

Reamed Versus Unreamed Intramedullary Interlocking Nail for Gustilo & Anderson Type II and IIIA in Open Fractures of Shaft of Tibia in Terms of Union and Infection Rate, A Prospective Comparative Study

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3. Final approval of the version for publication.
4. All authors agree to be responsible for all aspects of their research work

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ABSTRACT

Objective: To compare the rate of infection and fracture union in reamed versus unreamed interlocked IM nailing in patients with open tibia fractures.

Methods: It was prospective comparative study done at Department of Orthopedics, Sheikh Zayed Hospital, Rahim Yar Khan. 100 patients were enrolled who fulfilled the inclusion criteria and were divided randomly into two groups i.e. 50 in each group. Patients in Group A underwent unreamed IM nailing, whereas Group B underwent reamed IM nailing and patients were followed up at 2, 6, 12 weeks and then at 6 months for assessment of outcomes.

Results: The mean age of the patients in Group A was 37 ± 8.3 years and in the Group B, it was 36 ± 8.49 years. In Group A versus B, fracture union occurred in 40 (40%) and 47 (47%) patients ($p=0.037$) and SSI occurred in 2 (4%) and 5 (10%) patients ($p=0.240$), respectively.

Conclusion: Reamed IM interlocking nail was better in terms of fracture union compared to unreamed nail and there was no significant difference in terms of frequency of SSI between both interventions.

Keywords: Gustilo & Anderson Type II and IIIA, Open Fractures, Shaft of Tibia

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INTRODUCTION

Tibia shaft fractures are very prevalent in emergency orthopedics services and usually occur after high energy trauma in young men of economically productive age¹. According to current consensus, open fractures are more likely to have high-energy trauma, require longer-term care and experience higher rates of sequelae than closed fractures². One of the most serious orthopedic injuries are open tibial shaft fractures. Reamed or unreamed nailing, plating, Ender nails, Ilizarov fixation and external fixation are surgical

therapeutic alternatives³. The preferred form of treatment for both open tibia fractures and closed shaft fractures of the tibia is IM fixation of diaphyseal fractures of tibia, which has significantly reduced reoperation rates compared to plate or external fixation⁴.

Ideally, the treatment of choice for closed tibia fractures is IM fixation of the diaphyseal fractures of tibia, which has significantly lower reoperation rates than plate or external fixation whereas secondary nailing is regarded as an effective technique for

treating open fractures of the lower limb yielding positive radiological and functional results⁵. In a study comparing closed TSF with reamed IMN versus unreamed IMN, Bhandari *et al.*, (2008) reported that as a little reduction in the rate of nonunion was found by the SPRINT study with reamed IMN, there was no significant difference between the two approaches⁶. On the other hand, there are higher chances of infection in open TSF if managed with reamed IMN compared to unreamed IMN.

A study conducted by Ahmad *et al.* (2016) included patients having Gustilo and Anderson type I-II fracture showed that thirty three percent of patients had wound infection⁷. Moreover, interlocked IMN for the open fracture of the shaft of tibia will be safe in 80% patients while this intervention will yield better outcomes in 85% of cases. In literature there is continuous controversy over the advantage of one technique over the other. Authors mainly prefer a reamed nail due to its advantage of increased biomechanical stability for treatment of closed or open tibia fractures. However, there is still much confusion about the use of reaming during IM nailing of open tibia fractures involving the shaft.

To better understand this discrepancy between results of reamed vs unreamed intramedullary nailing by various authors, this prospective comparative study was planned by our department to compare the union rates of reamed versus unreamed interlocked IM nailing and to know the infection rate of reamed versus unreamed interlocked IM nailing.

MATERIAL AND METHODS

It was Prospective comparative study carried out at the Department of Orthopaedic Surgery, Sheikh Zayed Medical College/Hospital, Rahim Yar Khan.

All the patients presenting in ER of hospital, from Feb 2021 to Feb 2022, with Gustilo & Anderson Type II & IIIA open fractures of tibia, who were operated within 24hrs of injury, were included in this study irrespective of gender and age.

However patients with pathological fracture, poly traumatized patients, previously operated on same tibia, patients with uncontrolled diabetes mellitus and medical unstable patients were excluded from the study.

