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Original Article

Orthopaedics Section

Clinical and Functional Outcome of Infected Non Union of the Femur Managed with Monolateral External Fixator: A Prospective Interventional Study

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ABSTRACT

Introduction: The treatment of infected non unions of long bones is one of the most challenging tasks in modern orthopaedic trauma practice. With the increasing prevalence of Road Traffic Accidents (RTAs) and associated high-energy trauma, primary fractures are often presented with gross contamination, soft-tissue degloving, bone loss and vascular compromise. Infected non unions of the femur are managed through debridement, external fixation, bone grafting, microvascular composite tissue transfer, bone transport via an external fixator over a nail and Ilizarov circular or monolateral fixators.

Aim: To evaluate the clinical and functional outcomes in infected non unions of the femur treated with a monolateral external fixator.

Materials and Methods: This study was a prospective interventional study that included 17 males and one female patient, with a mean age of 35 years, who were treated at Dr. D. Y. Patil Tertiary Care Hospital in Pune city, Maharashtra, India with a monolateral external fixator between January 2021 and January 2024. All patients had high-energy RTAs, compound fractures and gross contamination initially. Implant removal was performed, followed by radical debridement and stabilisation with the rail fixator. The mean duration of non union was 13 months (range: 4-24 months). The mean number of previous surgical procedures was 3.4 (range: 1-4). Corticotomy and bone transport were performed in six patients who had shortening or bone loss of more than 2 cm. Distraction of the corticotomy was initiated one week later at a rate of 1 mm per day until lengthening was achieved. Monthly outpatient department follow-ups, with X-rays, were conducted and the fixator was maintained until the healing of three cortices and eradication of infection were confirmed. The average follow-up duration was 2.3 years (range: 1-4 years). A paired t-test was used for statistical analysis during follow-up.

Results: Union was achieved in 17 out of 18 patients, resulting in a union rate of 94.4%. The mean time to bony union was 7±2 months (range: 4-12 months). Infection was eradicated in all but one patient, who continued to experience a discharging sinus. The mean length achieved in the corticotomy and lengthening group was 4±0.75 cm. According to Paley's bone and functional outcome scoring, all but one patient had excellent to good results at the one-year follow-up. Significant improvement was observed in the Lower Extremity Functional Score (LEFS) and in the Physical Component Score (PCS) of the 36-Item Short Form Health Survey questionnaire (SF-36) at the one-year follow-up (p-value <0.05); however, there was no improvement in the Mental Component Score (MCS) of the SF-36.

Conclusion: A monolateral external fixator can provide stable fixation for the management of infected non unions of the femur and is an effective method for eradicating infection.

Keywords: Bone healing, Limb reconstruction system, Osteosynthesis alternatives, Outcomes

INTRODUCTION

The treatment of infected non unions of long bones is one of the most challenging tasks in modern orthopaedic trauma practice [1], with infected femoral non unions accounting for 2.24% of all long bone non unions [2]. With the increasing prevalence of RTAs and associated high-energy traumas, primary fractures are often presented with gross contamination, infection, soft-tissue degloving, bone loss and vascular compromise [3].

The primary treatment of these critically injured limbs is important for the prevention of future non unions. However, the loss of periosteal blood supply, severe degloving injuries of the soft tissues and bones, further stripping of the periosteum for plating and damage to the endosteal blood supply due to nailing all predispose patients to non union [4-6]. These non unions may present with resistant infections, deformity, limb length discrepancy, joint stiffness, disuse osteoporosis and soft-tissue atrophy. Infected non unions of the femur are managed through debridement with external fixation and bone grafting, microvascular composite tissue transfer, bone transport through an external fixator over a nail, and the Ilizarov circular fixator. Among these methods, the ring fixator is the most popular. However, due to the pain caused by tensioned wires, its cumbersome nature, and its heavy and complicated construct, it is less preferred for femoral shaft non unions [7-14].

