OUTCOME OF DISTAL TIBIA FRACTURES TREATED BY ILIZAROV EXTERNAL FIXATOR V/S T-CLAMP NASEER AWAIS EXTERNAL FIXATOR

ABSTRACT:

BACKGROUND: Distal tibia fractures generally considered to be a difficult surgical technique because, lies subcutaneously, has precarious blood supply, high risk of infection, risk of necrosis after internal fixation and also develops malunion and non-union. Our research question was that the Naseer Awais external fixation systems with T-clamp have the advantages over the Ilizarov external fixation. We compared the outcome of both fixators and the following factors were considered to evaluate the results, like age, sex, mode of injury, classification of fractures, and effect of early and late weight bearing on union time of distal tibia fractures. Our hypothesis was that there is no significant effect of weight bearing on union time in these types of fractures.

METHODS: Thirty distal tibia fractures with single limb injury were randomized to be treated with Ilizarov Fixator and Naseer Awais External Fixation with T-Clamp. There were 23 men and 7 women were divided in two groups A and B, 15 patients were treated with the Ilizarov external fixator (Group A) and 15 with the Naseer Awais External Fixator with T-Clamp (Group B) between May 2005 to April 2007. The fractures were classified according to modified Gustilo classification. The systems allowed early and late weight bearing in all patients.

Our surgical delay was not more then 24 hours. All patients were mobilized either on bed or non or partial weight bearing with walking aids after 06 hours or when the patient tolerated the pain and maximum time of mobilization was not more then 24 to 48 hours.

RESULTS: Twenty (66%) patients road traffic accident victims, 05 (16%) fall from height, 04 (13%) fire arm injury and fallen a heavy object on leg in only 01 (3.33%) patients. Fractures were classified according to Gustilo classification, five (n=05) 16% type I, six (n=06) 20% type II, twelve (n=12) 40% type IIIA and seven (n=07) 23% were type IIIB. Tolerance in both the groups was generally good and the pin track infection, superficial was seen in two cases. There were neither thromboembolic nor neurological complications. Bone healing was achieved at 18.37 weeks in group A patients and at 17.25 weeks in group B patients and P-value of both groups was 0.368. Partial weight bearing walking in group A was 13.3 week as against 11.88 weeks in group B, likewise full weight bearing was 8.27 week and 16.67, respectively and P-value of both group was 0.000***.

CONCLUSION: Although application of both External Fixators was in same age group (15-45 years) but union time did not differ significantly between group A & B. However, weight bearing was significantly earlier in Group A. Early weight bearing did not enhance union in the distal tibia fractures.

KEY WORDS: Distal tibia fractures, Ilizarov, NAEF with T-clamp

INTRODUCTION:

Supramalleolar fractures are generally considered to be a difficult surgical challenge because they occur in area where the tibia lies superficially with precarious blood supply to the skin, exposing to the risk of infection and skin necrosis after internal fixation. These fractures are also situated close to the tibiotalar joint making centromedullary nailing difficult, even with distal locking. However Ilizarov external fixator could be an attractive alternative in this indication.

The Ilizarov external fixator is best indicated for tibial fractures, because of its advantage of allowing early weight bearing. Ilizarov method has proved that to be effective in the treatment of post-traumatic nonunion of the tibia where other types of treatment had
Ilizarov external fixator allows correction of three-dimensional deformities such as rotation, translation, angulation, and correction of shortening, widening, lengthening, and soft tissue defects. On the other hand, Naseer Awais External Fixator (NAEF) is uniaxial, has few components, is developed locally, and is cheap. It has performed the desired function. The first Naseer-Awais External Fixator (NAEF-1) was developed and used in early 1981. Since then, based on local experience, different types of NAEFs have been developed and used in the management of different problems like fractures and for leg lengthening. The system has been successfully used for treatment of open fractures, segmental fractures, open fractures with segmental loss of bone, infected fractures, and leg lengthening in cases of segmental bone defects. In 2004, T-clamp was introduced by the same department for the small proximal and distal fracture fragment of various long bones. Nonarticular distal tibia/fibula fractures are difficult to treat because limited soft tissue coverage in the area can present significant soft tissue problems in these high-energy injuries. The distal tibia also presents problems with stabilization, particularly when the fracture is within the distal 3 to 4 cm of the tibia. A variety of other options have been used, including spanning fixation, hybrid and Ilizarov external fixation. Despite use of various techniques, soft tissue problems, malunion, and nonunion may complicate treatment. We compared the Ilizarov external fixation system with our modified local made hybrid type Naseer Awais external fixation system with T-clamp to assess the early and late weight bearing effect on union in open distal tibia fractures. Our research question was that the Naseer Awais external fixation system with T-clamp have the advantages over the Ilizarov external fixation. We also compared the outcome of both fixators and the following factors were considered to evaluate the results, like age, sex, mode of injury, classification of fractures, and effect of early and late weight bearing on union time of distal tibia fractures. Early weight bearing is not possible in NAEF with T-clamp due to stability as against the Ilizarov but the patients are not bearing full weight due to pain in ankle and foot after application of Ilizarov external fixator in distal tibia fractures and our hypothesis was that there is no significant effect of weight bearing on union time in these types of fractures.