The sample size was calculated by the following formula keeping the power of study equal to 90% and level of significance equal to 7%

$$n = \frac{\left(Z_{1-\alpha} \sqrt{2p(1-p)} + Z_{1-\beta} \sqrt{p_1(1-p_1)p_2(1-p_2)} \right)^2}{(p_1 - p_2)^2}$$

(Sample Size determination in health studies version 2.0.21 WHO)

Z 1 - β was the desired power of study = 85%

Z 1-α/2 was the desired level of significance = 5%

P1 was the anticipated infection rate with unreamed nail = 33% (Ahmad *et al.*, 2016)

P2 was the anticipated infection rate after reamed nail = 62.5% (Petrisor *et al.*, 2005)

p1 - p2 was the difference between proportions = 29.5%

n was the calculated sample size in each group = 100

The sample size of the study was 100 patients. The patients were divided into two groups (50 in each group) namely Group-A and B by Non-probability convenient sampling followed by randomization

Group A underwent treatment by unreamed intramedullary interlocking nail and Group B underwent reamed intramedullary interlocking nail.

METHODOLOGY (DATA COLLECTION PROCEDURE)

After approval from the local ethical review committee, patients fulfilling the inclusion criteria were selected from Orthopedic Surgery Department, SZH, RYK according to sample size. The informed consent was taken for the particular procedure and using their data for research. They were assured regarding confidentiality and expertise. The study comprised the individuals who met the inclusion criteria and presented with open tibia fractures. According to the Gustilo and Anderson categorization system (Gustilo & Anderson, 1976; Gustilo *et al.*, 1984), the fractures were categorized. In an emergency, sterile dressing was applied, the wound was extensively irrigated with normal saline, and the limb was splinted. Following this, the patient received appropriate analgesia, tetanus vaccination, and an IV injection of Cefoperazone/Sulbactam 2 gm that was administered every 12 hours.

The patients were examined and followed up by the researcher himself, counter confirmed from the supervisor whenever needed and results were noted on the Proforma/Case Report Form (Attached as Annexure).

POST OPERATIVE REHABILITATION PROTOCOL

As soon as the pain permitted, physiotherapy was started on the 3rd postoperative day and was performed while using the proper walking aids. Depending on the callus formation, mobilization began with non-weight bearing crutch support walking and

progressed to toe touch crutch support walking and weight bearing.

FOLLOW UP

Follow-up was done at 2nd, 6th and 12th weeks and 6 months post-operatively. SSI assessed by Southampton score and Union of the fracture assessed both clinically and radiographically by RUST score was the primary outcome variable and the secondary outcome was the operation time, blood loss, hospital stay and complications.

1st FOLLOW UP	2 nd Week
2nd FOLLOW UP	6 th Week
3rd FOLLOW UP	12 th week
4th FOLLOW UP	6 th month

STATISTICAL ANALYSIS

Data was analyzed using SPSS 25. Quantitative data like age was described in terms of mean and SD. Qualitative variables like gender, outcome and knee or

thigh pain were described as frequencies and percentages. Comparison of antegrade and retrograde nailing was done using chi-square test. Independent sample t-test was applied to compare mean scores between the groups. P value ≥ 0.05 was taken as significant.

RESULTS

A total of 100 patients were enrolled in the study. The mean age of the patients in Group A (unreamed IM nailing) was 37 ± 8.3 years and in the Group B (reamed IM nailing) it was 36 ± 8.49 years (Table 2). The mean interval between injury and surgery in Group A was 12 ± 6 hours and in Group B it was 11 ± 6.1 hours . The mean operative duration in Group A was 40 ± 5.12 minutes and in Group B it was 60 ± 5.49 minutes. The mean estimated blood loss in Group A was 155 ± 12.7 ml and in Group B it was 388 ± 19.3 ml. The mean RUST score in Group A was 11 ± 1.73 and in the Group B it was 12 ± 0.61 and the difference between two groups in terms of RUST score was statistically significant as indicated by a $t = -2.535$, $p = 0.013$.

