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Original Research Article

Management of infected non-union of lower limb long bone fractures using ilizarov technique: a study of outcomes

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ABSTRACT

Background: Nonunion of long bone fractures is a common condition treated by an orthopaedic surgeon. Many nonunions can be treated effectively by internal fixation with or without bone grafting but, an infected nonunion can prove to be a tough challenge. The Ilizarov method is effective in managing infected nonunion of long bones. This study aims to assess the outcome of management of infected nonunions of long bones of lower limb with Ilizarov Ring fixator using bone and functional results as per Association for the Study and Application of Methods of Ilizarov (ASAMI) Scoring System.
Methods: We retrospectively analysed 18 patients (16 Male: 2 Female; Mean age 43.2 years) managed with Ilizarov technique for an infected tibial or femoral nonunion between 01 January 2013 and 31 December 2014. They were followed up for an average of 25.4 months after removal of fixator. They were assessed for functional and Bone (radiological) outcomes using the Association for the Study and Application of Methods of Ilizarov (ASAMI) criteria.
Results: 17 limbs were salvaged and union could be achieved. One limb required amputation due to severe persistent intractable infection. None required any additional skeletal stabilisation after removal of fixator frame except casting in a few patients for a period of 6 weeks. Mean time to union was 211.83 days (range 136 - 320days/median 184) or 7.01 months. As per the ASAMI score, Bone results were excellent in 10, good in 5, fair in 2 and poor in 1. Functionally 7 were graded as excellent, 6 as good, 3 as fair and 1 as poor and 1 patient underwent amputation.
Conclusions: The Ilizarov's method remains one of the most versatile and successful means of achieving bone healing in infected nonunions of long bones of lower limbs with additional benefits of correcting bone defects, deformities and limb length inequalities.

Keywords: Ilizarov, Infected nonunion, Tibia, Femur

INTRODUCTION

Nonunions of long bones are fairly common in everyday clinical orthopaedic practice of a developing country. Most long bone nonunions are treated effectively by internal fixation with or without bone grafting but an infected nonunion can be a difficult proposition. The Ilizarov technique is a well-known method of management of nonunion of long bones.[1-3] However infected nonunions still remain an important challenge due to presence of multiple systemic and regional considerations like prior deformity, bone loss or malfunction of previous internal fixation. The Ilizarov technique tackles all the regional problems concurrently and offers a sound remedy for infected nonunions.[1] This method involves thorough debridement of the infected area, removal of previous hardware followed by skeletal stabilisation using percutaneous thin wires which are

connected and tensioned to rings which are interconnected to give a sturdy construct.[4] Additionally, free or local soft tissue transfers are utilized to conceal any soft tissue defects. Because of surgical expertise, and labor intensive postoperative care, its use remains limited.[5]

The Ilizarov technique allows distraction, compression, lengthening and correction of deformity. The construct stability allows immediate weight bearing and mobilization of joints. Also, bone defects can be filled up by a corticotomy and bone transport. Infection control is attained by radically debriding the bone ends.[6] One of the major risks of infected nonunions is amputation of the limb, and the Ilizarov technique is capable of reducing this possible consequence.[4]

Aims and objectives

The aim of the present study was to assess the outcome of management of infected nonunions of long bones of the lower limbs using Ilizarov ring fixator.

The objectives of the study were to eradicate infection and achieve bony union while maintaining length and alignment of the limb with/without correction of old and prevention of appearance of new deformities along with early mobilisation and weight bearing in order to prevent disuse atrophy of the limb.

