

## Predictors of Bone and Functional Outcomes Of Ilizarov Ring Fixation in the Treatment of Infected Non-Union of the Distal Femur

Kaneriya Aas Rajendrakumar<sup>1</sup>, K. Srikant<sup>2</sup>, Anuraag Mohanty<sup>1</sup>, Priyankar Nanda<sup>1</sup>, Mihir Anantbhai Tejura<sup>\*3</sup>, Subhrajee Dash<sup>1</sup>

<sup>1</sup> Orthopaedics Resident Doctor, Department of Orthopaedics, Kalinga Institute of Medical Sciences, KIIT Deemed to be University, Bhubaneswar, Odisha, India

<sup>2</sup> Professor, Department of Orthopaedics, Kalinga Institute of Medical Sciences, KIIT, Deemed to be University, Bhubaneswar, Odisha, India

<sup>3</sup> Senior Resident, Department of Orthopaedics, Civil Hospital, Morbi, Gujarat, India

### Corresponding Author

Dr. Mihir Anantbhai Tejura  
Senior Resident, Department of Orthopaedics  
Civil Hospital, Morbi, Gujarat, India  
Email: mihirt97ortho@gmail.com  
Phone: +91-9426394042

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### ABSTRACT

**Background:** Infected non-union of the distal femur is a major clinical challenge. While the Ilizarov technique is used, success predictors are poorly defined. This study aimed to identify predictors of bone and functional outcomes after Ilizarov fixation for this condition.

**Methods:** A prospective cohort study followed 20 patients (mean age 34.1) treated for infected distal femur non-union from 2023-2024. All underwent radical debridement and Ilizarov stabilization. Outcomes were evaluated using ASAMI criteria.

**Results:** Successful bone and functional outcomes were achieved in 85% and 70% of patients, respectively. Pin site infection occurred in 65%. Significant predictors for poorer bone outcomes included: >3 previous operations (p=0.035), treatment >45 weeks (p=0.022), hospital stay >15 days (p=0.030), pin site infection (p=0.027), axial deviation >7° (p=0.022), and delayed weight-bearing (>10 days, p=0.011). Significant predictors for poorer functional outcomes included: the presence of comorbidities (p=0.003), >3 previous operations (p=0.036), treatment >45 weeks (p=0.007), hospital stay >15 days (p=0.008), pin site infection (p=0.004), axial deviation >7° (p=0.007), and delayed weight-bearing (>10 days, p=0.011).

**Conclusions:** Success is achievable but significantly associated with surgical history and postoperative care. A history of multiple failed surgeries, prolonged treatment, and complications like pin site infection are strong negative predictors. Findings support early Ilizarov treatment and meticulous postoperative management.

Level of Evidence: Therapeutic Level IV.

**KEYWORDS:** Study Design and Patient Selection, Preoperative Assessment and Surgical Technique.

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### INTRODUCTION

Infected non-union of long bone is a complex and debilitating condition that presents a substantial obstacle in orthopaedic surgery, particularly in the context of high-energy trauma [1, 2]. The distal femur is an especially challenging anatomical location for this pathology due to a confluence of adverse factors, including poor metaphyseal bone quality, the presence of a short distal fragment that complicates stable fixation, and frequently compromised surrounding soft tissues [3, 4]. These challenges are often compounded by previous implant failure and extensive scarring from prior surgical interventions. Consequently, patients face a high risk of profound complications, including persistent infection, limb length discrepancy, post-traumatic osteoarthritis, severe knee stiffness, and, in refractory cases, the need for amputation [1, 5].

The Ilizarov method, an external fixation system based on the principles of distraction osteogenesis, has emerged as a powerful limb-salvage strategy for these complex cases [6]. The technique offers a unique, multifaceted solution by enabling the simultaneous management of infection, bone loss, and deformity [7, 8, 9]. The standard protocol involves meticulous debridement of all infected and necrotic tissue, removal of any existing hardware, and application of a stable circular frame construct [10].

This approach not only provides the mechanical stability necessary for bone healing but also allows for correction of angular and rotational deformities, limb lengthening via corticotomy and bone transport, and early patient mobilization with weight-bearing, which mitigates disuse osteoporosis [11, 12].

