Original Article

Bone Outcome after Treatment of Infected Nonunion Femoral Shaft Fracture by Ilizarov Method

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ABSTRACT

Introduction: *This study addresses the challenging issue of infected nonunion femoral shaft fractures, a condition complicated by soft tissue and bone involvement, persistent multi-bacterial infection, limb length discrepancy, deformities, joint stiffness, and multiple draining sinuses. This study aimed to analyze the bone outcome of treatment of infected non-union femoral shaft fracture by the Ilizarov method.* ***Methods and materials:*** *This prospective observational study, conducted at the National Institute of Traumatology and Orthopedic Rehabilitation (NITOR) in Dhaka, Bangladesh, spanned from May 2018 to August 2020. The study included 20 patients selected through purposive sampling. Data analysis was performed using the SPSS version 22.0 computer software program.* ***Result:*** *The mean bone gap was 2.7±1.7 cm, with 60% having a gap of 0 to 2 cm and 40% more than 2 cm. Radiological union took an average of 7.85±2.1 months, with 50% achieving union within 4 to 7 months and 50% within 8 to 11*

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months. Regarding limb length discrepancy, 25% had none, and the mean discrepancy was 1.2±0.9 cm. According to the Association for the Study and Application of the Method of Ilizarov (ASAMI) criteria, 40% had excellent bone outcomes, 45% were good, and 15% were fair. ***Conclusion:*** *This study concludes that the Ilizarov ring fixator offers a reliable and successful method not only for stabilization and satisfactory bone union but also for correcting length discrepancies and eradicating infection.*

Keywords: *Femur, Ilizarov method, Infected, Non-union, Limb length discrepancy*

INTRODUCTION

Infected non-union of the femur poses a common challenge in clinical practice, complicating factors such as bone loss, deformities, limb-length inequalities, and polybacterial infection [1,3]. Ilizarov's methods prove effective by eliminating infection, addressing bone defects, and promoting bone union through progressive histogenesis [4]. Simultaneously, it corrects deformities and limb-length discrepancies during bone transport, offering a comprehensive approach to the complexities of infected non-union cases [5]. The treatment goal for an infected non-union femur is a well-aligned, healed, painless, and functional limb, prioritizing limb salvage and reconstruction over amputation and prosthesis, particularly when the distal neurovascular status remains intact [3]. Factors contributing to the complexity of infected non-union cases include repeated surgeries, cicatrization of soft tissues, avascular environment, sinus tract formation indicating dead bone, thrombosis of blood vessels leading to necrosis, and joint stiffness due to prolonged immobilization and multiple surgical interventions. Another crucial concern is antibiotic resistance development. The high rate of limb length incongruity and malformations necessitates multiple sessions in reconstructive surgeries [3,6]. The Ilizarov method provides a comprehensive solution for infected non-union [7]. The construct's stability enables early weight-bearing and joint mobilization, offering effective modification of angulation and rotation at the non-union site [8,9]. Additionally, the Ilizarov ring fixator, with its multiplanar stability, facilitates bone defect management through corticotomy, bone transport, and mono-focal or bifocal compression distraction, depending on the specific requirements [10]. The regeneration of new bone to fill the defect is achieved through distraction osteogenesis, based on Gavriil Abramovich Ilizarov's "Theory of Tension Stress" from 1951 [8]. Radical debridement of bone ends is crucial for controlling infection [4]. Ilizarov claimed that the regeneration of new bone not only addresses the bone defect but also eliminates infection, stating that "Osteomyelitis burns in the flame of regenerate" [10]. The Ilizarov method minimizes the potential hazard of amputation in cases of infected non-union [11]. While there have been numerous reports on the successful treatment of infected non-union of the femur using Ilizarov methods, some studies reported fewer satisfying outcomes and a relatively high complication rate [1]. This study aims to evaluate the bone outcome of treating infected non-union femoral shaft fractures with the Ilizarov method at NITOR.

OBJECTIVES

General Objective

- To evaluate the bone outcome of treatment of infected non-union femoral shaft fracture by the Ilizarov method.

