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**Original Research Article**

# Complications of Ilizarov method treatment for infected nonunion femoral shaft fracture

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## ABSTRACT

**Background:** Infected non-union of the femur is complicated by the involvement of soft tissue and bone, long-term resistant multi-bacterial infection, limb length discrepancy, deformities, joint stiffness, and multiple draining sinuses, and poses a challenge for orthopedic surgeons. This study aimed to analyze the complications of Ilizarov method treatment for infected non-union femoral shaft fracture.
**Methods:** This prospective observational study was conducted at the national institute of traumatology and orthopedic rehabilitation (NITOR), Dhaka, Bangladesh, from May 2018 to August 2020. A total of 20 patients were selected as study subjects by purposive sampling technique. All data were collected using a pre-formed questionnaire. Data were processed and analyzed using computer software program SPSS version 22.0.
**Result:** The mean bone gap created during the operation was 2.7±1.7 cm of them, in 12 (60%) patients, it was 0 to 2 cm, and in 8 (40%) patients it was more than 2 cm. The mean time needed for radiological union was 7.85±2.1 months ranging from 5 months to 11 months. In 10 (50%) patients, union was achieved within 4 to 7 months, and in 10 (50%) patients it was 8 to 11 months. Regarding limb length discrepancy, in 5 (25%) cases there was no limb length discrepancy (LLD). Twelve patients had 1 cm to 2.4 cm LLD and 3 (15%) patients had ≥2.5 cm LLD. The mean LLD was 1.2±0.9 cm. Regarding complications, in 10 (50%) cases, there was no complication and 10 (50%) patients had complications. The complications were pin tract infection in 7 (35%) patients and wire loosening in 3 (15%) patients.
**Conclusions:** The study concludes that while the Ilizarov ring fixator proves to be a dependable and successful method for stabilizing, correcting length discrepancies, and eliminating infections, it is not without its share of complications. The findings of this research indicate a 50% complication rate among the patients undergoing this treatment.

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

## INTRODUCTION

Infected nonunion of the femur is not uncommon in clinical practice, but the treatment of this disease has been a challenge for orthopedic surgeons.[1,2] Some related factors usually complicate the infected non-union including bone loss, deformities, limb-length inequalities, and polybacterial infection.[3] Ilizarov's methods can eliminate infection, recompense for bone defects, and

promote bone union through progressive bone histogenesis at the same time, it can correct the deformities and limb-length discrepancy during bone transport.[4,5]

The goal of treatment in an infected non-union femur is a well-aligned, healed, painless, and functional limb. Despite bone loss, limb salvage and reconstruction are superior to amputation and prosthesis as long as the severely injured limb has an intact distal neurovascular status.[3] Firstly, non-union had been operated more than 3 to 4 times resulting in cicatrisation of the soft tissue with an avascular environment around the fracture site. Secondly, sinus tract formation leads to the fracture site indicating dead bone or sequestrum inside. Moreover, a considerable distance from the non-union site of long bones, due to the thrombosis of blood vessels of Haversian canals, results in necrosis of bone. Also, lingered immobilization and manifold surgical procedures with fibrosis of the muscles lead to a stiff joint and may cause fracture disease.

Another important issue is the development of antibiotic resistance. The rate of limb length incongruity and malformations is so high. Finally, erratic degrees of soft tissue loss or defects require multiple sessions in reconstruction surgeries.[3,6]

The Ilizarov method addresses several problems simultaneously and offers a good solution for infected nonunions.[7] The stability of the construct permits early weight bearing and joint mobilization. The Ilizarov ring fixator offers multiplanar stability and facilitates the modification of angulation, and rotation at the non-union site much more effectively.[8,9] Furthermore, bone defects can be filled by a corticotomy and bone transport. The Ilizarov ring fixator can be used for mono-focal or bifocal compression distraction and bone segment transport depending upon the bone defect at the site of nonunion.[1,10] The regeneration of new bone to fill the defect is distraction osteogenesis and is based upon the "Theory of tension stress" introduced by Gavriil Abramovich Ilizarov in 1951.[8] The control of infection is achieved by radical debridement of the bone ends.[4] The regeneration of new bone not only covers the bone defect but also eliminates infection as claimed by Ilizarov that "Osteomyelitis burns in the flame of regenerate".[10]

