured in IM nails was similar to that found in other studies (21, 23). Pin-tract infection rates with EF were also similar (15, 22, 24). Notably, we found no statistically significant difference in infection rates between the two treatments, a finding which is similar to that of Henley *et al* (22). Although this conclusion implies that development of infection in the short term is not significantly affected by choice of implant, it is important to consider that the IM nail poses greater risks for deep infection which may occur up to one year post-operatively (22). Thus, it is still uncertain whether IM nail or EF ultimately carries lower risks of infection in the long-term.

IM nail patients in this study also attained full weight bearing earlier than our EF patients. Much evidence in the literature exists to support this finding. For instance, Shannon *et al* (25) found that the mean time to full weight bearing was 37.4 weeks (EF) versus 22.2 weeks (IM). Furthermore, a similar result was reported by Alberts *et al* (26) where return to weight bearing was 21 weeks in IM group versus 34 weeks in the EF group. It is unknown at this time whether or not this difference will remain or equalize with time. However, our results support the notion that IM nail is better at restoring weight function early on.

No IM nail patients in this series developed malalignment. This is in contrast to 3 EF patients who developed either 10° varus or valgus malalignment and an additional 3 EF patients who had >5° procurvatum or recurvatum. Similarly, Henley *et al* (22) showed that IM nail group had significantly fewer incidences of malalignment than the EF group. Furthermore, in a meta-analysis by Tu *et al* (27), IM nails had lower rates of malunion compared to EF such that treating 6 open tibia shaft patients with IM nail instead of EF could prevent one malunion. Therefore, both our study and the literature support the conclusion that IM nail is superior to EF when considering malunion and malalignment.

The timing of when to remove the external fixator is an important factor to consider. At our study center, the standard protocol is to remove the external fixator and place the patient on a cast once the wound has healed. This is done primarily due to a lack of external fixators, as most centers in developed countries keep the device on patients for longer. Unfortunately, this treatment protocol likely contributes to higher rates of malalignment associated with EF. For instance, a study by Court-Brown *et al* (23) found a loss of reduction when external fixators were removed. Therefore, it is unknown at this time what the appropriate length of time for a patient treated in a developing setting to remain in an external fixator is. While longer times in the external fixator is likely to facilitate fracture union, it also increases the risk of infection.

This study was limited by the lack of randomization. Since the treatment modality chosen was at the discretion of the operating surgeon, it may be possible that higher AO/OTA grade fractures, which are more comminuted/unstable, were preferentially chosen to receive external fixation. This could potentially be one of the reasons for worse outcomes in the external fixation group. Another limitation of the study was the small sample size. Additionally, the short follow-up period of 18 weeks is not sufficient to adequately assess long-term outcomes. There were also no cultures performed on wound infections to confirm and identify the causative agent due to a lack of funds. Future work on this subject matter would involve larger sample sizes that are randomized and followed up with for longer periods.

In summary, patients treated with the IM nail were found to have similar rates of infection compared to EF. However, the IM nail resulted in earlier fracture union and return of weight bearing function, lower rates of infection, and better

outcomes in terms of both limb alignment and limb length. Due to the number of measures in which the IM nail was found to perform better than EF, our results show that reamed intramedullary nail is superior to external fixation for the treatment of Gustilo 3A open tibia fractures.

CONCLUSION

Short-term outcomes of Gustilo 3A open tibia shaft fractures appear to be superior when treated by intramedullary nail as compared to uniplanar external fixation. Advantages of the IM nail include faster rate of callus formation and lower rates of limb length discrepancy and malalignment. These preliminary results are limited by a small sample size and by a lack of randomization in the study methodology. Future studies are warranted to more definitively assess the best treatment option for Gustilo 3A open tibia fractures.

Conflicts of interest: None

Sources of support: None

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