Monofocal and bifocal management of infected femoral nonunion by an Ilizarov fixator: midterm results

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Introduction
Infected nonunion of the femur with associated bone loss represents one of the most difficult problems in orthopedic practice. The purpose of this study was to evaluate the midterm treatment outcome of the Ilizarov technique in infected nonunion of the femur.
Patients and methods
This is a retrospective study of 24 patients with infected nonunion of the femur treated by an Ilizarov external fixator. The mean age of the patients was 37.71 years. The study included 19 men and five women. Eighteen (75%) patients had draining sinuses while six (25%) were quiescent. Four cases had associated deformity, and 18 patients had preoperative shortening with a range of 1–6 cm. Failed previous surgeries ranged from two to seven times and the mean duration of nonunion was 28.75 months.
Results
Monofocal technique was used in eight patients, and bifocal technique was used in 16 patients. All fracture nonunions were fully united with a mean fixator period of 12.75 months. The average follow-up duration was 50.88 months. Persistent infection occurred in two cases after frame removal and managed by further debridement. Two cases had residual valgus deformity and two other patients had 2.5 cm shortening. According to the Association for the Study and Application of the Method of Ilizarov criteria, the bone results were evaluated as excellent in 19 patients, good in four patients, and fair in one patient. The functional results were excellent in 18 patients and good in six patients.
Conclusion
In spite of the several problems, obstacles, and complications that may occur with the long treatment course, the Ilizarov fixator was effective in treating the difficult disabling problem of infected nonunion of the femur.

Keywords:
external fixator, femoral fractures, Ilizarov technique, infection, nonunion

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Introduction

Infected nonunion has been defined as a state of failure of union and persistence of infection at the fracture site for 6–8 months [1]. Infected nonunion of the femur is one of the most serious complications of long-bone fractures with a debilitating impact on the patient's quality of life [2,3]. It is a challenging problem to orthopedic surgeons with difficulty to obtain union and, at the same time, addressing the coexisting problems of deformity, polybacterial infection, and leg-length discrepancy [4]. The main goals of treatment include eradication of infection, achievement of bone union, restoration of bone length, correction of alignment, and having an optimal functional outcome [5]. Both single-staged and multiple-staged surgical procedures have been described [6].

Several methods have been proposed, including bone grafting, and free vascularized fibular grafts. However, these treatment methods have obvious limitations such as the size of bone defects, donor site morbidity, and extended graft incorporation time. Free vascularized fibular graft is a technically demanding surgery, and it is usually associated with stress fractures and nonunion [4,7–9]. Antibiotic cement is used to control the infection efficiently, but it is only suitable for the treatment of infected nonunion with small defects or none, and bone grafting is usually necessary to achieve bone union [10]. In addition, none of these methods can address the coexisting problems simultaneously.

Ilizarov method and fixator have several roles in managing nonunions. Mechanically, it offers stability and allows early weight-bearing and

functional limb use. Biologically, corticotomy promotes vascularity to the entire bone and the surrounding soft tissues. Moreover, the Ilizarov method offers simultaneous solution for several problems related to nonunion such as instability, infection, deformity, bone loss, joint contracture, and limb length discrepancy [4,9,11].

The purpose of this study was to evaluate the midterm bony and functional outcomes of monofocal and bifocal techniques by Ilizarov fixation in patients with infected nonunions of the femur.

Patients and methods

This retrospective study was conducted at Benha University Hospital, Egypt after approval of the Institutional Ethics Committee and included 24 patients with infected nonunion of the femur operated from January 2006 till June 2012. The inclusion criteria for this study included draining and quiescent infected nonunited fractures of femur treated by an Ilizarov external fixator with a minimum follow-up of 3 years. Patients lost to follow-up were excluded from the study. Patients were thoroughly evaluated. Radiographs were taken in at least two planes. Computed tomographic scan was done in cases of doubtful union. Sinogram was performed in patients with sinuses for better identification and resection planning of the septic focus. There were 19 men and five women. The age of patients ranged from 29 to 55 years with an average of 37.71 years. Fourteen nonunions were on the right side and 10 were on the left side. Three nonunions were in the upper third, 16 were in the middle third, and five were in the lower third.

