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Management of infected non-union of tibia treated with the circular ring fixator: A prospective study

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Abstract
Introduction: Infected non-unions of the tibia pose significant challenges due to problems like osteomyelitis, draining sinuses, soft tissue distortion, demineralization of bone, joint stiffness, and multidrug-resistant polybacterial infection.
Material and Methods: We report the outcome of 18 patients (15 males and 3 females) with infected non-union tibia treated with a Circular ring fixator (Ilizarov). The causes were open fracture in 15 cases and infection following internal fixation in 3 cases. We assessed Ilizarov's method in the management of infected non-union of the tibia in terms of, union rate, control of infection, and associated complications. The assessment parameters were based on the Association for the Study and Application of Methods of Ilizarov (ASAMI) criteria.
Result: 83.3% were male and 16.7% were female, the mean age was 32 ±9. The mean bone gap was 3.2±1.0. Draining sinus was present in 10 (55.6%) of the patients. Corticotomy and fibula osteotomy was performed in 14 (77.8%) of the patients. Bony union was seen in 17 (94.4%) of the patients. The mean time of union was found to be 9.7±1.7 months. The mean limb length discrepancy was 1.1±0.6 cm. A deformity angle of less than 7 degrees was present in 16 (88.9%). 15 (83.3%) patients had excellent ASAMI bone scores and the remaining 02 (11.1%) had a good score. One patient in which the union was not observed had a poor score. For the functional component, 12 (66.7%) had an excellent score, 05 (27.8%) had a good score and 01 (5.6%) with non-union of the tibia bone was found to have a poor score.
Conclusion: The Ilizarov method is a time-tested and very famous technique of control of non-union of a long bone. It lets in distraction, compression, lengthening, and correction of deformity and also allows weight-bearing and mobilization of joints. Ilizarov method is a minimally invasive, cheaper, versatile, cosmetic and 360-degree stable method. Early weight-bearing is the key factor that distinguishes it from other conventional methods of fixation infected non-union Tibia.

Keywords: Infected non-union tibia, circular ring fixator, ASAMI criteria

Introduction
Infected non-unions of the tibia pose significant challenges for complete resolution and functional restoration [1]. Bone healing is a unique but a complex biologic phenomenon. Most other tissues in the human body can only manage to heal with a scar, but bone heals by forming new bone [2].
With the increase in open long bone fractures due to road traffic accidents, the incidence of complex non-unions is on the rise [3]. Among non-union treatment of infected non-union of the tibia is one of the perplexing dilemmas in orthopedic surgery because of its delayed management after a high energy trauma, as it has insufficient soft tissue coverage with poor vascular supply and complex fracture patterns that result usually in an unfavorable outcome.
As per the American Food and Drug Administration definition of Non-union is "established when a minimum of 9 months has elapsed since the injury and there is no visible progress of healing seen at the fracture site for 3 months [3]. Non-union is a debilitating chronic medical condition with a negative substantial effect on health [4]. In order to deal with these cases, the operating surgeon faces a challenge in the planning of treatment, deal with functional disability, psychosocial impairment, non-compliance of patients, and stressful impact on the health care system [5].

Bone healing is a complex biologic phenomenon where healing occurs by formation of new bone unlike other tissues in the human body which manage to heal with scar formation. The treatment is usually very prolonged and involves multiple surgeries, risk of long-term disability, and social stigma [6]. Treatment options for tibia fractures vary according to the fracture type, age, bone density, status of soft tissues, and associated complications [7]. Operative techniques used are fixation with plates and screws, intramedullary nailing, and external fixation. The main issues which complicate the undergoing treatment are devitalization of bone, soft tissue atrophy and scarring, complex deformity, joint stiffness, limb length discrepancy, and secondary osteoporosis [4].

Infected non-union is associated with problems like osteomyelitis, soft tissue distortion, draining sinuses, demineralization of bone, joint stiffness, and multidrug-resistant polybacterial infection [7]. Various treatment modalities for infected nonunion of long bones described in literature are extensive debridement with robust fixation, microvascular soft tissue flaps, bone grafting and fixaiton, Ilizarov ring fixator, bone transport through external fixator over the nail, and unilateral limb reconstruction system (LRS)[8]. Antibiotic-impregnated cement for control of infection is a common technique before union at the fracture site is achieved [7].

