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Original Article

Staged protocol for the treatment of chronic femoral shaft osteomyelitis with Ilizarov's technique followed by the use of intramedullary locked nail

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Abstract

Background: Infected nonunion of the femoral shaft is uncommon, and usually presents with challenging therapeutic and reconstructive problems. There are still controversies over treating infected nonunion of the femoral shaft. The purposes of this retrospective study were to review the treatment outcomes and describe a staged protocol for spontaneous wound healing.
Methods: Six patients with chronic femoral shaft infected-nonunion from October 2002 to September 2010 were included in this retrospective study. Serial plain films and triple films of lower legs were performed to evaluate the alignment of the treated femoral shaft and bony union following our staged protocol of Ilizarov distraction osteogenesis and intramedullary nailing.
Results: An average bone defect of 7 cm was noted after staged osteotomy. Mean follow-up was 87.5 (range, 38−133) months. Union was achieved in all six patients, with an average external fixation time of 6.8 (range, 5−11) months. There was no reinfection. One complication of a 4-cm leg discrepancy was noted, with an initial shortening of 15 cm. The mean knee ranges of motion (ROM) before staged protocols and at final follow-up were 64.2 ± 8.6 (range, 60−75)° and 53.3 ± 9.3 (range, 40−65)°, respectively. The ROM at the knee joint statistically decreased following staged protocols.
Conclusion: In the treatment of chronic femur osteomyelitis, the staged protocol of Ilizarov distraction osteogenesis followed by intramedullary nailing was safe and successful, and allowed for union, realignment, reorientation, and leg-length restoration. With regard to the soft tissue, this technique provides a unique type of reconstructive closure for infected wounds. It is suggested that the staged protocol is reliable in providing successful simultaneous reconstruction for bone and soft tissue defects without flap coverage.

Keywords: femoral shaft; ilizarov fixator; nonunion; osteomyelitis

1. Introduction

Many complications may occur following treatment of femoral shaft open fracture such as nonunion, malunion, delay union, bone defect, bone and joint deformity or stiffness, limb-length discrepancy, and osteomyelitis.[1−3] Severe chronic osteomyelitis may lead to nonunion and massive skeletal defects caused by procedures such as radical debridement and sequestrectomy.[4] Soft-tissue damage around the fractures and subsequent wound management are other important factors affecting the outcome. A distinct advantage of Ilizarov treatment is the active use of the affected limb to improve its physiological function, which consequently minimizes the development of disuse osteoporosis and atrophy of the soft tissue.[5]

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

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However, there is no consensus in the literature regarding the ideal management of osteomyelitis after treating open femoral shaft fractures. In this study, we retrospectively reviewed the treatment of patients with chronic femoral shaft osteomyelitis, and provided a staged protocol with spontaneous wound healing using wet-to-dry dressing followed by simultaneous distraction–compression osteogenesis with Ilizarov's technique to restore soft-tissue defects and the bony gap without further flap coverage for the docking site. The external fixator was shifted early to an intramedullary locked nail when callus formation was visible at the distraction site. The combined technique reduces external fixation time and the consolidation index compared with classic techniques for the treatment of long-bone nonunion associated with chronic osteomyelitis.[6]

2. Methods

Six consecutive cases of infected nonunion of the femur between October 2002 and September 2010 were included. The study population consisted of three men and three women, with a mean age of 37.8 (range, 28–55) years at the time of injury. Four cases of infected femoral nonunion or osteomyelitis had developed after a closed fracture, and two after an open fracture. Informed consent for participation in the study was obtained from patients.

All patients underwent the same protocol at the authors' institution. Inclusion criteria were: absence of pin-tract infection when shifting the external fixator to a locked nail, and the existence of a suitable space in the intramedullary canal to accommodate a locked nail. Additional bone grafting was performed around the docking site in all patients. Full weight-bearing was allowed to enhance callus maturation during the distraction stage. All cases were followed, with complete data for final evaluation.