Specific Objectives

- Examine demographics: Observe age, sex distribution, and limb length discrepancy (LLD) in respondents.
- Evaluate fracture aspects: Investigate the mechanism of injury, types of fractures, corticotomy status, and radiological union duration.
- Assess Ilizarov application outcomes: Observe infection stage, complications of the Ilizarov fixator, and overall patient status.

METHODS & MATERIALS

This prospective observational study took place at the National Institute of Traumatology and Orthopedic Rehabilitation (NITOR), Dhaka, Bangladesh, spanning from May 2018 to August 2020. Study subjects, totaling 20 patients, were chosen using purposive sampling, adhering to specific inclusion and exclusion criteria.

Inclusion criteria

- Patients diagnosed with infected nonunion of the shaft of the femur.
- Individuals with fractures of the femoral shaft, specifically those located 5cm distal to the lesser trochanter proximally and 5 cm proximal to the epicondylar axis of the femur.
- Patients who expressed willingness to provide informed consent for participation in the study.

Exclusion Criteria

- Patients with pathological fractures.
- Individuals with fractures involving the joints of the same limb.
- Patients with involvement of the metaphyseal or epiphyseal portion of the bone.
- Patients who did not provide consent to participate in the study.

Data were obtained through face-to-face interviews and investigation reports, using a pre-formed questionnaire. Patient evaluation included history, clinical examination, and radiological findings. Surgery was performed after ensuring patients were fit for anesthesia. Follow-ups were attempted at the 2^{nd} week, 6^{th} week, 18^{th} week, 6 months, and 1-year post-surgery. Outcomes were assessed using the ASAMI score. The collected data were analyzed using descriptive statistics and processed with SPSS version 22.0. Categorical data were presented as frequency and percentage, while quantitative data were expressed as mean and standard deviation (SD). Ethical clearance was obtained from the Institutional Review Board (IRB) at the National Institute of Traumatology and Orthopedic Rehabilitation (NITOR), Dhaka, Bangladesh. Informed written consent was secured from participants, ensuring confidentiality.

RESULTS

The study included participants with a mean age of 32.1±15.5 years, ranging from

11 to 70 years. The highest proportion of patients (45%) fell within the 11 to 25 years age group, followed by 30% in the 26 to 40 years age group, 20% in the 41 to 55 years age group, and 5% in the 56 to 70 age group [***Table I***].

Table I: Age distribution of patients (N=20)

Age (years)	n	%
11-25	9	45.0
26-40	6	30.0
41-55	4	20.0
56-70	1	5.0
Mean ±SD	32.1±15.5	

The study included 19 males (95%) and 1 female (5%), resulting in a male-to-female ratio of 19:1 [***Figure 1***].

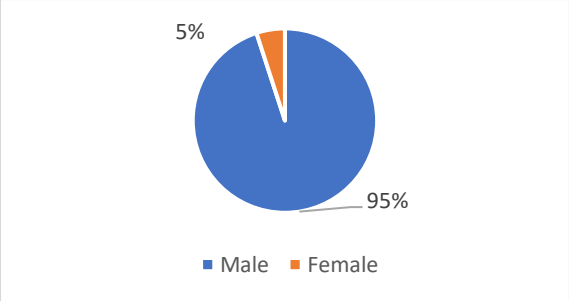

Figure 1: Sex distribution of the respondents

Motor vehicle accidents were the leading cause of injury, accounting for 18 cases (90%), while falls from height contributed to 2 cases (10%) [***Figure 2***].

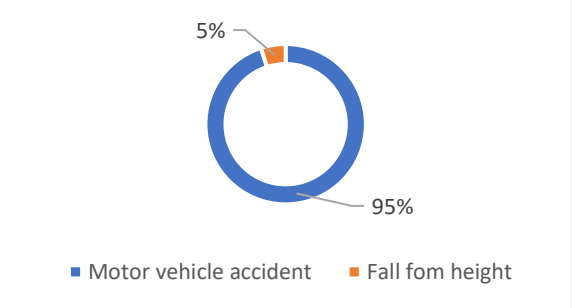

Figure 2: Mechanism of Injury

Participants included 6 students (30%), 6 laborers (30%), 4 farmers (20%), and 4 individuals with other occupations (20%). Out of the 20 cases, 11 (55%) had injuries on the right side, while 9 (45%) had left-sided injuries [***Figure 3***].

