Comparative Study of Treatment in Open Tibia Fracture Treated with Jugdesh-Awais Solid Tibial Nail (JA-STN) and AO External Fixator

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Introduction: The tibia is most commonly fractured long bone in the body, as it has poor soft tissue coverage, medial surface is completely subcutaneous. The optimum method for skeletal stabilization of open fractures of the tibial shaft remains controversial. In recent years, unreamed intramedullary nailing has become an increasing attractive treatment method for tibial fractures. Due to high price of imported unreamed tibial nail (UTN), therefore we first designed the nail according to the measurement of our tibia, and then manufactured the solid UTN nail from 316L steel and inserting instrument from stainless steel. Two average size i.e. 350 mm and 330 mm in length and 9 mm diameter after analyzing the measurements of tibia in 20-40 years old male population of tibia of 50 healthy males by using CT scan. The sizes of long bones are slightly different in Western and Asian societies.

Aims and Objectives: (1) The Development of solid intramedullary nail for tibia shaft; (2) to evaluate efficacy of internal fixation and external fixation for treatment of open type IO_1 and IO_2 fractures of tibia (3) to evaluate the time required for healing of fracture and soft tissues, and return to the function with each method of treatment and (4) to observe and compare the rate of complications in both procedures.

Material and Method: This study was carried out in the Department of Orthopaedic Surgery, Mayo Hospital, Lahore between June 1995 to June 1998. This study was carried out in three phases: Phase I – collection of data regarding measurements of tibia in 20-40 years old male population by using CT scan, Phase II – designing and manufacturing of solid tibia nail alongwith inserting and interlocking instruments and Phase III – comparative study of treatment of 40 open fractures (IO_1 and IO_2) 50% treated with solid unreamed interlocking nail and 50% with the AO external fixators.

Results: The duration of hospital stay between 3-8 days, 85% patients in unreamed tibial nail (group A) and 30% in external fixation (group B), statistically the difference is highly significant ($P<0.0001$). The average time off work in group A was 13.9 weeks while 21.19 weeks in group B, $P<0.05$ (significant). The average time to union was 21 weeks in group A and 24.3 weeks in group B, statistically the difference is not significant ($P>0.05$). Full weight bearing without support 75% patients in 11-20 weeks in group A and 40% patients in group B, statistically the difference is very highly significant ($P<0.0001$). The average wound healing time was 2.8 weeks in group A and 5.4 weeks in group B. Wound infection develop in 2 patients (10%) in group A and 4 patients (20%) in group B. Breakage of distal locking bolts in 2 patients but no breakage of nail and Schawnz screw in group A and B respectively. Two patients (10%) develop infection at distal locking bolt site in group A and 10 patients (50%) got pin tract infection in group B.

Conclusion: This study supports the use of the URTN over external fixation in the treatment of severe open tibial fractures.

Introduction

The tibia is the most commonly fractured long bone in the body, as it has poor soft tissue coverage and medial surface is completely subcutaneous.[1] Severe injury particularly combined with inadequate, or inappropriate treatment can lead to severe complications and major disability.[2]

The optimal methods of fixation of these injuries remain debatable. In recent years, unreamed intramedullary nailing has become an increasing attractive treatment method for tibial fractures.[3,4]

In AO classification for soft tissue injuries to skin, muscle, tendon and neurovascular structures.[5] Skin lesion with open fracture further divided into: IO_1 – skin breakage from inside out; IO_2 – skin breakage from outside in of less than 5 cm contused edges; IO_3 – skin breakage more than 5 cm increased contusion, devitalized edges and IO_4 – considerable full thickness, contusion, abrasion, extensive open degloving, skin loss.