2.1. Staged protocols

The staged protocols for treating chronic osteomyelitis and soft tissue loss around the femoral shaft included (Fig. 1): (1) radical debridement for infected bone and soft tissue and the additional insertion of an antibiotic-impregnated cement-rod for 10 days in cases of previously existing septic medullary implant; (2) the use of Ilizarov's apparatus for all patients except those needing a delayed application because of a previously existing septic medullary implant; (3) osteotomy in healthy bone; (4) simultaneous distraction–compression osteogenesis and histogenesis; (5) additional docking-site bone grafting; and (6) shifting the external fixator to a locked nail with a closed technique when callus formation was visible at the distraction site. Appropriate intravenous antibiotics based on intraoperative culture results were used throughout treatment for all patients.

2.1.1. Radical debridement

Radical debridement is necessary before performing Ilizarov's procedure. With regard to infected bone, adequate debridement should give the remaining bone a healthy appearance with an opened intramedullary canal and bleeding surface, and is performed on a fracture table under traction. During sequestrectomy, the typical bone cut is made perpendicular to the anatomic femoral axis using a power saw cooled with saline irrigation. Under C-arm fluoroscopy, a K-wire is used as a guide for the bone cut. The remaining bone edges require soft tissue coverage to avoid desiccation, secondary necrosis, and osteomyelitis. When determining the amount of diseased bone to be removed, bone quality, rather than bone volume, was given priority. The remaining bone surfaces had visible bleeding spots and serosanguinous fluid discharge from the opened intramedullary canal or the multiple pin tracts made on the cancellous bone. The surgical wound was left open, and wet dressing was necessary. The presence of granulation tissue around the proximal or distal bone surface ensured adequate debridement. Ilizarov's apparatus was applied immediately following radical debridement.

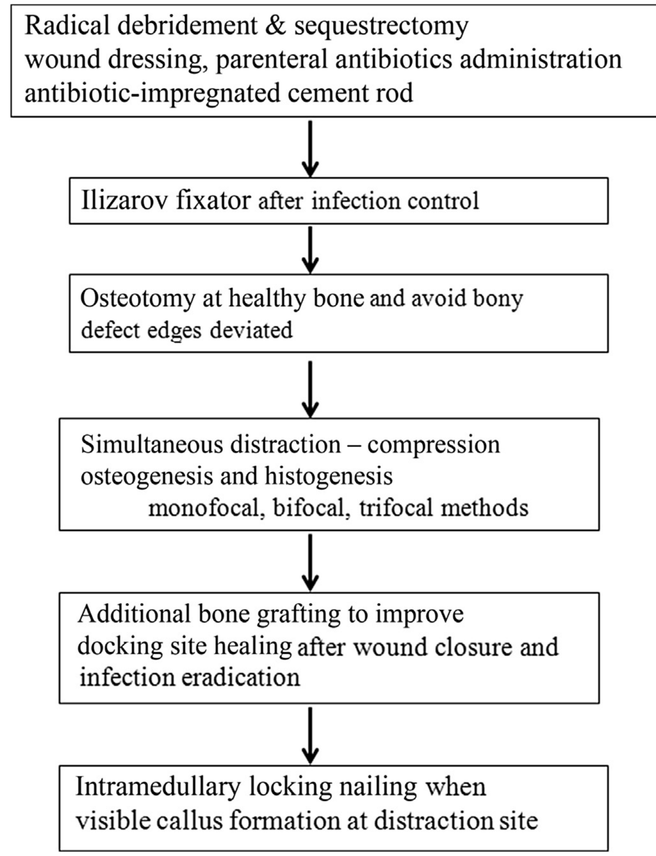

Fig. 1. Flowchart of the staged protocols. In the first stage, the intraoperative wound cultures were performed, and then appropriate parenteral antibiotics were prescribed throughout the protocols. The first stage of radical debridement and sequestrectomy might be arranged several times based on the wound conditions.

2.1.2. Osteotomy

One week later, osteotomy of the healthy bone was performed after applying the external fixator. The fracture table position and two-level osteotomies were suggested. When a short bone segment is left after an osteotomy of the femoral shaft, extending the circle frame across the knee joint should be considered, at least temporarily. When using the intraoperative olive-wire reduction technique, the bone defect edges should be pointed perfectly toward each other to avoid deviation during bone transport and to optimize contact at the anticipated docking site.