Table 1: Comparison of fracture union between two groups based on demographics and clinical parameters (n=100)

Parameters	Categories	Group A (n=50)		Mean±SD	Group B (n=50)		Mean±SD	p-value
		Fracture Union			Fracture Union			
		Yes	No		Yes	No		
Gender	Male	30	9		37	2		1.000
	Female	10	1		10	1		
Age				36.94 ± 8.30			35.78 ± 8.50	0.484
Interval Between Injury And Surgery				12.14 ± 6.01			11.58 ± 6.14	0.646
Duration Of Surgery				39.92 ± 5.12			60.18 ± 5.50	<.001
Estimated Blood loss				154.60 ± 12.73			387.80 ± 19.33	<.001
RUST score				11.20 ± 1.74			11.86 ± 0.61	0.013
Mechanism of Injury	RTA	25	7		28	1		
	Fall	9	3		12	1		0.919
	Sports	4	-		5	-		
	Direct Below	2	-		2	1		
Side	Right	22	7		22	25		0.423
	Left	18	3		2	1		
Wound Infection	Yes	0	2		2	3		0.436
	No	40	8		45	0		
Southampton Score	Grade 0	40	8		45	0		
	Grade I	0	1		0	1		
	Grade II	0	1					0.131
	Grade III	0	0		1	2		
	Grade IV	0	0		1	1		

Knee Pain	Mild	40	8		45	0		0.317
	Moderate	0	2		1	2		
	Severe	0	0		1	1		

Table 2: Comparison of fracture union and RUST score between two groups

	Group A	Group B	p-value
Fracture Union			
Yes	40	47	.037
No	10	3	
RUST score	11.20±1.74	11.86±0.61	0.013