Bony stabilization can be achieved in a variety of methods such as plate and screws, external fixation and with intramedullary nails. Each of these modalities has inherent complications associated with specific method of stabilization.[4]

Intramedullary nailing is often the treatment of choice in the management of fractures in the tibial diaphysis.[6] External fixation of open or closed tibial shaft fractures with severe soft tissue injury has been the standard treatment during the 1980s. More recently, unreamed nailing of open tibial fracture has become popular.[7]

Unreamed tibial nails (UTNs) have been shown to be a reasonable treatment option to external fixator in tibial shaft fracture with severe soft tissue damage.[7] The method of external fixation has many complications e.g. pin track infection, need for bone graft, nonunion, refracture, but has the known advantage of a low infection rate.[8] Nailing especially reamed nailing in open tibial fractures is said to have

a high rate of septic nonunion. An infection rate comparable with external fixation is expected in unreamed nailing, because of the reduced damage to the cortical blood supply.[9] Also patient comfort during the healing period is greater with an intramedullary nail, compared with an external fixator especially fracture with severe soft tissue injury.[10]

Singer and Kellam[11] suggested that unreamed locked intramedullary nailing is the treatment of choice in the management of open tibial diaphyseal fractures because locked unreamed nails have improved rate in open tibial diaphyseal fractures. In contrast, reamed intramedullary nailing of acute tibial fractures have been associated with a much higher rate of complications. These include linear pro-pagation of the fracture from the insertion of ankle joint, neurologic injury, malunion, nonunion and deep infection.[12]

The close intramedullary nailing on the other hand is only practiced in prestigious few institutions in our country. Although it is the norm in developed world for closed or open fractures, the reason why it is not practiced in our domestic setup is financial. The cost of implant and instrumentation is too high.

The purpose of this study is to use of self made JA-STN (Jugdesh Awais – Solid Tibial nail) and jigs for insertion and interlocking of these nails and to evaluate its efficacy in comparison with external fixation in open type IO_1 and IO_2 fractures of tibias regarding healing of soft tissue and fracture.

Material and Methods

This study was carried out in the Department of Orthopaedic Surgery, Mayo Hospital, Lahore between June 1995 to June 1998. Forty open tibia fractures (IO1 and IO2) 50% treated with JA solid tibial nail and 50% with AO external fixator. The patients received in emergency department with IO_1 and IO_2 open tibia fractures were thoroughly accessed for life threatening conditions by checking airway breathing and circulation. History was taken to know the exact mode of injury. Complete physical examination was done to find out any chest, abdominal or pelvic injuries. Intravneous lines were established. The wounds were examined and fractures were classified according to AO classification. Distal neurovascular status was checked of the injured extremity and compared with the normal side. X-rays of the injured leg were done to assess the fracture geometry and classified using AO classification. Routine investigations were sent to the emergency laboratory immediately. Patients were given prophylaxis against tetanus and antibiotics. After making through assessment the operating planning was done and the patients now haemodynamically stable after receiving intravenous fluids or blood as required, were shifted to the operation theatre for wound debridement and stabilization of the fracture under general anaesthesia of spinal. External fixator was applied on the 1st day and nailing was done on the next coming routine operation day.

Debridement, the ends of principal bone fragments were washed and cleaned of debris. After irrigation and debridement, stabilization of bone was done by applying the external fixator. The unilateral modalities were applied i.e. unilateral uniplanar and unilateral biplanar. Preference was given to apply uniplanar unilateral external fixator. The post-operative care of external fixator: pin inserting site were cleaned daily with pyodine and light dressing was applied. Partial weight bearing was allowed as soon as the wound had healed. Dynamization of external fixator was done when fracture become sticky. Full weight bearing was allowed gradually. External fixator was removed when fracture was healed solidly. PTB cast was applied for a period of one month to protect pin tracts. The nails were provided free of cost to all patients; but locking bolts were purchased by patients themselves. In 18 patients solid nail of size 9 mm x 330 mm was inserted and in remaining two patients 9 mm x 350 mm.

Results

Most common fracture in this series was A3 (simple fracture transverse, according to AO classification) (Table 1) which was in 12 patients in both groups. In group A simple fracture, transverse (A3) was in 4 (20%) Patients and in group B, it was in 8 (80%) patients.

