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Original Research Article

Management of infected non-unions of long bones using limb reconstruction system (LRS) fixator

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ABSTRACT

Background: Due to increasing number of high-energy traumatic events, the incidence of complex and compound fractures are also in the rise. Such fractures are often exposed to various environmental contaminants, inadequate debridement and sometimes erroneous decision making leading to cases of infected nonunions. Eradication of infection in such cases and achieving union may sometimes pose serious challenge to orthopaedic surgeons. Presence of comminution, bone gap or deformity can seriously complicate the situation. No definite surgical technique has been found to be full proof in dealing with these infected nonunion cases. In this scenario the limb reconstruction system (LRS) fixator is emerging as a useful option for infected nonunions with deformity or gap nonunion.
Methods: Twenty seven cases of infected nonunions involving tibia (n=19), femur (n=7) and humerus (n=1) were treated by LRS fixators after debridement of the infected nonunion site. Flap cover procedure was done as per necessity. Bone gaps and limb length discrepancies were dealt with bone transport or limb lengthening by the LRS instrument. Weight-bearing and removal of fixator was decided according to the radiological evidence of healing.
Results: All the nonunions and the regeneration sites healed uneventfully, although the union time was varied (range, 21-52 weeks). Commonest complication was pin-tract infection and pain. The mean lower extremity functional score (LEFS) was 60.3 out of 80.
Conclusions: LRS fixator is an excellent tool for management of infected nonunions which is easy to apply, comfortable for the patient with minimum complications and predictable as well as reproducible outcomes.

Keywords: Infected Bone, Nonunion, Bone transport, Limb lengthening, LRS, Fixator

INTRODUCTION

Incidences of complex open injuries of the limbs are on the rise owing to the increased number of high energy vehicular accidents in recent times, which subsequently giving rise to more cases of infected non-unions.[1] Infected non-union of long bones are not only a source of functional disability but also can lead to economic and social hardship. Infected non-union has classically been defined as a state of non-union of fracture for at least six months with persistent infection at the fracture site. Infected non-union can result from various aetiologies, commonest being, open fractures, previous surgical procedures or as sequelae to osteomyelitis of bone.

Infected non-unions have been the menace for Orthopaedic surgeons since decades, because of factors, i.e. a) previous surgeries would have resulted in cicatrisation of the soft tissue with an avascular environment around the fracture site, b) chronic discharging sinus suggestive of pus collection and possible presence of sequestrum, c) necrosis of fracture ends near the non-union site up to variable lengths, due to thrombosis of vascular channels of the bones, d) prolonged immobilization, multiple surgeries with fibrosis of the muscles resulting in stiffness of adjacent joints, e) the microorganism may have developed resistance to multiple antibiotics, f) occurrence of limb length discrepancy and deformities, and g) variable degree of soft tissue loss or defects requiring multiple sessions of plastic surgical reconstructions.[2,3]

Various researchers over the years have used many different approaches to deal with these complex problems. But, it has not been possible to address all the problems mentioned above by using any single technique. Therefore attempts are often made to follow a technique which can minimise the total number of additional surgical procedures, apart from being able to achieve union and controlling infection. External fixation devices which are compatible with "distraction osteogenesis" and gradual correction of deformities are gaining popularity in recent times in the management of infected non-unions.[4,5] Limb reconstruction system (LRS) is such an external fixation device which has shown great promise in such cases. In this study, we present our experience of treating infected non-unions of long bones by use of LRS external fixators with or without distraction osteogenesis.

METHODS

This study was prospectively conducted in the Department of Orthopaedics of a tertiary care hospital during the period October 2011 to November 2015. A total number of 27 patients presenting during this period with infected non-union of long bones like femur, tibia and humerus were included in the study. Among the study group 25 patients were males and two were females. Out of them seven were femoral, 19 were tibial and one case was humeral infected non-unions. All the patients were treated by the LRS external fixator of various dimensions and configurations.