FREQUENCY OF FRACTURE UNION

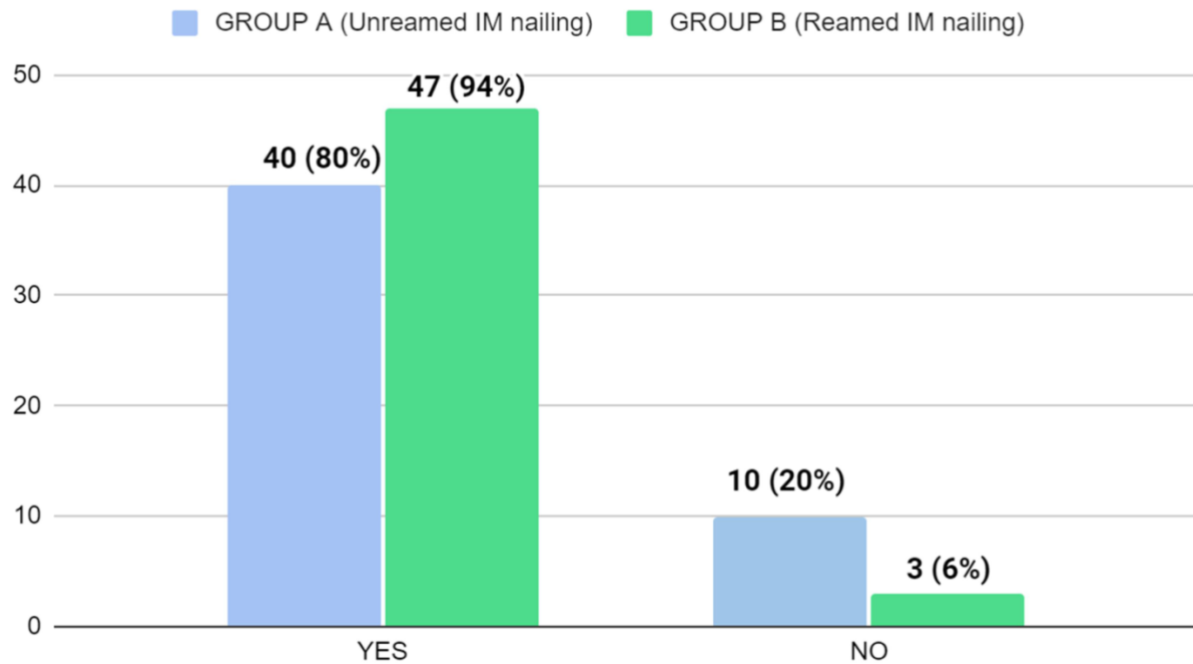


Figure 1: Comparison Of Both Groups In Terms Of Fracture Union

There were 81 (81%) males and 19 (19%) females in the study. Gustilo Andersen type II fracture was seen in 77 (77%) patients and type IIIA was seen in 22 (22%) patients. In terms of mechanism of injury, 61 (61%) patients had road traffic accidents, 25 (25%) patients had fall, 9 (9%) patients had sports injury and 5 (5%) patients had injury due to a blow . Fracture of the right tibia occurred in 53 (53%) patients and of the left side occurred in 47 (47%) patients.

In terms of fracture union, it was found that 40 (80%) patients in Group A had complete union compared to 47 (94%) patients in Group B and comparison of fracture union in both groups revealed that there was a significant difference between both

groups in terms of rate of fracture union as indicated by a p value of 0.037.

In terms of SSI, it was revealed that 2 (4%) patients in Group A had SSI compared to 5 (10%) patients in Group B and comparison of frequency of SSI between both groups revealed there was no significant difference between the two groups as was indicated by a p value of 0.240.

With respect to Southampton grading, in Group A, 48 (96%) patients wound fell into grade 0, 1 (2%) patients had Grade I wound and 1 (2%) patients had Grade II wound and in Group B, 45 (90%) patients had Grade 0 wound, 3 (6%) patients had Grade III and 2 (4%) patients had Grade IV wound (Table 9).

With respect to pain in knee after treatment, in Group A, mild pain was present in 48 (96%) patients,

moderate pain was present in 2 (4%) patients and none had severe pain, whereas, in Group B, 45 (90%) patients had mild pain, 3 (6%) patients had moderate pain and 2 (4%) patients had severe pain the study revealed the existence of important surgical parameters concerning disparities. The operation time was significantly longer in unreamed intramedullary interlocking nail technique strongly highlighting the possible consequences of using this method. Moreover, a study has yielded the highest blood loss of the unreamed group in terms of intraoperative blood management. It has emphasized a possible issue regarding this type of approach. These results instead highlight the necessity of taking into account the advantages and disadvantages associated with these methods, particularly for surgery and blood conservation purposes.

RUST Index manifested that there was a statistically reliable difference between the 2 groups. Of note, factors associated with the mechanism of injury, injury location and wound infection rates, Southampton scores and knee pain did not demonstrate statistical difference between the two groups studied as $p > .05$. (Table 1 & 2).

DISCUSSION

The results of the current study revealed that in patients with open tibial fractures of the shaft, reamed IM interlocking nail was significantly associated with higher union rates compared to unreamed IM nail and there was no significant difference in terms of rate of SSI between both groups. The majority of the patients in the current study were males, of early middle age (31 to 45 years), had Gustilo Andersen type II fractures and had injury to the tibia following road traffic injury.

There are still many unsolved problems regarding how to manage open tibial shaft fractures⁸. These fractures which are typically brought on by high-energy trauma cause malunion, non-union, infection, and occasionally even necessitate amputation because of the poor soft tissue coverage and restricted vascular supply of the tibia. The occurrence of these problems has recently decreased thanks to advancements in fixation devices and wound coverage techniques, but the best way to treat open tibial shaft fractures is still being developed⁹.

When it comes to the outcome of tibial shaft fractures, two main elements come into play. First, there is fracture severity, which is determined by Nicoll's classification of the degree of displacement initially, comminution and damage to the soft tissue.

The injury to the tibial blood supply is the second factor. After significant damage to the soft tissue and periosteal stripping from the bone, the periosteal circulation is also affected in open fractures in addition to the endosteal circulation¹⁰.

Plaster casts have been the most popular form of treatment for open tibia fractures, although they have a number of drawbacks. After placing a cast on 140 open tibial fractures, Nicoll observed a 15% infection rate¹¹. In 63 open tibial shaft fractures, 27% had healed with a shortening of more than 10 mm, while 6.3% had a shortening of more than 30 mm, according to Brown and Urban (1969). In a group of 24 open tibial fractures treated with a cast, Puno *et al.* more recently found a 12.5% rate of malunion. Solely stable fractures with little soft tissue damage should be immobilized in a plaster cast.

