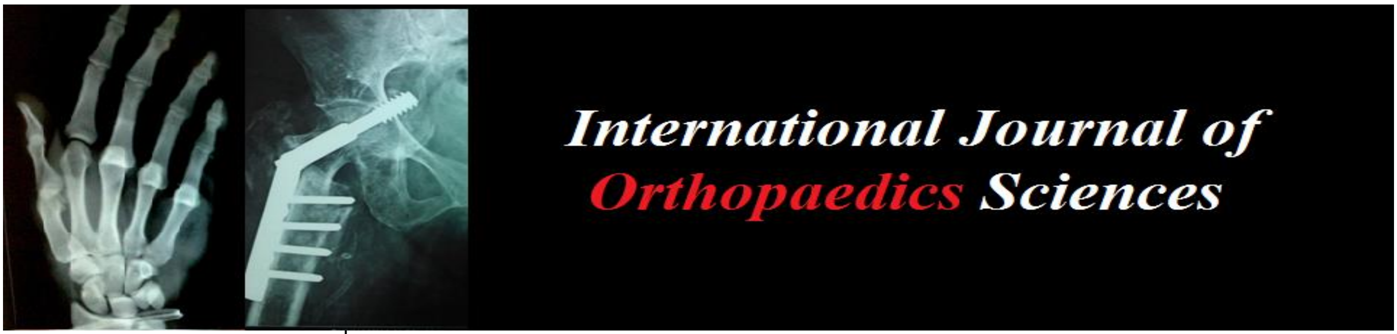

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Infected non-union of tibia treated with limb reconstruction system (LRS): A prospective study

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Abstract
Introduction: Infected non-union of the tibia is difficult to manage due to problems like osteomyelitis, soft tissue distortion, draining sinuses, demineralization of bone, joint stiffness, and multidrug-resistant polybacterial infection.
Material and Methods: We report the outcome of 18 patients (16 males and 2 females) of infected non-union tibia treated with the Limb reconstruction system. The causes were open fracture in 15 cases and infection following internal fixation in 3 cases. We assessed the limb reconstruction system 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: 88% were male and 11% were female, mean age was 32 ±9. The mean bone gap was 3.1±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. 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: Limb reconstruction system is easy to perform, has predictable healing for infected non-union, has a short learning curve, ensures compliance in patients, and provides reliable results with lesser complications.

Keywords: infected non-union tibia, LRS, ASAMI criteria

Introduction

Injuries and fractures have become very common in the 21st century. According to World Road Statistics 2019, India ranks number one in the number of deaths caused due to road traffic accidents [1]. As per the World Health Organisation Global Report on Road Safety 2018, India accounts for almost 11% of accident-related deaths in the world [1]. Long bones majorly femur, tibia and humerus are the most commonly fractured and their management contributes significantly to the cost of orthopaedic care. The annual estimated incidence of open fractures of long bones is 11.5 per 100,000 persons, with 40% occurring in the lower limb [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]. Non- union is a debilitating chronic medical condition with a negative substantial effect on health [4]. In such cases the surgeon faces a formidable challenge in the planning of treatment, dealing with functional disability, lost wages causing financial constraints, psychosocial impairment, non-compliance of patients and stressful impact on 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 which are available for tibia fractures vary according to the type of fracture, age, bone density, soft tissue status and associated complications. Conservative methods used are casting or bracing for stable closed fractures [7].

Operative techniques used are fixation with plates and screws, intramedullary nailing and external fixation. The issues complicating the treatment are devitalisation of bone, soft tissue scarring & atrophy, deformity, limb length discrepancy, joint stiffness and secondary osteoporosis [4].

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

Circular ring fixator and limb reconstruction system are popular modalities as they are single staged procedures. They correct the deformity and limb length along with excellent infection control and facilitate bone union. Weight-bearing can also be initiated simultaneously during treatment.

Ilizarov fixator is cumbersome to the patient, bulky and heavy, painful, relatively difficult to mount and requires a high learning curve [9, 10]. Limb reconstruction system is less bulky with better compliance, easy to apply and remove with the advantage of being a dynamic fixator which is the most important principle in the treatment of non-union [11, 12].

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 limb reconstruction system in the management and stabilisation of infected nonunion of the tibia. In this study, we assessed the limb reconstruction system in management in terms of union rate, control of infection and associated complications.