Monolateral external fixators help conserve the vitality of the soft-tissues and the remaining bone. They are more comfortable, less bulky and better tolerated by patients compared to the Ilizarov ring fixator. Additionally, their design is simple, mechanically stable and more familiar to surgeons [15-18]. Thus, the aim of this study was to assess the union rate, infection control, complications and functional outcomes of infected femoral non unions managed with a monolateral external fixator. The novelty of this study lies in its inclusion of a larger group of non union cases and specifically studying a single bone—the femur.

MATERIALS AND METHODS

This prospective interventional study was carried out between January 2021 and January 2024 at Dr. D. Y. Patil Tertiary Care Hospital in Pune city, Maharashtra, India. Institute ethical clearance was obtained before the commencement of the study (IEC: IESC/298/2020). Informed consent was acquired from each patient.

Inclusion criteria: Patients above 18 years of age who were admitted with non unions of a fractured femur, including both aseptic and infected non unions were included in the study.

Exclusion criteria: Patients with associated concomitant long bone fracture non union and pathological fractures leading to non union were excluded form the study.

Sample size: This study included 18 cases of infected non union of the femur, which were diagnosed clinically and radiologically and satisfied the inclusion criteria. Convenience sampling was used and 18 samples were selected.

Study Procedure

Patient demographics, presenting symptoms, medical history, number of surgeries performed in the past, presence of tenderness, sinus tracts and pus discharge, skin condition, shortening, deformity and the functions of the hip and knee joints- particularly the flexion Range of Motion (ROM)- were recorded. Complete blood counts, erythrocyte sedimentation rate and C-reactive protein levels were measured and pus was evaluated for Gram/Zn staining, culture, and sensitivity.

Under spinal anesthesia, patients were prepared with all aseptic precautions in a lateral position, with the affected side facing up on a radiolucent table. Initially, removal of implants was started. After that, dead bone was resected, and the infected, fibrosed soft tissues were adequately debrided, with sinus tracts excised. Cortical bleeding, known as the "paprika sign," was taken as the endpoint of bone resection. Tissues were obtained for aerobic and anaerobic cultures and biopsy.

Fixation was performed using a monolateral external fixator. Monofocal procedures with a neutralisation mode were performed when the shortening was equal to or less than 2 cm. Bifocal procedures were conducted when shortening was more than 2 cm and an ascending technique with distal femoral metaphyseal corticotomy was utilised.

Augmentation for delayed union and filling the bone gap was accomplished using iliac crest bone grafting, with or without fibular strut grafting. Antibiotic-impregnated cement beads were used in cases with long-standing resistant infections without significant bone loss and antibiotic-impregnated cement blocks were used when there was both fulminant infection and primary bone loss or significant lengths of bone were resected due to non viability. Another procedure was required to remove the cement beads or block when the infection came under control.

In 14 patients, the adult limb reconstruction system (Saturn Ortho Equipments, Pune, India) was used, while in four patients, the rail external fixator system (SH Pitkar Orthotools, Pune, India) was employed. The principles of both fixators were the same; the choice of implant company differed based on patient affordability. The wound was lavaged thoroughly and closed in layers over a suction drain.

Postoperatively, injectable antibiotics in the form of cefuroxime (1.5 g every 12 hours) and amikacin (500 mg every 24 hours) were started empirically. Corticotomy and bone lengthening were performed in 11 patients with limb shortening, while seven patients received no lengthening procedure. Bone transport commenced seven days after corticotomy, with a transport rate of 1.00 mm per day in four divided increments. Joint motion was initiated as early as possible after the operation. Partial weight-bearing was started for all cases, depending on the patient's pain, compliance, local soft-tissue condition and bone quality. Full weight-bearing was initiated after three cortex healings were observed on radiographs and as tolerated by the patient. The monolateral external fixator was maintained until three cortex healings and clinical signs of union were observed by checking for active straight leg raising after removing the rail, with pins left in situ.

Patients were asked to follow-up on an outpatient basis at six weeks, three months, six months and one year. At the follow-up visits, signs of infection, including discharge, sinus tracts, fever, tenderness, and radiological signs of healing (callus formation) were assessed. Lengthening Index (LI), defined as the number of months an external fixator is mounted to achieve one centimeter of lengthening (months/cm), ROM of the hip and knee were assessed.