Smith examined 219 open fractures treated with internal fixation the day of the injury in plate osteosynthesis, finding that delayed union occurred in 48% of cases and infection in 20%¹². When open fractures were treated with plating, non-union was found to be twice as common and infection to be five times more likely, according to Johner and Wruhs (1983).¹³

Locking nails have been effective in treating closed tibial fractures, which has sparked interest in its use to open tibial fractures⁸. The preferred approach for treating open fractures is now intramedullary nailing following reaming, however its use to open tibial fractures is still debatable¹⁴. It has been hypothesized that the soft tissue injury and the vascular damage caused by reaming together significantly enhance the risk of infection and delayed union. This theory appears to be supported by early accounts of the use of unlocked nails along with reaming for open tibial fractures¹⁵. The current study compared the outcomes of reamed versus unreamed IM interlocking nails in patients who had open tibia fractures.

In our study, the frequency of fracture union in patients who underwent reamed IM nailing was 94% compared to 80% in the unreamed group and this difference was found to be statistically significant i.e. $p=0.037$. Huang *et al.* in a meta-analysis compared reamed with unreamed IM nailing and revealed that the rates of union were significantly higher in the reamed group as indicated by a p value of <0.0003 ¹⁵. Ullah *et al.* revealed that unreamed IM nailing led to fracture union in 87.9% patients¹⁷. Xue *et al.* in another meta-analysis revealed that the rates of non-union were significantly lower in the reamed IM nailing of open tibia fractures compared to unreamed nailing

as was indicated by $RR=0.41$, $p=0.008$ ¹⁸. Akhtar *et al.* revealed that the rate of union in the unreamed IM nailing of open tibia fractures was 70%¹⁹. Ali *et al.* revealed that the rate of fracture union in the reamed nailing was 80% and in the unreamed nailing was 70% in patients who had tibial fractures²⁰. These findings by the previous studies support our study findings that reamed IM nailing was associated with higher rates of fracture union compared to the unreamed nailing and the differences were statistically significant.

In terms of postoperative rate of infection, our study revealed that in patients who underwent unreamed IM nailing, the frequency was 4% compared to 10% in the reamed IM nailing and this difference was statistically insignificant i.e. $p=0.240$. Shobha and Punith revealed that there was no significant difference in terms of rate of infection and other complications postoperatively in the reamed versus unreamed IM nailing of open tibia fractures²¹. Omrani *et al.* revealed that in the reamed group the frequency of infection was 10.8% versus 22.7% in the unreamed nailing and this difference was statistically insignificant²². Puri *et al.* revealed that in the unreamed IM nailing the rate of surgical site infection was 10% and in the reamed group it was 15% and this difference was statistically insignificant²³. These findings support our study findings that although reamed IM nailing was associated with higher rates of infection, however reamed and unreamed IM nailing in patients with open tibia fractures did not have significant differences in terms of rate of infections.

Our study findings are consistent with previously conducted few local and various international studies in that in patients with open tibia fractures, reamed IM nailing is significantly associated with higher rates of union compared to unreamed nailing and has no difference in terms of rate of infection. Hence, reamed IM nailing could be preferred in patients with open tibia fractures.

The study had certain limitations:

Firstly, the study was carried out at a single center and on limited patients, so the results cannot be generalized.

Secondly, the follow up period was brief, so the long term outcomes could not be assessed.

Thirdly, patients with open tibial fractures were enrolled only and hence the outcomes in patients with closed tibial and other fractures could not be commented on.

The current study concluded that in patients reamed IM nailing was significantly associated with higher rates of fracture union compared to unreamed IM nailing. However, in terms of surgical site infection, although the frequency was less in the unreamed nailing yet the difference was not statistically significant. Hence, the current study results proposed that reamed IM nailing was a better surgical intervention for repair of open fractures of the shaft of tibia and should be considered as a primary treatment option for such patients. Future studies must be carried out on a larger sample size in order to validate the findings of current study.

Conflict of Interest: None

Grants/Funding: None

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CONCLUSION

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