The primary fracture was closed in 14 patients, open grade II in six patients, and open grade III in four patients. The mechanisms of initial cause of injury included traffic accidents (20 patients), and gunshot injuries (four patients). The initial treatment of the fracture included internal fixation (20 patients) and external fixation (four patients). All patients had previous surgical procedures, for example ORIF, external fixation, repeated debridement, and implant removal. At presentation, 18 patients had nonunion with active infection and discharging sinuses, while six had no signs of active infection though quiescent sinuses were present. Seventeen patients were smokers and 11 were diabetics. One patient had sciatic nerve palsy with history of repair of femoral artery injury after a gunshot injury. Six patients had knee joint stiffness. Four patients had angulation deformity of more than 10° (one varus and three valgus). Preoperative shortening was present in 18 patients.

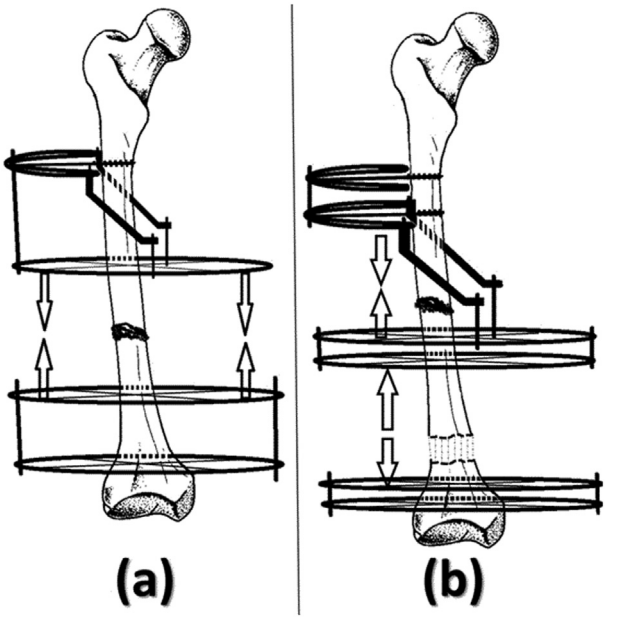
Explanation of the procedure in detail, meeting with other patients having Ilizarov fixation, smoking cessation, and good blood sugar control were essential preoperative preparatory steps. Informed consent was obtained from all patients.

Operative technique

Spinal or epidural anesthesia was used in most cases. The patient was positioned supine on a traction table to permit access to the thigh all around. Sinus tracts were marked by methylene blue before excision to delineate the extent of the infection and bone destruction. The infected area was exposed by a lateral approach. Internal fixation implants were removed together with debridement of all necrotic and infected tissues. Samples were obtained and sent for culture and sensitivity (aerobic/anaerobic). The necrotic bone was excised till exposure of healthy vascular bone creating opposing transverse bony surfaces. The bone ends were freshened. The wound was irrigated and closed over suction drain.

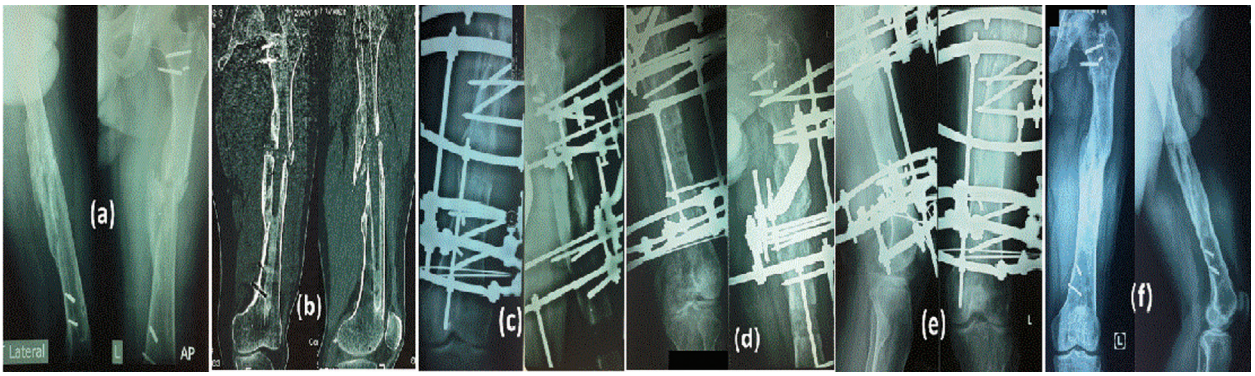
After debridement, if the combined postdebridement defect and preoperative shortening was less than 2 cm, monofocal technique was used. Bifocal technique was used if the combined defect and shortening was more than 2 cm (Figs 1, 2). Monofocal management was

