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Original Research Article

Comprehensive Evaluation of Efficacy and Safety Profile of Limb Recontruction System (LRS) in Patients with Non Unions of Long Bones

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Abstract

Introduction: Long bones like the tibia and femur have a weak blood supply and stabilisation, making nonunion fractures difficult. These issues affect people and healthcare systems. The Limb Reconstruction System (LRS) has promising results with firm fixation and rapid rehabilitation, although further study is required in non-union patients. More study is needed to determine LRS's efficacy and safety in treating long bone non-unions.

Aim and Objectives: The objective is to thoroughly evaluate the efficacy and safety of the Limb Reconstruction System (LRS) in the full treatment of long bone non-unions.

Method: A single-site observational research ran from March 2022 to August 2023 at the National Institute of Medical Science and Research (NIMS) in Jaipur on Ilizarov ring fixation for infected non-union long bone fractures in 30 patients aged 18–60. The NIMS Jaipur institutional review board-approved study investigated functional outcomes and problems using standardised treatment regimens and ethical data gathering. Patients' limb conditions were assessed pre- and post-surgery for Ilizarov ring fixation results and sequelae.

Result: Infected non-union long bone fractures were treated with Ilizarov rings in 30 patients at NIMS Jaipur. Most were 20–40, mostly males (76.7%), and 90% were injured in road traffic incidents. Tibia suffered the most (66.7%). Pin tract infections, limb differences, and joint stiffness were complications. Overall, 83.3% had good functional results and 73.3% had good bone healing. The duration of non-union varied by bone type but not significantly.

Conclusion: Indian Limb Reconstruction, with an 80% success rate, is a simple, successful treatment for diseased nonunion in long bones, rivalling Ilizarov fixation.

Keywords: Limb Reconstruction System, Long Bones, Non-Unions, Clavicle, Humerus.

Introduction

Long bones experiencing nonunion depict the intricate challenge of fractured bone healing beyond anticipated timelines. This orthopedic complexity involves bones like the tibia, femur, humerus, and clavicle. Several contributors, encompassing insufficient stability, infections, compromised blood flow, and patient-specific aspects like smoking or medical conditions, orchestrate this phenomenon [1-4].

When bones fracture, the body's natural healing response typically restores integrity, yet complications like non-unions arise when this process fails, especially in long bones. Factors like inadequate blood supply, poor stabilization, infections, excessive movement, and health conditions like osteoporosis or diabetes hinder normal healing, impeding solid union formation. In long bones, like the femur or tibia, this becomes more challenging due to their length and susceptibility to weight-bearing forces [5-8].

Nonunion fractures pose substantial challenges for patients, affecting their daily lives and placing significant stress on healthcare systems. These complications bring chronic pain, restricted mobility, and functional limitations, impacting patients' independence and reducing their quality of life. Additionally, the healthcare burden escalates due to necessary follow-up treatments like surgeries, prolonged care, and increased risk of infections, raising resource demands. Identifying and addressing nonunion risk factors are crucial to prevent their occurrence, enhance fracture healing, and alleviate the strain on healthcare systems [9-13].

Traditional techniques for managing non-unions encompass orthopedic modalities like centromedullary nailing, pinning, plating, and

external fixation. Yet, these methods carry challenges: prolonged immobilization can trigger muscle atrophy and joint stiffness, hindering functional recovery. Surgical procedures also entail infection risks, and success rates are variable. Emerging alternatives, such as screw plate fixation coupled with cancellous bone grafting, have displayed promising outcomes with minimal complications [14].

The Limb Reconstruction System (LRS) stands out as an invaluable solution for intricate fractures and bone defects, offering notable advantages like sturdy fixation, enabling early weight-bearing, and addressing soft tissue injuries. Research showcases its efficacy in managing various conditions, including open fractures, calcaneal and tibial diaphyseal fractures, femoral lengthening, and complex non-unions. With its ability to provide robust fracture stability, accommodate bone transport and lengthening, studies reveal favorable outcomes, boasting impressive union rates and improved functional results. LRS is hailed as a patient-friendly and cost-effective option in the realm of orthopedic treatments [15-18].