The patients were evaluated by routine blood investigations like complete blood counts, quantitative CRP and erythrocyte sedimentation rate. Swab samples were taken from the discharging sinuses for culture/ sensitivity and Gram staining. AP and lateral view radiographs of the affected limbs were taken to check for deformity, bone cavity, sequestrum, bone loss or comminution. Distal vascularity of the limbs and soft tissue as well as skin conditions was evaluated. Plastic reconstructive surgery opinion was sought for any possible need for soft tissue coverage surgery.

Inclusion /exclusion criteria

Patients of age more than eight years with radiological evidence of non-union and signs of infection at the non-union site were included in the study. Patients those were excluded were less than eight years of age, non-unions of congenital aetiologies and pathological fractures due to non-infective causes or cases with radiological signs of progressing union.

Surgical procedure

The surgical planning was done depending on the radiological diagnosis and soft tissue conditions. Patients with bone loss, dead sclerotic or sequestrated bone and limb-length discrepancy were planned for excision of devitalized tissues and the gap was managed by bone transport or limb lengthening after acute docking. Cases without any limb-length inequality or gap or less than 2.5 centimetres inequality were just debrided of infected material and compression done at fracture site with LRS fixator. Acute docking and bone lengthening following debridement was done in cases with bone gap less than five centimetres. For more than five centimetres gap bone transport was preferred.

In most cases "three-clamps LRS" construct was used, with two clamps in the segment where corticotomy was planned as shown in Figure 1, 2 and 3. Three tapered Schantz screws were used in the end-clamps on either sides in most cases and two screws used in the clamp over the transported segment. A transverse clamp is used when the proximal or distal fragment was found to be too small to accommodate three screws in longitudinal configuration. The nonunion site was opened and all the infected, scarred and devitalized tissues were debrided. The avascular sclerotic segment of the bone ends were excised till punctate bleeding was seen from the cortex. It must be emphasized that the tourniquet must be deflated at this stage to witness the bleeding from bone ends. The surgical site was cleaned thoroughly with antibiotic solutions. In few cases where frank pus was obtained at nonunion site, antibiotic impregnated bone substitute was also used before closing the wound. In cases planned for bone transport or lengthening, corticotomy was done in the metaphysio-diaphyseal region of the longer segment (in most cases in the proximal segment). The nonunion and corticotomy sites were closed gently without drains with well-padded dressings. Distraction is started on the seventh day of corticotomy at a rate of 0.5 millimetres twice a day. Gradually the patients or their relations were trained to do supervised distraction in the wards, so that they can continue distraction at home. Patients were discharged after suture removal at around two weeks from surgery. They were advised to report back every tenth day for radiological evaluation of distraction at correct rate or detect the appearance of any deformity. Patients were also advised to do rigorous quadriceps strengthening exercises as well as passive and active ankle range of motion (ROM) exercises; hip muscle strengthening and ROM exercises were advised in cases of femoral nonunion and the humeral nonunion case was trained in shoulder and elbow rehabilitation regime.

Patients were allowed to continue non-weight-bearing walk with the help of a walker for lower limb cases. Toe touch weight bearing was started only after stopping the distraction process and appearance of callus in radiographs at a mean duration of 12.4 weeks (range, 9-19 weeks) after surgery. Full weight bearing was allowed after the evidence of good callus in both AP and lateral radiographs at a mean of 22 weeks (range, 16-41 weeks) post-operatively. The mean duration of removal of fixator from the date of surgery was recorded for tibia, femur and other cases separately as given in Table 1. None of the patients required secondary surgeries such as bone grafting or deformity correction.

Figure 1: (A) Boy of 13 years presenting with old compound & comminuted fracture of left tibia with infection and discharge; (B) Treated with LRS and bone transport; (C) Union seen at both sites after removal of LRS; (D) Remodelling after 3-years follow-up; (E) & (F) Functional recovery.

Figure 2: (A) Infected nonunion of sub-trochanteric fracture of right femur with implant failure; (B) Radiograph after debridement and application of LRS fixator in compression mode; (C) Patient with LRS; (D) Radiograph at the time of union.

Figure 3: (A) Infected nonunion of distal third of right humerus with implant loosening; (B) Discharging sinus near the nonunion site; (C) Application of LRS in compression mode with antibiotic impregnated bone substitute; (D) Radiograph of union; (E) & (F) Functional recovery of the shoulder and elbow.

