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Original Article

Outcome of distraction osteogenesis by ring fixator in infected, large bone defects of tibia

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ABSTRACT

Background: Salvage of large, infected bone defects in tibia poses a formidable problem. The present prospective study aimed to evaluate radiologic and functional outcome of ring fixator in infected, large (≥ 6 cm) bone defects of tibia treated with distraction osteogenesis. **Materials and methods:** The study included 35 patients (30 males and 5 females) who had minimum of 6 cm gap after radical resection of necrotic bone and presence or history of active infection. Mean age was 36.1 years. Mean bone gap was 7.27 cm. Mean follow-up period was 25.4 months.

Results: Fracture united primarily in 17 cases and after fixator adjustment with freshening of fracture margins in 15 cases. Fixator adjustment with bone grafting was done in one patient to achieve union. One patient had nonunion and another had amputation. The bone result was excellent, good, and poor in 19, 13, and 3 patients, respectively. The functional results were excellent, good, fair and failure in 14, 19, 1, and one patient, respectively. 24 patients had superficial pin tract infection and 18 patients had ankle stiffness.

Conclusion: Ring fixator systems reliably achieve union in infected, large bone defects of tibia and help in treating infection, shortening, bone and soft tissue loss simultaneously. We advocate early freshening of fracture ends and removal of interposed soft tissue at docking sites to achieve union. Superficial pin tract infection and ankle stiffness are common problems in managing large tibial defects. But good to excellent functional outcomes can be achieved in majority of patients.

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1. Introduction

Large defects of bone and soft tissue in the leg may be the result of high-energy trauma or may follow surgical debridement. Salvage of large, infected bone defects in tibia poses a formidable problem. Different modalities of management like

extensive debridement and local soft tissue rotational flaps, packing the defect with antibiotic impregnated beads, Papineau type cancellous bone grafting, tibio-fibular synostosis, cancellous allograft in fibrin sealant mixed with antibiotics and or free micro vascular soft tissue and bone transplants, etc. are described to treat infected nonunions.^{1–6} Fractures with ≥ 6 cm bone defect require individualized

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treatment. Vascularized fibular grafts have been used successfully to treat large defects. But this procedure requires considerable technical expertise and it is technically challenging¹ and is beyond the competence of average orthopedic surgeon. Patients with large bone defects are often complicated with infection, deformity, shortening, soft tissue loss, osteopenia, muscle contractures and joint stiffness. The distraction osteogenesis principle has the potential to treat these complications simultaneously. Bone transport can be done through many devices like ring fixators, monolateral fixators or intramedullary nail system. Each device has its own advantages and disadvantages. Ring fixators have been in use for many years. But very few studies in literature have focused on outcome of ring fixator in infected, large bone defects of tibia treated with distraction osteogenesis.^{6–8} The present prospective study aimed to evaluate radiologic and functional outcome of ring fixators in infected, large (≥ 6 cm) bone defects of tibia treated with distraction osteogenesis.

2. Materials and methods

The present prospective study included patients of posttraumatic, infected defects of tibia presenting to author's tertiary level institute between May 2008 and February 2013. The study was approved by institutional review board. The study included only those patients who had minimum of 6 cm gap after radical resection of necrotic bone and presence or history of active infection. Patient was considered to have active infection if there was a discharging sinus or positive culture swab from the wound. The patients excluded from study were defects of tibia of reason other than trauma, with non-sensate foot, age >65 years, pathological fractures, any medical or skeletal illness affecting bone healing and patients with less than 6 months postoperative follow-up. 35 patients met the inclusion criteria. There were 30 males and 5 females with the mean age of 36.1 (12–60) years. At presentation, a full history was obtained which included details of initial injury and previous treatments. On examination, the presence of shortening, deformity, neurovascular deficiency, and condition of soft tissue was documented. All patients were informed about the approximate duration of treatment and the associated complications prior to reconstructive surgery and informed consent was taken for inclusion into the study. Right side was involved in 27 patients and left side was involved in 8 patients. The fracture site mainly involved proximal third of tibia in 11 patients, middle third in 9 patients, and distal third in 15 patients. 30 patients had open fractures at the time of original injury. The mode of trauma was road traffic accidents in 34 patients and gun shot injury in one patient. The previous treatment was spanning external fixation in 29 patients, intramedullary nail in 3 patients and locking compression plate in 3 patients. Average number of operations performed before application of definitive frame was 1.22. The mean time between injury and definitive frame application was 25.1 weeks (range, 4–98 weeks). Five patients were chronic smokers. At the time of presentation, 6, 1, 19, 5, and 4 patients had type A1, A2, B1, B2, and B3 injury, respectively as per Paley et al. classification.⁹ Ten patients already had ankle joint stiffness due to their previous walking inability. Active purulent