PCS and MCS from the SF-36 [19] survey, as well as the LEFS [20], were evaluated, along with complications such as pin tract discharge and pin loosening. The PCS and MCS from the SF-36 are widely used survey tools to assess health-related quality of life, with higher scores indicating better health status. The LEFS [20] is a questionnaire used to measure a patient's functional status in the lower extremities. It consists of 20 questions, each scored from 0 to 4, with a minimum score of 0 (worst function) and a maximum score of 80 (best function). All three scores were obtained preoperatively and at the one-year follow-up.

Paley's score [21] was used to assess the bone healing outcome, evaluating both bone healing and functional recovery and categorising results into excellent, good, fair, or poor. This assessment was conducted at the one-year follow-up. Complications were classified according to the Paley classification as problems, obstacles, or true complications. A problem represented difficulties that required no operative intervention to resolve.

STATISTICAL ANALYSIS

All collected data were analysed using Statistical Package for the Social Sciences (SPSS) or EPI INFO software, applying both descriptive and inferential statistical methods such as the paired t-test. The level of significance considered was 0.05.

RESULTS

The results were analysed for 18 patients with a one-year follow-up. The cohort consisted of 17 male patients and one female patient. Among the total patients, 12 (66.7%) were in the age group of 20 to 40 years, while 6 (33.3%) were in the age group of 40 to 60 years. There was no significant difference between the age groups and gender in terms of union rates or functional outcomes. Out of the 18 patients, 3 (16.67%) had co-morbidities, including hypertension, diabetes, and hypothyroidism, while 15 (83.33%) had no co-morbidities. The mode of injury for all patients was a RTA.

In 12 patients (66.67%), the site of non union was the shaft of the femur; in five patients (27.78%), the site of non union was the supracondylar area of the femur; and one patient (5.56%) had concomitant non union in both the shaft and the supracondylar area. The mean duration from trauma to surgery for non union, using a monolateral external fixator, was 13 months (range: 4-24 months). The mean number of previous surgical procedures was 3.4 (range: 1-4).

All patients had a compound fracture at the onset and all presented with infected non union. Seven patients had oligotrophic non union, six patients had defect non union, three had the "elephant foot" type of non union, and two had the atrophic type of non union. Clinical and radiological signs of infection, such as discharging sinuses in various stages, were present in all 18 patients; fever was observed in 10 patients, and increased local temperature and tenderness at the non union site were clinically evident in all patients.

Augmentation for delayed union and filling the bone gap was accomplished through iliac crest bone grafting, fibular strut grafts, or both. In four cases (22.2%), only iliac crest bone grafting was performed, while in two cases (11.11%), iliac crest bone grafting was combined with fibular strut grafting to address primary bone loss [Table/Fig-1]. In two cases (11.11%), antibiotic-impregnated cement beads were inserted along with the fixator application in situations where three to four previous surgeries had been performed and frank signs of infection persisted without bone loss. In two additional

cases (11.11%), an antibiotic-impregnated cement block was used in cases of both fulminant infection and primary bone loss, or where greater lengths of bone were resected due to non viability.

Graft used	n (%)
ICBG	4 (22.2)
ICBG+ Fibula	2 (11.1)
No graft	12 (66.7)
Total	18 (100)

[Table/Fig-1]: Patient distribution as per the type of graft used.
*ICBG: Iliac crest bone graft

Signs of persistent infection were observed in seven patients at six weeks postsurgery, in three patients at three months postsurgery, and in one patient each at six months and one year postsurgery [Table/Fig-2].

Sign of infection at	n (%)		Total
	Yes	No	
6th week	7 (38.89)	11 (61.11)	18
3rd month	3 (16.67)	15 (83.33)	18
6th month	1 (5.56)	17 (94.44)	18
1st year	1 (5.56)	17 (94.44)	18

[Table/Fig-2]: Patient distribution as per sign of infection on respective follow-up.

