Comparision of Ilizarov Ring Fixator and Rail Fixator in Infected Nonunion of Long Bones: A Retrospective Followup Study

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Abstract

Background: About 70 million trauma injuries that occur annually, around the world. More than 4.5 million open fractures occur per year in India. Long bone fractures nonunion (NU) rate varies from 2% to 7%. The management of open fracture is challenging for the orthopedic surgeon. The conventional protocol of management of compound fracture are debridement, temporary stabilization by external fixators, wound and definitive management. Very few prospective studies have been done comparing Illizarov and RF in infected nonunion. Thus we performed a retrospective study to compare the acceptance, complications, and functional outcome of Ilizarov ring fixator (IRF) and rail fixator (RF) in the treatment of infected NU. **Materials and Methods:** A retrospective cohort study of fifty infected long bone NU patients, who consulted Orthopedics Department of a tertiary care hospital of North-India from 2010 to 2014 was undertaken.Patients were divided into two Groups (Gp) of 25 each: one group was treated with IRF, another with RF and both followed for one year. Results were analyzed as per the ASAMI criteria (Association for the Study and Application of Methods of Illizarov) and complications as per Paley's classification. Patient's satisfaction was assessed by Visual Analog Scale (VAS) ranging from 0 to 100 mm. **Results:** Majority of the patients were in age group of 31- 45 years males with right sided involvement with previously treated infected NU of tibia involving distal one-third. According to VAS score, patients had mild to moderate pain in 13 cases in Gp-IRF and in 16 cases in Gp-RF, whereas severe pain was present in 12 cases of Gp-IRF and 9 cases of Gp-RF. Pin tract infection and pain were the commonest complication. Mean bone gap was 7.76 cm and 5.78 cm; average total treatment time was 17.64 and 13.40 months in Gp-IRF and Gp-RF, respectively. Duration of IRF application was more than RF ($P < 0.01$). Both the limbs were equated in 20 cases (80%) in Gp-IRF and 18 cases (72%) in Gp-RF. Results were found to be excellent in 7 (28%) and 8 (32%), good in 8 (32%) and 13 (52%), and fair in 10 (40%) and 4 (16%) cases in Gp-IRF and Gp-RF, respectively. Bony union achieved in 100% cases. Treatment index was 68.45 days/cm and 64.29 days/cm in Gp-IRF and Gp-RF, respectively. **Conclusion:** In view of the patient acceptance, functional outcome and complications, rail fixator shows a better result than Ilizarov.

Keywords: *Bone gap, corticotomy site, distraction, limb length discrepancy, treatment index*

Introduction

About 70 million trauma injuries occur annually, around the world.[1] More than 4.5 million open fractures occur per year in India.[2] Long bone fractures nonunion (NU) rate varies from 2% to 7%.[1,2] US Food and Drug Administration defined NU as "established when 9 months have elapsed since injury and the fracture shows no visible signs of healing for 3 months."[3] Most cases of infected nonunion have component of infection in soft tissue and bone ends. Both have to be debrided extensively. This creates gap in the soft tissue and bone as well. The management of open fracture is challenging for the orthopedic surgeon. The conventional protocol of management of compound fracture are debridement, temporary stabilization by external fixators, wound management and definitive management.[4] However, distraction osteogenesis using some sort of external fixator is the only answer to bridge the defect.[5] Ilizarov ring fixator (IRF) in infected NU achieves union, corrects deformities by the technique of bone pulling, fragment deviation correction, re-establishes limb length, and maintains function.[6,7] Unilateral rail fixator (RF) in infected NU maintains stability and limb function.[8] The present study compares the acceptance, complications, and functional

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outcome of IRF and RF in the treatment of infected NU of long bones.