drainage was present in 20 patients. Pus was sent for culture and sensitivity in patients with active purulent discharge. These patients were started antibiotic according to culture report on the day of surgery. Other patients were given broad spectrum antibiotics for prophylaxis. Operative treatment included thorough soft tissue debridement, removal of implant, exposure of fracture site, radical resection of necrotic, or sclerotic bone so as to obtain healthy bleeding bone on either side of nonunion, and opening of medullary canal. The bone ends were cut transversely to provide broad surface for achieving union. The transporting bone fragment end was cut till coverage of skin was possible so that transporting bone fragment carried skin over it during distraction. After thorough debridement and adequate lavage, the patient was draped again with fresh autoclaved sheets and whole of the operative team rescrubbed. The ring fixator frame was applied and corticotomy was done. Cultures of the infected bone, obtained at the time of debridement procedure, dictated the choice of antibiotic treatment postoperatively. The mean bone gap was 7.27 cm (range, 6–12 cm). The mean size of wound was 5 cm $\times$ 2.5 cm. The standard ring fixator frame included four rings, with four rods and on an average of 10 wires per patient. During insertion of wires the muscle being penetrated was stretched at the time of transfixion to ensure maximum joint movement. The frame was applied according to the technical principles reported by Ilizarov.¹⁰ The limb was kept in normal frontal, sagittal, and rotational alignment during the frame application. All patients had corticotomy at one level. All patients had compression osteosynthesis at fracture site with distraction osteosynthesis at corticotomy site. Proximal metaphyseal corticotomy was performed in 21 patients; distal metaphyseal corticotomy in 13 patients, and mid-diaphyseal corticotomy was done in one patient. No patient had acute docking at fracture site at the time of frame application. The fibular osteotomy or resection was performed wherever needed for deformity correction or to achieve union later at the time of fixator adjustment. Closure of the wound was attempted by giving relaxing incisions. Split-skin grafting or flaps were done in two patients before index operation and in two patients at the time of frame application. In the post-operative period, joint motion and partial weight bearing mobilization with crutches or walker was encouraged depending on patient's compliance and status of pain. Distraction at an initial rate of 1 mm per day in four increments was started on day 7. The broad spectrum antibiotics were given for 5 days and thereafter choice of antibiotic (for another 10 days) was determined by the culture sensitivity report. Pin site care and hygiene were taught to all patients before discharge. All patients were seen in out patient department on regular monthly follow-up. Assessment of complications like muscle contractures, axial deviations, premature consolidation, delayed consolidation, refracture, and pin tract infections was done at each follow-up. Pin tract infections were classified according to Paley's classification¹¹ into grade 1, grade 2, and grade 3. Grade 1 and grade 2 infections were labeled together as "superficial pin tract infections". Grade 3 infections were labeled as "deep pin tract infections". Superficial pin tract infection was treated by local care, incision and drainage, and oral antibiotics. Deep pin tract infection was treated by local care, incision and drainage, intravenous antibiotics, and pin removal if necessary. The clinical and radiographic assessment was done at each

follow-up and initial rate of distraction was altered based on the radiologic appearance of the regenerate. Radiologic assessment of the alignment was undertaken to ensure adequate docking. If necessary, the frame was adjusted under anesthesia to correct malalignment. The fixator adjustment also included freshening

of fracture margins and excision of interposed soft tissue. After successful docking, if there was no radiologic evidence of union at 6 weeks, bone grafting from iliac crest or fibula was done at docking site after excision of interposed soft tissue. The frames were retained until adequate consolidation of the regenerate