Signs of union were present in 15 out of 18 patients at six weeks, both radiologically and clinically. At three months postsurgery, three patients again showed poor signs of union; therefore, iliac crest bone grafting was performed in these patients around three months post-surgery. At six months postsurgery, all except one patient demonstrated good signs of radiological and clinical healing [Table/Fig-3]. The success rate regarding clinical and radiological union in this study was 94.4%. The mean follow-up duration was 2±1 year. The mean time to bony union in this study was 7±2 months. The mean healing time in the corticotomy and bone-lengthening group was 10.5±1 months, while the mean healing time in the non lengthening group was 6±1.5 months. The mean length achieved in the corticotomy and lengthening group was 4±0.75 cm.

Union	n (%)		Total
	Yes	No	
6th week	15 (83.33)	3 (16.67)	18
3rd month	15 (83.33)	3 (16.67)	18
6th month	17 (94.44)	1 (5.56)	18
1st year	17 (94.44)	1 (5.56)	18

[Table/Fig-3]: Patient distribution for signs of union at respective follow-ups.

At the one-year follow-up, the mean residual limb length discrepancy was 1.75±1.25 cm, and there was no limb length discrepancy in 33.33% of patients (six patients) at the one-year follow-up. The mean time to gain one centimeter in length (Lengthening Index) was 2.8±0.42 months/cm.

The mean limb length discrepancy significantly decreased from preoperative to postoperative assessments at the 6th month and the 1st year (p-value <0.05) [Table/Fig-4]. The mean hip flexion ROM significantly improved from preoperative to postoperative at the 6th week, 3rd month, 6th month, and 1st year (p-value <0.05) [Table/Fig-5]. A significant difference was found between the preoperative and postoperative mean knee flexion ROM at the 6th week, 3rd month, 6th month, and 1st year (p-value <0.05) [Table/Fig-6]. According to Paley's bone and functional outcome scoring, all patients except one achieved bone union. For the bone outcome, 11 patients had an excellent outcome, six patients had a good outcome, no patients had a fair outcome, and one patient had a poor outcome [Table/Fig-7]. Similarly, for functional outcomes, six patients had excellent outcomes, and only one patient had a poor outcome [Table/Fig-8]. Significant improvement was observed in the mean PCS from preoperative to the one-year postoperative assessment (p-value <0.001) [Table/Fig-9]. However, no significant improvement was found in the mean MCS from preoperative to postoperative assessment at one year, using the paired t-test (p-value=0.122) [Table/Fig-10].

Limb length discrepancy at	Number of patients	Limb length discrepancy	p-value
		Mean±SD	
Preoperative	18	3.18±1.89	
6th week	18	3.27±1.85	0.796
3rd month	18	2.82±1.40	0.371
6th month	18	2.18±1.33	0.049
1 year	18	1.44±1.29	0.042

[Table/Fig-4]: Limb length discrepancies at respective follow-ups.
p-value is in comparison with pre-operative data

Hip flexion ROM	Number of patients	Hip flexion ROM	p-value
		Mean±SD	
Preoperative	18	109.09±10.44	
6th week	18	28.64±13.80	<0.001
3rd month	18	46.36±18.59	<0.001
6th month	18	70.91±21.19	0.017
1 year	18	103.33±14.95	<0.001

[Table/Fig-5]: Hip Range of Motion (ROM) achieved at respective follow-ups.

Knee flexion ROM	Number of patients	Knee flexion ROM	p-value
		Mean±SD	
Preoperative	18	108.18±7.51	
6th week	18	7.27±7.86	<0.001
3rd month	18	24.55±16.95	<0.001
6th month	18	47.27±27.14	<0.001
1 year	18	95.56±14.23	<0.001

[Table/Fig-6]: Knee flexion achieved at respective follow-ups.

Paley score for bone outcome	n (%)
Poor	1 (5.6)
Fair	0
Good	6 (33.3)
Excellent	11 (61.1)
Total	18 (100)

[Table/Fig-7]: Patient distribution as per Paley's score bone outcome.

Paley score for functional outcome	n (%)
Poor	1 (5.6)
Fair	2 (11.1)
Good	9 (50.0)
Excellent	6 (33.3)
Total	18 (100)

[Table/Fig-8]: Patient distribution as per Paley's functional outcome.