Materials and Methods

Fifty cases of infected NU of long bones, treated by IRF or RF between 2010 and 2014 were included in this retrospective cohort study. These cases were divided into two groups (Gp) of 25 each based on their treatment modality. First group was treated with IRF, a circular external fixator system, named Gp-IRF. Second group was treated with RF, a uniplanar system consisting of an assembly of clamps, which can slide on a ridge rail, connected by compression and distraction units, was named Gp-RF. Both the groups were comparable, as patient profile and bony profile (infection and NU) were same, working on the principle of distraction histogenesis but with different treatment modalities. The inclusion criteria were (1) Patients who were being treated in the tertiary care hospital of North India for infected NU with IRF and RF (2) Age between 18 and 60 years age and (3) Followup of 1 year. The exclusion criteria were: Patients with incomplete data, age less than 18 yrs, segment transport associated with tumor resection, and lengthening over an intramedullary nail were excluded from the study.

Paley's classification was used for noting difficulties that occurred during limb lengthening. It was subclassified as problems, obstacles, and complications.[1] Problem of lengthening is defined as a potential expected difficulty that arises during the distraction or fixation period and is fully resolved by the end of treatment period by nonoperative means. An obstacle of lengthening is defined as a potential expected difficulty that is fully resolved by the end of the treatment period by operative means. True complications included all intra-operative injuries and problems during limb lengthening that were not resolved before the end of treatment. Types of infected NU[9] were classified as:-(A1) Quiescent infection, defect <4 cm, (A2) >4 cm, (B1) Actively discharging sinus, defect <4 cm, (B2) defect >4 cm.

Clinical and radiological examination: The diagnosis was established. Patient's satisfaction was assessed based on distribution of pain in post surgical period. The pain Visual Analog Scale (VAS) was recommended from 0 to 100mm, with no pain (0-4 mm) being completely satisfied, Mild pain (5-44 mm), Moderate pain (45-74 mm) and Severe pain (75-100 mm). Final results were analyzed and graded as per Modified Association for the Study and Application of Methods of Ilizarov (ASAMI)[1] criteria [Table 1]. Institutional ethical committee approval was obtained for the study.

Results

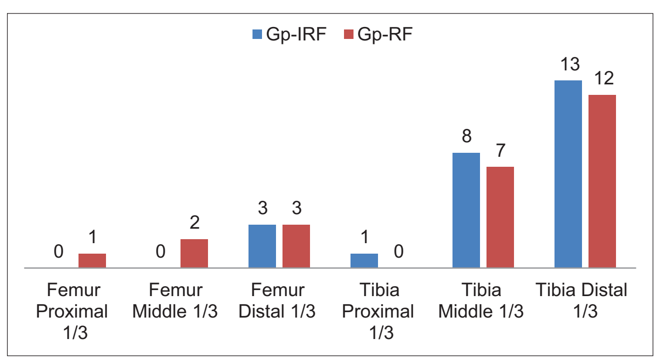
All factors like age, sex, other associated injury, preoperative history, infection and nonunion were almost same in both groups which didn't affect the results. The average age of patients was 39.48 years in Gp-IRF and 36.96 years in Gp-RF. All the patients were male with right sided involvement in both the groups. Maximum number of cases had infected NU of tibia involving the distal one-third [13 cases (52%) in Gp-IRF and 12 cases (48%) in Gp-RF] [Graph 1].

Majority of cases (20 in Gp-IRF and 19 cases in Gp-RF) had been already operated once, and treated by tubular external fixator (12 in Gp-IRF and 8 in Gp-RF), interlock nailing (2 in Gp-RF and none in other group), and ORIF (14 cases in Gp-IRF and 11 in Gp-RF). Only three cases in Gp-IRF and one case in Gp-RF were operated twice, whereas two cases in Gp-IRF and 5 cases in Gp-RF had Plaster of Paris[POP] cast only. Type of infected NU in Gp-IRF, maximum cases were in the category of B2 (14 (52%)) and A2 (11 (44%)) and in Gp-RF, were in

Table 1: Association for the Study and Application of Methods of Ilizarov classification based on radiological and clinical criteria1

Final result	Radiological criteria	Clinical criteria
Excellent	Bone union no infection deformity <7° limb length discrepancy <2.5 cm	Ability to perform previous (ADL). No pain or mild pain, no limp, no soft tissue sympathetic dystrophy, knee or ankle joint contracture <15°. Loss of ankle/knee motion <15°
Good	Bone union failure to meet one of the above criteria	Almost all ADL with minimal difficulty. No pain or mild pain. Failure to meet one of the above criteria
Fair	Bone union failure to meet two of the above criteria	Most ADL with minimal difficulty. No pain or mild pain. Failure to meet two of the above criteria
Poor	Nonunion or refracture failure to meet three of above criteria	Significantly limited ADL significant pain requiring narcotics. Failure to meet three of the above criteria