Among the various modalities, Circular ring fixator and Limb reconstruction system are popular single staged procedures. They correct the deformity and limb length along with excellent infection control and facilitate bone union. During treatment, weight-bearing can also be initiated simultaneously. There is an increased burden of infected non-united tibia fractures culminating in multiple surgeries and persistence of infection, a study was conducted to assess the limb reconstruction system in the management and stabilization of infected non-union of the tibia [5]. A well-aligned, painless, healed and functional limb is the goal of treatment which is achieved by adequate and complete debridement, stable fracture stabilization, good soft tissue coverage, and reconstruction of the bony defect [6].

In this study, we assessed the ring fixator system in management in terms of union rate, control of infection, and associated complications.

Material and Methods

A prospective clinical intervention study of a Circular ring fixator in infected tibia non-union was conducted at a tertiary care hospital. All patients with infected nonunion of the tibia admitted to the study setting during the study period (Jan 2018 to Jan 2020) were included in the study. A total of 18 patients with infected non-union tibia fractures were included of which 15 were males and 3 were females. The causes of the infected non-union tibia were open fracture in 15 cases and infection following internal fixation in 3 cases. All the cases had an established non-union for at least 6 months or more with evidence of infection. 10 patients had active draining sinuses were and 8 were non-draining. All patients in the study had a prior history of surgeries either in the form of multiple debridement's, application of external fixator, soft tissue coverage either in the form of skin grafting or flap surgery. Standard anteroposterior and lateral skiagrams were taken of all patients. Pre-operative workup was done and pre-anesthetic fitness was obtained. Patients with active infection underwent debridement and were stabilized with the simple external fixator in cases that were presented acutely under spinal anesthesia. Any previous implant and fixators in cases of established non-union was removed during the debridement. All non-viable bone was radically excised from the fracture site until punctate fresh bleeding spots from the cortex were seen. Also, during debridement pus from the sinus or wound was sent for extended antibiotic culture and sensitivity. The tibia defect was measured and noted after radical excision and gap non-union was later subjected to ring fixation. Patients received antibiotics according to culture and sensitivity from deep bone tissue and were subjected to daily dressing. In some patients, soft tissue coverage was extensive and plastic surgery intervention was called for either pedicled myocutaneous gastrocnemius flap or other local flaps. After the restoration of soft tissue cover and subsidence of infection, patients were subjected to ring fixation (Figure 1) with pertinent pre-operative planning, taking into consideration the fracture or non-union configuration. A day before surgery appropriate size rings were chosen and the apparatus was pre-constructed to reduce the intra-operative time. It was kept in mind while making the ring construct that the internal diameter of the rings was at least 4 cm larger than the maximum diameter of the limb segment being treated to allow space for any post-operative swelling and avoid any impingement of soft tissue structure with the rings. All the rings were of the same size. After the construct, the frame was sterilized for use during the surgical procedure. All patients were counselled regarding the long duration of treatment and possible complications associated with it.

Surgical procedure

At surgery under appropriate anaesthesia usually either spinal or spinal with epidural anaesthesia, the non-union was exposed and radically debrided inclusive of skin, fascia, and muscles. Sequestrae and implants were removed and granulation curetted out. The ends of the bone were excised till fresh bleeding bone was visible all around. Acute docking was done as per pre-operative planning and during this the angulation if present was corrected. 3 to 4 rings and 4 connecting rods were applied along with 10-12 wires and a Schanz pin. Usually, one ring was applied to the advanced or docked segment and 2 rings on either side. If one of the segments at the extreme was short enough, then only one ring was applied. The optimum diameter of the wire is 1.8mm for adults and large bones. The frame was fixed to the bone with at least 2 wires for each ring and the first wire was inserted from lateral to medial just anterior to the head of the fibula and parallel to the tibial joint line (Figure 2). Once the wire was inserted through the second cortex, it was not drilled but was gently tapped through the soft tissue to avoid wrapping the neurovascular structures. The second wire was placed parallel to the first, 2 cm proximal to the ankle joint. These wires are then fixed to the ring frame. All K-wires were tensioned using a dynamometer before fixing to the ring. First, the proximal block of rings was centered on the leg. The distal block was positioned such that the anterior distance from the leg to the rings was the same as that of the proximal blocks, i.e., at least 2 cm on either side. Additional Schanz pins were used to improve the stability whenever necessary. Drop wires were introduced to minimize the unsupported length if the length between the two rings of the component was more.