The results were analysed using the radiological skeletal results and functional results using association for the study and application of methods of Ilizarov (ASAMI) scoring system.[7]

METHODS

We retrospectively analysed 18 patients managed with Ilizarov technique for an infected tibial or femoral nonunion between 01 January 2013 and 31 December 2014, at our centre. Patient demographics are as given in Table 1. There were 16 men and 2 women with an average age of 43.22 years (27-59 years). 3 patients were primarily managed at our centre immediately after the injury, 15 were either referred from our dependent peripheral hospitals after the primary management or presented to our OPD with infected nonunion having been initially treated elsewhere. All the patients had nonunion of one of the long bones of lower limb with presence of active discharge from sinuses around the fracture site. Patients who had significant comorbidities included, 8 patients with diabetes mellitus with 3 of them being on insulin therapy, 1 had alcoholic liver disease and 1 had COPD. 7 were smokers/tobacco abusers, they were counselled about the negative effects of smoking on bone formation and asked to quit tobacco use.[8] As per Cierny and Mader host classification, 4 were classified as A, 12 were classified as B and 2 were classified as C.[9] As per Cierny and Mader anatomic location classification, 1 was stage 2, 7 were stage 3 and 10 were stage 4.[9] 15 patients had an infected nonunion of tibia and 3 had infected nonunion of femur. In 10 patients, the fracture was at the level of diaphysis in tibia and femur, 3 in the proximal 1/3rd tibia and 5 in the distal 1/3rd tibia. Previous procedures done on the patients included 7 intramedullary nailing, 08 AO tubular external fixator applications and 3 plating. 11 out of 18 patients underwent one or more debridement with change of fixation and 4 patients underwent antibiotic bead placement around the previously placed fixation implant. The average number of surgical interventions that each patient underwent prior to frame application were 2.38 (Range 1 to 4). Of the 18 nonunions, 14 were initially open injuries as per Gustilo and Anderson classification (Grade II – 1, Grade III A – 4 and Grade III B – 9).[10] The mean leg length discrepancy at presentation was 3.83 cm (02-07 cm). The Treatment details are given in Table 2. The average duration from injury to application of ilizarov fixator frame was 9.56 months (Range 7 to 18 months).

Table 1: Patient demographics.

Feature	Variable
Total (n)	18
Mean age (range), years	43.2/42.5 (27-59)
Gender (M: F)	16:02
Site of initial fracture (no's)	Femur : 3 , Tibia 15
Mean no of previous surgical procedures per patient	2.38/2 (1-4)
Initial injury	Closed 4, Open 14
Cierny & Mader physiological staging of host	A: 4; B: 12; C:02
Cierny & Mader anatomical staging of host	Stage II -01, Stage III-07, stage IV – 10
Gustillo Anderson classification for open fracture (at initial injury) (no's)	Grade II:1; Grade IIIA:4; Grade IIIB:9.
Previous procedures done (no's)	IM Nailing 7; Plating 3; Ext Fixation 8
Pre-intervention limb length discrepancy-mean, median (range) cm	3.83/45 (2 to 7)
Duration (injury to ilizarov frame application) in months. Mean, Median (Range)	9.56/8.5 (7 to 18)

Inclusion criteria

18 adult patients (>18 years of age) who reported/referred with an infected fracture nonunion of tibia or femur to our hospital between 01 January 2013 and 31 December 2014 were included in this study.

Table 2: Details of treatment.

Details of treatment	
Soft tissue coverage of exposed bone required during frame application (with local flaps done by plastic surgeon)	4 patients
Follow up time, Mean, Median (range) in Months	23.4/30 (19-40)
Time as in-patient Mean/Median (range) in days	23.11/19.5 (12-45)
Bone gap after radical debridement - Mean/Median (range) in cm	5.13/5 (3-8)
Ilizarov fixator time (application to removal or time to union) in days- Mean/Median (range)	211.83/210 (136 – 320)
Limb length discrepancy at completion of treatment, Mean/Median (range) in cm	0.52/0 (0-1.5)
Additional procedures after the frame application - Mean, Median (range)	0.83/0 (0-5)
Complications during treatment	
Minor pin site infections (35) (managed without changing the pin/wire)	5
Major pin site infections (35) (requiring change of wire/pins)	2
Wire breakage	1
Recurrence of infection at fracture site during treatment(requiring additional debridement)	3
Ankle stiffness	1
Knee stiffness	1
Nerve/ vascular injury	Nil
Systemic sepsis	1
Bone regeneration index	1.52
Follow up (Mean, median and range) in months	25.4/30.5 (18 to 42)

Initially there were twenty patients but only 18 could be followed up (1 died of unrelated cause while the fixator was still in place and another one was lost to follow-up after removal of fixator).