Fig. 1 – (A) Radiographs of 40-year-old male showing fractures of both bones of right leg (Open grade IIIB). **(B)** Immediate postoperative radiographs of the same patient showing 7 cm bone gap with ring fixator and proximal metaphyseal corticotomy. **(C)** Radiographs showing transported bone fragment and regenerate formation at 9 months follow-up. **(D)** Radiographs after ring fixator removal at final follow-up. **(E)** Clinical photographs at final follow-up showing stiffness at knee and ankle. Patient had excellent bone result and good functional result.

Fig. 2 – (A) Immediate postoperative radiographs of 45-year-old male showing proximal metaphyseal corticotomy and 9 cm bone gap. **(B)** Radiographs of the same patient after 9 months follow-up showing transported bone fragment

and fracture union was achieved or when patient insisted because of some pain or any other complication during treatment. The frames were dynamized before removal. Patients were given PVC brace for 6 months after removal of fixator. The results were assessed as bone results and functional results according to the classification of the Association for the Study and Application of the Method of Ilizarov (ASAMI).^{6,8} The bone results were determined according to four criteria: union, infection, residual deformity, and limb length discrepancy. The fracture was considered united when it appeared so radiologically (bridging trabeculae at three of four cortices on anteroposterior and lateral radiographs), when there was no motion at the fracture site after loosening of the frame and when the patient was able to walk without pain at fracture site. An excellent bone result was defined as union, no infection, deformity of $<7^\circ$, and limb length discrepancy of <2.5 cm; a good result, as union and any two of the other criteria; a fair result, as union and one of the other criteria, and a poor result, as nonunion or refracture or as union but none of the remaining three criteria. Functional results were based on five criteria:

1. A noteworthy limp;
2. Stiffness of either the knee (loss of $\geq 15^\circ$ knee extension) or the ankle (loss of $\geq 15^\circ$ ankle dorsiflexion);
3. Soft tissue sympathetic dystrophy;
4. Pain that reduced activity or disturbed sleep;
5. Inactivity.

The functional results were considered excellent if the patient was active and none of the other four criteria were applicable; good if the patient was active but one or two of the other criteria were applicable; fair if the patient was active but three or four of the other criteria were applicable; and poor if the patient was inactive. Amputation was considered as failure. External fixator index was calculated by dividing the frame-keeping period in months by the length of the regenerated bone in centimeters.

3. Results

There were no intraoperative complications, such as neurovascular damage due to pin insertion or compartment syndrome due to tibial corticotomy. The mean operative time was 86.1 min (range, 70–120 min). The mean time in external fixation was 11.9 months (range, 6–20 months) with mean external fixator index of 1.8 months/cm (range, 1.25–3.1 months/cm). Mean follow-up period was 25.4 months (range, 6–48 months). Fracture united primarily in 17 cases (Figs. 1A–E and 2A–D) and after fixator adjustment with freshening of fracture margins in 15 cases. Fixator adjustment with fibular bone grafting was done in one patient to achieve union. One patient had premature removal of ring fixator due to excessive pain and had amputation. One

and regenerate formation. **(C)** Radiographs at 3 years follow-up showing union and remodeling of regenerate. **(D)** Clinical photographs at final follow-up showing stiffness of ankle, full knee range of motion, and no limb length discrepancy. (Bone result = excellent, functional result = good.)