2.1.3. Simultaneous distraction–compression osteogenesis and histogenesis

With the adjustable rods longitudinally placed between the rings, simultaneous distraction–compression osteogenesis and histogenesis were performed 7 days after the osteotomy. Osteogenesis was periodically monitored during the 1st postoperative month and after full weight bearing. During the Ilizarov procedure, monofocal (Fig. 2), bifocal (Figs. 2 and 3), and trifocal (Figs. 2 and 4) approaches were used for bone and soft tissue transport. In the monofocal approach, the two bony segments next to the defect were transported toward each other, which caused limb shortening. An osteotomy was performed outside of the healthy bone injury zone using a bifocal approach. The intercalary segment was then transported and used to compress the defect site. A simultaneous lengthening occurred through the corticotomy site, which maintained the limb length. The trifocal approach (tandem procedure) was indicated when bone loss of > 6 cm occurred and involved the use of two lengthening osteotomies and compression of the defect. The Ilizarov method of intercalary bone transport was used to treat bone loss and achieve limb salvage.

2.1.4. Bone grafting

Periodic assessment of the regenerated bones was carried out, and bone marrow injection was indicated in patients with slow maturation of regenerative bone at the 2-month follow-up. Additional bone grafting also improved docking site healing after wound closure and eradicated infection in all patients. Bone resorption was noted at the docking site during lengthening, and could increase the amount of lengthening required. This may have been a result of the chronic osteomyelitis or lack of normal stresses on the bone.[7]

2.1.5. Intramedullary locking nail application

The appearance of callus formation at the distraction site was considered the appropriate time to apply the intramedullary locking nail (Smith & Nephew Richards, Inc., Memphis, TN, USA). However, when callus formation was visible at the distraction site, there would be regenerative solid bone on the pathway, and intramedullary nailing would be more technically demanding. An external fixator was used to maintain the anatomical reduction, a long, rigid guide-pin (Rush Pin LLC, Meridian, MS, USA) with sharp ends was used to make a tract break through the regenerative callus. Then, after adequate reaming, the locking nail (Smith & Nephew Richards, Inc., Memphis, TN, USA) was introduced across the docking site. A locked intramedullary nail was used after adequate reaming.

2.1.6. Wound management

Necrotic and devitalized tissues were debrided while preventing exposure of the remaining healthy bone. The wounds were left accessible, with the leg maintained in the circular frame. Several self-incremental adjustments were made each day. Patient involvement and cooperation were important when using this method. The self-care of wounds was also essential during the transporting phase, until closure