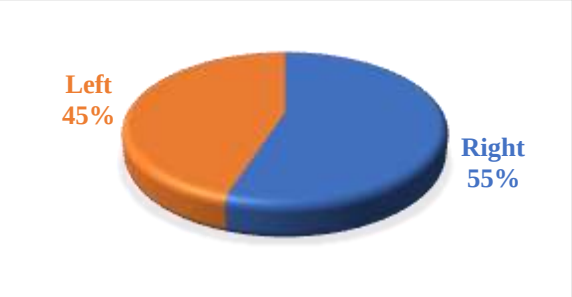

Figure 3: Side of injury

Out of the 20 patients, 8 (40%) had closed fractures, while 12 (60%) had open fractures initially. Among the open fractures, 8 (40%) were Gustilo III A, 2 (10%) were Gustilo II, and 2 (10%) were Gustilo IIIB [***Table II***]

Table II: Types of fracture (N=20)

Type of fracture	n	%
Closed fracture	8	40.0
Open fracture	12	60.0
G II	2	10.0

G III A	8	40.0
G III B	2	10.0

Femur infections were classified according to Rosen (1998). Eleven (55%) cases had an active, draining type (Type I) infection, while 9 (45%) patients had an active, non-draining type (Type II) infection at the beginning of the Ilizarov treatment [***Figure 4]***.

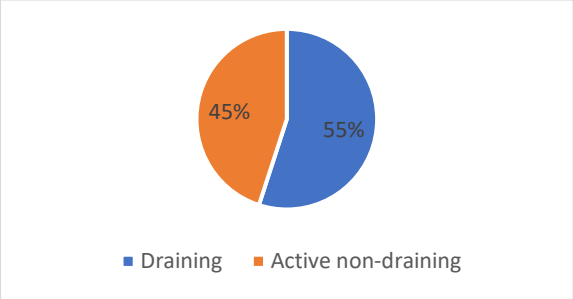

Figure 4: Stages of infections

Out of 20 patients, Ilizarov was applied between 0 to 4 months after injury in 7 (35%) patients. For 9 (45%) patients, the duration was 5 to 9 months, while for 2 (10%) patients, it was 10 to 14 months, and for another 2 (10%), it was 15 to 19 months. The mean duration from injury to the operation was 7.1±4.8 months, ranging from 1 month to 18 months. The Ilizarov fixator application involved corticotomy in 8 (40%) of the patients, while in the remaining 12 (60%) patients, corticotomy was not performed [***Figure 5].***

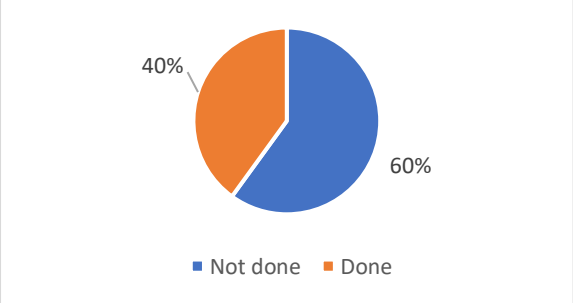

Figure 5: Corticotomy status of patients

The mean bone gap created during the operation was 2.7 ± 1.7 cm. Among the patients, 12 (60%) had a bone gap ranging from 0 to 2 cm, while 8 (40%) had a gap exceeding 2 cm [***Table III].***

Table III: Bone gap during operation

Bone gap (cm)	n	%
0-2	12	60.0
>2	8	40.0
Mean ±SD	2.7±1.7	

The mean duration for controlling infection was 4.35±2.1 months, ranging from 2 to 9 months ***[Table IV].***

Table IV: Control of infection duration

Duration (Months)	n	%
2-5	14	70.0
6-9	6	30.0
Mean ±SD	4.35±2.1	

The mean time for radiological union was 7.85±2.1 months, ranging from 5 to 11 months. Union occurred within 4 to 7 months in 10 (50%) patients and within 8 to 11 months in the remaining 10 (50%) patients [***Table V].***