Figure 1



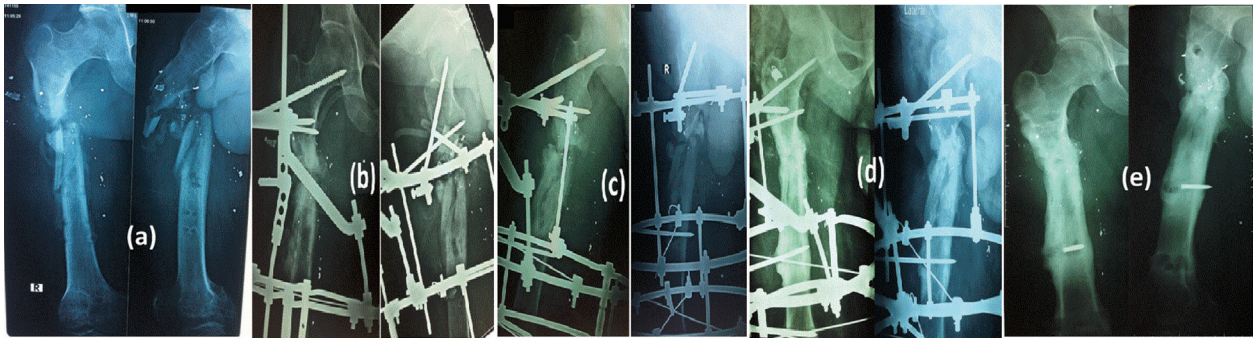
A descriptive diagram explaining (a) the monofocal and (b) the bifocal techniques.

Figure 2



Infected nonunion of the left femur with shortening: (a) preoperative radiographs, (b) preoperative computed tomographic scans clarifying the nonunion, (c) during bone transport, (d) with progression of consolidation, (e) after complete consolidation, and (f) radiographs showing sound union and lengthening after frame removal.

Figure 3



Infected nonunion of the right femur after gunshot injury: (a) preoperative radiographs, (b) immediate postoperative radiographs, (c) with progression of union, (d) radiographs showing sound union before frame removal, and (e) radiographs showing sound union after frame removal.

targeted at the nonunion site only without corticotomy (Figs 1, 3). In bifocal management, an osteotomy was done for bone transport and/or lengthening in addition to managing the nonunion focus. A subperiosteal transverse osteotomy was performed through a 2 cm incision with an osteotome after multiple predrillings. Distal femoral osteotomy was performed in 14 patients and a proximal femoral osteotomy was done in two. The monofocal frame consisted of two rings for the distal segment, and one ring and an arch for the proximal segment. In the bifocal frame, the intercalary segment was fixed by two rings. For the upper third nonunion, the proximal segment was anchored by one or two arches. Full rings of the middle and distal constructs were fixed to the bone by tensioned 1.8 mm wires and 4.5 mm Schanz screws. The proximal construct was fixed by 3–5 Schanz screws. The wire and Schanz screw insertion was guided by the goniometric atlas of the Association for the Study and Application of the Method of Ilizarov [12]. The reduction and alignment were checked clinically and under an image intensifier. In three patients with aggressive purulent infection, a second-stage osteotomy was performed at 1-month postoperatively.