Table 1: *Classification of Fractures (AO Classification).*

Fracture Pattern	Group A	% age	Group B	% age
A = Simple Fracture				
A1 Spiral	3	15.02	2	10.0
A2 Oblique	3	15.0	4	20.0
A3 Transverse	4	20.0	8	40.0
B = Wedge Fracture				
B1 Spiral Wedge	4	20.0	3	15.0
B2 Bending Wedge	4	20.0	0	0.0
B3 Fragmented Wedge	1	5.0	1	5.0
C= Complex Fracture				
C1 Spiral	1	5.0	0	0.0
C2 Segmental	0	0.0	2	10.0
C3 Irregular	0	0.0	0	0.0

The site of fracture (Table 2) Group-A segment 1 there was no fracture in this category, Segment 2 twelve patients (60%) belong to this category and Segment 3 Eight patients (40%) belong to this category. Group B Segment 1 two patients (10%), fracture in proximal segment 10 patients (50%), Belong to segment 2 and 8 patients (80%) in distal segment.

Table 2: *Classification of Fractures (AO Classification).*

Site	Group A	% age	Group B	% age
Segment 1 (proximal 1/3)	0	0.0	2	10.0
Segment 2 (proximal 1/3)	12	60.0	10	50.0
Segment 3 (proximal 1/3)	8	40.0	8	40.0

Table 3: *Duration of stay in hospital (days).*

Duration of Stay (Days)	Group A	% age	Group B	% age
3 – 8	17	85.0*	6	30.0*
9 – 14	2	10.0**	12	60.0**
15 – 21	-	-	2	10.0
22 – 28	1	5.0	-	-

*P<0.001 (Highly significant)
**P>0.0001 (Very highly significant)

Table 4: *Time off work.*

Time Off Work (Weeks)	Group A	% age	Group B	% age
0 – 10	6	30.0	-	-
11 – 20	12	60.0	10	50.0
21 – 30	2	10.0	8	40.0
> 30	-	-	2	10.0

P<0.05 (significant)

Table 5: *Time to Union.*

Time to Union (Weeks)	Group A	% age	Group B	% age
16 – 20	8	40.0	3	15.0
21 – 24	10	50.0	10	50.0
25 – 28	1	5.0	4	20.0
> 28	1	5.0	3	15.0

P>0.05 (Not significant)

There were 12 patients (60%) open type IO_1, and 8 patient (40%) IO_2 in Group-A according to AO Classification, There were 6 patients (30%), IO1 and 14 patients (70%), IO_2 in Group-B.

Table 6: *Full weight bearing without support (weeks).*

Duration (Weeks)	Group A	% age	Group B	% age
4 – 10	4	20.0	-	-
11 – 20	15	75.0	8	40.0
21 – 30	1	5.0	12	60.0

P<0.0001 (Very highly significant)

In Group A, the mean duration of stay in hospital was 5.8 days range 3-12 days except one patient remained for 26 days. In group B, the mean time duration of stay in hospital was 8.15 days range 6-19 days (Table 3). In group A, the average time off work was 13.9 weeks and in group B, 21.19 weeks (Table 4). The average wound healing time was 2.8 weeks in group A and 5.4 weeks in group B. The average time to union in group A was 21.6 weeks and in group B 24.3 weeks (Table 5). Full weight bearing without support 75% patients in 11-20 weeks in group A and 40% patients in group B, statistically the difference is very highly significant (P<0.0001) (Table 6). The average wound healing time was 2.8 weeks in group A and 5.4 weeks in group B. Wound infection develop in 2 patients (10%) in group A and 4 patients (20%) in group B. Breakage of distal locking bolts in 2 patients but no breakage of nail and Schawnz screw in group A and B respectively. Two patients (10%) develop infection at distal locking bolt site in group A and 10 patients (50%) got pin tract infection in group B.

Discussion

The goal of open tibial fracture management is to obtain an anatomically functionally normal limb and return the patient to their preinjury level of function as quickly as possible.[2] To achieve this goal, complications, particularly infection must be prevented.[13] The high rate of complications seen in association with open tibial fracture has been well documented by Chan et al.[14] Intramedullary fixation of fractures was popularized in Columbia in the mid 1930s by Leslie and Lowry Rush of Mississippi using thin, solid and flexible rods.[15]