RESULTS

Out of 27 patients of infected nonunion of femur, tibia and humerus, 12 were managed with debridement and compression, whereas 10 needed bone lengthening and rest five required bone transport. Four patients had significant soft tissue defect to warrant flap-cover procedure and two needed only skin grafting. Soft-tissues in all the patients healed nicely.

The mean lengthening achieved in cases of tibial infected nonunions was 4.0 cms (range, 3.0-5.0 cms) and the mean length of bone transport in tibia was 5.6 cms (range, 5.0-6.5 cms). Mean lengthening done in femur was 3.2 cms (range, 3.0- 3.5 cms) and none needed bone transport.

All the nonunion sites united without any bone grafting; all the corticotomy regenerate sites also consolidated uneventfully. The mean time of radiological union in the tibia patients was 26.4 weeks (range, 22-52 weeks), whereas the same in femoral patients was 24.7 weeks (range, 21-34 weeks). The functional assessment of all the lower limb patients was done using the Lower Extremity Functional Scale (LEFS) score. The mean LEFS score among all the patients was 60.3 (range, 24-74); LEFS scoring of tibial and femoral patients was done separately too as given in Table 1.

The commonest complication encountered in this study was pin-tract infection and pin-tract pain, which was seen in at least three pin-tract sites per patient. But none of the cases needed revision or removal of the tapered Schantz pins; all healed well with regular dressings with antibiotic solutions. Six patients had restrictions of motion in the knee joint with lowest flexion of 80 degrees in a patient of proximal tibial nonunion and four patients complained of restriction of ankle dorsi-flexion and the resulting difficulty in walking. Two patients continued to have a single sinus each with serous discharge even after two years of follow-up, but they refused any further intervention. One patient started weight bearing against advice before consolidation of the regenerate and subsequently developed a slight curvature near the corticotomy site, but it did not result in any serious functional disability.

Table 1: Data of patients and radiological & functional outcome values expressed by calculating the mean.

	Tibia	Femur	Humerus
Total No. of cases	19	7	1
Debridement & compression	6	5	1
Debridement & lengthening	8	2	--
Debridement & transport	5	--	--
Mean length gained by limb lengthening	4.0 cms	3.2 cms	--
Mean length gained by bone transport	5.6 cms	--	--
Mean duration to radiological union	26.4 weeks	24.7 weeks	17 weeks
Mean duration of fixator removal	33.8 weeks	33.1 weeks	25 weeks
Mean LEFS outcome score (60.3)	61.5	56.9	-NA-

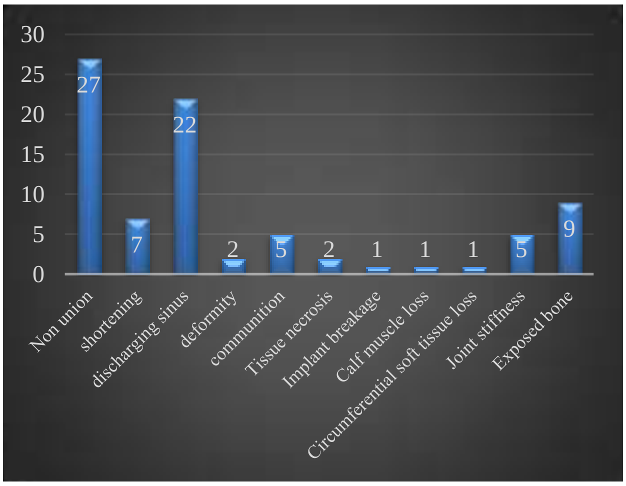

Figure 4: A bar chart showing the prevalence of chief complaints and associated clinical problems among the patients at the time of presentation.