Material and Methods

A prospective clinical intervention study of Limb Reconstruction System (LRS) in infected tibia non-union was conducted at a tertiary care hospital. All patients with infected non-union of tibia admitted in the study setting during the study period (Jan 2018 to Feb 2020) were included in the study. A total of 18 patients with infected non-union tibia fractures were included of which 16 were males and 2 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. Active draining sinuses were found in 10 patients and 8 were non-draining. All patients had a prior history of surgeries either in the form of multiple debridements, external fixator application, 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-anaesthetic 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 anaesthesia. Any previous implant and simple fixators in cases of established non-union which 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 LRS fixation. Antibiotics were given according to culture and sensitivity and patients 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 LRS fixation (Figure 1) with pertinent pre-operative planning, taking into consideration the fracture or non-union configuration. The length of the rail, type of clamp, and configuration of the pin in each clamp was pre-planned. All patients were counselled regarding the long duration of treatment and possible complications associated with it.

Surgical procedure

The patient was placed in the supine position. Three clamps were applied, one each to the proximal and distal tibia and the third one to the advancing or docked segment. The proximal and distal tibial pins were placed parallel to the joint line at the level of the head of the fibula and 2 cm above the ankle joint respectively (Figures 2a and 2b). After the pins were secured, the rail was put in place along with the template. Rest of the pins were inserted via the template which acted as the guide. Majority of the pins were placed in 1,3,5 configuration. Later, dummy clamps were removed and were replaced with central/end clamps. All clamps were tightened to provide a rigid stable fixation at the fracture site. Through separate incisions, corticotomy and fibular osteotomy were performed in required selected cases as per preoperative planning. Closure of wound was done in layers. Knee, ankle range and distal pulse of motion was 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 interval 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[12]. Data were collected at baseline using a semi-structured questionnaire and clinical examination on serial follow up sessions in outpatient clinics.

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 was calculated for qualitative variables.

Results

The patients were in the age group of 19-55 years with 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. Majority 16 (88.9%) were males and 02 (11.1%) were females.

Baseline Characteristics

Tibia Shaft was found to be the most prevalent site of non-union; 10 (55.6), followed by Distal found in 05(27.8%) of the patients, followed by Proximal seen in 03 (16.7%).

Prevalence was co-morbidity was found in only 03 (16.7%) of the patients with 02 (11.1%) patients have hypertension and only 01 (5.6%) patient 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. Mean bone gap was found to be 3.1±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. 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 majority 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 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 infected which was treated by revision of pins and administration of parenteral antibiotics.

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.

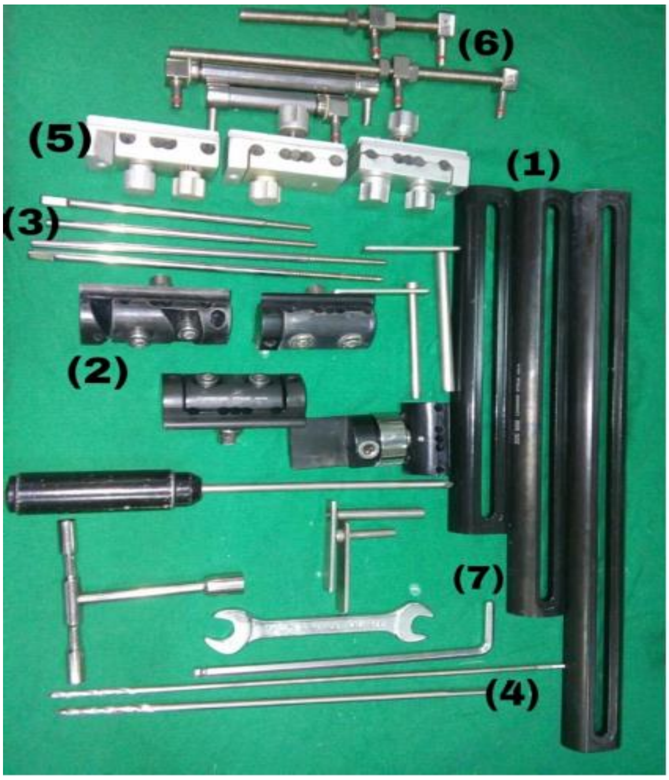

Fig 1: Instrument set for LRS (1) Rail: 240mm, 300mm, 400mm (2) Clamps: central, end, swivel, ball and socket (3) Tapered threaded pins (4) Drill bits (5) Dummy clamps used as the template (6) Compression-distraction unit (7) Allen key

Fig 2a, 2b: C: Arm image showing first Schanz pin parallel to knee joint at the level of the fibular head; Second Shanz pin at 1cm above and parallel to ankle joint