ADL=Activities of daily living



Graph 1: Bone involved and site of infected nonunion in both groups

A2 (10 cases) [Graph 2]. During treatment, majority of cases underwent soft tissue removal by freshening the bony ends at the docking site (21 and 22 cases in Gp-IRF and Gp-RF, respectively).

Unifocal corticotomy was performed in all the cases. Corticotomy site was metaphyseal in 12 cases in Gp-IRF and 4 cases in Gp-RF whereas it was diaphyseal site in 13 cases in Gp-IRF and 21 cases in Gp-RF ($P < 0.01$). Bone grafting was done more in Gp-RF (14 cases) as compared to Gp-IRF (10 cases). Bone gap of more than 8.0 cm was created in nine cases of Gp-IRF, and eight cases of Gp-RF. Average bone gap in Gp-IRF was 7.76 cm and 5.78 cm in Gp-RF [Graph 3]. The maximum bone gap was 15 cm in both the groups.

Mean duration of IRF application was 17 months in Gp-IRF and 11.56 months in Gp-RF ($P < 0.01$) [Table 2].

In majority of the cases, there was reduced range of motion, more at the ankle. Loss of range of motion was more at the knee (17 cases) than at the ankle joint (14 cases) in Gp-IRF [Figures 1 and 2], whereas it was similar at ankle and knee joint (eight cases each) in Gp-RF [Figure 3]. The average mean time for union was 17.64 ± 4.79 months and 14.08 ± 4.31 months in Gp-IRF and Gp-RF, respectively [Graph 4] ($P < 0.01$).

The limb length was equal in most of the cases (Gp-IRF 23 cases and 20 cases in Gp-RF). Less than 2 cm discrepancy was there in Gp-IRF in six cases, whereas in Gp-RF, two cases. In three cases of Gp-RF and 1 case of Gp-IRF, the discrepancy was >2 cm.

In Gp-IRF, patient's satisfaction was assessed by using visual analog scale. Patients with mild pain in Gp-IRF were 2 and 8 cases in Gp-RF. Moderate pain in 11 cases in Gp-IRF and 8 cases in Gp-RF. Severe pain in 12 cases of Gp-IRF and 9 of Gp-RF.

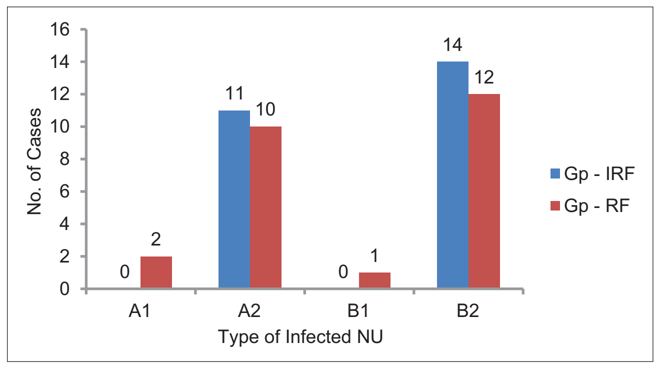
Out of 25 cases, 18 complications were seen in Gp-IRF and 14 in Gp-RF. Pain and difficulty in sleeping are other problems that arise during limb lengthening, especially in the more extensive cases. None of the major neurovascular complication, like jeopardizing distal neurovascular status, occurred in any case. Two most common complications were, pin tract infection (PTI) and pain. Hypertrophic granulation tissue at wire insertion site was seen in three cases each, which was near the joints due to repetitive stretching of the skin at that site during joint motion. Three cases of IRF had refracture of the docking site and hence again treated with Ilizarov by four cycles of compression and distraction (accordion maneuver) and finally union was achieved. Patients that developed equinus deformity were treated by triple arthrodesis (one case of RF), TAL lengthening, and delta frame fixation.