Through separate incisions, corticotomy and fibular osteotomy were performed in required selected cases as per preoperative planning. Closure of the wound was done in layers. Knee, ankle range, and distal pulse of motion were checked. The post-operative latency period was 7 days and

later, distraction was taught and started at the rate of 1mm/day divided into 4 intervals done every 6 hours. Subsequent follow-up was done at monthly intervals till bone union was achieved.

Ethical approval was obtained from the Institutional Review Board before commencing the study. Written informed consent was obtained from each patient.

Data Collection

Socio-demographic data like age and gender, site of non-union, co-morbidities, history, and the number of previous surgeries and presentation of infection including presence or absence of draining sinus, erythrocyte sedimentation rate (ESR), C- reactive protein levels, and antibiotic culture and sensitivity were recorded at baseline. Corticotomy and fibular osteotomy was performed based on the requirement. Adjunctive treatment was provided to the patients like acute docking, bone grafting, and antibiotic depot. The postoperative assessment included parameters based on the Association for the Study and Application of Methods of Ilizarov (ASAMI) criteria (Table 1) and patients were followed up until the union of tibia fracture fragments was achieved. Data were collected at baseline using a semi-structured questionnaire and clinical examination during serial follow-up sessions in outpatient clinics. (Figure 3)

Statistical Analysis

Data collected were tabulated using Microsoft excel. Data were analyzed by the SPSSv25 statistical package software for the Social Sciences (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) Descriptive statistics of the outcome variables were calculated by the mean, standard deviation for quantitative variables, frequency and proportion were calculated for qualitative variables.

Results

The patients were in the age group of 19-55 years with the majority 15 (83.3%) in the age range of 20-40 years. The mean age of study participants was found to be 32.3±9.9. The majority 15(83.3%) were males and 03 (16.7%) were females.

Baseline Characteristics

Tibia Shaft was found to be the most prevalent site of non-union; 11 (61.1), followed by Distal found in 05(27.8%) of the patients, followed by Proximal seen in 02 (11.1%).

Prevalence was co-morbidity was found in only 03 (22.2%) of the patients with 02 (11.1%) patients having hypertension and only 02 (11.1%) patients having diabetes mellitus. External fixation was found in only 15 (83.3%) of the patients. Nail/plate was found in 03 (16.7%) of the patients. The mean bone gap was found to be 3.2±1.0. The mean values of infection markers ESR and C-reactive proteins were found to be 1.3±0.6 respectively. Culture and staining found methicillin resistance staphylococcus aureus (MRSA) to be the most prevalent pathogen in the infected site found in 08 (44.4%) of the patients, followed by methicillin-sensitive Staphylococcus aureus MSSA in 04 (22.2%), pseudomonas in 02 (11.1%), acinetobacter in 01 (5.6%) of the patients. No bacterial growth was seen in only one patient. Draining sinus was observed in 10 (55.6%) of the patients. (Table 01)

Corticotomy and fibular osteotomy was performed in 14 (77.8%) of the patients. Adjunctive Treatment was given to half of the patients (Table 02).

Final Follow-up Characteristics

The bony union occurred in 17 (94.4%) of the patients. The mean time for the bony union was found to be 9.7±1.7 months with a monthly range of 9 months to 13 months.