PCS at	Number of patients	PCS	p-value
		Mean±SD	
Preoperative	18	28.11±8.09	<0.001
1 year	18	46.83±4.61	

[Table/Fig-9]: PCS score preoperative and postoperative at one year.
*PCS: Physical component score

Using the paired t-test, with a p-value <0.05, there was significant difference between preoperative and postoperative assessments at one year for the mean LEFS (p-value <0.0001) [Table/Fig-11]. In this study, pin tract infection (n=6, 33.33%) was the most

MCS at	Number of patients	MCS	p-value
		Mean±SD	
Preoperative	18	53.66±3.77	0.122
1 year	18	51.22±7.15	

[Table/Fig-10]: MCS score preoperative and postoperative at one year.
*MCS: Mental component score

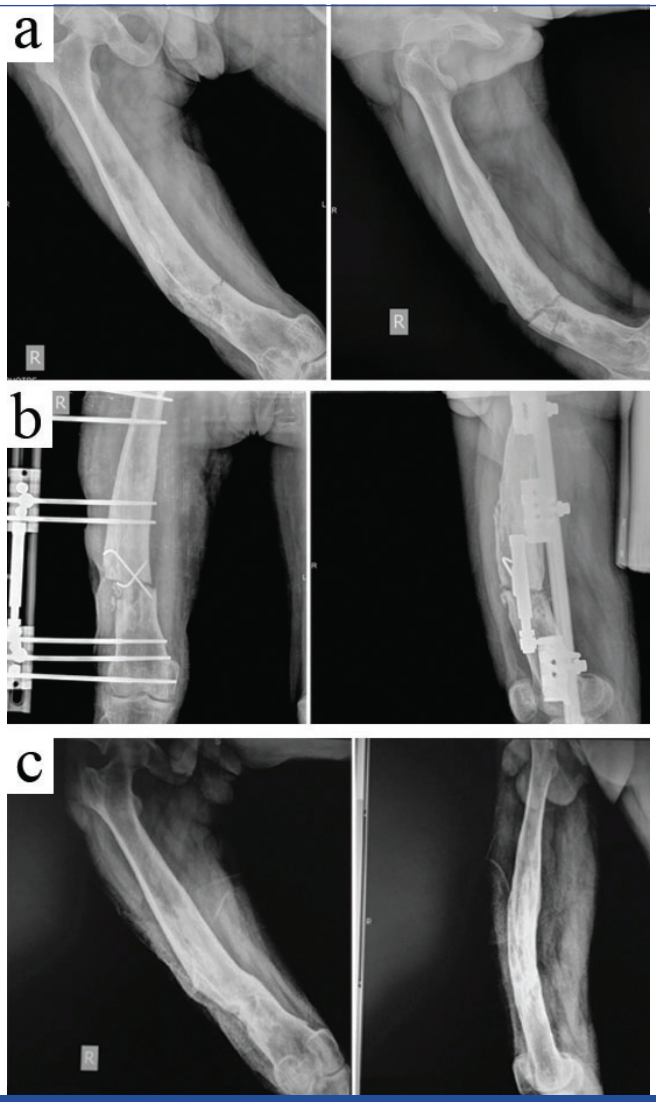
common problem, followed by pain during the distraction phase (n=5, 27.78%) [Table/Fig-12]. Progressive union of the fracture is illustrated in [Table/Fig-13,14], demonstrating gradual union from preoperative X-rays to complete union by the one-year X-rays.

LEFS	Number of patients	LEFS	p-value
		Mean±SD	
Pre-operative	18	21.22±1.07	<0.0001
1 year	18	70.22±1.67	