The Limb Reconstruction System (LRS) stands as an innovative orthopedic solution crafted to tackle non-unions and bone defects. This rail external fixator employs compression and distraction techniques, fostering bone healing and restoring limb function. Its prowess shines in managing open fractures, infected non-unions, and bone loss in long bones like the femur and tibia. Studies affirm its prowess, showcasing remarkable bone and functional recoveries with high union rates, elevating patient outcomes vis-a-vis traditional treatments. Its benefits include superior union rates, accelerated rehabilitation, simplified soft tissue care, and averted need for multiple surgeries. Yet, it's imperative to discern that LRS might not universally fit all cases, warranting tailored treatment choices based on individual patient nuances and the distinct traits of the non-union or bone defect [19-22].

The Limb Reconstruction System (LRS) is an external fixator pivotal in orthopedic care, orchestrating fracture stabilization, bone rejuvenation, and limb restoration. Comprising interconnected rings, connecting rods, hinges, tensioning devices, and fixation pins or wires, this system executes a symphony of functions: rings offer sturdy support, connecting rods allow fine-tuning, hinges permit controlled movement, tensioning devices apply calibrated forces for compression or distraction, and pins or wires stabilize bones. Its essence lies in delicately manipulating fractured bones, aligning them through tensioning device adjustments. This methodical approach fosters bone healing, warding off issues like non-union or misalignment. Ultimately, the LRS stands as a vital tool, nurturing bone revival, and enabling limb reconstruction through precise manipulation and support [23-26].

Research examining the limb reconstruction system (LRS) in managing non-unions showcases promising outcomes. A collection of studies highlighted its efficacy: achieving union in 70-90% of cases, eradicating infections in 70-91% of instances, and delivering excellent bone outcomes in around 54-85% of scenarios. The LRS appeared effective in handling complex non-unions, open femur fractures, and infected bone cases. Its merits were evident in aiding swift rehabilitation, promoting union, and simplifying care for soft tissue injuries or bone loss. However, these studies, while encouraging, have limitations and require further exploration to validate the LRS's effectiveness in non-union treatments [27,28].

Limited research exists specifically examining the effectiveness and safety of the Lengthening and Reconstruction System (LRS) in managing non-unions of long bones. Existing literature predominantly focuses on traditional external fixators like the Ilizarov technique in treating non-unions. Despite LRS's potential advantages, including motorized lengthening and improved patient outcomes, there's a scarcity of direct comparative studies between LRS and other treatments for non-unions [29].

Method

Research Design

This prospective observational research at the National Institute of Medical Science and Research (NIMS) in Jaipur lasted 18 months from March 2022 to August 2023. The study examined the results of Ilizarov ring fixation for infected non-union long bone fractures in patients aged 18–60. The study examined functional results, comorbidities, and fracture union in this patient group. The National Institute of Medical Science and Research in Jaipur hosted the hospital-only trial. A focused and regulated single-site trial ensures identical treatment regimens and data collecting. Thirty instances in the indicated age range were studied. Patients with infected non-union long bone fractures treated at NIMS Jaipur between March 2022 and August 2023 were included. Missing patients were omitted from the analysis. People who fulfilled the diagnostic based on trauma history, injury date, clinical examination, and radiographic evidence of infection and non-union were included. The NIMS Jaipur institutional review board authorised the therapy regimens before the trial began. To uphold ethical norms and patient rights, all research participants gave signed informed permission. Upon presentation, patients were evaluated for limb length, joint range of motion, skin condition, vascularity, ligamentous instabilities, and overall

medical condition. Baseline anteroposterior and lateral X-rays of the afflicted limb were taken before surgery. The Ilizarov ring fixation technique for infected non-union long bone fractures was analysed for functional results and complications using the obtained data.

Inclusion and Exclusion Criteria

Inclusion

- Patients aged 18-60 with clinical and radiographic signs of infected non-union of long bones of either sex.
- Patients providing consent for study participation

Exclusion

- People who have experienced many types of trauma.
- Both vascular deficiency and non-union fractures that are not infected
- Situations involving co-morbidities, such as chronic smoking and non-union diabetes,

Statistical Analysis: The data was examined using IBM-SPSS 23.0. Data descriptive statistics included frequency, percentage, and mean & S.D. for categorical and continuous variables, respectively. ANOVA was used to analyse quantitative and qualitative parameters independently. Data were given as means ± standard deviation (SD) and deemed significant if p-value ≤0.05 and highly significant if p-value <0.01.