Despite its established efficacy, the application of the Ilizarov technique is technically demanding and is associated with a distinct profile of complications, most notably pin site infections, which have been reported in up to 65% of cases in some series [12, 13]. The prolonged treatment duration and the need for intensive postoperative care place a significant burden on both the patient and the healthcare system [5]. While the benefits of the technique are clear, there is a relative paucity of evidence systematically identifying the specific patient and treatment factors that predict a successful outcome. A clearer understanding of these predictors is crucial for optimizing patient selection, managing expectations, and developing tailored interventions to mitigate risks. Therefore, the purpose of this study was to identify the clinical, surgical, and postoperative predictors of bone and functional outcomes in patients treated with Ilizarov ring fixation for infected non-union of the distal femur.

## MATERIALS AND METHODS

### Study Design and Patient Selection

A prospective cohort study was conducted at a single tertiary care hospital between March 2023 and March 2024. The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrollment. (IEC number: Ref. No.: KIIT/KIMS/IEC/1236/2023)

A consecutive series of 20 patients who presented with infected non-union of the distal femur and met the eligibility criteria were included. No formal sample size calculation was performed due to the low incidence of this complex condition and time constraints on patient recruitment at a single center. Inclusion criteria were an age of 18 years or older and a confirmed diagnosis of infected non-union of the distal femur based on clinical, radiological, and microbiological findings. Patients were excluded if they had pathological fractures, pre-existing degenerative or inflammatory joint disease, malignancy, or segmental femur fractures. Patients receiving systemic corticosteroids at the time of presentation were also excluded to maintain a homogenous study population.

### Preoperative Assessment and Surgical Technique

All patients underwent a standardized preoperative evaluation. Clinical assessment included evaluation of mobility at the fracture site, local signs of infection such as a discharging sinus or erythema, the status of the surrounding soft tissue envelope, limb-length discrepancy, and the condition of the adjacent hip and knee joints. Radiological assessment involved anteroposterior and lateral radiographs of the full-length femur to evaluate the bone ends, quantify the fracture gap, and identify any sequestra or deformity. Microbiological assessment included culture and sensitivity testing of any discharge from sinus tracts.

All patients were treated with a single-stage surgical procedure. The protocol consisted of radical debridement of the non-union site, with removal of all nonviable soft tissue, sequestra, and previously implanted hardware. Multiple deep tissue samples were obtained intraoperatively for microbiological culture and histopathological examination. The sclerotic bone ends were resected back to healthy, bleeding bone (the “paprika sign”), and the medullary canal was reconstituted. Following debridement, the fracture was reduced, and a pre-constructed Ilizarov ring fixator was applied for definitive stabilization. The decision to perform a proximal femoral cortotomy for subsequent bone transport was made intraoperatively, based on the size of the bone defect created after debridement.

### Postoperative Management and Follow-up

A standardized postoperative protocol was implemented for all patients. This included regular pin site care with antiseptic solutions, a structured rehabilitation program emphasizing early mobilization of knee and ankle joints, and progressive weight-bearing as tolerated. Patients were followed up clinically and radiologically at 6 weeks, 3 months, 6 months, and 12 months postoperatively.

### Outcome Measures

The primary outcomes were the bone and functional results at the final follow-up, which were graded according to the criteria established by the Association for the Study and Application of Methods of Ilizarov (ASAMI). The standard ASAMI criteria were used.

\* Bone results were categorized as excellent, good, fair, or poor based on the achievement of union, absence of infection, residual angular deformity of less than 7°, and limb length discrepancy of less than 2.5 cm.

\* Functional results were categorized similarly based on the patient’s ambulatory status, presence of a limp, joint stiffness, pain, and reflex sympathetic dystrophy.

Secondary outcomes included the final KSS, the total duration of treatment with the external fixator, the total length of hospital stay, and the incidence of postoperative complications, including pin site infection and axial deviation.

### Statistical Analysis

Data were entered into a Microsoft Excel spreadsheet and analyzed using SPSS software (version 22.0). Continuous variables were expressed as “mean and standard deviation” (SD), while categorical variables were expressed as frequencies and percentages. The cut-off points for time-dependent variables—duration of treatment (>45 weeks), total hospital stay (>15 days),

and time to full weight-bearing (>10 days)—were determined by identifying clinically relevant thresholds corresponding approximately to the mean or a key percentile within the study cohort, rather than a formal median split.