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

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

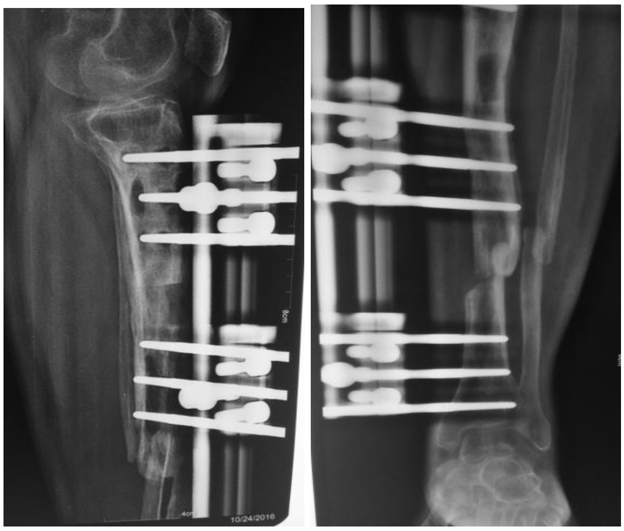

Fig 3c: Postoperative image showing distraction osteogenesis at 20 weeks

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

Fig 3e: Clinical images showing excellent functional outcomes before removal of LRS

Fig 3d: Functional outcome after 6 months of removal of LRS

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 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	10	55.6
	Distal	05	27.8
	Proximal	03	16.6
Co-morbidities	Absent	15	83.3
	Hypertension	02	11.1
	Diabetes	01	5.6
External fixation	Present	16	88.9
	Absent	02	11.1
Bone gap	2 cm	06	33.2
	3 cm	05	27.8
	4 cm	05	27.8
	5 cm	02	11.1
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	06	33.3
	No	12	66.7
Bone Grafting	Yes	03	16.6
	No	15	83.3
Antibiotic Depot	Yes	01	5.6
	No	17	94.4
Infection	Present	00	0.0
	Absent	18	100.0
Deformity	< 7 degree	17	94.4
	>7 degree	01	5.6
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

Discussion

Open tibial fractures subsequently leading to infected non-union of the tibia are occurring commonly due to increasing high-velocity road traffic accidents. Although multiple approaches and methods are available yet management of infected non-union tibia remains a challenge for any orthopaedic surgeon. Limb reconstruction 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]. Pin placement is predetermined as compared to simple monolateral external fixators where pins could be placed in different angles. LRS offers ease of application, need for fewer pins which are advantageous when dealing with bulky soft tissue bulge, can correct deformity in multiple planes, bone transport can be done simultaneously and the patient can perform daily activities with the fixator in-situ much easier than using circular frames for the same indications [11]. 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 Patil MY *et al* [13] who treated 54 patients with a compound fracture of the tibia using the Limb reconstruction system. In the study by Patil MY *et al* [13], 67% of the patients had an excellent score and 25% had a good score, and in the functional component assessment, nearly 80% had excellent scores based on ASAMI criteria. The most common complication encountered in the study by Patil MY *et al*. [13] was pin tract infection, which 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 Khan A *et al*. [15] excellent bony scores were reported in 75% and good in 10% of the patients, the excellent functional score was seen in 60% of patients and 20% 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 Patil MY *et al*. [13] where the average time for the union was found to be 7-8 months. Range of motion especially at 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 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. Jilani *et al* treated 22 patients of non-union of using rail fixator, the union was seen in 20(90.1), 2 patients had a failure. ASAMI bone results were excellent in 12 (54.5%), good in 5 (22.7%), fair in 3(13.6%), poor in 2 (9.1%), Functional were excellent in 11 (50%), good in 5(22.72%), fair in 4 (18.18%) and failure in 2 (9%) [16]. LRS is easy to apply, light-weighted, simple in design, easy to handle, and has a short learning curve compared to a circular ring fixator. LRS holds equally good in achieving union in infected non-union tibia patients as the circular ring fixator. Also, it provides more stability due to increase diameter tapered pins, permits wound care easily and also allows early mobilisation and rehabilitation providing an increased level of activity in patients thus restoring self-confidence, independence and improving their quality of life. It is a relatively simple technique providing rigid fixation which is also cost-effective, thus reducing the financial burden on the patient Lastly, axial compression can be achieved by compression and distraction principle.

The limitations of the present study are a small sample size. The follow-up period is short. The complex multiplanar deformity is difficult to correct with limb reconstruction system. Periarticular infected non-union of the tibia cannot be treated with limb reconstruction system.

Conclusion

Bone healing occurs by the formation of new bone and the method adopted in treating infected non-union tibia with the help of a limb reconstruction system is dynamic in nature and provides corticotomy, bone transport, the fusion of bone ends with consolidation. Also, it facilitates in dealing with limb length discrepancy, infection control, simultaneous correction of deformity, and early mobilization. Fracture healing with LRS is equally effective in comparison to circular ring fixator. It is easy to perform, has predictable healing for infected non-union, has a short learning curve, ensures compliance inpatients, and provides reliable results with lesser complications. Careful pre-operative planning, proper surgical techniques, and systematic routine follow-up will establish an LRS fixator as one of the definitive treatment modalities in the treatment of infected non-union of the tibia.

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