None of the sites of fracture was found to be infected at the final follow-up assessment. The mean LLD was found to be 1.1±0.6 cm. The deformity angle of less than 7 degrees was found to be 16 (88.9%). Active functional patients were found to be 17 (94.4%). Limping was not found in the majority of 15 (83.3%) and two patients had a short limb gait which was corrected by shoe raise. Maximum 16 (88.9%) had no stiffness in the ankle and two had stiffness of which one patient developed severe equnius deformity at the ankle joint. Only 01 (5.6%) patient-reported stiffness in the knee. The study also reported superficial pin tract infection in 6 patients and was managed by pin tract dressings and oral antibiotics. In the study, two patients had deep pin tract infection which was treated by revision of pins and administration of parenteral antibiotics. Persistent infection was reported in one patient (5.6%) and none had refracture.

ASAMI Bone and Functional Score

Of the 18 patients, 15 (83.3%) had excellent ASAMI bone scores and the remaining 02 (11.1%) had a good score. One patient in which bony union was not observed had a poor score. For the functional component, 12 (66.7%) had an excellent score, 05 (27.8%) had a good score and 01 (5.6%) with non-union of the tibia bone was found to have a poor score.

Discussion

Infected non-union is still an extremely difficult clinical problem despite major advances in the fixation technique, soft tissue management, and antibiotic therapy. The infection at the fracture site not only prevents stable internal fixation but also delays fracture healing. The combination of mechanical instability and infection of a fractured bone provides an unfavourable condition for fracture healing.

The circular ring fixator system is based on the principle of distraction osteogenesis where the mechanical induction of new bone occurs between bony surfaces that are gradually pulled apart [11]. The ring fixator is preferred in all cases and additionally was preferred when there was deformity or severe angulation present. Also, when the proximal or distal fragments were short, ring fixators were preferred.

The presented study demonstrated excellent bone and functional scores based on ASAMI criteria in the majority of 83.3% and 66.7% of the patients respectively. The findings are similar to the study conducted by Maini L *et al*. [13] who treated 30 patients with a compound fracture of the tibia using the ring fixator. In the study by Maini L *et al*. [13], 66.7% of the patients had an excellent score and 13% had a good score, and in the functional component assessment, nearly 66.7% had excellent and good scores based on ASAMI criteria. The most common complication encountered in the study by Maini *et al*. [13] was pin tract infection, and eventually was treated with suitable antibiotics. A study by Singh AK *et al*. [14]. achieved an ASAMI Bone healing score of Excellent (67%) to Good (19%) in 86% of cases. The functional score excellent group (63%) and good group (26%) together achieved 89% of the score. The study by Singh AK *et al*. [14] also reported Pin tract infection as the most common complication. Also, in a study by Paley D *et al*. [12] excellent bony scores were reported in 72% and good in 20% of the patients, the excellent functional score was seen in 64% of

patients and 28% of the patients had a good score. The mean time for the bony union was found to be 9.7±1.7 months which is similar to the findings of the study by Maini L *et al*. [13]. Where the average time for the union was found to be 7-8 months. Range of motion especially at the knee and ankle joint were restored in the majority of cases with passive and assisted physiotherapy. Limb length discrepancy was nearly normal in the majority of cases and the rest were treated with shoe raise. Pin tract infections and pin loosening problems were addressed in every follow-up and pin tract dressing was taught and re-adjusting the frame was done in cases of pin loosening. Bari MM *et al*. [16] treated 51 patients with non-union using a ring fixator, the union was seen in 49 (95.1), 2 patients had a failure. ASAMI bone results were excellent in 22(43.1), good in 19 (37.2%), fair in 7(13.7%), poor in 2 (5.9%), Functional were excellent in 24 (47.1%), good in 21(41.2%), fair in 4 (7.8%) and failure in 2 (3.9%) [16]. The ring fixators are quite a versatile tool in the armamentarium of orthopedic surgeons and can treat not only fractures but also bone gap/loss, limb length discrepancy, and deformity simultaneously. The most important advantage of ring fixators is the ability of the patient to be ambulatory and bear weight from the start allowing functional loading of the extremity and treating disuse osteoporosis and soft tissue dystrophy that many of these neglected patients have because of prolonged periods of no weight-bearing. Ring fixators are still suited overall and additionally when mechanical correction of more complex deformities with angulations or rotations and more than two sites of involvement are present. 15 (83.3%) had excellent ASAMI bone scores and the remaining 02 (11.1%) had a good score. One patient in which bony union was not observed had a poor score. For the functional component, 12 (66.7%) had an excellent score, 05 (27.8%) had a good score and 01 (5.6%) with non-union of the tibia bone was found to have a poor score.