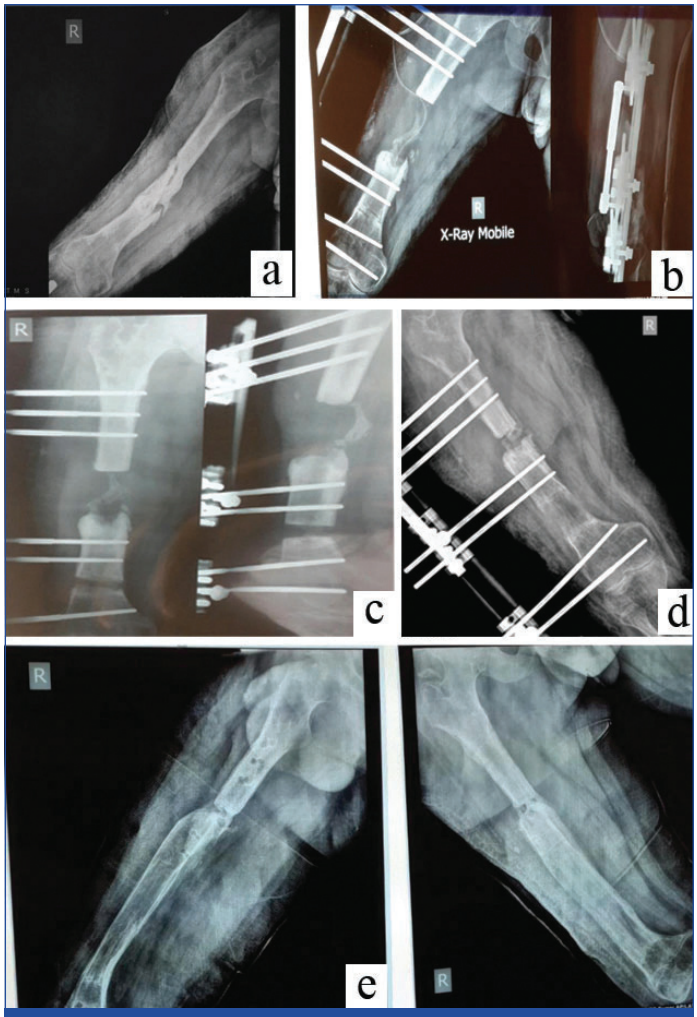
[Table/Fig-11]: LEFS score preoperative and postoperative at one year.
*LEFS: Lower extremity functional score

Complications	n (%)
Joint stiffness	13 (72.22)
Pin tract infection	6 (33.33)
Pain during distraction	5 (27.78)
Delayed union	3 (16.67)
Non union	1 (5.56)
Persistent discharge	1 (5.56)

[Table/Fig-12]: Complications.



[Table/Fig-13]: (a) Pre-operative X-rays; (b) Immediate postoperative X-rays; (c) 1 year postop X-ray.



[Table/Fig-14]: (a) Preoperative X-ray; (b) Immediate Postoperative X-ray; (c) 6 weeks postoperative; (d) 6 months postoperative; (e) 12 months postoperative X-ray.

DISCUSSION

All of the non unions in this study united between 4 to 12 months, with a mean time of 7±2 months, compared to 12.6 months in a study by Hashmi MA et al., [15], 7.3 months (range 5-15 months) in a study by Arora S et al., 37-48 weeks in a study by Seenappa HK et al., and nine months (range 6-14 months) in a study by Lakhani A et al., [15,22-24].

The success percentage regarding clinical and radiological union in this study was 94.4%. Of these, 22.3% of patients required augmentation with cancellous autologous iliac crest bone grafting for union, while 11.1% were augmented with both iliac crest graft and fibular strut grafting. There was no union in one patient despite iliac crest bone grafting. This was comparable to the study by Seenappa HK et al., in which the union rate was 89.2% [23]. It was also comparable to the results by Hashmi MA et al., where the success rate in terms of clinical and radiological healing with initial fixation was 90%, and 100% union was reported in a series by Lakhani A et al., [15,24].

A 94.44% eradication of infection was achieved upon follow-up ranging from four months to one year, compared to an eradication rate of 91.66% of cases in the study by Seenappa HK et al., [23]. Infected femoral non unions have multiple aetiologies, including compound fractures, contaminated wounds, soft-tissue degloving, bone loss, vascular insults and multiple surgeries. The Ilizarov method revolutionised the management of these conditions by enabling simultaneous treatment of non union and infection [21]. The variety of surgical techniques described in the literature makes comparing surgical outcomes across different studies difficult. This study emphasises the application of the principles of distraction histogenesis and the use of external fixation for controlling infection together in the treatment of infected femoral non union.