Postoperative care

All patients were encouraged to perform isometric muscle and joint range-of-motion (ROM) exercises on the second day after operation. Systemic antibiotics were given for 6 weeks according to culture/sensitivity results. Anticoagulant therapy with low-molecular-weight heparin was given to each patient. Weightbearing with crutches/walker was started as soon as tolerated. The patients were followed up clinically and radiographically every 2 weeks for 1 month (or more often if wound care was required), and monthly till frame removal. Then, the follow-up was every 3 months for 1 year, and yearly thereafter. The patients were monitored for pin care, maintenance of position and alignment, ROM, progression of weightbearing, and progression of healing. The latency period before bone transport was 10 days, and the rate of distraction was 1 mm/day. Then the rate was modified according to the radiographic findings of callus formation. Bone transport was

done till closure of the defect, and then continued till limb length equalization. When bone transport was completed, the docked ends were compressed by 0.5 mm/day in order to provide full contact until the patient felt pain at the docking site. In monofocal management, repeated cycles of compression and distraction were done.

The Ilizarov external fixator was removed when radiographs showed solid union. Radiological union was defined as the absence of a radiolucent line at the site of the nonunion and filling of the bone defect with new bone at a minimum of three cortices on standard anteroposterior and lateral radiographs [13,14]. Bone results and functional results were evaluated according to the Association for the Study and Application of the Method of Ilizarov criteria [15,16]. The bone results were based on four criteria: union, infection, deformity, and leg-length discrepancy. Functional results were based on five criteria: presence of a limp, joint stiffness, pain, soft-tissue sympathetic dysfunction, and the ability to perform previous activities of daily living (Table 1).

Table 1 Bone results and functional results, according to the Association for the Study and Application of the Method of Ilizarov [15,16]

Grades	Bone results	Functional results criteria
		1. Inactivity (inability to return to daily activities because of leg injury) 2. Significant limp 3. Joint stiffness (loss of >70° of knee flexion or loss of >15° of extension) 4. Soft-tissue sympathetic dystrophy 5. Pain that reduced activity or disturbed sleep
Excellent	Union, no infection, deformity <7°, and LLD <2.5 cm	Active individual with none of the other criteria
Good	Union with any 2 of the other parameters	Active individual with 1 or 2 of the other criteria
Fair	Union with one of the other parameters	Active individual with 3 or 4 of the other criteria
Poor	Nonunion or refracture or union but with none of the other parameters	Inactive individual regardless of the other criteria

LLD, leg-length discrepancy.

Statistical analysis

The descriptive statistics was done in the form of frequencies and percentages for qualitative variables, and means, SD, and ranges for quantitative variables. Pearson's correlation coefficient and Spearman's correlation coefficient were used to test the correlation between the external fixation period (EFP) and age, duration of nonunion, number of previous surgeries, preoperative shortening, smoking, and type of infection (draining and quiescent). Level of significance was set at a *P* value of less than 0.05. The descriptive analysis and statistical analysis were performed with IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, New York, USA).

Results

Relevant clinical data before and after the Ilizarov treatment are summarized in Table 2. The mean duration from fracture to surgery was 28.75 months (SD, 12.72 months; range, 17–58 months). The mean number of previous surgeries was 3.29 (SD, 1.33; range, 2–7) procedures. The preoperative shortening in 18 (75%) patients ranged from 1 to 6 cm with a mean of 3.11 cm (SD, 1.45 cm). Monofocal treatment was used in eight (33.3 %) patients, and bifocal treatment was used in 16 (66.7 %) patients according to the personality of the nonunion. The mean hospitalization period was 21.58 days (SD, 7.90 days; range, 10–45 days). The follow-up period ranged from 36 to 72 months with an average of 50.88 months (SD, 11.69 months). The mean EFP was 12.75 months (SD, 2.01 months; range, 9–18 months). All cases were united without any refracture. Bone grafting was not needed in any patient. Repeated debridement was required in four patients during external fixation. Persistent infection in two cases needed further debridement after frame removal. Infection was eventually controlled in all cases. Continuous mild pain requiring analgesia was felt in all patients during the distraction phase. Delayed consolidation of the distraction regenerate zone was seen in one patient and was managed by compression and slower distraction. Pin-tract infection was reported in seven patients. It was controlled by pin site care and oral antibiotics. One pin was changed in three patients (two for septic loosening and one for pin breakage). None developed neurovascular complications.