The association between potential predictor variables (including age, comorbidities, number of previous surgeries, treatment duration, hospital stay, and postoperative complications) and the final ASAMI outcomes (categorized as successful Excellent/Good vs. unsuccessful Fair/Poor) was assessed using the Chi-square test or Fisher exact test, as appropriate. A p-value of less than 0.05 was considered statistically significant. No data were missing for the primary or secondary outcome measures.

#### Additional Information

No funding was received for this study. The authors declare no conflicts of interest.

## RESULTS

### Cohort Demographics and Baseline Characteristics

The study cohort comprised 20 patients, of whom 18 (90%) were male and 2 (10%) were female. The mean age of the participants was  $34.1 \pm 11.4$  years, with 15 patients (75%) being in the 18 to 40-year-old age group. The majority of initial injuries were high-energy, resulting in Gustilo-Anderson Type IIIB open fractures in 17 patients (85%). Comorbidities were present in 4 patients (20%).

The mean time from the initial trauma to the application of the Ilizarov fixator was  $12.3 \pm 8.5$  months. A significant portion of the cohort had a history of multiple prior surgical interventions, with 8 patients (40%) having undergone more than three previous operations. Microbiological analysis of intraoperative samples identified *Staphylococcus aureus* as the most common infecting organism in 11 cases (55%), followed by *Pseudomonas* species in 6 cases (30%) (Table 1).

### Treatment and Clinical Outcomes

The mean duration of treatment with the Ilizarov external fixator was  $43.2 \pm 20.5$  weeks, and the mean total hospital stay for the index procedure was  $15.3 \pm 5.9$  days (Table 2).

Based on the ASAMI criteria for bone results at final follow-up, 6 patients (30%) achieved an Excellent outcome, 11 (55%) achieved a Good outcome, 2 (10%) had a Fair outcome, and 1 (5%) had a Poor outcome. Overall, a successful bone outcome (defined as Excellent or Good) was achieved in 17 patients (85%).

According to the ASAMI functional criteria, 5 patients (25%) had an Excellent outcome, 9 (45%) had a Good outcome, 4 (20%) had a Fair outcome, and 2 (10%) had a Poor outcome. A successful functional outcome was achieved in 14 patients (70%) (Table 3). The mean final KSS for the cohort was  $123 \pm 28.1$ .

### Representative Cases

**Figure 1: Case Example 1** A multi-part figure showing the treatment course for a patient with infected non-union of the distal femur. (A) Pre-operative X-ray showing the infected non-union with a plate *in situ*. (B) Follow-up X-ray at 1 year, after Ilizarov treatment, showing complete union at both the fracture site and the proximal corticotomy site. (C) Final functional outcome after fixator removal, demonstrating the patient's ability to sit cross-legged with good knee range of motion.



**Figure 1(A)** Preop xray of infected non union of distal femur with plate in situ



Figure 1(B) Follow up x ray after 1 year Fracture site union achieved



Figure 1(C) Patient functional outcome followed at 1 year after ilizarove removal , able to sit with cross legs

**Figure 2: Case Example 2** A multi-part figure showing the treatment course for a second patient. (A) Pre-operative X-ray showing the infected non-union of the distal femur with a plate *in situ*. (B) Follow-up X-ray at 1 year showing consolidated union at both the fracture and corticotomy sites. (C) Final functional outcome demonstrating the patient's ability to flex the knee to 90° (C1) and stand without pain (C2).