Exclusion criteria

Patients <18 years of age and those presenting with non-infected nonunions and following pathological fractures were excluded from the study.

Surgical technique and treatment progress and follow up

We performed one stage revision in all 18 cases. All hardware was removed and reaming was done in those patients who previously had an IM nail. The Surgical incisions for radical debridement of infected nonunion were determined by the previous scars/ presence of sinuses. The ends of the fractured bone were freshened & debrided till punctate bleeding points (Paprika sign) were noticed at both the ends of the bone.[11] The mean bone defect after radical debridement was 5.13 cm (range 3 to 8 cm). Tissue samples were taken during the surgery for culture and antibiotic sensitivity testing. The samples included any bone and soft tissue/ biofilm obtained from the nonunion site. The Ilizarov frame was applied with transosseous wires ± half pins to maintain the anatomical alignment and/or length of the limb. The frames were prolonged spanning either knee or ankle wherever adequate stability was not possible without crossing the joint or for correction of preexisting deformities.

For fracture gap less than 4 cm, acute docking at the fracture site was done intraoperatively and distraction of corticotomy done at the rate of 0.25 mm four times/day starting on the seventh to tenth post-operative day and the process was continued till the length of the limbs equalised. Further compression at fracture ends was given @ 0.25 mm/day for one week. For shortening of ≥ 4 cm, the ilizarov frame was applied keeping original length of the limb intact, compression at fracture site and distraction at opposite end was done simultaneously (Bone transport) @ 0.25 mm four times/day and the process was continued till there was docking and adequate compression at fracture site. Lengthening was then continued till the limb length was restored (as compared with opposite side).

Soft tissue coverage, if required, was done by the plastic & reconstructive surgeons (4 cases in the same sitting). All patients were ambulated and urged to bear weight immediately with the assistance of crutches from the first/second post op day. Immediately after taking the intraoperative samples, patients were started on broad spectrum antibiotics till results of antibiotic sensitivities were obtained. The postoperative antibiotic regime was altered thereafter based on microbial culture and antibiotic sensitivity in consultation with the hospital infection control committee. Injectable antibiotics were continued for two weeks. Sutures were removed at two weeks and patient discharged home after educating about distraction and care of pin tracts and fixator. Patients were reviewed weekly in outpatient department for

problems concerning pin tract infection and pin loosening till the distraction continued and monthly thereafter. X-rays were taken at two weekly intervals till distraction continued and at monthly intervals thereafter during maintenance phase. After radiological union of fracture and ossification of the regenerate, fixator frame was weakened by loosening the connecting threaded rods from the rings and patients were allowed full weight bearing on the limb for an additional 4 weeks for better consolidation. Fixator was subsequently removed in the OPD under sedation and analgesia.

A few patients required additional surgical procedures during the course of treatment (repeat debridement, change of wires for infection/breakage and bone grafting). All the complications were noted. Functional and radiological outcomes were assessed after removal of fixator using the association for the study and application of methods of Ilizarov (ASAMI) criteria 6 monthly after removal of fixator. Union was defined as the existence of bridging trabeculae on at least three cortices, no pain on dynamisation, no abnormal movement at the site of union clinically and ability of the patient to ambulate independently without support (Figure 1: Representative X-ray photographs of the patient with bone defect of 08 cm after debridement).

Statistical analysis

This study is an observational study and data analysis for demographic characteristics and follow up functional and radiological parameters was performed by using SPSS (statistical package for social sciences) software version 20.0.