Table V: Time for radiological union

Duration (Months)	n	%
4-7	10	50.0
8-11	10	50.0
Mean ±SD	7.85±2.1	

Complications were observed in 10 (50%) cases, with pin tract infection in 7 (35%) patients and wire loosening in 3 (15%) patients [***Table VI].***

Table VI: Complications

Complication of Ilizarov	n	%
Absent	10	50.0
Present	10	50.0
Pin tract infection	7	35.0
Wire loosening	3	15.0

Among the 20 patients, 5 (25%) had no deformity. Two (10%) patients had deformities ranging from 1 to 7 degrees, while 13 (65%) patients had deformities exceeding 7 degrees [***Table VII].***

Table VII: Deformity of bone

Deformity (degree)	n	%
0	5	25.0
1-7	2	10.0
>7	13	65.0
Mean ±SD	8.2±6.1	

Regarding limb length discrepancy, 5 (25%) cases showed no LLD, 12 patients had an LLD ranging from 1 cm to 2.4 cm, and 3 (15%) patients had an LLD of ≥2.5 cm. The mean limb length discrepancy was 1.2±0.9 cm [***Table VIII].***

Table VIII: Limb length discrepancy (LLD)

LLD	n	%
0	5	25.0
1-2.4	12	60.0
≥2.5	3	15.0
Mean ±SD	1.2±9	

The final bone outcome was assessed based on the ASAMI criteria. Among the patients, 8 (40%) achieved excellent bone outcomes, 9 (45%) had good outcomes, and 3 (15%) had fair outcomes [***Table IX]***

Table IX: Bone outcome of patients

Bone outcome	n	%
Excellent	8	40.0
Good	9	45.0
Fair	3	15.0
Total	20	100.0

DISCUSSION

In this study, the mean age was 32.1±15.5 years (range: 11 to 70 years), and out of 20 patients, 19 (95%) were male, yielding a male-to-female ratio of 19:1. Motor vehicle accidents were the leading cause of injury, accounting for 18 (90%) cases, while falls from height contributed to 2 (10%) cases. Comparable findings in other studies show that femoral fractures commonly occur in males aged 25 to 44 years, with motor vehicle accidents being the primary cause [12-14]. In Baruah & Kumar's study, 79% of cases resulted from motor vehicle accidents, and 21% were due to falls from height [13]. Among the 20 cases, 11 (55%) had right-sided injuries, and 9 (45%) had left-sided injuries. This right-sided predominance aligns with findings in other studies; for instance, Hassan et al. and Kanagasarathy et al. reported right-sided involvement in 80% and 63% of cases, respectively [10,15]. Regarding the nature of fractures, 8 (40%) were closed fractures, and 12 (60%) were open fractures initially. Among the open fractures, 8 (40%) were Gustilo IIIA, 2 (10%) were Gustilo II, and 2 (10%) were Gustilo IIIB. Although infection rates are typically lower in closed fractures, they are not uncommon following surgery. In the series by Jain & Sinha et al., out of 16 patients with femoral infected non-union, nine (56%) developed infected non-union