PATIENTS AND METHODS

This quasi experimental study was conducted at department of orthopaedics Liaquat
University of Medical & health Sciences Jamshoro, Sindh, Pakistan. The duration of study was two years from May 2004 to April 2006. We selected the fractures randomly to include a particular case in each group by fracture configuration like transverse, oblique, segmental, spiral & comminuted and also according to Gustilo & AO type A and divided the patients in two groups, 15 in each group A and Group B. Group A fractures were stabilized with Ilizarov external fixation system and group B were stabilized with Naseer Awais external fixation system with T-clamp. Inclusion criteria of study were according to Modified Gustilo and Anderson type I, II, IIIA and IIIB and A1, A2 & A3 extra – articular fractures according to AO classification. We also include the age group from 15 years to 45 years. Patients less then 15 years and more then 45 years were excluded from study. All intra articular type B and C according to OTA classification and type IIIC Gustilo fractures were excluded.

Patients with supramalleolar fractures of tibia brought to the casualty department were enrolled to the study after taking consent from the patient about participate in the study. After counselling the patients and attendants regarding the nature of injury, its importance & possible complications, also explained about the method of treatment selected (Group A or Group B) for that patient.

All patients with distal tibia fractures, either through casualty or through out patient department, direct arrivals or those mishandled by potters and quakes selected according to inclusion criteria were treated with “ILIZAROV EXTERNAL FIXATOR TECHNIQUE” and “NASEER AWAIS EXTERNAL FIXATION WITH T-CLAMP”. The surgery was done within 06 to 12 hours in acute open fractures and within 24 hours after arrival and admission in the hospital. The duration of delayed arrival was not more then 72 hours. Type I and II wounds were closed primarily after wound irrigation, split skin graft was done in type IIIA and type IIIB naked bone and tendons were covered by either mobilizing the skin by release incision or local fasciocutaneous flaps.

All cases were followed with immediate postoperative radiographs and clinical assessment. Then followed through OPD weekly and then twice monthly when discharged from hospital otherwise thrice weekly radiographs had taken and alternate dressings done in ward. Alternative compression and distraction was performed at weekly interval after first 03 weeks of application of external fixators in both groups to enhance osteoblastic activity for achievement of early callus formation. Dynamization of external fixator done when patient achieved full weight bearing. In group A Ilizarov was removed after 22.33±1.3 and
in group B NAEF with T-clamp was removed 20.07±0.84 weeks and the P-value in both groups was 0.145.

After removal of fixators sarmento plaster was applied for 02 to 03 weeks and followed in review clinic from 06 to 12 months.

Record of all the cases were maintained in the proforma which include all the information's regarding the patients' history, status of his/her general condition and wounds and fractures from the time of arrival to discharge. Also, include clinical and radiological assessments in the review clinics with view of healing of wounds, union of fracture, complications, total hospital stay, weight bearing status and functional outcome. In all cases healing was assessed by radiological as well clinical examination and fractures were labeled united when the fracture line obliterated and not visible radiologically and no movement was seen clinically at fracture site.

DATA ANALYSIS:
Mean, Median, Mode, Frequencies, and Percentages & Standard deviations were calculated by SPSS version 10.0

OPERATIVE PROCEDURE:
After complete pre-operative investigations & assessment by pre-anesthetic clinic, the patients were placed on operating table. Usually epidural anesthesia had been given to all patients.