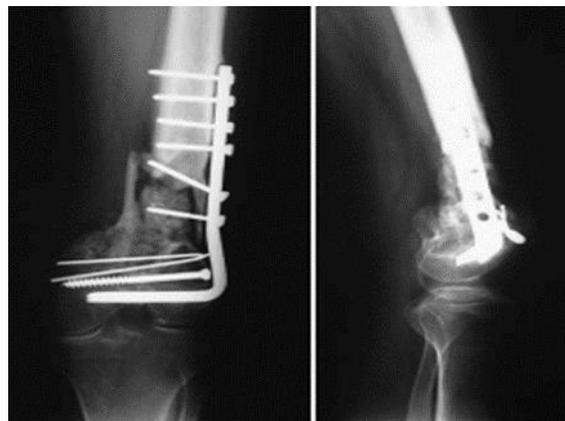
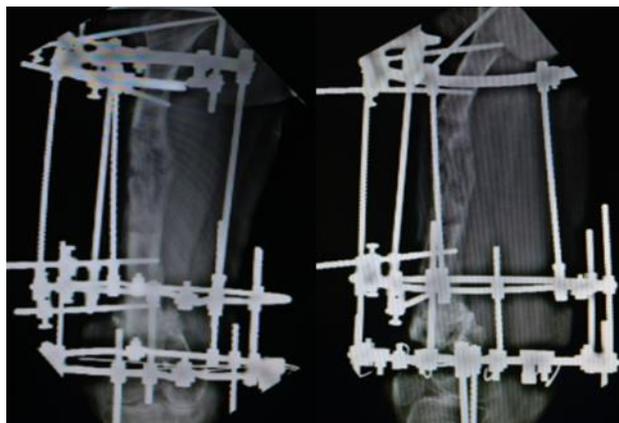


Figure 2(A) re-operative X-ray showing the infected non-union of the distal femur with a plate *in situ*.



**Figure 2 (B) Follow-up X-ray at 1 year showing consolidated union at both the fracture and corticotomy sites**



**Figure 2 (C1) Final functional outcome demonstrating the patient's ability to flex the knee to 90° (C1)**



**Figure 2 (C2) Final functional outcome demonstrating the patient stand without pain (C2).**

The ethics statement in the Methods section should confirm that written informed consent was obtained from all patients

### **Complications**

The most frequently encountered complication was pin site infection, which occurred in 13 patients (65%). These infections were managed with local wound care and oral antibiotics and did not necessitate pin or K-wire removal in any case. At the time of frame removal, residual axial deviation greater than 7° was observed in 6 patients (30%) (Table 2).

### **Predictors of Outcomes**

The statistical analysis identified several factors that were significantly associated with both bone and functional outcomes (Table 4 and Table 5). A history of more than three previous operations was a significant predictor of an unsuccessful result, for both bone outcomes ( $p = 0.035$ ) and functional outcomes ( $p = 0.036$ ). Similarly, a prolonged duration of treatment ( $> 45$  weeks) was

associated with poorer bone ( $p = 0.022$ ) and functional ( $p = 0.007$ ) results. A total hospital stay of more than 15 days was also a significant predictor of worse bone ( $p = 0.030$ ) and functional ( $p = 0.008$ ) outcomes.

The development of postoperative complications was strongly predictive of the final result. The presence of a pin site infection was significantly associated with poorer bone ( $p = 0.027$ ) and functional ( $p = 0.004$ ) outcomes. The presence of residual axial deviation greater than  $7^\circ$  was also a significant predictor of worse bone ( $p = 0.022$ ) and functional ( $p = 0.007$ ) results. Finally, a delay in achieving full weight-bearing walking ( $> 10$  days) was significantly associated with unsuccessful bone and functional outcomes ( $p = 0.011$  for both).

The presence of a comorbidity was found to be a significant predictor of a poor functional outcome ( $p = 0.003$ ) but did not reach statistical significance as a predictor for the bone outcome ( $p = 0.084$ ). Age group and gender were not found to be significant predictors of either outcome in this cohort.

**Table 1: Patient Demographics and Baseline Clinical Characteristics (N=20)**

Characteristic	Value
<b>Age (years)</b>	
Mean $\pm$ SD	34.1 $\pm$ 11.4
Range	18-62
<b>Gender</b>	
Male	18 (90%)
Female	2 (10%)
<b>Fracture Type (Gustilo-Anderson)</b>	
IIIB	17 (85%)
IIIC	3 (15%)
<b>Presence of Comorbidity</b>	4 (20%)
<b>Time from Trauma to Ilizarov (months)</b>	
Mean $\pm$ SD	12.3 $\pm$ 8.5
<b>Number of Previous Operations</b>	
3 or $<$ 3	12 (60%)
$>$ 3	8 (40%)
<b>Infecting Organism</b>	
<i>Staphylococcus aureus</i>	11 (55%)
<i>Pseudomonas</i> spp.	6 (30%)
<i>Streptococcus</i> spp.	2 (10%)
<i>E. coli</i>	1 (5%)

Data are presented as n (%) or mean  $\pm$  standard deviation (SD).

