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Original Research Article

An evaluation of effectiveness of Ilizarov external fixation in treating infected non-union tibial fractures: a prospective observational study

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ABSTRACT

Background: Infected non-union tibial fractures pose significant challenges in orthopedic care. Ilizarov external fixation has emerged as a promising treatment option for such complex fractures. The purpose of this research is to evaluate the efficacy and safety of Ilizarov fixation in non-union, infected tibial fractures.
Methods: A prospective observational study was conducted on 30 patients at Indira Gandhi Institute of Medical Sciences. Inclusion criteria involved patients aged 20-65 with clinical and radiological signs of infection and non-union of the tibia. Data on patient demographics, injury details, treatment history, and outcomes were collected. Ilizarov fixation was performed, and patients were followed up.
Results: The study cohort, primarily males (80%), with mean age of 35.75 years, displayed a high incidence of type III compound injuries (63.33%). Monofocal and bifocal osteosynthesis effectively reduced limb shortening, with an overall average residual shortening of 1.8 cm. Bony outcomes were favorable, with 16 cases achieving excellence. Functional outcomes were also promising. Complications included stiffness, infections, and deformities.
Conclusions: Ilizarov external fixation demonstrates potential in managing infected non-union tibial fractures, offering favorable bony and functional outcomes. However, post-operative complications require vigilant management. Further research is needed to validate and optimize this approach.

Keywords: Ilizarov fixation, Tibial fractures, Non-union, Infection, Orthopedic surgery

INTRODUCTION

Infected non-union tibial fractures present a challenging clinical scenario that demands innovative approaches to achieve successful outcomes. Among the various treatment modalities available, Ilizarov external fixation has emerged as a promising technique for addressing this complex orthopaedic condition.[1]

Tibial fractures, particularly those complicated by infection and non-union, pose significant clinical dilemmas.[2] Such fractures can lead to persistent pain, deformity, disability, and a substantial reduction in the patient's quality of life. Traditional treatment options, including surgical debridement, internal fixation, and bone grafting, may not always provide satisfactory results, making it imperative to explore alternative therapeutic measures.[3]

The Ilizarov external fixation method, developed by Dr. Gavriil Ilizarov in the mid-20th century, represents a unique and versatile approach to addressing these complex fractures.[4] It involves the use of a circular external fixator device that enables multiplanar correction of deformities, controlled distraction osteogenesis, and stabilization of the fracture site.[1] This technique has gained popularity for its ability to manage a wide range of bone pathologies, including non-unions and infected fractures.[5]

Despite its growing utilization, there remains a need for comprehensive prospective studies that rigorously assess the outcomes associated with Ilizarov external fixation in the context of infected non-union tibial fractures. This

study aims to fill this gap by systematically evaluating parameters such as fracture healing rates, infection control, functional outcomes, patient satisfaction, and complications.

The aim of the study is to estimate the safety and effectiveness of Ilizarov external fixation in individuals with non-union, infected tibial fractures.

METHODS

Study design

This study was designed as a prospective observational investigation.

Study setting

The research was conducted at Indira Gandhi Institute of Medical Sciences, Patna, Bihar, from time duration of April 2021 to September 2022.

Participants

The study included a total of 30 participants.

Inclusion criteria

Patients aged between 20 and 65 years, patients who had sustained leg injuries, whether open or closed, who presented with clinical and radiological signs of infection and non-union tibial fractures site, and patients who had received prior treatment, either outside or within the hospital were included.

Exclusion criteria

Individuals who are expected to cooperate poorly, and have peripheral vascular disease, psychological illnesses, including senile dementia, and substantial damage to the tibial nerve were excluded.

Bias

Bias was not explicitly addressed in the provided information. Standard measures to minimize bias should have been implemented during the study.

Variables

The primary variables in this study included presence of infection and non-union in tibial fractures and treatment outcomes following debridement and Ilizarov external fixation.

Data collection

Data collection involved the following steps: enrolment of eligible patients meeting inclusion criteria, obtaining informed consent from patients, operative treatment with debridement and Ilizarov external fixation, and regular follow-up for the entire period of treatment.