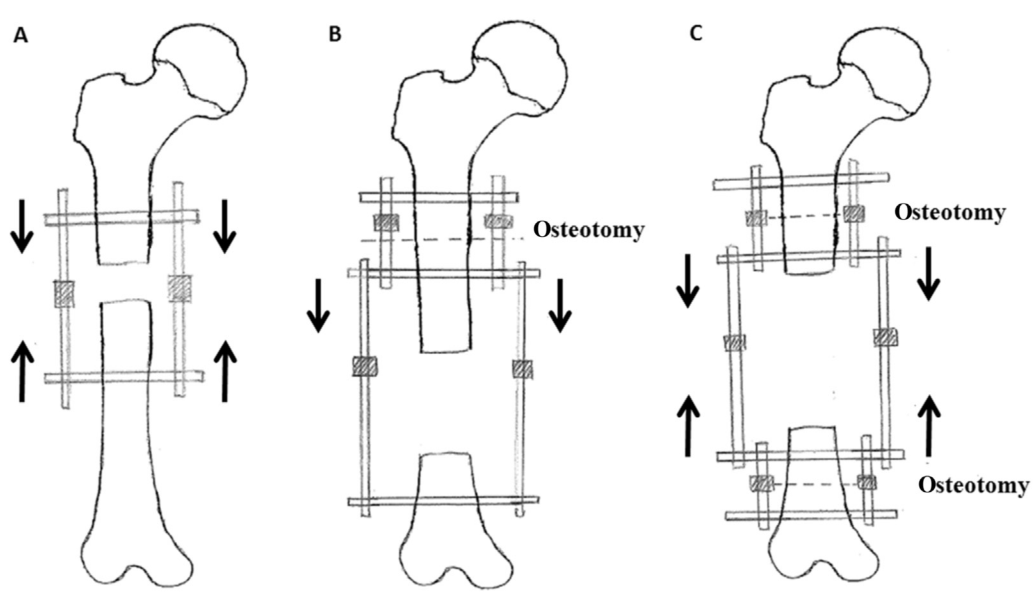

Fig. 2. Monofocal, bifocal, and trifocal methods in the Ilizarov fixator. The dotted transverse line represented the osteotomy site. The arrow indicated the direction of bone transport in the osteogenesis. (A) Monofocal method. Two bony segments next to the defect were transported toward each other, which caused limb shortening. This method was indicated in bone loss < 2 cm; (B) bifocal method. An osteotomy was performed outside the injury zone. The intercalary segment was transported and then compressed at the defect site. Lengthening also occurred at the contralateral site, which maintain limb length. This method was indicated in bone loss between 2 cm and 6 cm; (C) trifocal method. Two sites of osteotomy were performed. We used two lengthening osteotomies and compressed the defect. This method was indicated in bone loss of > 6 cm.

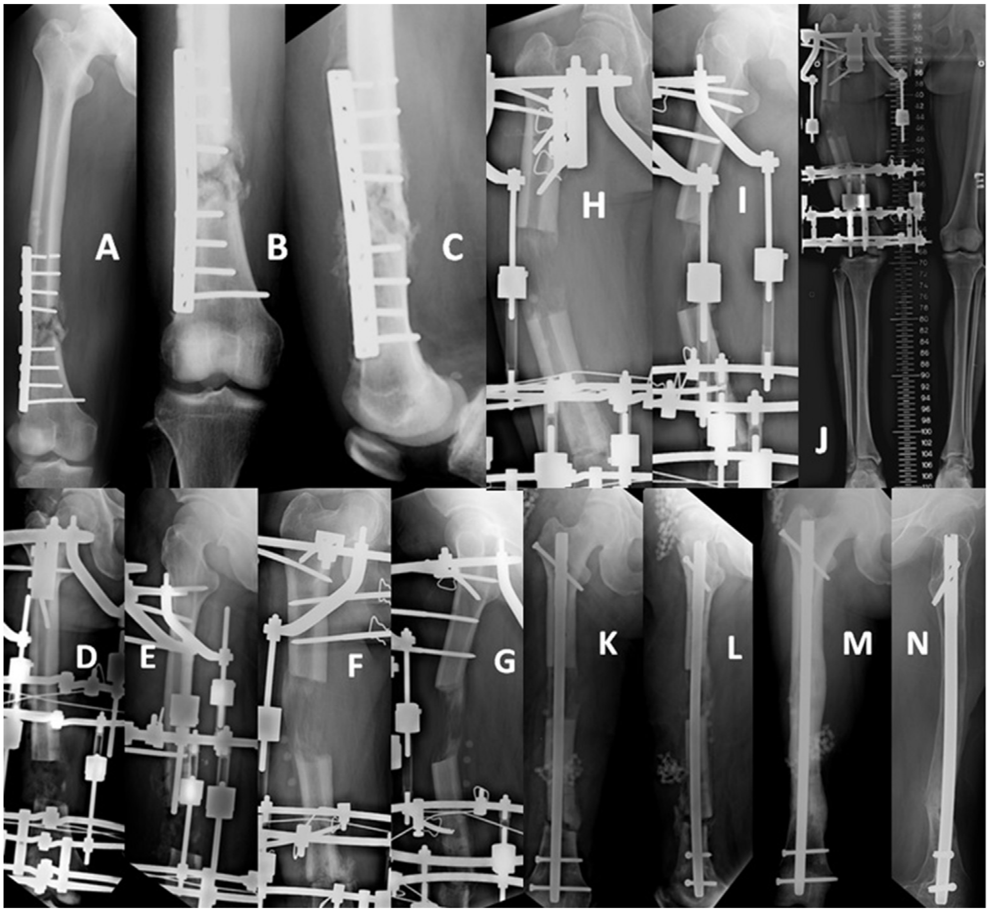

Fig. 3. The patient sustained infected fracture of the right femoral shaft for 4 months. (A) Radiograph shows the whole femur; (B, C) radiographs show comminuted fracture with plate-screw fixation; (D, E) radiographs show sequestrectomy and the use of Ilizarov's apparatus; (F, G) radiographs show proximal osteotomy and distraction osteogenesis via a bifocal approach with wet-to-dry dressing; (H–J) radiographs show callus formation at the docking site with equal leg length after additional bone grafting; (K, L) radiographs show intramedullary locked nailing applied; (M, N) radiographs show bony union at latest follow-up.