According to modified ASAMI[1] classification, results are shown in Table 3 ($P = 0.12$).The treatment index (duration of external fixation divided by length of bone regeneration) was 68.45 days/cm and 64.29 days/cm in Gp-IRF and Gp-RF, respectively.

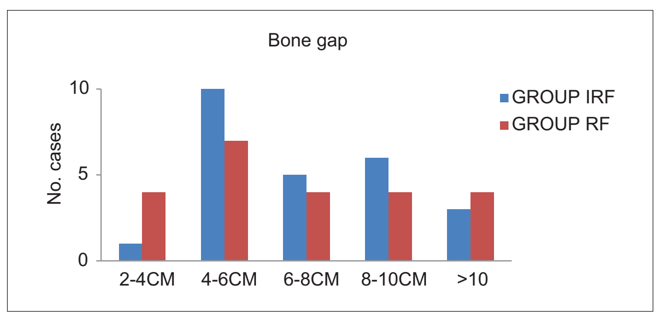
Table 2: Duration (months) of external fixators application in both groups

Duration of external fixators (months)	Number of cases	
	Group-IRF	Group-RF
4-12	4	19
12-16	8	4
16-20	9	2
>20	4	0

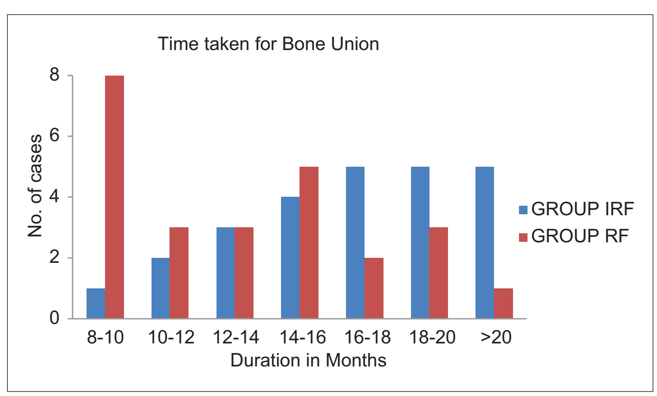
χ^2=19.6, df=3, P<0.01. IRF=Ilizarov ring fixators, RF=Rail fixator



Graph 2: Type of infected nonunion



Graph 3: Bone gap (in centimeter) in both the groups: *P* = 0.01 (significant)



Graph 4: Comparison of time taken for union in group Ilizarov ring fixator and rail fixator

Discussion

In developing country like India, with an increase demand of travelling long distance for work, there is also increased risk of motor vehicular accidents. The management of these high velocity injuries can be best treated with method of distraction histogenesis.

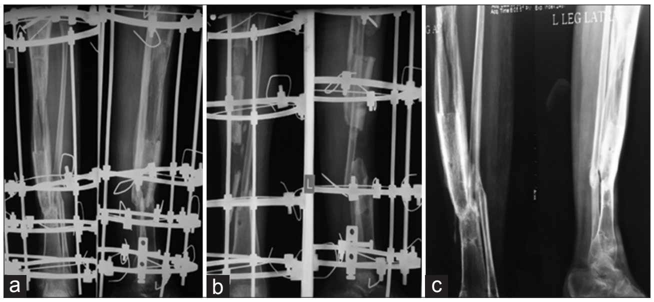


Figure 1: X-ray of patient with fixator during distraction and showing the regenerate (a), X-ray following docking (b), and after removal of fixator showing bony union (c)

According to Paley *et al*. the Orthofixmonobody frames was more rigid than the IRF, preventing axial motion at the osteotomy site, with weight-bearing monolateral frames experiencing cantilever bending delivering asymmetric compression to the fracture site. In contrast, the Ilizarov frame provided even loading of the bone ends leading to uniform compression.[10] The low frame rigidity seen at lesser loads allows more axial motion and is presumed to be useful for stimulation of fracture callus formation. The

Table 3: Results according to modified Association for the Study and Application of Methods of Ilizarov classification; with *P*=0.12, statistically nonsignificant