patient had nonunion at final follow-up and refused further treatment. All corticotomy sites healed. Tibio-talar arthrodesis was achieved in one patient who had complete loss of distal tibial articular surface (Fig. 3A–E). Mean gain in bone length was 6.6 cm (range, 4–12 cm). Limb length discrepancy >2.5 cm persisted in 4 patients. Deformity $>7^\circ$ persisted in 8 patients. No patient had persistent infection at fracture site. Seven patients had loss of $>15^\circ$ knee extension. 18 patients had loss of more than 15° ankle dorsiflexion at final follow-up. Two patients had wire breakage in the study. Wire cutthrough occurred in one patient. Superficial pin tract infection occurred in 24 patients. Deep pin tract infection occurred in one patient. Correction of deviation of transporting fragment was required in 16 patients. The transported bone carried overlying skin with it, thus, avoiding flap reconstruction. One patient had refracture after 1 year of removal of the frame which required reapplication of ring fixator to achieve union. The bone result was excellent, good, and poor in 19, 13, and 3 patients respectively. The functional results were excellent, good, and fair in 14, 19, and one patient. One patient had amputation, so his functional result was categorized as failure. A total of 84 complications occurred with mean of 2.4 complications per patient (Table 1).

4. Discussion

Nonunion of a long bone is not merely a failure of two bony segments to unite, but most frequently it represents a significant loss of limb function with concomitant muscle atrophy, loss of range of motion of adjacent joints, osteopenia, surrounding soft tissue compromise especially in the presence of infection.^{2,9,12} Usually, multiple surgical interventions are necessary in order to eradicate the infection and restore other orthopedic problems such as bone defect, shortening, deformity, and joint contracture. Some of the bony reconstruction procedures include open cancellous bone grafting, posterior bone grafting with tibiofibular synostosis, anterior cancellous bone graft beneath a flap, vascularized or nonvascularized transfer of ipsilateral fibula into the tibia, nonvascular autogenous cortical bone grafts, transplant of allograft bone, and distraction histiogenesis.^{1–3} However, options for bony

Table 2 – Comparison of bone results with those in literature.

S. no.	Name of study	Excellent result (%)	Good result (%)	Fair result (%)	Poor result (%)
1	Present study	54.3	37	0	8.5
2	Maini et al. ⁶	70	10	0	20
3	Chaddha et al. ⁸	52	4	0	44
4	Yin et al. ¹³	67	23	7	3
5	Patil et al. ¹⁴	41	34	10	15
6	Farmanullah et al. ⁵	57	21	14	8

Table 3 – Comparison of functional results with those in literature.

S. no.	Name of study	Excellent result (%)	Good result (%)	Fair result (%)	Poor result (%)	Failure (%)
1	Present study	40	54.3	2.85	0	2.85
2	Maini et al. ⁶	27	40	10	23	0
3	Chaddha et al. ⁸	24	36	16	36	0
4	Yin et al. ¹³	40	43	17	0	0
5	Patil et al. ¹⁴	41	41	6	6	6
6	Farmanullah et al. ⁵	57	31	7	5	0

defects 6 cm or more in tibia are limited. The present prospective study reports outcome of ring fixator in infected, large (≥ 6 cm) bone defects of tibia treated with distraction osteogenesis.

Goal of treatment in infected nonunion is to obtain solid bony union and eradication of infection with maximum functional use of the extremity.¹ The bone and functional results in the present study were comparable to those reported in literature (Tables 2 and 3).^{5,6,8,13,14} A thorough debridement to vascularized, living tissue seems necessary, even when using Ilizarov technique to repair the bony portion of non-union.^{6,9,12,15,16} Union was achieved primarily in 17 patients in the present study. One more procedure of fixator adjustment, removal of interposing soft tissue, and freshening of bone ends resulted in union in additional 15 patients. One patient required bone grafting in the present study. Whereas Chaddha et al. reported bone grafting in 36% patients,⁸ Mahaluxmivala et al. reported that additional bone grafting at the docking site was required in 83.3% patients in the bone transport group as compared to 16.7% in the acute shortening group.¹⁷ More procedures were necessary in the bone transport group mainly to correct alignment to ensure accurate docking and bone grafting at the docking site.¹⁷ We advocate early freshening of fracture ends and removal of interposing soft tissue at docking site to achieve union. It also corrects malalignment. Iacobellis et al. also recommended removal of interposed fibrous or cutaneous tissue at docking site to achieve union.¹⁸

Soft tissue loss often complicates the treatment of tibial nonunion with bone loss and may require skin grafts, local pedicled muscle and myocutaneous flaps, and free flaps. Such surgery may require a microvascular team and increase hospitalization time, cost, and morbidity.⁷ We believe that if

Table 1 – Complications in the present study.