occurred. In most patients, this involved managing the wounds with daily normal saline wet-to-dry dressing. In addition to normal saline, diluted H_2O_2 (~ 1:1) in wet gauze was used as a disinfectant for treating wounds 3 days post-operatively (radical debridement), and was continued for 2 more weeks. As the transport progressed, granulation tissue was expected to appear, and the wound size gradually decreased until it was healed. High rates of pin-related complications, including tract infection, loosening, and deep infection have been reported.[1,3] With this wound management, there was no concomitant infection that required further intervention.

2.2. Statistical analysis

Statistical analysis was performed using SPSS for Windows version 17.0 (SPSS, Inc., Chicago, IL, USA). All data were expressed as the mean (range). Statistical comparison regarding knee range of motion at preoperative and final follow-up was performed using the Wilcoxon signed rank test. A p value ≤ 0.05 was considered to be statistically significant.

3. Results

The mean follow-up after use of the external frame was 87.5 (range, 38–133) months. No patient was lost to follow-up. The mean external fixator time was 6.8 (range, 5–11) months. The mean length of bone and soft tissue defects after radical debridement was 7.5 (range, 6–15) cm. Clinical and radiological union and elimination of infection were achieved in all patients. The most common infective organisms were methicillin-resistant *Staphylococcus aureus* (MRSA, 4 of 6 patients; Table 1).

At the time of the latest follow-up, no patients had neurovascular complications, joint subluxations, or refracture of the regenerated bone. The mean knee range of motion (ROM) before staged protocols and at final follow-up were 64.2 ± 8.6 (range, 60–75)° and 53.3 ± 9.3 (range, 40–65)°, respectively. Limited knee range of motion and loss of range of motion of ~11° were observed in these six patients following staged protocols (Table 1). The ROM at the affected knee after staged protocols decreased significantly when compared with the preoperative range (Wilcoxon signed rank test, $p = 0.03$).