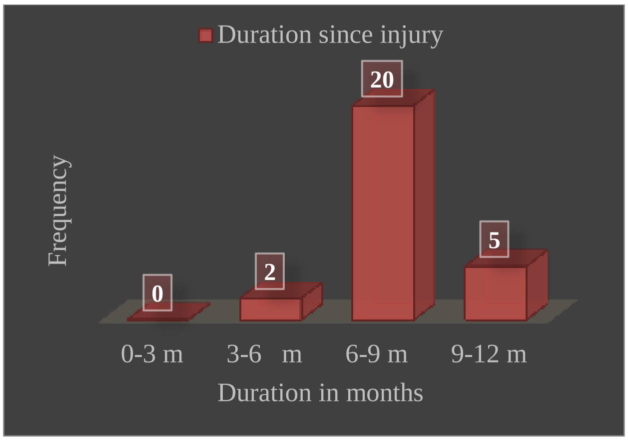

Figure 5: A bar chart showing the duration of the disease from the time of injury to the time of presentation.

DISCUSSION

The management of infected non-union has remained a constant challenge. The associated factors like delayed presentation, bone defects or gaps, shortening, deformities and poor soft tissue conditions complicate the treatment further as presented in Figure 4 and 5.[6] Treatment recommendations for non-union of long bones range from non-invasive and semi-invasive methods to extensive surgical interventions. The non-invasive methods include electric stimulation, low-intensity pulsed ultrasound and extracorporeal shock wave therapy etc.[7-10] The various surgical methods include bone marrow injection, autologous bone grafting, fixations using intramedullary, extramedullary and external fixation devices.[11-16] But the presence of infection at the fracture site changes the scenario significantly and forces alterations in the management protocols. Use of the otherwise popular technique of non-vascularized cortico-cancellous bone grafts becomes unpredictable in presence of active infections.

Internal fixation methods usually require extensive surgical procedures and the implants themselves may behave like foreign bodies in an infected surrounding and may further help colonization of the pathogens. Although these internal fixation methods are known to be useful in cases of aseptic non-union, they do not address problems like infection, shortening and bone loss. Moreover, the condition of the soft tissues may further limit the scope of large surgical exposures.[17-18] On the other hand, the advantages of an external fixator are that, it provides stable fixation staying away from the site of trauma or infection; it can be used as a minimally invasive method and there is no need of too much dissection through the already traumatized soft tissues apart from the debridement. At the same time, by using the modern external fixators like LRS, problems such as shortening and deformity can also be addressed simultaneously. The patient can be mobilised early, which will act as a physiological stimulus for bone healing.

The Ilizarov ring fixator has proven to be a useful method to treat infected non-union cases. But it requires a long learning curve, expertise and is technically a demanding surgery. Although Ilizarov is a multi-planar strong and stable assembly, it may be quite cumbersome an apparatus for both the doctor and the patient alike. On the other hand the LRS is a simple, unilateral assembly with excellent strength and rigidity. It is less cumbersome, quicker to apply and better tolerated by the patient. Progressive correction of the deformity and shortening is possible at the same time by this instrument.[3-5,19,20]

The overall goal in the reconstruction of an infected non-union of long bone involves more than control of infection and includes creation of a healed, aligned and drainage free limb which is functionally better than a amputated and prosthetic fitted limb. Several factors must be considered in reconstruction of bone including the patient's age, socioeconomic status, metabolic status, mobility of the knee, foot and ankle, integrity of neuro-vascular structures and also the patient's motivation.

The extent of bony debridement is defined by the appearance of punctate bleeding points at bone ends. The non-union site must be resected as it is better to substitute a biologically poor atrophic bone area with two bone surfaces of good quality modelled in such a way so as to allow easy stabilization and compression. The decision to proceed with the reconstruction is based on not only the surgeon's ability to restore a functional limb but also the duration anticipated for treatment and the anticipated residual disability. Thorough wound debridement and removal of the bone and soft tissues with doubtful vascularity is necessary for achieving bone healing and eradication of infection. The patient must be co-operative and made to understand the duration for which the LRS frame has to be in place and complications like pin-tract pain and infection necessitating pin revision. In elective situations the patients can be made to meet other patients who have undergone this process, have preoperative counselling and voluntarily elect this treatment protocol. Patients are more likely to accept these techniques better when they have chosen it as an elective reconstruction rather than when it is inflicted up on them.