In the study, the majority of patients were in the age group of 20-40 years. RTA were the mode of injury in all cases. This can be explained by the fact that people in this age group are more prone to open fractures of long bones secondary to high-velocity trauma (RTA). In this study, the mean number of previous surgical procedures was 3.4 (range 1-4). The mean number of previous surgical procedures was 3.2 per segment (range 1-11) in the study by Hashmi MA et al., [15]. This was also comparable to the study by Arora S et al., where patients underwent a mean of 2.9 (range 1-7) surgical procedures before presentation, and the mean duration from trauma to presentation was 7.7 months (range 6-18) [22].

The mean length achieved in the corticotomy and lengthening group was 4±0.75 cm, and the mean residual limb length discrepancy at the 1-year follow-up was 1.75±1.25 cm. A study by Hashmi MA et al., reported a mean length gain of 4.5 cm (range: 1.5-12 cm), while the average lengthening achieved was 4.57 cm (range: 3-8 cm). The mean residual limb length discrepancy in the study by Seenappa HK et al., was 1.36 cm [23].

In this study, a significant decrease was observed in the mean ROM for hip and knee flexion when comparing preoperative and postoperative measurements at the one-year follow-up. In contrast, there was no significant difference in preoperative and post-treatment joint movements (p-value >0.05) in the study by Seenappa HK et al., [23]. This lack of improvement may be attributed to longstanding infection, secondary fibrosis, extra-articular adhesions around the quadriceps and prolonged immobilisation in the patients of this study.

A significant improvement in the mean PCS was noted when comparing preoperative and postoperative scores at the 1-year mark. However, there was no significant improvement in the MCS between preoperative and postoperative measurements at one year. This suggests that while patients were physically satisfied postoperatively, there was no corresponding improvement in their mental status, and they were not mentally satisfied. A significant improvement was observed in the mean LEFS score postoperatively at the 1-year follow-up, further supporting the conclusion that patients were functionally satisfied.

According to Paley's functional and bone outcome scoring, the results were comparable to outcomes in the studies by Hashmi MA et al., Arora S et al., Seenappa HK et al., and Lakhani A et al., [Table/Fig-15] [15, 22-24].

Results	Present study n (%)	Hashmi MA et al., [15] n (%)	Arora S et al., [22] n (%)	Seenappa HK et al., [23] n (%)	Lakhani A et al., [24] n (%)
Bone					
Excellent	11 (61.1)	67 (61.5)	5 (33)	22 (79)	10 (50)
Good	6 (33.3)	38 (34.8)	8 (54)	3 (11)	8 (40)
Fair	- (-)	4 (3.7)	2 (13)	- (-)	2 (10)
Poor	1 (5.6)	- (-)	- (-)	3 (10)	- (-)
Functional					
Excellent	6 (33.3)	46 (42.2)	12 (80)	11 (40)	9 (45)
Good	9 (50)	55 (50.5)	3 (20)	14 (50)	8 (40)
Fair	2 (11.1)	4 (3.7)	- (-)	- (-)	2 (10)
Poor	1 (5.6)	- (-)	- (-)	- (-)	-
Failure	- (-)	5 (4.6)	- (-)	3 (10)	1 (5)

[Table/Fig-15]: Comparison chart according to Paley's functional and bone outcome scoring.

Limitation(s)

A limitation of this study was the lack of a comparison treatment group, which hampers the formulation of true evidence-based guidelines for optimal treatment of this patient group. Additionally, the study included more men than women, which may influence the inflammatory response and outcomes after trauma. Nevertheless, this study represents a significantly large prospective group of patients in whom infected non union of the femur was treated successfully.

CONCLUSION(S)

The monolateral external fixation can provide stable fixation for the treatment of established non unions and is an effective method for eradicating infection. It serves as an alternative to Ilizarov fixation in the management of infected non union of the femur.

Further studies with larger sample sizes and longer follow-up periods are recommended to validate these findings. Comparative studies between monolateral external fixation and Ilizarov fixation could help establish definitive treatment protocols. Additionally, research into the integration of newer biomaterials or adjuvant therapies (e.g., local antibiotic delivery systems) may enhance outcomes in the management of infected non unions.

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