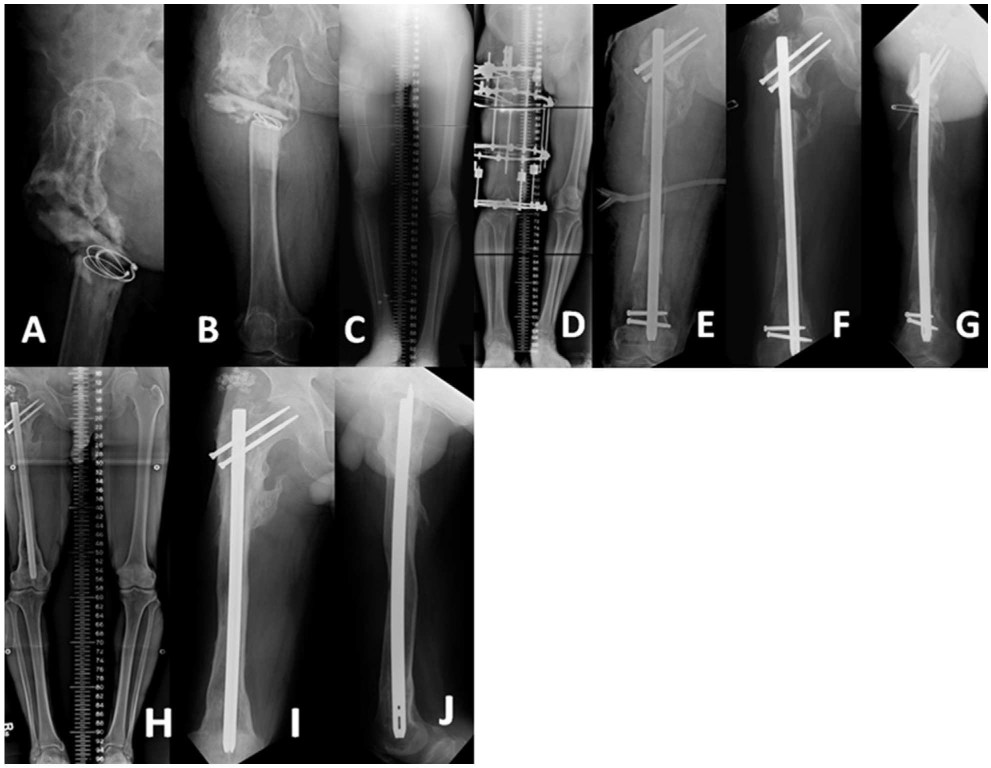

Fig. 4. The patient sustained infected nonunion of the right proximal femur. (A, B) Radiographs before staged protocols; (C) lower-extremity scanogram revealed an estimated 16-cm leg length discrepancy; (D) lower-extremity scanogram following sequestrectomy, using Ilizarov's apparatus, and two distal osteotomies in healthy bone via a trifocal approach with wet-to-dry dressing at wound; (E) radiograph shows intramedullary locked nailing; (F, G) radiographs show bony defect at the proximal femur; autogenous bone grafting was performed; (H) lower-extremity scanogram shows complete consolidation with a residual 4-cm leg length discrepancy; (I, J) radiographs at the latest follow-up.

Four patients were able to bear weight fully on the affected leg without a walking aid or brace, and the other two patients suffered from limping due to leg discrepancy (Nos. 2 and 6). They felt no pain or only mild pain when performing their normal activities of daily living. Mean lower leg discrepancy was 1 (range, 0–4) cm. One patient had the complication of a 4-cm residual leg discrepancy due to poor compliance (Table 1).

4. Discussion

Many methods exist for the obliteration of dead space after radical debridement of necrotic bone and soft tissue, including cancellous bone grafting or bone substitutes, transfer of living tissue, and the simultaneous treatment of bone and soft tissue using Ilizarov's method. The Ilizarov method is valuable in overcoming the problems of delayed maturation and insecure healing of the docking site.[8]

Previous experimental findings and clinical outcomes showed that multilevel defect fragment lengthening could provide sufficient bone formation and reduction of the total osteosynthesis time in one stage, compared with traditional Ilizarov bone transport.[9] In our experience with chronic tibial osteomyelitis, osteotomies of at least two levels were performed in the femoral shaft due to larger defect after radical debridement.[10]

The time to use the distraction–osteogenesis apparatus in children was suggested to be after infection eradication.[11] We used the Ilizarov apparatus immediately following radical debridement to provide stability and prepare for distraction–compression osteogenesis 1 week later.

Circular external fixation is an established method to solve the problem of complex tibial nonunion.[12] There is currently a consensus regarding the superiority of circular-type external fixators over uniplanar fixators for lengthening of complex tibia. However, there was a greater incidence of pain during lengthening, and patient satisfaction was lower in the circular external fixator group in a study comparing circular and uniplanar external fixators.[13] The Ilizarov frame construct is very resistant to torsion and bending, but allows axial compression during physiological loading.[14] In this study, we found a minimal incidence of axis deviation and no refracture at the lengthening site. The Ilizarov technique is a good salvage operation for infected nonunion of the femur. Limb salvage is preferable to prosthesis if the limb is viable and adequately innervate and the patient is mentally and financially committed to saving the limb.[14]

The Ilizarov distraction–compression osteogenesis method was modified to adequately resect necrotic and infected bone for both hypertrophic and atrophic nonunion[1] to achieve a satisfactory docking site healing process.[15] The distraction–compression method is simpler and is used to close

Table 1
Demographic data and clinical results of these patients.