**Table 2: Summary of Treatment Parameters and Postoperative Complications (N=20)**

Parameter / Complication	Value
<b>Duration of Treatment (weeks)</b>	
Mean $\pm$ SD	43.2 $\pm$ 20.5
<b>Total Hospital Stay (days)</b>	
Mean $\pm$ SD	15.3 $\pm$ 5.9
<b>Time to Full Weight-Bearing</b>	
10 or $<$ 10 days	9 (45%)
$>$ 10 days	11 (55%)
<b>Pin Site Infection</b>	13 (65%)
<b>Axial Deviation <math>&gt;</math> <math>7^\circ</math></b>	6 (30%)

Data are presented as n (%) or mean  $\pm$  standard deviation (SD).

**Table 3: Distribution of Final ASAMI Bone and Functional Outcome Scores**

ASAMI Score	Bone Results	Functional Results
	n (%)	n (%)
Excellent	6 (30%)	5 (25%)
Good	11 (55%)	9 (45%)
Fair	2 (10%)	4 (20%)
Poor	1 (5%)	2 (10%)
<b>Total</b>	<b>20 (100%)</b>	<b>20 (100%)</b>

**Table 4: Analysis of Predictors for Final ASAMI Bone and Functional Outcomes**

Predictor Variable	ASAMI Outcome (Excellent/Good) (%)	Bone n	ASAMI Outcome (Fair/Poor) (%)	Bone n	Bone P-value	ASAMI Functional Outcome (Excellent/Good) (%)	Functional n	ASAMI Functional Outcome (Fair/Poor) (%)	Functional n	Functional P-value
<b>Presence of Comorbidity</b>					<b>0.084</b>					<b>0.003</b>
No	15 (93.8%)		1 (6.2%)			14 (87.5%)		2 (12.5%)		
Yes	2 (50%)		2 (50%)			0 (0%)		4 (100%)		
<b>Number of Previous Operations</b>					<b>0.035</b>					<b>0.036</b>
3 or less than 3	12 (100%)		0 (0%)			11 (91.7%)		1 (8.3%)		
>3	5 (62.5%)		3 (37.5%)			3 (37.5%)		5 (62.5%)		
<b>Duration of Treatment</b>					<b>0.022</b>					<b>0.007</b>
45 or less than 45 weeks	14 (100%)		0 (0%)			13 (92.9%)		1 (7.1%)		
>45 weeks	3 (50%)		3 (50%)			1 (16.7%)		5 (83.3%)		
<b>Total Hospital Stay</b>					<b>0.030</b>					<b>0.008</b>
15 or less than 15\$ days	11 (100%)		0 (0%)			11 (100%)		0 (0%)		
>15 days	6 (66.7%)		3 (33.3%)			3 (33.3%)		6 (66.7%)		
<b>Pin Site Infection</b>					<b>0.027</b>					<b>0.004</b>
No	7 (100%)		0 (0%)			7 (100%)		0 (0%)		
Yes	10 (76.9%)		3 (23.1%)			7 (53.8%)		6 (46.2%)		
<b>Axial Deviation &gt; 7°</b>					<b>0.022</b>					<b>0.007</b>
Absent	14 (100%)		0 (0%)			13 (92.9%)		1 (7.1%)		
Present	3 (50%)		3 (50%)			1 (16.7%)		5 (83.3%)		
<b>Time to Weight-Bearing</b>					<b>0.011</b>					<b>0.011</b>
10 or less than 10 days	9 (100%)		0 (0%)			9 (100%)		0 (0%)		
>10 days	8 (72.7%)		3 (27.3%)			5 (45.5%)		6 (54.5%)		

## DISCUSSION

This study confirms that the Ilizarov method is a highly effective limb-salvage technique for the complex problem of infected non-union of the distal femur, with **85%** of patients in this cohort achieving a successful bone outcome. However, the analysis also identifies several critical predictors that significantly influence the likelihood of success, providing valuable insight for clinical decision-making and patient management.