Result	Group A (%)	Group B (%)
Excellent	7 (28)	8 (32)
Good	8 (32)	13 (52)
Fair	10 (40)	4 (16)
Poor	0	0

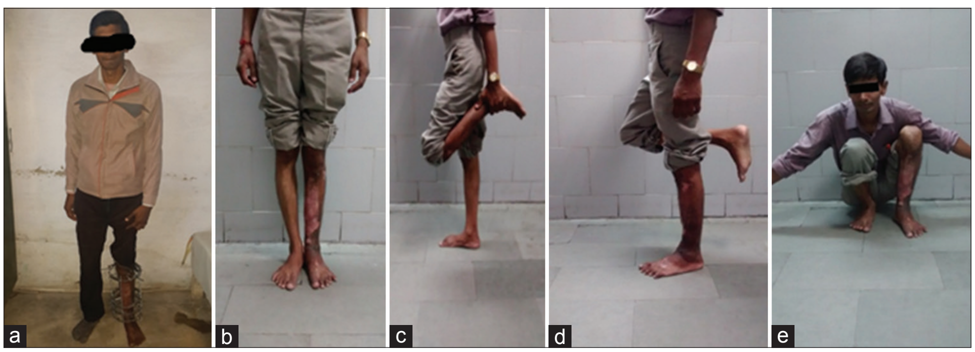


Figure 2: Patient bearingweight with Ilizarov *in situ* (a), weight bearing after fixator removal (b), range of movement over ankle and knee (c), full weight bearing over the affected leg (d), and squatting (e)

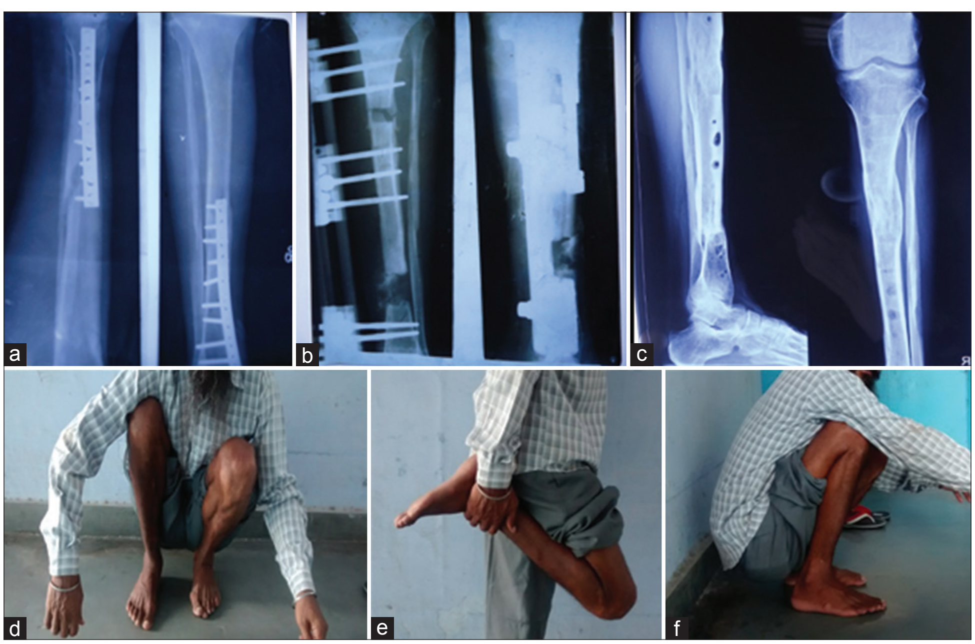


Figure 3: X-ray of implant *in situ* (a), X-ray of rail fixator *in situ* during distraction osteogenesis (b), X-ray showing union (c), after removal of rail fixator the patient is able to squat with good functional outcome (d), and showing range of motion at adjacent joints (e and f)

higher frame rigidity seen at increased loads is thought to protect the healing fracture tissues from excessive motion preventing pain and fibrous NU. This nonlinear behavior may explain how the IRF has been able to promote osteogenesis where other frames have failed.