Amputation is one of the hazards of infected non-union and so the Ilizarov method can minimize this potential outcome.[11] Up to now, there have been several reports on the treatment of infected non-union of the femur by Ilizarov methods, and it has progressively been the key treatment for infected non-union. Though infected nonunion treated by Ilizarov methods acquired a suitable outcome in most studies, there were still some relatively unsatisfying results in numerous studies.

In addition, a relatively high rate of complication by Ilizarov methods has been reported in some clinical research.[1] Therefore, the present study aimed analyze the complications of Ilizarov method treatment for infected non-union femoral shaft fracture in the context of the NITOR.

### *Objectives*

#### *General objectives*

General objectives were to analyze the complications of Ilizarov method treatment for infected non-union femoral shaft fracture.

#### *Specific objectives*

Specific objectives were to observe the age and sex distribution of the respondents, to know the mechanism of injury of the study subjects, to assess the types of fractures among the patients, to see the stage of infection during the application of Ilizarov, to observe the corticotomy status of the study patients, to analyze the duration of the radiological union of the fracture and to assess LLD of the patients.

## METHODS

This prospective observational study took place at the NITOR in Dhaka, Bangladesh, spanning from May 2018 to August 2020. 40 patients were selected as study subjects through purposive sampling, adhering to specific inclusion and exclusion criteria. Inclusion criteria comprised patients with infected nonunion of the shaft of the femur, including fractures within 5 cm distal to the lesser trochanter proximally and 5 cm proximal to the epicondylar axis of the femur, who were willing to provide consent. Exclusion criteria involved patients with pathological fractures, fractures involving the limb joints, or those with bone involvement in the metaphyseal or epiphyseal regions, as well as those who declined participation. Data collection involved a combination of face-to-face interviews and investigation reports, utilizing a pre-formed questionnaire. Upon enrollment, patients underwent thorough evaluation through history taking, clinical examination, and radiological assessments, aligning with the study objectives. Subsequent to preparing patients for anesthesia, surgeries were performed.

Follow-up was attempted at intervals of the 2$^{nd}$ week, 6$^{th}$ week, 18$^{th}$ week, 6 months, and 1-year post-surgery. Outcome evaluation relied on the ASAMI score. Collected data underwent analysis employing descriptive statistics, processed and interpreted using the SPSS version 22.0 software.

Categorical data were presented as frequency and corresponding percentages, while quantitative data were expressed as mean and standard deviation (SD). Ethical clearance was secured from the institutional review board (IRB) at NITOR, Dhaka, Bangladesh. Informed written

consent was obtained from all participants, ensuring confidentiality throughout the study.

## RESULTS

In this study, the mean age was 32.1±15.5 years with a range from 11 to 70 years. The highest number of patients (45%) were 11 to 25 years age group followed by 12 (30%) cases in the 26 to 40 years age group, 8 (20%) in the 41 to 55 years age group, and 2 (5%) in 56 to 70 age group. 38 of the participants were male and 2 were female. In terms of occupation, 30% were students, 30% were laborer, 20% were farmers and another 20% were involved in other occupation. Motor vehicle accidents accounted for 36 (90%) cases which was the most common cause of injury. Fall from height was accounted for 4 (10%) cases. Side of injury was right for 55% and left for 45%.