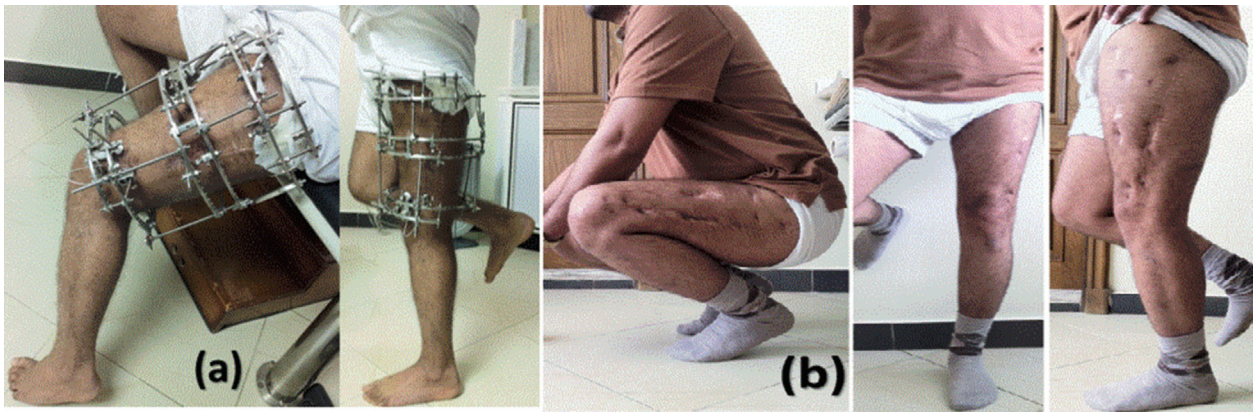
Two patents had residual valgus deformity (7° and 9°). Residual postoperative shortening occurred in five cases (1 cm in three patients and 2.5 cm in the other two). The bone grade was excellent in 19 (79.2 %) patients, good in four (16.7 %), and fair in one (4.2 %). All patients returned to their normal daily activities. The case with sciatic nerve palsy showed gradual recovery during treatment. Improvement in the knee ROM occurred in most patients in the last follow-up compared with that just after frame removal except four cases (Fig. 4). Limp was noted in six patients including the four cases with residual knee joint stiffness. One

Table 2 Relevant clinical data before and after the Ilizarov treatment

Patients	Infection type	Nonunion duration	Previous surgeries	FU	EFP	Residual deformity	Residual shortening	Bone grade	Function grade
1	Draining	24	2	69	13	–	–	E	E
2	Draining	17	2	38	14	–	–	E	G
3	Draining	29	2	40	12	–	–	E	E
4	Draining	20	2	64	11	–	1 cm	E	G
5	Quiescent	19	3	39	14	–	–	E	E
6	Draining	24	6	50	14	–	–	G	E
7	Quiescent	20	3	44	9	–	1 cm	E	E
8	Quiescent	26	3	62	12	–	–	E	E
9	Draining	58	5	36	18	–	2.5 cm	G	G
1	Quiescent	49	4	48	12	–	–	E	G
11	Draining	32	3	45	12	–	–	E	E
12	Draining	24	2	70	15	–	–	E	E
13	Draining	33	4	55	12	–	–	E	E
14	Draining	18	2	40	11	–	–	E	E
15	Draining	51	7	43	16	–	2.5 cm	G	G
16	Draining	20	4	57	11	9°	–	G	E
17	Quiescent	58	4	72	12	–	–	E	E
18	Draining	24	3	63	10	–	–	E	E
19	Draining	17	4	37	12	–	–	E	E
20	Quiescent	21	2	52	13	–	–	E	E
21	Draining	32	4	49	14	7°	–	F	G
22	Draining	34	3	39	15	–	1.0 cm	E	E
23	Draining	18	2	65	11	–	–	E	E
24	Draining	22	3	44	13	–	–	E	E

E, excellent; EFP, external fixation period; F, fair; FU, follow-up; G, good.

Figure 4



Clinical photographs: (a) showing range of knee flexion and functional limb use during bifocal management, (b) at the last follow-up with the patient squatting and standing on the previously affected limb.

patient reported chronic lower limb pain. There was no sympathetic dystrophy in any patient. Based on the mentioned parameters, the functional grade was excellent in 18 (75%) patients, and good in the remaining six (25%).