The current limitations of the present study are the small sample size. The follow-up period is short.

Fig 1: Instrument set for Circular ring fixator

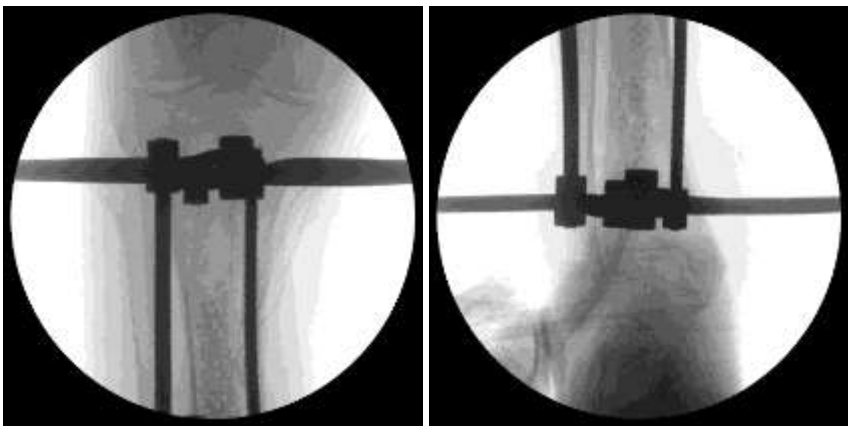


Fig 2a and 2b: C–arm image showing proximal ring parallel to knee joint at the level of the fibular head; Second ring at 1cm above and parallel to ankle joint

Fig 3a: Clinical image of the right-sided infected non-union tibia with discharging sinus

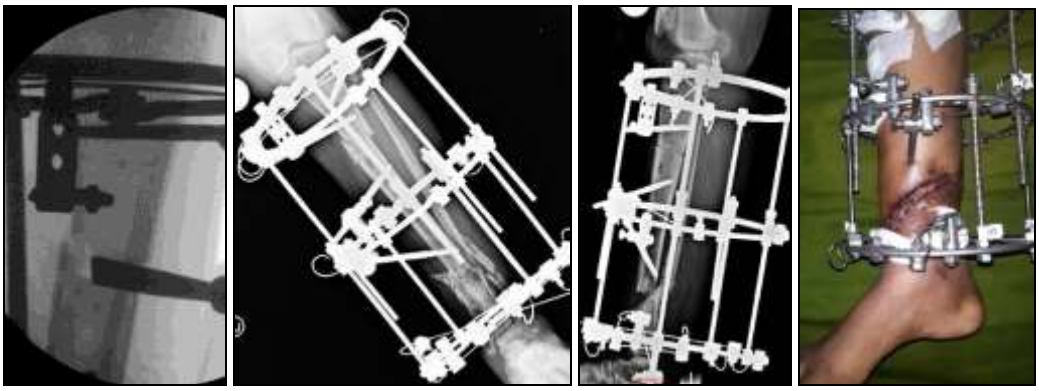
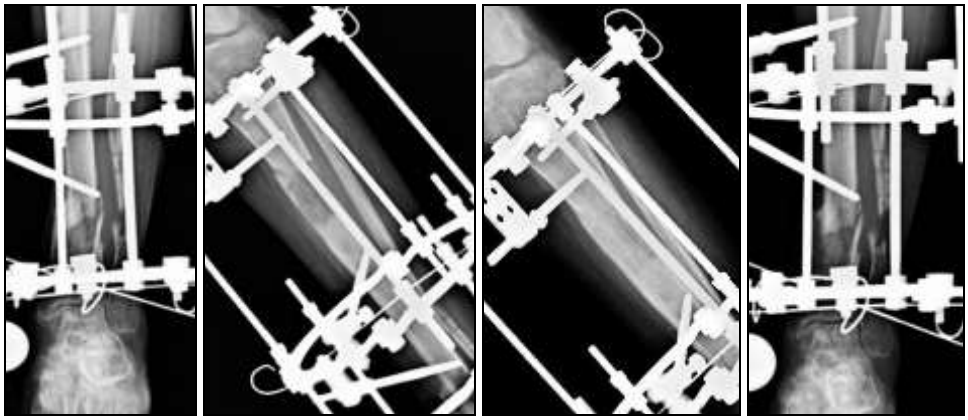