RESULTS

Nonunions healed in 17 out of 18 patients (94.4%). Mean number of days in hospital for each patient was 23.11days (12 to 45). The average bone gap before debridement was 3.83 cm (range 2 to 7 cm) and after thorough debridement was 5.13 cm (range 3 to 8 cm). The time to union defined as the time from application to removal of Ilizarov frame was 211.83 days (range 136 to 320 days) or 7.01 months. The average residual limb shortening after removal of fixator was noted as 0.52 cm (Range 0 to 1.5 cm). Average bone regenerated (total bone gap after debridement minus the residual shortening) was 4.61 cm. The mean Bone regeneration index (number of months in fixator frame divided by length of bone regenerated in cm) was 1.52. The mean follow up period was 25.4 months (range 18 to 42). 7 patients acquired pin site infections (All three patients with fixator in femur and four with fixator in tibia), 5 of them were successfully treated with pin tract care & oral antibiotics, 1 patient required removal and reinsertion of half pins and Ilizarov wires with frame readjustment and 1 patient with severe intractable infection, pin loosening, breakdown of soft tissue, exposure of nonunion site with systemic sepsis, underwent transtibial amputation. 3 patients required bone grafting at the docking site due to unsatisfactory radiological evidence of healing. We encountered 1 wire breakage (when 1.5 mm diameter wire was used), which was successfully managed by reinsertion of 1.8 mm diameter wires. 3 patients required repeat debridement at the infected nonunion site due to recurrence of infection.

Table 3: Bone results (ASAMI scoring system).

Bone Results	Description	Score
Excellent	Union, no infection, deformity < 7^o, limb length discrepancy < 2.5 cm	10
Good	Union + any two of the following: absence of infection, < 7^o deformity and limb length inequality of < 2.5 cm	5
Fair	Union + only one of the following: absence of infection, deformity < 7^o and limb length inequality < 2.5 cm	2
Poor	Non-union/ Refracture / union + infection + deformity > 7^o + limb length inequality > 2.5 cm	1

Table 4: Functional results (ASAMI scoring system).

Functional	Description	Score
Excellent	Active, no limp, minimum stiffness (loss of < 15^o knee extension/ < 15^o dorsiflexion of ankle), no reflex sympathetic dystrophy (RSD), insignificant pain	7
Good	Active, with one or two of the following: limp, stiffness, RSD, significant pain	6
Fair	Active, with three or all of the following: limp, stiffness, RSD, significant pain	3
Poor	Inactive (unemployment or inability to perform daily activities because of injury)	1
Failures	Amputation	1

Overall 7 out of 18 (38.89%) patients required a total of 15 additional interventions under anaesthesia in the operation theatre with a mean of 2.14 (range 1 to 5) additional procedures per patient for those 7 patients and

an average of 0.83 (range 0 to 5) additional interventions for the entire series of 18 patients.

ASAMI scoring (Table 3 and 4)

As per the ASAMI score, bone/ radiologically 10 were categorized as excellent, 5 were good, 2 were fair and 1 was poor. As per the ASAMI score, functionally 7 were assessed as excellent, 6 as good, 3 as fair, 1 as poor and 1 had failure of the procedure (amputation). 5 had an evident limp. 1 had a noticeable 10^0 equinus deformity at the ankle, 1 had 5^0 FFD at knee which persisted even 18 months after the completion of the procedure but the patients had adjusted to these and refused any further intervention. 5 had dystrophic changes of the soft tissues, 4 had persistent limb oedema for up to 12 months after removal of frame. 9 out of 18 (50%) patients went back to their original jobs which required moderate to heavy exertion. 5 patients (including the one who underwent amputation) had to change to a more sedentary job. Two female patients who were house wives could do their daily chores with minimal restriction.

DISCUSSION

Infected nonunions of fractures are a difficult challenge which most often than not require meticulous planning and execution of complex, time consuming surgeries. The options for treatment in an established infected bony nonunion are thorough debridement along with skeletal stabilization, using of antibiotic coated nail, use of antibiotic beads along with nail/plate, use of vascularised grafts, open cancellous bone grafting, use of an antibiotic impregnated, osteoconductive, bioabsorbable bone substitute, use of ring/rail fixator etc.[12-23] Ilizarov technique has been employed as a successful and dependable modality of treatment for infected nonunions of long bones.[2,3] Jain et al, in their study of infected nonunions, suggested that distraction histiogenesis is the preferred procedure in nonunions with active or quiescent infection and a bone gap of 4 cm or more.[24]

Table 5. A comparison of the results using association for the Study and application of the methods of Ilizarov (ASAMI) criteria.