There was a positive correlation between EFP and smoking (Spearman's rho=0.506, P=0.012), between EFP and number of previous surgeries (Pearson's correlation=0.418, P=0.042), between EFP and preoperative shortening (Pearson's correlation=0.911, P<0.001), and between EFP and duration of nonunion (Pearson's correlation=0.470, P=0.021). There was no correlation between EFP and the type of infection (Spearman's rho=−0.149, P=0.488) or between EFP and age of patients (Pearson's correlation=0.351, P=0.093).

Discussion

The development of fracture nonunion is attributed to inadequate fracture stability, insufficient blood supply,

bone loss, and/or presence of infection. Treatment recommendation for nonunion of long bones ranges from noninvasive and semi-invasive methods such as electric stimulation, and low-intensity pulsed ultrasound to invasive methods such as bone marrow aspirate infiltration, autologous bone grafting, internal fixation using an interlocking nail, plate–screw fixation, and external fixation using devices such as a monolateral external fixator and the Ilizarov ring fixator [5–9,17]. Conventional management methods of nonunion are successful in cases of noninfected nonunions, in which bone vascular supply and soft-tissue integrity are not compromised. Infection represents an additional complicating factor leading to the delay of fracture union, loosening of the fixation devices, and chronic osteomyelitis. It is a challenging problem and complex management strategies are needed to be employed. Multiple factors should be considered such as different treatment modalities, deformity correction, treatment of infection, and rapid rehabilitation of the patient. The Ilizarov method is the method of choice in these situations and can be considered as a limb salvage operation [16,17].

Prasarn *et al*. [5] achieved infection-free union in all 13 patients with infected femoral nonunion treated by a single-staged protocol of debridement, local and systemic antibiotics, revision open reduction and internal fixation, and bone grafting. Five of their patients required reinterventions to ultimately attain fracture union. However, Bose *et al*. [18] found that the use of internal fixation was associated with a higher risk of recurrent infection than external fixation in the management of infected nonunion of the long bones. The external fixator provides stable fixation away from the site of trauma or infection. Harshwal *et al*. [19] reported two nonunions on treating seven femoral nonunions by a monolateral external fixator. Marsh *et al*. [20] reported healing in 20 of 25 long-bone nonunions after using a monolateral external fixator.

In infected femoral nonunion, the Ilizarov fixator is advantageous over other modalities. The advantages include percutaneous application with minimal blood loss, three-dimensional deformity corrections, leg-length discrepancy correction by distraction osteogenesis and bone transport, and high stability allowing early motion and weightbearing. The disadvantages of this method include its limited use on noncomplaint and psychologically impaired patients, cost of the apparatus, long learning curve, and those related to external fixation devices such as pin-tract infection and risk of neurovascular injury at the time of wire insertion [4,9,11,12].

The presence of a segmental defect adds complexity to the problem. Recently, the two-stage induced membrane technique has been used as an alternative reconstruction method for segmental bone defects. Masquelet *et al*. [21] reported a union rate of 100% in a series of 35 patients with upper and lower extremity segmental defects. However, El-Alfy and Ali [22] in a series of 17 cases (13 tibiae and four femora) reported three (18%) nonunions by the end of treatment. Their reported complications during the course of treatment included nonunion of the graft in five cases, failure of graft maturation in two cases, reactivation of infection in two cases, and refracture after removal of the frame in one case.

The present series included 24 patients with infected nonunion of the femur treated by an Ilizarov external fixator with failed previous surgeries that ranged from two to seven procedures. The mean duration of nonunion was 28.75 months. Aronson and Cornell [23] identified the risk factors for failure of treatment of a given nonunion and found that nonunion with durations greater than 10 months and reattempts of failed methods are associated with a high risk of failure. This may point to one of the difficulties in this study and may explain why the mean EFP of 12.75 months was longer than EFP reported by Arora [24] (8.7 months), Krishnan *et al*. [25] (7.8 months), and Saridis *et al*. [26] (10.33 months).