after ORIF for closed fractures, and five (31%) developed infected non-union after open fractures [3]. Hassan et al. reported that 42.5% of their patients had closed fractures, aligning with the findings in the present study [10]. The stages of infection of the femur were classified according to Rosen [16]. At the initiation of Ilizarov treatment, 11 (55%) cases had active, draining-type (Type I) infection, while 9 (45%) patients had active, non-draining-type (Type II) infection. The prevalence of draining-type infection varies widely in the literature. For instance, in the series by Bari et al., Baruah & Kumar et al., and Kanagasarathy et al., Type I infection was present in 54%, 27%, and 93.7% of patients, respectively [13,15,17]. Among the 20 patients, Ilizarov was applied between 0 to 4 months after injury in 7 (35%) patients, 5 to 9 months in 9 (45%) patients, 10 to 14 months in 2 (10%) patients, and 15 to 19 months in 2 (10%) patients. The mean duration from injury to the operation was 7.1±4.8 months in the current study, ranging from 1 month to 18 months. Bari et al. reported a mean duration of 6.5 months, while Baruah & Kumar et al. found it to be 10.2 months [13,17]. The result of the present study aligns with the findings of Bari et al. [17]. In this study, if the bone gap after debridement was more than 2 cm, corticotomy was performed. Corticotomy was done in 8 (40%) patients, and bone distraction osteogenesis technique was used in 12 (60%) patients where the bone gap was 0 to 2 cm, and corticotomy was not performed. The mean bone gap created during the operation was 2.7±1.7 cm. In the study by Hassan et al. [10], distraction osteogenesis was needed in 62.5% of cases. Kanagasarathy et al. found a bone gap ranging from 1.2 cm to 6 cm, which is similar to the present study [15]. In this study, all 20 patients achieved fracture union following the application of the Ilizarov fixator. The mean time needed for the radiological union was 7.85±2.1 months, ranging from 5 to 11 months. Union was achieved within 4 to 7 months in 10 (50%) patients, and in 10 (50%) patients, it was achieved within 8 to 11 months. In the studies by Tahmasbi & Jalali et al. and Kanagasarathy et al., the mean duration for the union was 10 months and 8 months, respectively, which is comparable to the present study [15,18]. Regarding complications, in 10 (50%) cases, there were no complications, and 10 (50%) patients experienced complications. All complications were categorized as "problems" according to Paley, including pin tract infection in 7 (35%) patients and wire loosening in 3 (15%) patients [19]. Pin tract infections were managed with antibiotics based on culture and sensitivity, while tension was applied in cases of wire loosening. Pin tract infection was the most common complication, consistent with findings in other literature. For example, Ghaffar et al. encountered pin tract infections in 25% of cases, similar to the present study [14]. Out of 20 patients, 5 (25%) had no deformity, 2 (10%) had deformities ranging from 1 to 7 degrees, and 13 (65%) had deformities exceeding 7 degrees. Regarding limb length discrepancy, 5 (25%) cases had no discrepancy, 12 had discrepancies ranging from 1 cm to 2.4 cm, and 3 (15%) patients had a discrepancy of ≥2.5 cm. The mean limb length discrepancy was 1.2±0.9 cm. Ghaffar et al. reported a residual limb length discrepancy (LLD) of 1.9 cm, and Kanagasarathy et al. found an LLD of 1.5 cm at the last follow-up, aligning with the

present study [14,15]. The final bone outcome was assessed based on ASAMI criteria, where 8 (40%) patients had excellent bone outcomes, 9 (45%) were rated as good, and 3 (15%) were considered fair. Notably, there were no cases of poor bone outcome as all femurs had united, and the infection had resolved. This contrasts with some previous studies reporting poor bone outcomes ranging from 8% to 10% [1]. In Reza et al.'s study, they found 54.5% excellent, 18.2% good, 9.1% fair, and 18.2% poor results in terms of bone outcome, showing comparable results to the present study [20].

LIMITATIONS OF THE STUDY

The study's limitations include a single-hospital setting with a small sample size, limiting the generalizability of results to the broader community. The lack of uniform and relatively short follow-up periods following bone union may impact the assessment of long-term outcomes. Additionally, the purposive sampling method introduces the potential for bias that could influence the study's results.

CONCLUSION

The Ilizarov ring fixator stands out as a reliable and successful method in orthopedic practice, serving not only for the stabilization and promotion of satisfactory bone union but also for the correction of length discrepancies and the eradication of infection. This versatile device has demonstrated its efficacy across various applications, showcasing its adaptability and effectiveness in addressing complex orthopedic conditions. The multifunctional nature of the Ilizarov ring fixator highlights its significance as a valuable tool for orthopedic surgeons, offering comprehensive solutions for a range of challenges in bone stabilization, deformity correction, and infection management.

RECOMMENDATION

Ilizarov ring fixator is recommended for infected femoral nonunion. Larger-scale, multicenter research is crucial, emphasizing thorough debridement during fixator application.

FUNDING

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CONFLICT OF INTEREST

None declared

ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee

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