In the recent past, a tremendous interest has been generated in the method of distraction osteogenesis. The clinical fact that distraction can produce new bone formation was showed as early as in 1900 by Codivilla. The effect of rhythmical distraction resulting in new bone formation was enlightened by Ilizarov from 1951 onwards. The positive effect of corticotomy on the vascularity of the whole limb has also been a matter of interest since decades. The effect of corticotomy on the healing of bone is also explained by intact intramedullary blood supply by microangiographic studies. By the distraction force at the corticotomy site, the lining cells covering the bone ends are able to differentiate into osteogenic and chondrogenic cells under adequate stimulus and environment; this type of osteosynthesis has been termed as "intramembranous ossification of Ilizarov".[21-27]

The percentage of the patients in which union occurred and the time to union are the most important measures of biomechanical adequacy of the surgery. De Bastiani et al treated 50 cases of non-union or delayed union (16 femurs, 29 tibias, one humerus and one radius) with a dynamic external fixator.[5] A healing rate of 94% was reported, which was similar to the findings of the present study (100%). Marsh et al however, reported a lower healing rate (80%).[16] Most fractures in their series were 7–24 months old while, in our study, presenting time was 6-11 months.

Hashmi et al treated 110 long bone segments (60 tibias, 38 femurs and 12 humerus) with a mono-lateral fixator. There were 61 mono-focal and 49 bifocal procedures. Bone grafting was done in 71 cases in their series. The mean time to bone union was 12.6 months. The mean healing time in the bone lengthening group was 14 months (range 9–25 months) and in the non-lengthening group it was 12 months (range 3.5–64 months). The success rate in terms of clinical and radiological healing with initial fixation was 90%. The mean length gain was 4.5 cm (range 1.5–12 cm).[20] In our study, the majority of the patients (44.4%) were treated with compression at nonunion site, whereas 10 patients (37%) were treated with bone lengthening and only five patients (18.5%) needed bone transport. The choice between the methods was based on the amount of shortening or bone gap present after debridement. The mean time to bone union was 22.7 weeks which is similar to De Bastiani et al but much lesser than Hashmi et al. The average length gain in our series was 4.4cms in 15 patients which is similar to Hashmi et al. None of the patients required bone grafting in our series in contrast to Hashmi et al.

In our study, the results were interpreted through the LEFS scoring system. Out of a total score of 80, sixteen patients (61.5%) among 26 lower limb patients scored 60 or more and only one patient scored less than 40. The results are found to be similar to other studies in literature.[5,16,20,28] These results reinforce the utility of LRS in terms of union, limb-length equalisation, deformity correction and resolving of infection.

The LRS is a telescopic device that can be locked for rigid fixation or unlocked to permit load sharing. As the pins are unilateral it is comfortable for the patients and joint mobilization can be done with ease. Being rigid, early weight bearing can be allowed with the device in place. Patient himself can carry out day to day lengthening or transport with little training. Another advantage of the LRS fixator is the fact that, it does not interfere with plastic surgical soft-tissue procedures like cross leg flaps, free vascularised flaps, fascio-cutaneous flaps or skin grafting etc.

The commonest complication encountered in this series was pin-tract infection which is in accordance with many previous studies. Marsh et al have recommended proper fixator and pin-tract dressing at regular intervals for prevention of pin-tract complications.[16] Among other complications up to 10-15 degrees of angulation and 2.5 cms limb length discrepancy is thought to be well tolerated by patients; there was only one case of angulation at corticotomy site in our series and three cases of residual limb length inequality between 1-2 cms which the patients did not complain about. The other disadvantages include the high cost of the system, inability to use the apparatus for correction of gross deformities, in severe osteoporosis, stabilization very close to a joint, for which Ilizarov fixator could be a better option.

This study has weaknesses like small patient population, short duartion of follow-up and absence of a control or comparison group. Randomized control trials among different surgical methods may prove useful in identifying the best treatment protocol for these complicated problems.

The LRS is a reasonably simple instrument with less learning curve and patients themselves can do distractions once explained; it is also well tolerated by the patients for long durations. It is a strong and stable assembly in spite of being uniplanar, the results of treatment of infected nonunion by LRS fixator is quite satisfactory and also reproducible.

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