A principal finding of this study is the profound negative impact of **multiple previous surgical interventions**. Patients who had undergone more than three prior operations had significantly worse bone and functional outcomes. This finding highlights that each failed surgery inflicts a cumulative biological penalty on the host environment. Repeated operations lead to progressive periosteal stripping, disruption of the extraosseous and medullary blood supply, and the formation of avascular scar tissue. This cascade of insults depletes the local biological potential required for the robust regenerative response that is central to the Ilizarov principle of distraction osteogenesis [6]. By the time a patient has endured multiple failed procedures, the fracture site is often a hostile, ischemic environment, making infection eradication and bone healing inherently more difficult [1, 5, 2]. This suggests that the Ilizarov technique should not be relegated to a last-resort salvage procedure but should be considered a definitive treatment option earlier in the management algorithm for infected non-union, potentially after the first failure of internal fixation [8, 15, 9].

The analysis also underscores that the success of the Ilizarov method is as dependent on meticulous postoperative management as it is on the initial surgical procedure. The development of **pin site infection** and the presence of **residual axial malalignment** were powerful predictors of poor outcomes [13, 12]. A pin site infection is not a minor nuisance. It is a source of persistent inflammation and pain that can severely impede a patient's ability to participate in essential rehabilitation and weight-bearing. In some cases, it can serve as a conduit for the re-seeding of the primary non-union site, thereby jeopardizing the entire reconstruction [1, 13]. Similarly, a residual axial deviation of more than 7° is evidence of a failure to maintain mechanical stability and alignment throughout the prolonged treatment course. Such malalignment leads to abnormal loading of the knee joint, causing pain and limiting function, which directly contributes to a poor functional score [7]. As these complications are largely modifiable, their predictive power highlights the need for comprehensive patient education on pin care, frequent clinical monitoring, and prompt frame adjustment to correct any loss of reduction.

An interesting distinction was observed between the predictors of bone and functional healing. The presence of **comorbidities** was a significant predictor of a poor functional outcome ( $p = 0.003$ ) but not of a poor bone outcome ( $p = 0.084$ ). This divergence can be explained by the different natures of these two healing processes. Bone union is primarily a local biological phenomenon. In this relatively young cohort (mean age 34 years), the intrinsic capacity for osteogenesis remained high enough to achieve union in most patients, provided the local infection was eradicated and mechanical stability was achieved [6]. Functional recovery, in contrast, is a systemic process that depends heavily on the patient's overall physiological reserve, motivation, and tolerance for a long and arduous rehabilitation program [7, 5]. Systemic comorbidities can create substantial barriers to physical therapy and functional advancement, even after the fracture has successfully united. This finding implies that surgeons must counsel patients, particularly those with significant comorbidities, that achieving a solid bone union is only one part of the journey. A multidisciplinary approach involving internists and physical therapists is essential to optimize systemic health and manage expectations regarding the final functional result.

The findings of this study are consistent with the broader literature. The observed rate of pin site infection (65%) is within the range reported in other series on Ilizarov fixation for complex non-unions [13, 12]. The identified predictors, such as the number of prior surgeries and the presence of complications, align with principles established in studies by authors such as Paley et al. [12] and Madhusudhan et al. [13], reinforcing their clinical relevance.

These findings suggest that early adoption of Ilizarov fixation for failed distal femur non-unions and the implementation of stringent, protocol-driven pin site care are crucial steps that could improve both bone and functional outcomes.

**This study has several limitations:** The primary limitation is the **small sample size of 20 patients**, which restricts the statistical power of the analysis and the generalizability of the findings. The study was conducted at a single institution, which may introduce selection bias. Furthermore, the **12-month follow-up period is relatively short** and does not allow for the assessment of long-term outcomes such as the development of post-traumatic arthritis or the risk of late refracture. Future multicenter studies with larger cohorts and longer-term follow-up are needed to validate these findings.

## CONCLUSION

Ilizarov ring fixation is a reliable treatment for infected non-union of the distal femur, but successful outcomes are **significantly associated** with specific patient and treatment factors. A history of multiple failed surgical interventions and the development of postoperative complications, particularly pin site infections and residual malalignment, are strong negative predictors. These findings support considering Ilizarov fixation earlier in the treatment course and implementing meticulous postoperative management to optimize outcomes.

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