Author	Total limbs treated in the study	Mean Bone gap	Mean Bone regeneration index	Bone results (%Excellent, good, fair, Poor)	functional results (%Excellent, good, fair, poor)
Sala (29)	12	8 cm	2.0	83.3/16.7/0/0	50/41.7/8.3/0
Patil (5)	32	-	-	42/34/10/14	44/44/6/6
Dendrinos (27)	28	6 cm	1.67	50/28.5/3.6/17.9	25/39.3/14.2/17.9/3.6 (amputation)
Madhusudhan (6)	22	4.7 cm	1.95	18.2/27.3/36.3/18.2	4.6/18.2/40/18.2
Emara (30)	33	6 cm	1.03	97/3/0/0	75.7/9.1/15.2/0
Magadum (32)	27	10 cm	1.02	70.4/18.5/0/3.7	55.6/29.6/3.7/3.7
Krishnan(31)	20	6 cm	1.28	65/20/5/10	15/45/15/20/5 (amputation)
Yin (36)	120	6.15	1.49	68/28/12/2	37/42/21/0
Present Study	18	5.13 cm	1.52	55.6/27.8/11/5.6	38.89/33.3/16.7/5.6/5.6 (amputation)

7 out of 18 (38.89%) patients in our study had pin tract infections which included all 3 (100%) patients with fixator applied for femoral nonunion and 4 out of 15 (22.22%) patients with fixator in tibia. This is consistent with findings of Checkets et al who in their study brought out that pin tract infection are more likely when there is excessive movement of soft tissue at the pin/wire-soft tissue interface like in femur.[25]

In their study of single vs. two stage strategy in management of infected nonunions, Struijs et al noted that one stage debridement and bone transport using Ilizarov frame resulted in union in 70% to 100% of cases across various studies with the rate of persistent infections being 0% to 55% with no fresh evidence of progress of healing.[26] In the present study we achieved union in 94.4% cases and the rate of persistent infection was 5.6% (1 patient out of 18; the patient who required eventual amputation). All the patients who successfully completed the treatment were cured of infection and at the last review; none of the patients had a flare up of infection. In the present series, our bone and radiological results were better than the functional outcomes as per the ASAMI scoring system. This fact indicates that an excellent bone result does not guarantee a good function as shown by many previous studies because the functional result is influenced not just by bony union but also by the state of the soft tissues viz. condition of the skin, muscles, tendons, ligaments, vessels and lymphatics.[6,27-32]

The treatment of infected nonunion in elderly is even more challenging in view of reduced physiological reserve, presence of osteopenia/osteoporosis, reduced

healing capabilities. 6 out of 18 patients (33.33%) in our study were aged between 50 to 60 years. Older patients struggle to get satisfactory purchase with conventional fixators, however we found no major problems with use of tensioned ilizarov wires for fixation in them.[33] All these patients tolerated the frame well and we did not notice any increased incidence of pin/wire loosening in this subset of patients. The capability to bear weight is an enormous benefit to the older population, where recumbency has a negative impact on the overall physiology and can escalate the risk of thromboembolic disease & infections.

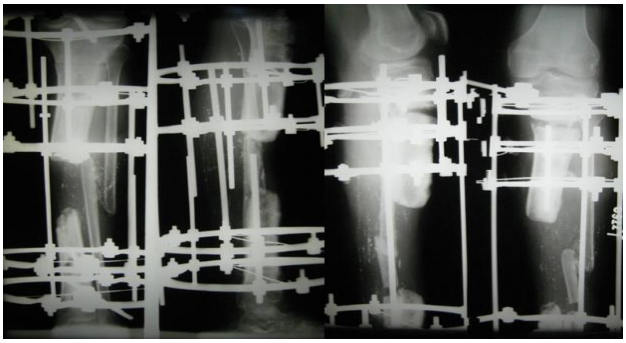

Figure 1: Immediate postoperative X-ray showing Ilizarov fixator application in a case of infected gap non-union of Tibia with proximal metaphyseal corticotomy.