Krishnan *et al*. [25] used the compactotomy (corticotomy) technique by an osteotome without predrilling for bone transport and reported poor regeneration in two of 20 femoral nonunions. In the present study, a low-energy osteotomy was done after predrilling to avoid the unexpected rotational effect to break the thick medial cortex of the femur or extension of the osteotomy into the nearby half-pin. To minimize heat generation, slow speed interrupted drilling was used with cooling by cold saline. One patient had delayed regenerate consolidation and responded well to compression and redistraction. Frierson *et al*. [27] compared corticotomy and complete osteotomy technique with predrilling and found no histological, radiographic, or clinical differences between them. Yasui *et al*. [28] demonstrated that preservation of the periosteum is more important for callus formation than is a perfect corticotomy. Moreover, blood circulation in the marrow recovers during the waiting period before beginning the distraction. Blum *et al*. [29] and Yin *et al*. [9] used the osteotomy

Table 3 Bone results and functional results evaluated by Association for the Study and Application of the Method of Ilizarov of the present study and other studies

	This study	Yin *et al*. [9]	Barbarossa *et al*. [16]	Krishnan *et al*. [25]	Saridis *et al*. [26]	Maini *et al*. [30]
Number of patients	24 F	110 (72 T; 38 F)	30 F	20 F	13 F	30 (6 F; 23 T; 1 H)
Bone results						
Excellent	19	68	13	13	8	20
Good	4	28	9	4	4	4
Fair	1	12	2	1	1	–
Poor	–	2	5+1 Amp	1+1 Amp	–	6
Functional results						
Excellent	18	37	5	3	3	8
Good	6	42	10	9	4	12
Fair	–	21	8	3	4	3
Poor	–	–	6+1 Amp	4+1 Amp	2	7

Amp, amputation; F, femur; H, humerus; T, tibia.

technique in the management of femoral nonunion and did not report any regenerate complications.

In this series, all cases were fully united without bone grafting, further procedures, or amputation. This was comparable to the reports of Saridis *et al*. [26] and Maini *et al*. [30]. Other studies reported variable union rates and bone grafting. Yin *et al*. [9] reported 100% union in 38 femoral nonunions after bone grafting in five cases. Arora [24] reported bone grafting in the regenerate and two union failures in eight cases. Barbarossa *et al*. [16] did not use bone grafting in any of 30 femoral nonunions and reported three docking site nonunions necessitated revision surgeries, and four nonunions of the regenerate treated by coxofemoral plaster in three and amputation in the fourth. Amputation was also reported by Krishnan *et al*. [25] (one case) and Blum *et al*. [29] (one case).

Two patents had residual valgus deformity, and residual postoperative shortening occurred in five cases (1 cm in three patients and 2.5 cm in the other two). Fortunately, it has been reported that patients may tolerate shortening well up to 2 cm without the need for a shoe lift. Those with up to 4 cm shortening, comply well with a shoe lift of 2 cm [31,32]. Blum *et al*. [29] reported a mean residual leg-length discrepancy of 1.9 cm. Krishnan *et al*. [25] reported five cases with more than 7° of axial deviation.

In this series, the bone grade was excellent in 19 patients, good in four, and fair in one and the functional grade was excellent in 18 patients, and good in the remaining six. The bone and functional grades of this study and other studies are summarized in Table 3. This study presents the midterm results of management of a nearly homogeneous group of infected femoral nonunion treated by one protocol. Most studies were heterogeneous and additionally included both noninfected and infected nonunion of other long bones [1,3,6–10,18–20,24]. Studies presenting management of infected femoral nonunions by an Ilizarov fixator are few [16,25,26,29]. The limitations of this study include the retrospective nature of the study, the absence of a control group, and the small cohort of patients which may be due to the restricted inclusion criteria to have a homogenous group.

Conclusion

Infected femoral nonunion represents a formidable challenge for the orthopedic surgeon. The Ilizarov technique offered an effective solution by which limb salvage, union, and eradication of infection could be achieved in most cases in spite of the high complication rates. Meticulous debridement, stable fixation, correction of associated deformities and shortening, and early functional limb use are the keys of successful management.

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Conflicts of interest

There are no conflicts of interest.

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