S. no.	Complications	Number of patients (%)
1	Superficial pin tract infection	24 (68.5)
2	Deep pin tract infection	1 (2.8)
3	Limb length discrepancy ≥ 2.5 cm	4 (11.4)
4	Knee stiffness (loss of $\geq 15^\circ$ knee extension)	7 (20)
5	Ankle stiffness (loss of $\geq 15^\circ$ ankle dorsiflexion)	18 (51.4)
6	Deformity	8 (22.8)
7	Refracture	1 (2.8)
8	Axial deviation requiring realignment	16 (45.7)
9	Significant pain	1 (2.8)
10	Cut through of wires	1 (2.8)
11	Wire breakage	2 (5.7)

Table 4 – Comparison of union and complications in the present study with those in literature.

S. no.	Study	Bones involved	No. of patients	Type of fixator used	Mean bone gap (cm)	Union (%)	Persistent infection (%)	Deformity $\geq 7^\circ$ (%)	LLD ≥ 2.5 cm (%)	Pin tract infection (%)	Ankle stiffness/joint stiffness (%)
1	Chaddha et al. ⁸	Tibia, femur	25	Ring	8.9	92	4			80	56
2	Maini et al. ⁶	Tibia, femur, humerus	30	Ring	7	100	10	0	3		63
3	Paley et al. ⁹	Tibia	25	Ring	6.2	100	12	16	4	20	20
4	Megas et al. ²³	Tibia	9	Ring	5	100	Nil	Nil	Nil	6	55
5	Baruah ⁴	Tibia	25	Ring	4.3	96	4			0	8
			25	Hybrid	2.6	96	8			4	0
6	Present study	Tibia	35	Ring	7.3	94	2.8	22.8	11.4	68.5	51.4

LLD, limb length discrepancy.

the transported bone fragment has intact, normal skin over it, it takes the overlying skin along during transport. This is more successful if the skin loss is longitudinal, i.e. along the length of bone and both soft tissue and bone grow at corticotomy site. Sen et al. also reported that in patients with a soft-tissue defect, acute or gradual compression at the docking site allowed primary or delayed primary closure without any secondary reconstructive procedure.⁷ There is less need for soft tissue coverage procedures in patients with bone transport, and this also decreases the need for surgery on other body areas for free tissue transfers.¹⁹ El-rosasy also reported acute limb shortening and appropriate skin incisions to close the defect.¹⁶ Similarly, Bumbasirević et al. reported that soft tissue defects can be successfully closed by soft-tissue transport in majority of patients and by split-skin grafting in remaining patients.²⁰ Mckee et al. reported single-stage osseous and soft tissue reconstruction using the Ilizarov method in patients with composite tissue defects.²¹ We agree with Robert Rozbruch et al. that the Ilizarov method can be successfully used to reconstruct the leg with tibial bone loss and an accompanying soft-tissue defect and it avoids the need for a flap.²²

The concept of burning an infection in the fire of an Ilizarov device has changed to the current philosophy that the only cure for osteomyelitis is radical debridement until live and bleeding bone is reached.²³ We were able to eradicate infection at fracture site in all patients because of radical debridement and extensive resection of dead bone. We have performed corticotomy during the same procedure and no corticotomy site was infected in the present study. Our protocol of redraping and rescrubbing after initial debridement might have also contributed in eradication of infection at fracture site