**Table 1: Baseline characteristics distribution of the study subjects (n=40).**

| Baseline characteristics | N | Percentages (%) |
|---|---|---|
| **Age (in years)** | | |
| 11-25 | 18 | 45.0 |
| 26-40 | 12 | 30.0 |
| 41-55 | 8 | 20.0 |
| 56-70 | 2 | 5.0 |
| Mean±SD (years) | 32.1±15.5 | |
| **Gender** | | |
| Male | 38 | 95 |
| Female | 2 | 5 |
| **Occupation** | | |
| Student | 12 | 30 |
| Laborer | 12 | 30 |
| Farmer | 8 | 20 |
| Others | 8 | 20 |
| **Mechanism of injury** | | |
| Motor vehicle accident | 36 | 95 |
| Fall from height | 4 | 5 |
| **Side of injury** | | |
| Right | 22 | 55 |
| Left | 18 | 45 |

**Table 2: Distribution of cases according to type of fracture (n=40).**

| Type of fracture | N | Percentages (%) |
|---|---|---|
| **Closed fracture** | 16 | 40.0 |
| **Open fracture** | 24 | 60.0 |
| **G II** | 4 | 10.0 |
| **G IIIA** | 16 | 40.0 |
| **G IIIB** | 4 | 10.0 |

Among the 40 patients, 16 (40%) were closed fractures and 24 (60%) were open fractures initially. Among the open fractures, 16 (40%) were Gustilo IIIA, 4 (10%) were Gustilo II and 4 (10%) were Gustilo IIIB (Table 2).

Types of infection of femur were classified according to Rosen, (1998). 22 (55%) cases had active, draining type (Type I) infection while 18 (45%) patients had active, non-draining type (type II) infection at the commencement of the Ilizarov treatment (Figure 1).

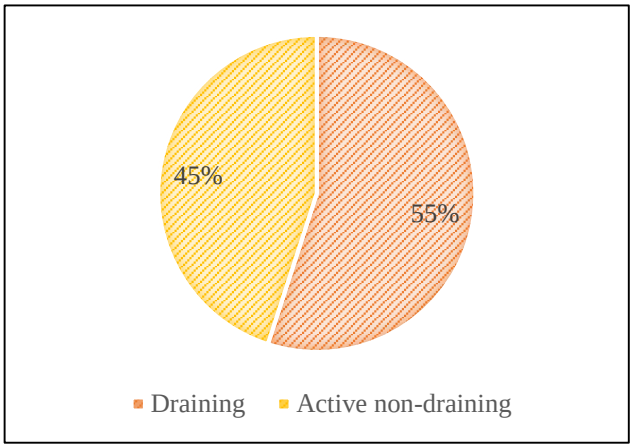


**Figure 1: Stage of infection during application of Ilizarov.**

**Table 3: Duration of injury to Ilizarov application (n=20).**

| Duration from injury to Ilizarov (months) | N | Percentages (%) |
|---|---|---|
| **0-4** | 7 | 35.0 |
| **5-9** | 9 | 45.0 |
| **10-14** | 2 | 10.0 |
| **15-19** | 2 | 10.0 |
| **Mean±SD** | 7.1±4.8 | |

Out of 20 patients, in 7 (35%) patients Ilizarov was applied between 0 to 4 months after injury. In 9 (45%) patients, the duration was 5 to 9 months, in 2 (10%) patients it was 10 to 14 months and in 2 (10%) it was 15 to 19 months. The mean duration of injury to operation was 7.1±4.8 months, ranging from 1 month to 18 months (Table 3).

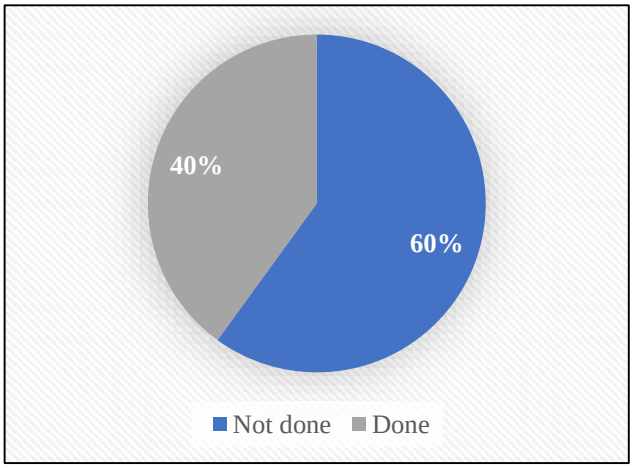


**Figure 2: Corticotomy status of the study patients.**

During the application of the Ilizarov fixator, corticotomy was done in 16 (40%) patients while in 24 (60%) patients corticotomy was not done (Figure 2).