GROUP A:
ILIZAROV EXTERNAL FIXATOR After draping, the preassembled then first transverse wire was passed most distal to the fracture site near the ankle joint and then ring was fastened after tensioning the wire either with wire tensioner or manually with spanners. Then another wire inserted transversely proximal to the fracture towards the knee joint. Then alignment of fracture site adjusted under image intensifier or x-ray control by passing other transverse wires near the fracture site. And other two wires were passed at least 45° to first wire. We had needed 1.8mm plain wires at diaphysis and Olive tip at metaphysis. Then getting reduction in all planes, rings proximal and distal to fracture site fastened with threaded rods. Some times, we used drops wires and attached them with the help of posts to rings. All the rings were larger of 2-finger breaths to diameter of leg over anterior aspect and 3-finger breaths to posterior aspect of leg. For each ring, minimum of 3 wires were used. While inserting the wires, they were first gently pushed up to the bone through skin and then drilled with pneumatic power drill. As soon as they come out
through other cortex, they were hammered gently to get out to other side. Muscles were at their maximum length while inserting the pins and all the wires were passed through safe zones. All the wires were tensionized before fasten to rings either with wire tensioner or manually with spanners at both ends simultaneously on plain wires and only opposite end on olive tip wires. The wire sites were dressed with hydrogen per oxide and pyodiene solution soaked gauzes. We also used two schanz screws in proximal and distal rings with one wire, schanz were held with AO clamps and Rancho cube system and tightened by nuts and bolts.

GROUP B:
NASEER AWAIS EXTERNAL FIXATOR WITH T-CLAMP

The first Naseer-Awais External Fixator (NAEF-1) was developed and used in the Department of Orthopaedic Surgery King Edward Medical College and Mayo Hospital Lahore Pakistan in early 1981. A mono-lateral Ex Fix was used for the various indications like management of open fractures where stabilization is needed., management of segmental fractures where three level fixation and some degree of compression is desired, where shortening of bone has occurred from loss of segment of bone, limb lengthening in polio and other disorders of the skeleton and to produce compression for arthodesis of knee and ankle joints. Since 1981 system has been successfully used for treatment of open and infected fractures, segmental fractures, leg lengthening and segmental bone defects. In February 1981 Fixator Tested on Bovine Bones and in April 1981 given the name “NASEER-AWAIS”, (NA Fix) & used in Patients. The first paper being presented during the 3rd National Orthopaedic Conference organized by Pakistan Orthopaedic Association at Peshawar in 1982. Until 1985 Multi-Axial Mono-Lateral NAFixator used for fractures and leg lengthening. In 1985 a more study Design of NAF-Fix conceived and “Mono-Axial & Mono-Lateral” was developed and in 1998 followed Ilizarov’s Method with NA. An addition were made in 2004, T- Pin Clamp was developed to allow Horizontal Shanz Screws for the small proximal & distal fracture fragment of various long bones. Components of NAEF are threaded rods (TR) and hollow pipes (HP). These rods and hollow pipes are made up of stainless steel, and are available in two lengths, 20 inches long TR and HP. (TR 20 AND HP 20) and 14 inches long TR and HP. (TR 14 AND HP 14). Another are simple threaded pin plate (S3PP), this is a big 50 x 50-mm square and 25 mm high plate for holding 3 Schanz Screws. This component moves on threaded rod and hollow pipe with the help of the nuts placed on each side of the component. Major part manufactured from Aluminum-Steel alloy to reduce the weight of the device. Simple 2 pin plate (S2PP), this small 50 x 32 mm rectangular pin plate, which is 25 mm high provides fixation with two Schanz screws, and is suitable for application of fixation system to small fragments of bone and in children. Rotating 2 pin plate (R2PP), this structure is similar to S2PP. The difference being built in ability of the plate to rotate through 360 degrees. Whole of the component is made up of stainless steel and therefore is heavy in weight than S2PP. The ability to rotate gives the opportunity to fix the bone fragments, which are not parallel to other fragments. After draping and wound debridement, predrilling done most proximally towards the knee joint for application of first shanz 90° to the axis of tibia. Then schanz screw inserted manually into the drilled hole by universal chuck or t-handle. Clamp with threaded and telescopic rods inserted into first shanz. Other three shanz were inserted parallel to first shanz according to predrilling method. Alignment of fracture achieved by manually under image intensifier or through already opened wound. T-clamp applied into distal ends of rods and put anterior to distal fragment. Predrill done through the clamp obliquely at 35° to 45° along the axis of tibia either medially or laterally and inserted schanz screw other schanz applied in opposite direction. Other two schanz applied by changing the position of clamps. At least minimum three schanz and maximum four in each T-clamp depends upon the size and strength of distal fragment. All clamps were tightened were proximally and distally by maintaining the alignment of fracture site in all directions.