Most of the patients were in their active period of life and were involved in outdoor activity, hence were prone to severe types of injury. All were males and in mean age o 39.48 years in Gp-IRF and 36.96 yrs in Gp-RF. Shahid *et al*.[11] had patients with average age of 43.3 years with 10 males and two females. Gupta *et al*.[12] had patients in the age groups between 21 and 52 years, both male and female whereas Singh *et al*.[5] 11 (45%) had cases between the age of 18 and 30 years, with 95% males. Males being bread earners of the family in our society tend to be more involved in outdoor work and are, hence, more prone to severe injury than females. This explains the skewed sex distribution of the present study, in which no female patient was found.

In both the groups, most common bone involved was tibia with distal one-third as a common site due to poor soft tissue coverage. Owing to poor vascularity, the junction of middle and lower third of tibia is more prone to NU, which was the most common NU site in this study. Majority of cases underwent at least one surgical procedure (20 cases in Gp-IRF and 19 cases in Gp-RF). This showed that there was either compound fracture initially or the implant got infected, leading to infected NU. The implant was removed, and either of the external fixators was used. In the present study, most of the patients had undergone open reduction and internal fixation (ORIF), after retracting infection it was followed by tubular fixator. Two cases were operated with interlocking nail (ILN). Arora *et al*.[13] and Singh *et al*.[5] had previously operated three (25%) patients. Unifocalcorticotomy was performed in majority of case of Gp-IRF at metaphysis, distraction was metaphyseal-diaphyseal, whereas in Gp-RF, majority had it at diaphysis, and distraction was diaphyseal-metaphyseal. Seenappa *et al*.[14] had done bifocal corticotomy in six cases. In the present study, procedures done during treatment were soft tissue removal at the docking site and additional bone grafting. Arora *et al*.[13] had three cases who underwent bone grafting with more than 10 cm gap. Cattaneo and Catagni[15] never required any bone grafting procedure while treating 28 cases of infected NU of tibia using ILR. In the present study, bone marrow aspirate was injected at the docking site in two cases of Gp-IRF and four cases of Gp-RF with successful union. Vignes *et al*.[16] used bone marrow aspirate injection in two cases. In present study, Gp-IRF, one case, a chronic smoker, had a cyst in the regenerate, which was managed by bone grafting at the time of soft tissue removal. In Gp-RF, two cases had undergone bone grafting and bone marrow aspirate injection in one case at the regenerate site due to poor regenerate formation. In Gp-IRF, bone gap was more than Gp-RF. Average bone gap in Gp-IRF was 7.76 cm and in Gp-RF was 5.78 cm. Vignes *et al*.[16] and Gupta SKV *et al*.[12] found the mean bone Gap to be 4 cm and 3.8 cm respectively. Our mean BG in Ilizarov was more than these studies.

In the present study, the mean duration of IRF application was 17 months, whereas in RF application was 11.56 months. Statistically, *P* value was significant. The total fixator time could have been more because of associated infection, patient compliance and other comorbidities, all cases were having severe infection and excessive scarring due to repeated trauma and surgery.

The most common complication in this study was PTI which was comparable in both groups and pain was present in 25 cases in Gp-IRF and 20 cases in Gp-RF. Paley *et al*.[1] and Paley and Mora *et al*.[6] had 14 patients with pain, Vignes *et al*[16] had 17 cases with PTI, Blum AL *et al*.[17] had 13/50 cases of persistent pain, and Shabir *et al*.[18] with RF had 28 cases with persistent pain. Soft tissue contracture at ankle causing equinus in five cases was managed by TA lengthening in Gp-IRF, and 2 cases in Gp-RF, where one case was treated by triple arthrodesis. Paley D, Mora *et al*.[6] also showed five cases of equinus foot, Vignes *et al*.[16] had two cases of persistent equinus deformity, and in RF study Shabir *et al*[18] had five (15.62%) patients of persistent equinus deformity which was comparable with our study. In present study, in Gp-IRF, one case had medialization of the construct due to size of the rings and refracture at the docking site which was readjusted. In present study, five cases had limb length discrepancy in Gp-IRF and eight cases in Gp-RF.