**Table 4: Distribution of outcome measurements of the study patients, (n=40).**

| Variables | N | Percentages (%) |
|---|---|---|
| **Bone gap (cm)** | | |
| 0-2 | 24 | 60.0 |
| >2 | 16 | 40.0 |
| Mean±SD | 2.7±1.7 | |
| **Duration of control of infection (months)** | | |
| 2-5 | 28 | 70.0 |
| 6-9 | 12 | 30.0 |
| Mean±SD | 4.35±2.1 | |
| **Duration to radiological union (months)** | | |
| 4-7 | 20 | 50.0 |
| 8-11 | 20 | 50.0 |
| Mean±SD | 7.85±2.1 | |
| **Complication of Ilizarov** | | |
| Absent | 20 | 50.0 |
| Pin tract infection | 14 | 35.0 |
| Wire loosening | 6 | 15.0 |
| **Deformity (degree)** | | |
| 0 | 10 | 25.0 |
| 1-7 | 4 | 10.0 |
| >7 | 26 | 65.0 |
| Mean±SD | 8.2±6.1 | |
| **Limb length discrepancy** | | |
| 0 | 10 | 25.0 |
| 1-2.4 | 24 | 60.0 |
| ≥2.5 | 6 | 15.0 |
| Mean±SD | 1.2±9 | |
| **Bone gap (cm)** | | |
| 0-2 | 12 | 60.0 |
| >2 | 8 | 40.0 |
| Total | 20 | 100.0 |
| Mean±SD | 2.7±1.7 | |

Regarding bone gap measurements, the majority of patients (60.0%) exhibited a bone gap of 0-2 cm, while 40.0% had a bone gap greater than 2 cm. The mean bone gap across all patients was 2.7±1.7 cm. In terms of the duration of control of infection, the data indicate that 70.0% of patients achieved control within 2-5 months, with 30.0% taking 6-9 months. The mean duration for infection control was 4.35±2.1 months. Furthermore, the duration to achieve radiological union was evenly distributed, with 50.0% of patients achieving union within 4-7 months and another 50.0% within 8-11 months, yielding a mean duration of 7.85±2.1 months.

Complications associated with Ilizarov fixator treatment were observed, with 50.0% of patients experiencing no complications, 35.0% developing pin tract infections, and 15.0% experiencing wire loosening. Analysis of bone deformity revealed that 25.0% of patients had no deformity, 10.0% had deformities ranging from 1-7 degrees, and a substantial 65.0% had deformities exceeding 7 degrees, resulting in a mean deformity angle of 8.2±6.1 degrees.

Additionally, limb length discrepancies were present in cohort, with 25.0% showing no discrepancy, 60.0% having discrepancies ranging from 1-2.4 cm, and 15.0% exhibiting discrepancies of 2.5 cm or greater, yielding a mean limb length discrepancy of 1.2±0.9 cm.

## DISCUSSION

In this study, the mean age was 32.1±15.5 years with a range from 11 to 70 years. Out of 40 patients, male was 38 (95%) and female 2 (5%) with a male-female ratio of 19:1. In most of the studies regarding femoral fractures, the mean age was between 25 to 44 years and males were predominant.[12-14] In this study, motor vehicle accidents accounted for 36 (90%) cases which was the most common cause of injury. Fall from height was accounted for 4 (10%) cases. In the study of Baruah et al 79% of their cases were due to MVA and 21% were due to fall from height.[13] Among the 40 cases, 22 (55%) had right and 18 (45%) had a left-sided injury. Most of the studies also showed a right-sided predominance. Likewise in the studies of Hassan et al and Kanagasarathy et al right-sided involvement was 80% and 63% respectively.[10,15]

Among the 40 patients, 16 (40%) were closed fractures and 24 (60%) were open fractures initially. Among the open fractures, 16 (40%) were Gustilo IIIA (10%) were Gustilo II and 4 (10%) were Gustilo IIIB. Although the infection rate is quite low in close fractures, it is not uncommon following surgery. In the series of Jain et al of 16 patients with femoral infected nonunion, 9 (56%) had infected nonunion caused by ORIF for closed fracture and 5 (31%) infected nonunion occurred after open fractures.[3] Hassan et al found 42.5% of their patients had closed fractures.[10] These results are similar to the present study. Stages of infection of the femur were classified according to Rosen.[16] The 22 (55%) cases had active, draining type (Type I) infection while 18 (45%) patients had active, non-draining type (type II) infection at the commencement of the Ilizarov treatment.