POST OPERATIVE MANAGEMENT

On return from Operation Theater, patients were patients were mobilized in 06 hours after epidural anaesthesia either on bed or non or partial weight bearing with walking aids because Bupivocane and Lidocane drugs were used by anesthetist and the effect of these drugs are 90-120 minutes of Bupivocane and 60 -75 minutes of
Lidocaine\(^8\) and then epidural analgesia were given to relieve the pain and on 2\(^{nd}\) or 3\(^{rd}\) day according to the condition of wound or when the patient tolerated pain. In group B weight bearing was delayed up to visible callus on radiograph. Patients were allowed non weight bearing walking with crutches. Parenteral antibiotics were given up to eradication of infection or wound healing for open and infected fractures. Eradication of infection was decided on the local condition of wound and general condition of patient and average time for eradication of infection in GIII\(A\) was 02 to 03 and GIII\(B\) 03 – 05 weeks. Epidural analgesia was used for 2 – 3 days usually than shifted to either parental or oral analgesics. Weekly alternate compression / distraction at fracture site started usually after 10 days of application of Ilizarov external fixator or NAEF with T-clamp by proximal or distal clamps through threaded connecting rods. Check x-rays were done on next day and adjustments were done on 2\(^{nd}\) or 3\(^{rd}\) day if required. Patients were trained for daily wash of fixator, pins, pin care and mobility of joints and Quads exercises.

**RESULTS**

Thirty (n=30) open distal tibia fractures were managed and stabilized with external fixation systems. The range of age was 15 to 45 years, mean age in group A was 29.40 and standard deviation was 9.16 and in group B mean 28.93, standard deviation was 9.43 and also the average age was 29 years in each group (Graph 1).

There were twenty three (n=23) males and seven (n=07) females in both groups, twelve (n=12) male and three (n=03) females in group A and eleven (n=11) male and four (n=04) females in group B and male female ration was 3:2:1 in both groups.
Twenty (66%) patients road traffic accident victims, 05 (16%) fall from height, 04 (13%) fire arm injury and fallen a heavy object on leg in only 01 (3.33%) patients. Time between injury and admission was less then 12 hours in 17 (56.66%), between 12 and 24 hours 06 (20%) and more then 24 hours up to 72 hours were 7 (23.33%).

Fractures were classified according to Gustillo classification, five (n=05) 16% type I, six (n=06) 20% type II, twelve (n=12) 40% type IIIA and seven (n=07) 23% were type IIIB. Type of bony fracture was classified according to AO classification type A. there were 4 (13.33%) A1.1, 7 (23.33%) A1.2, 3 (10%) A1.3, 5 (16.66%) A2.2, 2 (6.66%) A2.3, 4 (13.33%) A3.1, 3 (10%) A3.2 and 2 (6.66%) A3.3.

Mean hospital stay in group A was 20.80 days, standard error of mean was 3.6 days, with range from 2 days to 41 days and in group B mean was 12.93 days, standard error of mean was 2.3 days with range from 1 to 32 days and also P-value of both groups was 0.080 (Graph 2).

Bone healing in group A fractures was mean 18.37, median 18.14, mode 18 and standard deviation was 3.82 weeks and mean 17.25, median 17, mode 17 and standard deviation was 3.03 weeks respectively and P-value of both groups was 0.000***. We also compared our results of Naseer Awaits external fixator with T – clamp with lizarov external fixation but for discussion purpose to introduce or to prove the validity of NAEF with T-clamp results also discussed with available hybrid ex fix literature of distal tibia fractures because unavailability of the literature of our local fixator. We inserted the shanz screws anteromedial and anterolateral directions and convergence angle was 35° – 45° degrees through the T-clamp as described by Oh Jk et al14, in hybrid external fixation and their mean convergence angle was 30 degrees. We analyzed the data through the statistical program of social sciences (SPSS) 10.0 software for comparison in distal tibia fractures i.e not available frequently in published literature of these types of fractures.