Result

In Table 1, 30 patients treated with Ilizarov ring fixation for infected non-union fractures of long bones at the National Institute of Medical Science and Research, Jaipur, are categorised by age, gender, mechanism of injury, and bones involved. The age distribution is 20–60, with most between 20–30 and 30–40. The mean age was 41.47 years, with 76.7% men. Road traffic accidents (RTA) caused 90% of injuries, while falls caused 10%. The tibia (66.7%), femur (20%), and humerus (13.3%) were most afflicted. Understanding the research population begins with this demographic and clinical profile.

Table 1: Age and Gender distribution

Age Group (yrs)	**No. of Patients**	**Percentage**
20-30	8	26.67%
30-40	7	23.33%
40-50	7	23.33%
50-60	3	10.00%
60-70	5	16.67%
Mean Age	**41.47±14.071 yrs**	
Gender	Frequency	Percent
Male	23	76.7%
Female	7	23.3%
Total	30	100.0%
Mode of Injury	**Frequency**	**Percent**
RTA	27	90.0%
History of Fall	3	10.0%
Total	30	100.0%
Bone Involved	**Frequency**	**Percent**
Tibia	20	66.7%
Humerus	4	13.3%
Femur	6	20.0%
Total	30	100.0%

Figure 1 summarises the clinical consequences in 30 patients treated for infected non-union long bone fractures using Ilizarov rings at the National Institute of Medical Science and Research, Jaipur. Limb length disparity (>2.5 cm) and angulation (>7 degrees) affected 23.3% and 56.7% of patients, respectively. Joint stiffness (33.3%) and discomfort (36.7%) hampered postoperative function. Pin tract infections occurred in 36.7% of patients, indicating a prevalent external fixation problem. Also found were infection (30%) and sympathetic dystrophy (16.7%). The results highlight the difficulties of addressing such fractures, requiring careful treatment protocol consideration of possible consequences.

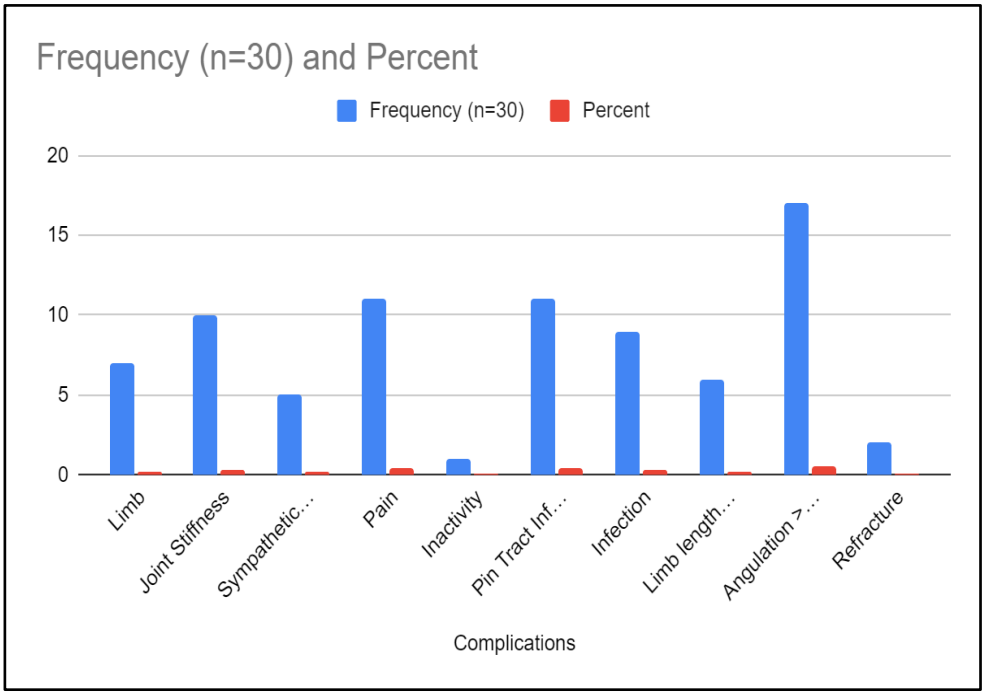

Figure 1: Various Clinical Complications

Table 2 shows the functional and bone healing results of 30 patients treated for infected non-union long bone fractures using Ilizarov rings at the National Institute of Medical Science and Research, Jaipur. The majority of participants had positive functional outcomes; 43.3% were rated as outstanding, 40% as good, 13.3% as fair, and 3.3% as bad. A large percentage showed favourable results in terms of bone healing; specifically, 26.7% were deemed fair, 20% as outstanding, and 53.3% as good. Importantly, no cases were shown to have a bad result for bone repair. These results indicate that the Ilizarov ring fixation technique had a favourable effect on the study population's functional abilities and bone healing process.