Pioneering work by Gerhard Kuntscher in Germany in the 40s provided additional experience and information about this technique of fracture stabilization.[16] The earliest varieties of intramedullary nail for the tibia to become popular were inserted in an unreamed, unlocked fashion. The rigid nail of Lottes[17] and the flexible nails of Enders have been used with success.[18] These early types of tibial nails did not have interlocking capabilities and thus they did not provide rotational stability nor resistance to shortening beyond that offered by the fracture pattern. The initial unlocked design of Kuntscher was modified to allow interlocking proximally and distally, which further improved stability and expanded the indications for nailing to include significantly comminuted fractures. The next step in deve-

lopment was the availability of thinner, solid section unreamed nails which also had interlocking capability that allowed stable fixation without intramedullary reaming.[15]

The advantages of unreamed interlocking nails include the avoidance of malunion, maloration or leg length discrepancy, the preservation of endosteal circulation better cosmetic results and easy access for soft tissue procedures. The disadvantages include hardware failure, a more complicated technique, radiation exposure and higher infection rate in mangled lower extremities.

In an attempt to stabilize severe open fractures quickly, external fixation has become increasingly popular throughout the orthopaedic and traumatologist world.[19] This type of fixation has much to be recommended because of its advantage of limited blood loss, limited soft tissue dissection, lower infection rate. Pin tract infections, malunion, cosmetic inadequacies and inadequate fixation of an intermediate fragmented or segmental tibial fracture are disadvantages of external fixation.

This study was carried out on male patients only. Because the published research showed males were common trauma victims. Naseer and Awais[20] reported in their study on epidemiology of trauma patients, that 79% were male patients.

Wound healing was achieved in average time of 2.8 weeks in patients treated with closed unreamed nailing and 5.4 weeks in patients treated with external fixator. The main difference in between two groups were that in group A 80% of patients, wound healed with 4 weeks of time while in group B 30% patients in this period.

Mean time to bony healing was 21.6 weeks in patients treated with unreamed intramedullary nailing and 24.3 weeks in patients treated with external fixator. But the difference between two groups was that in 40% patients bony healing occurred with 16-20 weeks in group A and 15% in group B. In both groups no additional procedure was done to achieve union.

Duwellus et al[12] reported 16 to 18 open fracture (89%) united within 9 months with unreamed interlocked intramedullary tibial nailing and 6 patients (33%) the fracture took more 6 months to consolidate and were considered delayed union.

Singer and Kellman[11] reported union rate 98% in open tibial diaphyseal fractures treated by unreamed locked intramedullary nailing. But 47% fracture united after at least one additional procedure to achieve union.

Schandelmair et al[7] reported in their series mean time to bony healing 25.8 ± 14 weeks. Sanders et al[21] reported a prospective randomized study which directly compared stabilization with external fixator and non-reamed locking nail. They found a higher union rate, a shorter of union and fewer malunion in their nailed group.

The average length of hospital stay were less in UTN group, average 5.8 days ($P<0.0001$) while 8.5 days in external fixator group. The main difference in between both groups, in UTN group 17 patients (85%) duration of stay was 3-8 days; in external fixator group 6 (30%) patients had same duration.

The average time off work in the UTN group was 13.9 weeks ($P<0.05$) and 21.1 weeks in external fixator group. In UTN group, 18 patients (90%) the time off was 0-20 weeks while in external fixator group only 10 patients (50%) had this time off work. Early mobilization was the cause of less time off work in UTN group.

Fischer *et al*[22] reported average time of hospital stay 31 days. Schandelmaier *et al*[7] reported in his series average 7.6 months time back to work. Krettek *et al*[23] reported 8.8 weeks time back to work. Infection rate was high (20%) in group A while 10% in group B. Whittle *et al*[24] reported 25% infection rate in unreamed interlocking nailing.

The major problem which we found in Group-A pin tract infection in 50% of patients, Burny[25] reports in his analysis of 5125 observations was less than 50% of the pins caused significant reactions.

In our study, out of 20 patients treated by static interlocking, one screw proximal and one distal, only in two patients (10%) distal locking bolts were broken. Court-Brown *et al*[26] reported in their series out of 25 fractures, one patient with a segmentally comminuted fracture with boneless experienced distal locking screw breakage.

Conclusion

We conclude that close unreamed intramedullary interlocking nailing is a safe technique and it combines a high rate of union with a low complication rate This technique has important advantages of enabling the patient early weight bearing on the extremity, avoiding external immobilization, achieving anatomical alignment and allowing early return to independent function.

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