Study procedure

The study began through collection of patient information, including injury details, previous treatments, time since injury, and disease progression. A comprehensive physical examination and assessment of the injury site were conducted. Key data, such as non-union duration, infection presence, limb shortening, and prior treatments, were documented.

Based on the gathered information, the decision to use the Ilizarov method for treatment was made. Patients were informed about the procedure and shown the equipment involved, which may include multiple surgical interventions such as infection site cleaning, bone grafting, osteotomy, or wire/pin adjustments.

Prior to surgery, a comprehensive patient evaluation and pre-anesthetic check were performed. Preparations included creating and sterilizing the Ilizarov frame pre-construct a day before surgery. Antibiotics were discontinued two days before surgery to facilitate intraoperative testing.

During surgery, patients were positioned appropriately on the operating table. Standard procedures were followed for wire insertion and frame construction, with a focus on minimizing bone damage. Infection and debris were removed from the non-union site until signs of healing were observed.

Samples for testing, including cultures and pathology samples, were collected during surgery, and antibiotics were administered to prevent infection. The Ilizarov frame was attached securely to the leg using wires and pins.

Additional procedures, such as implant removal or osteotomy, were performed as needed. Post-surgery, epidural anesthesia was used for pain relief for 48 hours. Antibiotics were prescribed based on bacterial test results and continued for 6-8 weeks.

Regular cleaning and dressing of pins and wires were performed, and pin tract infections were addressed. Patients were instructed on how to adjust the frame to compress or lengthen the bone, depending on their specific case.

Weekly X-rays monitored bone growth progress, with frame adjustments made accordingly. Lengthening continued until sufficient bone growth occurred, followed by a waiting period for proper consolidation. Patients received physical therapy to prevent stiffness and were provided with shoe lifts to address leg length differences.

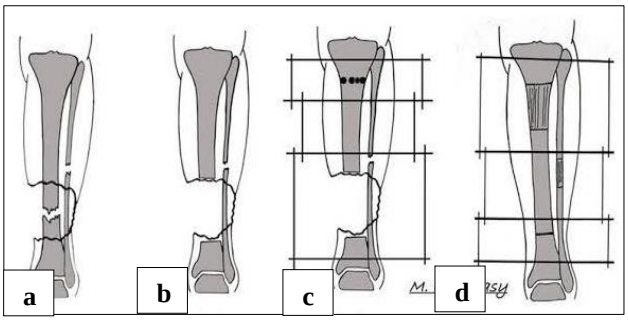

Figure 1: Bifocal distraction- compression to bridge composite tissue defect: (a) soft tissue defect with exposure of bones; (b) resection of infected and dead tissues with the result of osteocutaneous defect; (c) application of external fixator and metaphyseal osteotomy; and (d) distraction- compression for composite tissue transport.

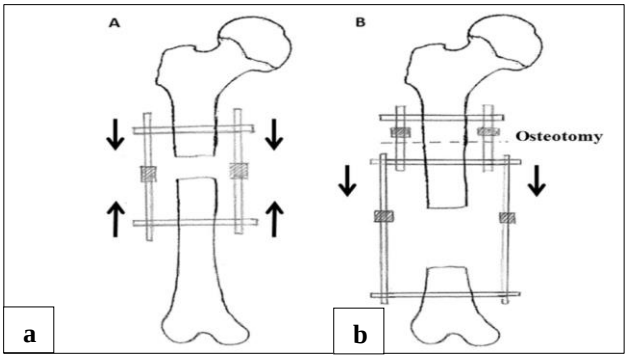

Figure 2: (a) Monofocal method. Two bony segments next to the defect were transported toward each other, which caused limb shortening. This method was indicated in bone loss <2 cm; (b) bifocal method. An osteotomy was performed outside the injury zone.