Factors like severe infection, excessive scarring disturb the local biology and result in decreased blood supply, fibrosis, and unhealthy tissue. Thus, this technique can be limb saving in the setting of high-energy trauma with soft tissue damage, in the medically unstable patients, where definitive fracture treatment must be delayed. The mean treatment index, obtained by dividing the duration of external fixator by length of the bone regenerate was 68.45 days/cm in Gp-IRF and 64.29 days/cm in Gp-RF. Eralp *et al*.[19] reported it as 56.32 days/cm. Infection itself is a great factor for the increased time of treatment. According to modified ASAMI classification, the results of the present study were compared with other studies.[4,6,13,14,16,20,22,23] There was no statistically significant difference in bone and functional results between the two groups. Functional outcome in both groups were excellent to good in 64% in Gp-IRF and 84% in Gp-RF. Gp-RF had better results than Gp-IRF. In both the groups bony union was achieved in 100% cases.

Our study, in Gp-IRF, was comparable with Vignes *et al*.[16] and Rohilla *et al*.[20] in functional outcome with respect to the excellent result. Our study was exclusively for treatment of infected nonunion. Our study was comparable with Arora *et al*.,[13] Pal *et al*.,[4] Mudiganty *et al*.[23] and Seenappa *et al*.[14] as rail fixator was more comfortable to patients compared to Ilizarov [Tables 4 and 5].

Table 4: Showing comparison of functional result with Ilizarov insitu in other studies

Ilizarov	Studies	Excellent	Good	Fair	Poor	No. of patients
1	Paley D, Mora[6] (2006)	16 (64%)	7 (28%)	1 (4%)	1 (4%)	25
2	Krishnan *et al*[21] (2006)	3 (15.7%)	9 (47.36%)	3 (15.7%)	4 (21.05%)	19
3	Vignes *et al*[16] (2014)	10 (50%)	8 (40%)	2 (10%)	0	20
4	Rohilla *et al*[20] (2016)	45.50%	48.50%	2.90%	0.00%	35
5	Present Study	8 (32%)	8 (32%)	9 (36%)	0	25

Table 5: Showing comparison of functional result with LRS in situ in other studies

LRS	Studies	Excellent	Good	Fair	Poor
1	Arora *et al*[13] (2012)	5 (33.3%)	8 (53.3%)	2 (13.3%)	0
2	Senappa *et al*[14] (2013)	40%	50%	0	10%
3	Rohilla *et al*[20] (2016)	62.80%	28.60%	0	8.60%
4	Mudiganty *et al*[23] (2017)	32.50%	65%	0	2.50%
5	Present Study	8 (32%)	13 (52)%	4 (16%)	0

Early weight bearing was started in Ilizarov; the even loading of bone ends provided by the frame leads to uniform compression. This enhanced healing and prevented NU, whereas monolateral frames experience cantilever bending, delivering asymmetric compression to fracture site. Therefore, early weight bearing was not done with LRS. Only when the union was evident on X-ray, dynamization was done allowing weight bearing in LRS. As the soft tissue and the bone were already compromised of vascularity and healthy tissue, internal fixation couldn't be our choice of treatment. Along with eradication of infection and recovering the bone gap, an external fixation is required, and distraction osteogenesis principle is followed to cover the bone gap. Moreover, this is an ideal treatment for eradication of the infection and limb lengthening. To get a definitive outcome, we could have increased the patient volume and have a multicentric study.

Conclusion

IRF and RF applications are both excellent methods to achieve union, even in the presence of infection which still maintains equal limb length and preserve reasonable range of joint motion in cases of infected NU of long bones such as tibia and femur. No doubt, that, in case of highly comminuted open fractures mainly involving the distal part of the bone near joint, Ilizarov is the best suited. However, the bulkiness of the frame and numerous wires are the main sources of discomfort to the patient. There was more number of complications in Ilizarov than rail fixator. More acceptance of patient for rail fixator was found. In nutshell, IRF is a versatile device, which can be used very effectively for the management of the infected NU of long bones such as femur and tibia. But we would prefer Rail fixator due to its more acceptance and less complications.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interests

There are no conflicts of interests.

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