Fig 3b: Intra-operative and Postoperative x-ray with ring fixation and corticotomy performed at proximal 1/3rd tibia



3 months 5 months 3 months 5 months

Fig 3c: Progression of healing of non-union site and consolidation of regenerate over 5-6 months

Fig 3d: Fixator removal done and goof bony alignment achieved at 28 weeks

Fig 3e: Clinical images showing the excellent functional outcome

Table 1: Association for the Study and Application of Methods of Ilizarov (ASAMI) scoring system [12]

	Bone results	Functional results	Number of patients (Bone/Functional results)
Excellent	Union, no infection, deformity<7°, limb length discrepancy<2.5cm	Active, no limp, minimum stiffness (loss of $<15^0$ knee extension/$<15^0$ Dorsiflexion of the ankle), no reflex sympathetic dystrophy, insignificant pain.	15/12
Good	Union + any two of the following. Absence of infection, deformity<7°, limb length discrepancy<2.5cm	Active, with one or two of the following: Limp, stiffness, RSD, significant pain	2/5
Fair	Union + any one of the following. Absence of infection, deformity<7°, limb length discrepancy<2.5cm	Union + any one of the following. Absence of infection, deformity<7°, limb length discrepancy<2.5cm	
Poor	Non-union/ re-fracture/union + infection +deformity>7°+ limb length inequality>2.5cm	Inactive (unemployment or inability to return to daily activities because of injury), Amputation	1/1

Table 2: Distribution of study subjects based on

Variable		Number	Percentage
Site of Non-unio	Shaft	11	61.1
	Distal	05	27.8
	Proximal	02	11.1
Co-morbidities	Absent	14	77.8
	Hypertension	02	11.1
	Diabetes	02	11.1
External fixation	Present	15	83.3
	Absent	03	16.7
Bone gap	2 cm	05	27.8
	3 cm	05	27.8
	4 cm	05	27.8
	5 cm	03	16.6
Erythrocyte sedimentation rate	30-40	08	44.3
	41-50	07	38.9
	51-60	03	16.6
Bacterial Culture and Staining	MRSA	08	44.3
	MSSA	04	22.3
	Acinobacter	01	5.6
	Klebsiella	02	11.1
	Pseudomonas	02	11.1
	ABSENT	01	5.6

Table 3: Distribution of study subjects based on adjunctive treatment and final follow-up characteristics

Variable		Number	Percentage
Acute Docking	Yes	08	44.4
	No	10	55.6
Bone Grafting	Yes	04	22.2
	No	14	77.8
Antibiotic Depot	Yes	07	38.9
	No	11	61.1
Infection	Present	01	5.6
	Absent	17	94.4
Deformity	< 7 degree	16	88.9
	>7 degree	02	11.1
Active	Yes	16	88.9

	No	02	11.1
Limping	Yes	03	16.6
	No	15	83.3
Stiffness in Ankle	Yes	02	11.1
	No	16	88.9
Stiffness in Knee	Yes	01	5.6
	No	17	94.4

Conclusion

Bone healing occurs by the formation of new bone and the method adopted in treating infected non-union tibia with the help of an Ilizarov ring fixator is dynamic and provides corticotomy, bone transport, the fusion of bone ends with consolidation. Also, it facilitates dealing with limb length discrepancy, infection control, simultaneous correction of deformity, and early mobilization. Ring fixator application has a slight learning curve has predictable healing for infected non-union, ensures compliance with inpatients, and provides reliable results with fewer complications. Careful pre-operative planning, proper surgical techniques, and systematic routine follow-up will establish a ring fixator as one of the definitive treatment modalities in the treatment of infected non-union of the tibia.

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