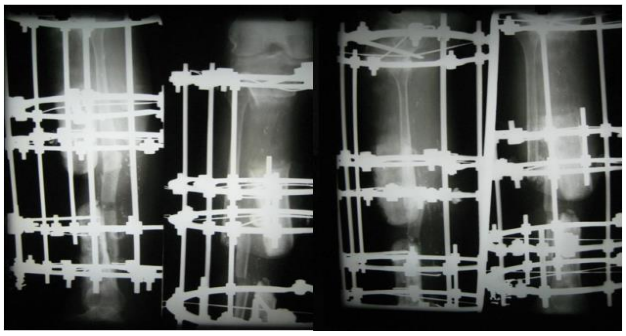

Figure 2: X-ray following bone transport with gradual distraction at the proximal corticotomy site.

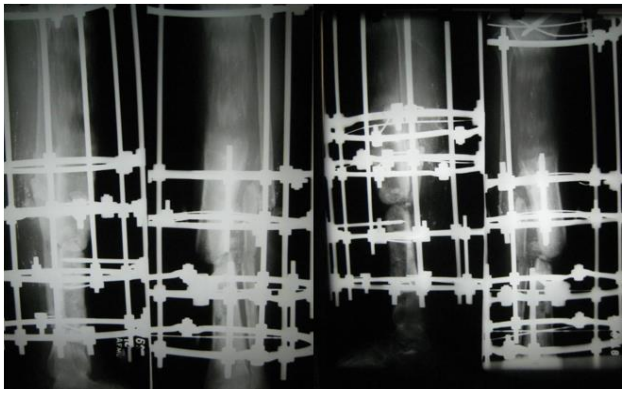

Figure 3: X-ray showing ossification of regenerate in progress following bone transport.

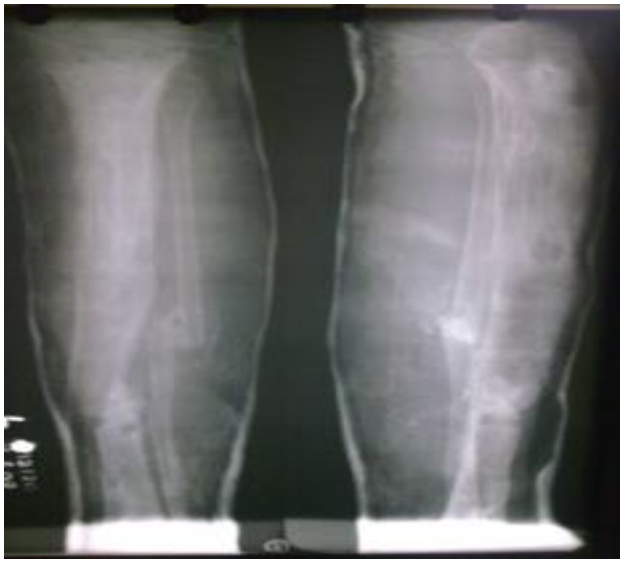

Figure 4: X-ray after removal of fixator.

Comparing our results with the Ilizarov method using the ASAMI criteria of evaluation with a few previous studies (Table 5), our bone and functional results are not drastically different from the ones obtained in those studies. The percentage of patients requiring amputation in various previous studies ranges from 0 to 5% and in present study the percentage was 5.6% (1 patient).

9 out of 18 (50%) patients could go back to their original jobs requiring moderate exertion, 2 female patients could carry out their household chores, 5 patients (including the one who underwent amputation) had to change to a more sedentary job. This shows that 16 out of 18 were able to be gainfully employed. Only 2 patients (both farmers) were unable to go back to active farming. Our figures show 88% returned to work. Outcomes for return to work reported from previous studies ranges from 22 to 87%.[5,27,34,35]

Limitations of the study

The main limitation of the study was our small sample size and lack of comparative arm.

CONCLUSION

Infected nonunions pose a daunting challenge to both patient and surgeon and the Ilizarov technique has been successful in their management. A favourable functional and radiological outcome is of paramount importance in order to restore the patient to some useful function. Our results are comparable to most previous studies done in various parts of the world. However further randomised, multicentre studies with a comparative arm using newer modalities of treatment such as unilateral rail fixator/ Ortho SUV frame etc. with larger cohort and longer follow up are needed to establish the superiority of one modality over the other for definitive management of infected nonunions.

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