and prevention of infection at corticotomy sites. This simple and effective per-operative measure of redraping the limb after debridement and lavage prior to corticotomy and ring application gave encouraging results in our study. 68.57% patients in the present study had superficial pin infection. El-rosasy and Sen et al. reported pin tract infection in 23.8–30% patients.^{7,16} Chaddha et al. reported pin tract infections in 80% patients treated with ring fixator.⁸ Wani et al. also found pin tract infection as the most common complication associated with Ilizarov ring fixator.²⁴ Pin tract problems are related to pin-skin motion, amount of soft tissue between skin and bone, and the diameter of the pin used.¹¹ Good care of pin sites and aggressive management of superficial infections is essential to prevent deep infections.²⁴ Ankle stiffness was observed in 51.4% patients in the present study. Significant joint stiffness has been reported in up to 56–63% patients operated with ring fixation system in literature (Table 4).^{6,8} Megas et al. also observed stiffness of ankle joint in 55% patients and reported it as a common and severe residual problem after such surgical intervention.²³ Impalement of muscles leading to difficulty in physiotherapy could be the cause of such a deformity in the patients treated with ring fixator.^{4,11} The overall complication rate in present study was 2.4 complications per patient as compared to 2.88 reported by Chadda et al.⁸ and 1.59 by Paley.¹¹

The Ilizarov method is a comprehensive approach to all aspects of chronic tibial nonunion that simultaneously addresses deformity, shortening, defects, infection, articular and limb function, weight bearing, osteoporosis, and soft tissue atrophy.^{9,10,24} The ring fixator is an ideal apparatus to treat infected gap nonunion of the tibia and to correct deformity in multiple planes. The main drawback of ring

Fig. 3 – (A) Radiographs of 28-year-old male showing complete loss of right side distal tibia. (B) Immediate postoperative radiographs showing proximal metaphyseal corticotomy and 7 cm bone gap with ring fixator. (C) Radiographs at 6 months follow-up showing transported bone fragment and regenerate formation. (D) Radiographs at 4 years follow-up showing tibiotalar arthrodesis. (E) Radiographs at 4 years follow-up showing remodeling and canalization of regenerate. (F) Clinical photographs at final follow-up showing stiffness of ankle, full knee range of motion. (Bone result = excellent, functional result = good.)

fixator system is the long duration of external fixation with marked patient discomfort. Two patients in the present study did not prefer limb lengthening equalization after achieving fracture union due to discomfort in ring frame. To overcome patient discomfort, Emara and Allam advocated early removal of external fixator and replacement by intramedullary nail.²⁵ Half pin frame is another option which is user friendly and less time consuming.⁴ Patient tolerability is better and that helps in early physiotherapy.⁴ Monolateral fixator has been reported to be light weight, easy to construct frame with short learning curve.²⁶ But it is difficult to correct three-dimensional deformities with uniplanar external fixator unlike Ilizarov fixator.²⁶ Circular frames are more popular than uniaxial devices since they confer greater stability and more flexibility in the configuration of the frame.¹

Attempting limb reconstruction in the presence of significant bone loss usually involves surgery which is technically difficult, time consuming, physically and psychologically demanding for the patient, and with no guarantee of a satisfactory outcome.¹ The dilemma faced by the treating surgeon is to decide when to opt for amputation and prosthetic replacement over salvage.⁶ We agree with Maini et al.⁶ and Chaddha et al.⁸ that all patients who are psychologically stable and with a sensate foot should be considered for salvage procedure, keeping in mind the financial burden and psychological support needed for the prolonged period of treatment.

5. Conclusion

Ring fixator systems reliably achieve union in infected large bone defects of tibia and help in treating infection, shortening, bone and soft tissue loss simultaneously. We advocate early freshening of fracture ends and removal of interposed soft tissue at docking sites to achieve union. This avoids the need of bone grafting. The transporting fragment carries overlying skin along with it during distraction, thus avoiding the need of flap or skin grafting. Superficial pin tract infection and ankle stiffness are common problems in management of large bone defects in tibia. But good to excellent functional outcomes can be achieved in majority of patients.

Ethical and humane considerations

All patients gave written informed consent to be included in this study, and the study was authorized by the local ethical committee carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Conflicts of interest

The authors have none to declare.

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