Table 2: Functional and Bone Healing outcome

Functional outcome	Frequency	Percent
Poor	1	3.3%
Fair	4	13.3%
Good	12	40.0%
Excellent	13	43.3%
Total	30	100.0%
Bone Healing Outcome	**Frequency**	**Percent**
Poor	-	-
Fair	8	26.7%
Good	16	53.3%
Excellent	6	20.0%
Total	30	100.0%

Figure 2 shows the mean duration of non-union sites in patients treated for infected long bone non-union fractures using Ilizarov ring fixation at the National Institute of Medical Science and Research, Jaipur. The tibia, femur, and humerus bones are used to classify the data. Tibial non-unions lasted 6.95 months on average, with a standard deviation of 1.731, ranging from 4 to 11 months. Femoral non-unions had a mean duration of 9 months, a standard deviation of 2.191, and a range of 6 to 12 months. Humerus non-unions lasted 7–8 months, with a mean of 7.75 months and a standard deviation of 0.5. The mean length for all non-union locations was 7.47 months, with a standard deviation of 1.871 and a range of 4 to 12 months. The p-values indicate that the mean durations of the tibia, femur, and humerus groups were similar. These results provide light on non-union resolution's temporal characteristics based on the research population's bones.

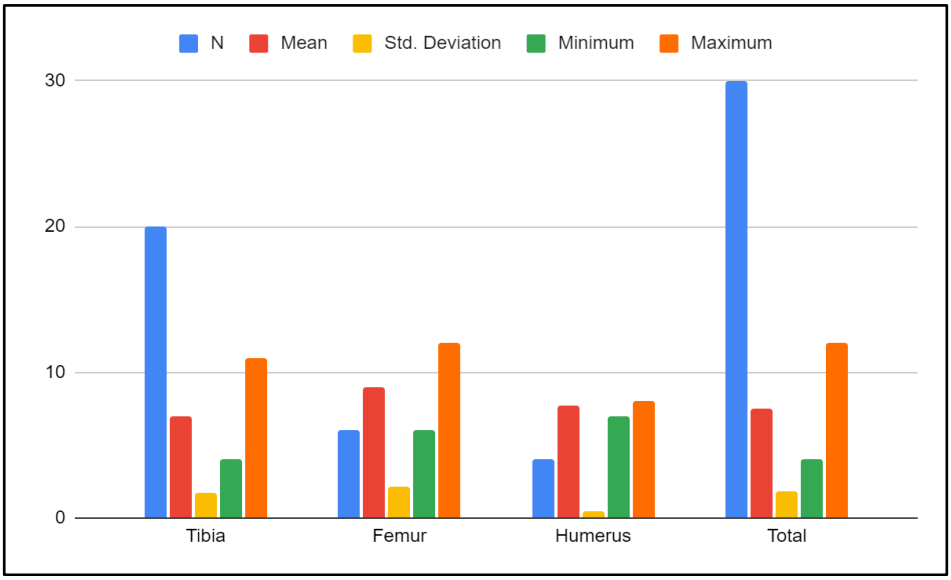

Figure 2: Mean duration of Non-union Site

Discussion

A retrospective case series by Chahar et al. (2021) investigated the efficacy of the Limb Reconstruction System (LRS) in managing 14 challenging cases of complicated open femur fractures and infected non-unions. The fixator was removed on average between 4 to 24 months, with patients followed up for an average of 18 months (range: 6-36 months). Results, evaluated using ASAMI criteria, revealed excellent bone outcomes in 85.72% of cases, with 7.14% showing good and poor outcomes each. Functionally, 71.43% displayed excellent outcomes, while 28.57% showed good and fair results. This study underscores the LRS's effectiveness in achieving enhanced union rates with complex open femur fractures and infected non-unions [19].