The draining type of infection is common but widely varies as stated by other works of literature. For example, in the series of Bari et al, Baruah et al, and Kanagasarathy et al type I infection was present in 54%, 27%, and 93.7% of patients respectively.[13,15,17] Out of 40 patients, in 14 (35%) patients Ilizarov was applied between 0 to 4 months after injury. In 18 (45%) patients, the duration was 5 to 9 months, in 4 (10%) patients it was 10 to 14 months and in 4 (10%) it was 15 to 19 months. The mean duration of injury to operation was 7.1±4.8 months, ranging from 1 month to 18 months. Bari et al found a mean duration of injury to the application of the Ilizarov fixator of 6.5 months while Baruah et al found it 10.2 months.[13,17] The result of the present study is comparable to the study of

Bari et al.[17] In the present study, if the bone gap after debridement was more than 2 cm, corticotomy was done. In 16 (40%) patients, the bone gap was more than 2 cm so corticotomy was done and the bone distraction osteogenesis technique was used in 24 (60%) patients where bone gap was 0 to 2 cm and corticotomy was not done. The mean bone gap created during the operation was 2.7±1.7 cm. In the study of Hassan et al distraction osteogenesis was needed in 62.5% of cases.[10] 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, in all 40 patients, the fracture united following the application of the Ilizarov fixator. The mean time needed for radiological union was 7.85±2.1 months ranging from 5 months to 11 months.

In 20 (50%) patients, union was achieved within 4 to 7 months, and in 20 (50%) patients it was 8 to 11 months. In the studies of Tahmasbi 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] In the present study, in 50 (50%) cases, there was no complication, and 50 (50%) patients had complications. All the complications were "problems" according to Paley which include pin tract infection in 7 (35%) patients and wire loosening in 3 (15%) patients.[9] Pin tract infection was managed by antibiotics according to culture and sensitivity. Tension was given in case of wire loosening. Pin tract infection was the most common complication as depicted in many literatures. For example, Ghaffar et al encountered 25% cases of pin tract infection which is similar to the present study.[14]

Among 40 patients, 10 (25%) had no deformity. Four (10%) patients had 1 to 7 degrees deformity and 26 (65%) patients had more than 7 degrees deformity. Regarding limb length discrepancy, in 10 (25%) cases there was no LLD, 24 patients had 1 cm to 2.4 cm LLD and 6 (15%) patients had ≥2.5 cm LLD. The mean LLD was 1.2±0.9 cm. Ghaffar et al found a residual LLD of 1.9 cm, and Kanagasarathy et al found an LLD of 1.5 cm at the last follow up which coincides with the present study.[14,15] The final bone outcome was assessed according to ASAMI criteria.

### *Limitations*

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community. Furthermore, the follow-up period could not be made uniform and shorter following achieving bone union. The sample was taken purposively. So, there may be a chance of bias which can influence the results.

## CONCLUSION

The study concludes that while the Ilizarov ring fixator proves to be a dependable and successful method for stabilizing, correcting length discrepancies, and eliminating infections, it is not without its share of complications. The findings of this research indicate a 50% complication rate among the patients undergoing this treatment.

### *Recommendations*

The findings of this study underscore the importance of healthcare professionals carefully considering the benefits and risks associated with the use of the Ilizarov ring fixator in individual cases. It is imperative for medical practitioners to stay abreast of the latest research and advancements in orthopedic treatments, and discussions about the risks and benefits of procedures like the Ilizarov ring fixator should be based on the most recent and pertinent evidence available.

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