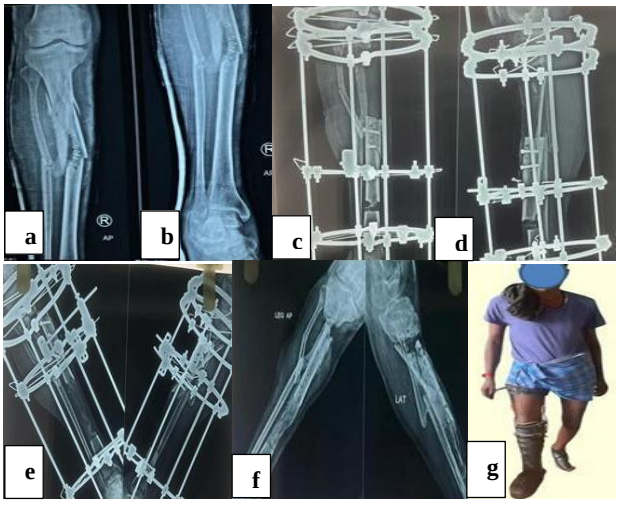

Figure 3 (a-g): Radiographs showing bifocal distraction- compession and after complication of bone transport and consolidation patient walking full weight bearing with hip knee ankle orthotics (HKFO).

Before frame removal, stability testing was conducted. Once the bone exhibited healing signs, frame removal took place in the operating room under local anesthesia. After removal, patients used a brace and were allowed weight-bearing as appropriate.

Statistical analysis

After the study's data was collected and organized in an excel sheet, statistical analysis (frequency, and percentages) was performed on the data. To perform statistical analysis, use the relevant software e.g., statistical package for the social sciences (SPSS). A change is deemed statistically significant if it is $p<0.05$.

RESULTS

In the study, a cohort of 30 patients, each corresponding to a specific limb segment, underwent examination and data collection, which were systematically recorded in a comprehensive chart. The key findings of the study are mentioned in Table 1. Among these individuals, 24 were male, and 6 were female (Figure 4). The age range of the participants spanned from a min. of 22 years to a max. of 64 years, with mean age of 35.75 years. The majority of the participants fell within specific age brackets, with 13 patients aged between 21 to 31 years, followed by 8 patients in the 32 to 42-year age group, 6 patients in the 43 to 53-year age group, 2 patients in the 54 to 64-year age group, and one patient aged over 65 years. All cases included in this study were the result of high-velocity injuries stemming from road traffic accidents.

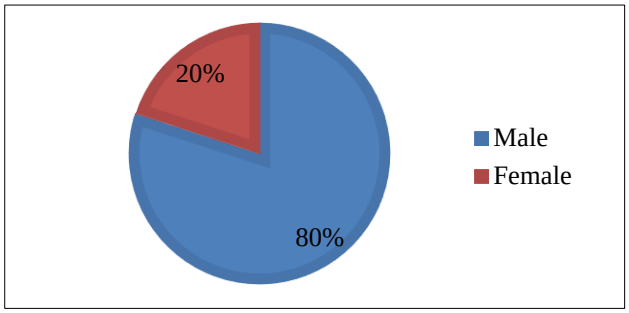

Figure 4: Gender distribution in the study population.

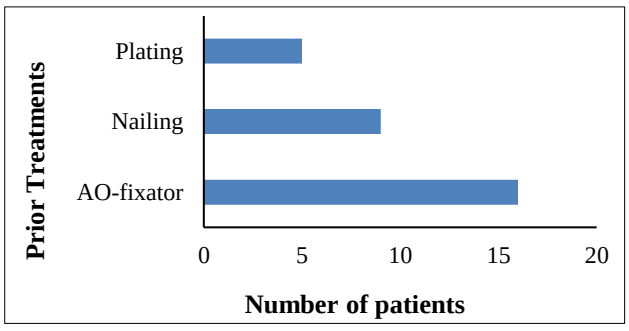

Figure 5: Prior treatments undergone by study population.

Table 1: Summary of key findings of the study.

Parameter	Value
Total number of patients	30
Gender distribution	
Male	24
Female	6
Average age (years)	35.75
Age distribution (years)	
21 to 31	13
32 to 42	8
43 to 53	6
54 to 64	2
Over 65	1
Type of injuries	
Compound	63.33
Closed	13.34
Prior treatments	
AO-fixator	16
Nailing	9
Plating	5
Location of non-union	
Distal	46.67
Middle	36.67
Proximal	16.67
Average duration of non-union (months)	9.3
Preoperative tibial shortening range (cm)	2-7
Average preoperative tibial shortening (cm)	3.1
Average residual shortening (cm)	1.8
Average duration of Ilizarov fixator (months)	7.8
Fixator duration	
Monofocal	7.3
Bifocal	6.5
Regenerate length (bifocal)	2.5-5.5
Average lengthening index (months/cm)	2.4

Regarding the nature of injuries, 19 patients (comprising 63.33% of the cohort) exhibited type III compound injuries, 4 patients (13.33%) presented with type II injuries, 3 patients (10%) displayed type I compound injuries, and 4 patients (13.34%) had closed injuries. Notably, the severity of trauma appeared to be directly related with an increased risk of infection in the study population.