A prospective study by Bakshi et al. (2022) comparing the efficacy of antibiotic-coated intramedullary nails (ACIIN) and external fixators (LRS/Ilizarov) in treating infected non-union long bones enrolled 40 participants, divided into two groups. Group A received ACIIN treatment, while Group B underwent LRS/Ilizarov external fixation. The results showcased a statistically significant difference in bony union, with 80% in Group A and 70% in Group B achieving union. Evaluation also focused on infection control, limb length discrepancy, and deformity in both groups. Notably, the ACIIN group displayed higher union rates and fewer complications, while the LRS/Ilizarov group revealed 55% with no infection, 15% with loosening, and 30% with infection. The study suggested that while LRS was effective in promoting union in non-union cases [22].

In a retrospective study by Jiang et al. (2023) spanning from June 2016 to April 2018, 34 consecutive cases of displaced intra-articular calcaneal fractures were treated using minimally invasive reduction and internal fixation, supported by temporary external fixation via the limb reconstruction system (LRS). X-rays and CT scans were utilized to assess pre- and postoperative parameters. Results from a follow-up averaging 20.66 months revealed stable reduction and bony union in all fractures without internal fixation failure or reduction loss. Notably, no soft tissue complications were encountered. Improved Bohler's angle, calcaneal dimensions, and hindfoot mechanical axis were observed. The American Orthopaedic Foot and Ankle Society scores averaged 84.12 points, with seven excellent, 20 good, four fair, and one poor outcome. This approach showcased effective reconstruction of calcaneal shape and sub-talar articular surface [30].

Complex nonunions, marked by infection, deformities, and prior surgeries, pose challenges often addressed through Ilizarov fixation. However, drawbacks like poor patient compliance led us to explore the limb reconstruction system (LRS) for 30 cases of long bone complex nonunions studied by Seenappa et al. (2013). Over the treatment duration averaging 9.68 months, prioritized implant removal, radical debridement, and LRS fixation, occasionally combining corticotomy and lengthening in 16 cases. Achieving an 89.28% union rate and 91.66% infection eradication, we managed an average lengthening of 4.57 cm. Our assessment using ASAMI criteria revealed 79% excellent bony results, 11% good, and 10% poor. Functionally, 40% cases were excellent, 50% good, and 10% faced failure. LRS emerged as a patient-friendly alternative to Ilizarov fixation for managing complex nonunions of long bones [27].

Multiple studies assessing the safety of the Limb Reconstruction System (LRS) in treating nonunion

bones have identified specific complications. These encompass pin loosening, infections associated with pins, stiffness in neighboring joints, and residual infections. Intriguingly, there's a notable absence of explicit mentions regarding implant failures or breakages in the available literature on LRS safety in treating nonunions. This distinct safety profile, especially the absence of implant-related issues, sets LRS apart from conventional methods used for similar purposes [19,22,27].

Studies examining the impact of LRS treatment on patients with nonunion bones consistently highlight positive outcomes, notably improved mobility, reduced pain, enhanced limb function, and overall quality of life. A comparative study by Arfee et al. (2022) between LRS fixator and Ilizarov treatment in infected tibial nonunions demonstrated similar outcomes, albeit the Ilizarov method showed slightly better clinical performance [31]. Additionally, another study by Singh et al. (2019) focusing on distraction osteogenesis for infected gap nonunions of the tibia treated by bone transport showcased predominantly excellent or good functional outcomes in the majority of patients. These findings collectively emphasize the favorable functional improvements associated with LRS treatment in enhancing patients' daily functioning and overall well-being [32].

The Limb Reconstruction System (LRS) has emerged as a promising avenue in managing non-unions, signaling a shift in conventional approaches. Its role as an alternative to Ilizarov fixation underscores its potential, offering encouraging prospects for improved union rates and infection eradication. With capabilities for effective lengthening and positive functional outcomes, LRS presents a patient-friendly route, simplifying care for soft tissue injuries and bone loss, potentially reducing the necessity for multiple surgeries [19,27].

Conclusion

This research had an 80% success rate, providing positive benefits for most patients. Therefore, we may deduce that the Indian adaptation of the Limb reconstruction technique is a very successful and easy approach for treating infected nonunion of long bones. Additionally, this technique may be used to concurrently address limb length disparities that may occur throughout the treatment process. Early weight bearing may be permitted for the patient without compromising bone union, alignment, and quality of life. It serves as a substitute for Ilizarov fixation in the treatment of complicated nonunion of long bones.

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