Generally following factors were considered to compare the results, like age, sex, mode of injury, fracture type according to Gustilo classification, hospital stay in days but our main objective was to assess the effect of partial and full weight bearing and union time in weeks. Demiralp B et al16, managed 27 patients with spiral and oblique fractures of distal 1/3 of tibia-fibula are relatively common fractures of long bones. Due to their types, aetiology, limited coverage and blood supply, these fractures often lead to union and soft tissue problems. Circular external fixator (CEF) might be a preferable alternative treatment for distal tibia-fibula fractures due to its easy application15.

The treatments of these fractures are rapid and ideal healing, minimisation of loss of function and prevention of any deformity11. Minor complications include pin tract irritation, pin tract infection, fractured trans-osseous wires or half pins, and pain secondary to positioning of the wires12. External fixation of open fracture with severe soft tissues injury has been standardized during the 1980s13. We compared our results of Naseer Awaits external fixator with T – clamp with lizarov external fixation but for discussion purpose to introduce or to prove the validity of NAEF with T-clamp results also discussed with available hybrid ex fix literature of distal tibia fractures because unavailability of the literature of our local fixator. We inserted the shanz screws anteromedial and anterolateral directions and convergence angle was 35° – 45° degrees through the T-clamp as described by Oh Jk et al14, in hybrid external fixation and their mean convergence angle was 30 degrees.

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Generally following factors were considered to compare the results, like age, sex, mode of injury, fracture type according to Gustilo classification, hospital stay in days but our main objective was to assess the effect of partial and full weight bearing and union time in weeks.

Demiralp B et al16, managed 27 patients with spiral and oblique fractures of distal 1/3 of tibia-fibula with circular external fixator. Ogugder DA et al15, treated 33 patients (26 males, 7 females; mean age 38 years; range 16 to 69 years) with open tibial fractures were included. Shtarker H et al16, stated the bone healing time was 21.9 weeks in the single injury and 25.7 weeks in the patients with multiple trauma. Ristinimi J et al17, described an average time to bone healing of 4.6 months. In our study bone healing in group A fractures was mean 8.27, median 6.71, mode 05 and standard deviation was 5.51 weeks. In group B mean full weight bearing was 16.67, median 17, mode 17 and standard deviation was 3.41 weeks in group B, respectively and P-value of both groups was 0.000***. We also encouraged the patients were in group A to bear the full weight but it was also observed that most of the patients were not bore full weight instead of stable fixation with lizarov due to pain in the ankle and foot. Behrens & Sears18, in their study of external fixation of the tibia showed 36 days average time to partial weight bearing walking and 65 days to full weight bearing walking. Full, unsupported weight-bearing was started after a median period of 65 days in 52 patients (71.2%).

Demiralp B et al16, described the mean framing time 14.1 +/- 1.8 weeks, and the mean treatment time 18.8 +/- 2.2 weeks.
(range, 15 to 24 weeks). We removed the Ilizarov after 22.33±1.3 and NAEF with T-clamp was removed 20.07±0.84 weeks and the P-value in both groups was 0.145. Oğüder DA15, stated the mean time to surgery was 5.7 days (range 3 to 12 days). Compression-distraction was applied in five patients to speed up union. In our study the time surgery was 06 to 12 hours in acute open fractures and within 24 hours after arrival and admission in the hospital. The duration of delayed arrival was not more then 72 hours. We also did the alternative compression and distraction at weekly interval in both groups to enhance osteoblastic activity to achieve early callus formation.

Shtraker H et al16 , stated that 11 patients had pin tract infection, and in 4 the pin had to be replaced. This treatment of open tibial fractures proved to be successful for anatomic restoration of the tibia and had a low complication rate19. Barbieri R et al18, described the complications occurred in 12 patients (35%) and included 1 skin slough, 5 pin tract infections, 3 deep infections, 3 nonunions, and 3 loss of reductions necessitating frame revision20. In our study the superficial pin tract infection developed in three cases, 08 pins were affected and resolved by aggressive pin care and short course of oral antibiotics.

CONCLUSION:

Although application of both External Fixators was in same age group (15-45 years) but union time did not differ significantly between group A & B. However, weight bearing was significantly earlier in Group A. Early weight bearing did not enhance union in the distal tibia fractures.

REFERENCES