With regard to the history of prior treatments, 16 patients had previously undergone AO-fixator procedures, 9 patients had been subjected to nailing interventions, and 5 patients had undergone plating (Figure 5). Among the participants, the most frequent location of non-union was in the distal 1/3rd of the limb, observed in 14 patients (46.67%). This was followed by non-union in the middle 1/3rd of the limb in 11 patients (36.67%) and in the proximal 1/3rd of the limb in 5 patients (16.67%). The average duration of non-union prior to surgical intervention was determined to be 9.3 months, with the minimum duration being 3 months and the maximum reaching 59 months.

Nineteen patients received monofocal osteosynthesis, while eleven patients underwent bifocal osteosynthesis. Before treatment, it was observed that the tibia had experienced preoperative shortening, ranging from 2 to 7 cm, with an average shortening of 3.1 cm. In the monofocal group, the average residual shortening remained similar to the pre-operative value at 2.1 cm. Conversely, bifocal osteosynthesis aimed to achieve lengthening, successfully reducing the average residual shortening from 4.5 cm to 1.8 cm by the conclusion of the study. On a broader scale, the overall average residual shortening among all 30 patients following Ilizarov fixation was calculated to be 1.8 cm.

The mean duration for which the Ilizarov external fixator was employed in the study was 7.8 months, with a min. duration of 4 months and a max. of 12 months. For patients undergoing monofocal fixation, the average duration was calculated as 7.3 months, while those undergoing bifocal fixation exhibited an average duration of 6.5 months. In cases where no lengthening was intended, as seen in monofocal osteosynthesis, the average length of the regenerate closely resembled the preoperative shortening, measuring 2.2 cm. Conversely, patients treated with bifocal osteosynthesis achieved a more substantial reduction in residual shortening, decreasing from an average of 4.5 cm to 1.5 cm upon completion of the study. The mean length of the regenerate among patients undergoing bifocal osteosynthesis was computed to be 3.2 cm, with a minimum of 2.5 cm and a maximum of 5.5 cm. To evaluate the rate of lengthening, a lengthening index was calculated, defined as the fixator period divided by the length gained. In the study, the mean lengthening index was determined to be 2.4 months per centimeter.

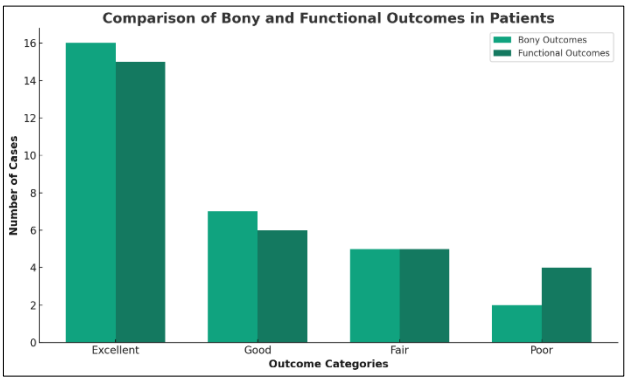

Figure 6: Comparison of bony and functional outcomes in patients.

In the cohort of thirty patients, the evaluation of bony outcomes revealed that 16 cases achieved excellence, 7 cases displayed good results, 5 cases yielded fair outcomes, and 2 cases exhibited poor bony results. On the other hand, when assessing functional outcomes, 15

patients demonstrated excellence, 6 patients were categorized as good, 5 patients achieved fair functional results, and 4 patients experienced poor functional outcomes (Figure 6).