Case No.	Age (y)	Gender	Site of bone defect	Preoperative knee ROM (°)	Size of bone defect (cm)	Infective organisms	Ilizarov method	Ilizarov period (months)	Bone graft in the docking site	Postop knee ROM (°)	Results	Complication
											Functional results	
1	35	M	Right femoral shaft	10–85	6	MRSA	Bifocal	11	Yes	10–75	Weight bearing without support	
2	55	M	Right subtrochanteric	10–60	15	MRSA	Trifocal	5	Yes	10–55	Limping	Residual 4 cm LLD
3	43	F	Right femoral shaft	0–60	6	MRSA, *Klebsiella pneumonia*	Bifocal	6	Yes	15–55	Weight bearing without support	
4	30	F	Left femoral shaft	10–75	4	MRSA, *Peptostreptoccus*	Bifocal	8	Yes	10–65	Weight bearing without support	
5	36	M	Left femoral shaft	5–70	6	*Pseudomonas*	Bifocal	5	Yes	15–70	Weight bearing without support	
6	28	M	Left femoral shaft	5–75	8	*Pseudomonas, Propionibacterium*	Trifocal	6	Yes	10–70	Limping	Residual 2 cm LLD

LLD = lower leg discrepancy; MRSA = methicillin-resistant *Staphylococcus aureus*; ROM = range of motion.

the defect directly.[1] Previous studies showed that simultaneous bone and soft tissue transport could successfully avoid the need for flap coverage.[2] Healing over soft tissue defects would be simultaneously achieved during the osteogenesis process.[10] Spontaneous wound healing using wet-to-dry dressing facilitates the restoration of soft tissue defects and healing of the bony gap without further flap coverage. Although the treatment time is long and patients report pain, especially during the transporting phase, there were no irreversible complications during the procedure.[16]

Although distraction osteogenesis is commonly used for the treatment of infected femoral nonunion with bone defects, it is associated with complications such as stiffness of knee joint, leg discrepancy, pin track infection, wires or pins loosening, deep vein thrombosis, thigh compression by tight ring, and neurovascular injury.[3] In our series, six patients had approximately 11° decrease in ROM at the knee joint. Two patients still had limping gait due to leg discrepancy. Other complications reported by Blum et al[3] were not observed in our series.

Hesketh[17] and Ali et al[18] quadricepsplasty methods and their modifications[19,20] might be possible alternatives to solve the stiff knee. In the Thompson technique, the vastus medialis, vastus lateralis, and vastus intermedius are freed from the rectus femoris through an anterior midline incision. The rectus femoris is then isolated from the rest of the quadriceps mechanism. In the Judet technique, the medial and lateral retinacula, suprapatellar gutter, vastus intermedius, vastus lateralis, and rectus femoris are released step by step to achieve knee ROM. Unfortunately, both methods have associated complications including skin necrosis, wound dehiscence, and extension lag caused by a long incision and extensive surgery, as well as edema of the lower leg and severe pain during the early postoperative period.[20] Moreover, the extensive soft tissue release may also jeopardize bone healing at the docking or distraction sites if these methods are not performed at the appropriate time. In our series, we did not arrange any quadricepsplasty for these six patients. In our opinion, quadricepsplasty might be one possible method to manage the knee stiffness following staged protocols, with some modifications at appropriate times.

This staged protocol seems to be a feasible treatment option in cases with large bone defects, and includes additional internal fixation after Ilizarov distraction osteogenesis. Internal fixation after distraction with femoral interlocking nailing ensures good clinical and radiological outcomes.[21] When combined with internal fixation, the lengthy external fixation time, which is poorly tolerated by patients and imposes long-term psychosocial hardships on families, is shortened.[22] The mean external fixator time was 6.8 months in this study, at which time callus formation was radiographically visible at the distraction site. The intramedullary implant occupied the healing space for osteogenesis and reduced the refracture rate after removal of the external frame.[23] Earlier removal of the external fixator is also associated with increased patient comfort, convenient and rapid rehabilitation,[24] and fewer pin-related complications.

In conclusion, in the treatment of chronic femur osteomyelitis, the staged protocol was found to be safe and successful. The same techniques were used for union, realignment, reorientation, and leg-length restoration. With regard to soft tissue, this protocol provides a unique type of reconstructive closure for infected wounds and is reliable in providing successful reconstruction simultaneously for bone and soft tissue defects without flap coverage.

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