Throughout the duration of the study, all patients demonstrated good tolerance to the Ilizarov fixator. However, several complications were noted, including persistent ankle stiffness and subtalar joint stiffness in four cases (Table 2). Additionally, all participants experienced varying degrees of edema, pain, and pin tract infections. Delayed regenerate formation was observed in four patients, while three patients presented with inadequate regenerate development. Infections necessitating the replacement of wires, pins, or rings were encountered in four patients, and two patients experienced wire breakage. Furthermore, isolated cases of significant shortening (>2.2 cm) and substantial deformity (>60 degrees of angulation) were documented. Lastly, four patients manifested equinus deformity of the ankle.

Table 2: Complications encountered occur during study.

Complications	No. of cases
Persistent ankle stiffness and subtalar joint stiffness	4
Edema, pain, and pin tract infections	30
Delayed regenerate formation	4
Inadequate regenerate	3
Infections necessitating the replacement of wires, pins, rings	4
Wire breakage	2
Significant shortening (>2.2 cm)	1
Deformity (> 60 degrees of angulation)	1
Equinus deformity of the ankle	4

DISCUSSION

In this study of 30 patients with non-union tibial fractures resulting from high-velocity injuries, Ilizarov fixation emerged as a valuable treatment option. The patients, predominantly male and aged between 21 to 31 years, exhibited a range of injury severities, with type III compound injuries being the most common. Prior treatments varied, but the study highlighted the challenge of addressing non-union, particularly in the distal third of the limb. Monofocal and bifocal osteosynthesis approaches were employed, with the latter successfully reducing residual shortening. The Ilizarov fixator was utilized for an average of 7.8 months, and patients undergoing bifocal osteosynthesis achieved substantial regenerate lengthening. Bony and functional outcomes varied, with many patients experiencing good results, although complications such as joint stiffness and pin tract infections were observed. Overall, Ilizarov fixation showed promise in treating these complex fractures, but careful consideration of patient-specific factors is crucial for optimizing outcomes.

Recent studies and case reports have provided valuable insights into the management of severe limb injuries and non-unions, particularly in the context of high-velocity trauma and road traffic accidents. One notable case report by Prasad et al discusses the complex challenge of treating severe trauma to an extremity, emphasizing limb salvage attempts in young patients without significant systemic involvement.[6] Another study by Lone et al contrasts Ilizarov ring fixators with limb reconstruction system (LRS) fixators in treating compound tibial shaft fractures, finding LRS easier for patients to manage despite the technical demands of the Ilizarov fixator.[7]

Further research, by Uikey et al highlights the effectiveness of LRS in treating lower extremity fractures with bone loss, achieving union, lengthening/transportation, and deformity correction simultaneously.[8] The study by Kumaresapathy concludes that the Ilizarov technique plays a definitive role in managing various types of fracture tibia.[9] Additionally, Tomić et al showcases the method's safety and efficiency, minimizing intraoperative trauma.[10]

A case report by Asadi et al discusses the successful management of severely angulated and deformed pseudarthrosis non-union of the tibia using a free non-vascularised fibular strut graft.[11] The study by Singh et al further supports the effectiveness of free fibular grafting in managing large segmental bone defects and biological failure of bone healing.[12] Lastly, Rengerla et al details the successful use of intramedullary nailing combined with autologous fibular cortical and cancellous grafts for managing aseptic femoral non-union.[13]

These studies collectively underscore the advancements in surgical techniques and approaches for treating complex limb injuries and non-unions, highlighting the importance of individualized patient care and the technical expertise required for optimal outcomes.

Limitations

The limitations of this study include a small sample population who were included in this study. The findings of this study cannot be generalized for a larger sample population. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

CONCLUSION

In conclusion, this prospective study assessed Ilizarov external fixation for non-union, infected tibial fractures in 30 patients, predominantly males, aged 22 to 64 years, mostly due to high-velocity road traffic accidents. Type III compound injuries were prevalent and linked to trauma severity and infection risk. The Ilizarov method, including both monofocal and bifocal osteosynthesis, effectively

reduced limb shortening. Bony and functional outcomes were favorable, despite post-operative complications such as stiffness, infections, and deformities. This study highlights Ilizarov fixation's potential for complex tibial fractures but underscores the need for rigorous post-operative care. Further research is needed for validation and optimization.

Recommendations

Enhanced post-operative care protocols and rigorous monitoring of complications are recommended for patients undergoing Ilizarov fixation for infected non-union tibial fractures.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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