International Journal of Medical Research Professionals
P-ISSN: 2454-6356; E-ISSN: 2454-6364
DOI: 10.21276/ijmrp

IJMRP

Original Research Article.

Complications and Functional Outcome in Patients with Limb Reconstruction System: An Institutional Based Study

Ritesh Kumar[1], Awadhesh Bhati[2], Vinod Kumar Anand[3*]

[1]GDMO, [2]Secondary DNB (Final Year), [3*]CMO,
Department of Orthopaedic Surgery, North DMC Medical College & Hindu Rao Hospital, New Delhi, India.

ABSTRACT

Introduction: Complex non-union cases, that involves attempting limb reconstruction in the presence of bone loss and infection involves surgery which is technically demanding, time consuming for the surgeon and physically and psychologically demanding for the patient with no guarantee of a satisfactory outcome. Even after prolonged treatment and repeated surgeries outcome is unsure and amputation may be the only option left at last. Hence, present study is undertaken to evaluate union rates with rail fixator in the treatment of complex non-union of long bones and to study the complications associated with this treatment modality.

Materials and Methods: The current clinical prospective study was conducted among 42 patients with complex non-union having infection at the site of non-union or a bone defect of more than 4 cm or cases with an attempt to achieve union that failed to heal after at least one supplementary intervention. Fixation was performed using a monolateral external fixator (Rail External Fixator System). Complications were classified according to the Paley classification as problem, obstacle, or true complication (minor or major). Results were calculated and graded as excellent, good, fair and poor based on ASAMI Scoring System.

Results: Results were calculated according to ASAMI scoring system. Bone results were excellent in 12 (54.5%), good in 4 (18.18%), fair in 3 (13.6%) and poor in 3 (13.6%) cases. Functional results were excellent in 10 (45.45%), good in 5 (22.72%), fair in 4 (18.18%). Three cases were declared failure. Pin tract infection was the most common complication. Other complications encountered were pain during distraction, pin loosening, joint stiffness. There was no significant angular deviation (>15 degree) in any case. Neurovascular complications, joint subluxation or fracture of regenerate was not seen in any of the cases.

Conclusion: We are of the opinion that in badly infected wound with bone loss and in cases where extensive soft tissue damage is there, rail fixator is a good choice to save the limb, to achieve union and to restore limb length. Successful treatment depends on proper wound care instructions, active participation, and careful monitoring. Collaboration with a physiotherapist is also important.

Keywords: Complex Non Union Cases; Limb Reconstruction; Rail Fixator.

***Correspondence to:**

Dr. Vinod Kumar Anand,
CMO, Department of Orthopaedic Surgery,
North DMC Medical College & Hindu Rao Hospital,
New Delhi, India.

Article History:

Received: 27-07-2018, **Revised:** 21-08-2018, **Accepted:** 04-09-2018

Access this article online	
Website: www.ijmrp.com	Quick Response code
DOI: 10.21276/ijmrp.2018.4.5.004	

INTRODUCTION

Complex non-union can be defined as an established non-union of at least six months in duration with one or more of the following criteria: infection at the site of non-union; a bone defect of more than 4 cm (defect non-union); an attempt to achieve union that failed to heal after at least one supplementary intervention.[1] The conventional treatment includes debridement and stabilization, cancellous bone grafting, non-vascularised fibular strut graft, vascularised bone grafting etc. Recently the use of osteoinductive substances such as recombinant bone morphogenic proteins and osteoconductive scaffolds such as calcium phosphate have found use in the treatment of these clinical situations. Microvascular techniques to transfer the fibula with its blood supply and sometimes with skin and muscles are highly demanding and have many drawbacks.[2]

Gap non-union of long bones with or without infection dramatically limits the role of conventional reconstructive techniques. With presence of significant skin loss or poorly vascularised recipient bed, complications and failure rate increase and solution often lies in amputation. In developing countries like ours, problem further intensifies as facilities and expertise may not be easily accessible and surgeon has to rely on simple techniques of treatment.

Distraction osteogenesis with a circular external fixator (Ilizarov fixator) has been the mainstay of treatment for treating complex non-union cases for decades. It can address bone and soft tissue

problems simultaneously. Rotation and angulation of the bone can be dealt with efficiently. Disadvantages of Ilizarov ring fixator are heavy frame, infection at pin tract site, joint stiffness, difficult and challenging surgical technique and poor patient compliance.[3] Limb Reconstruction System (LRS) / rail external fixator, which is a monolateral clamp and rail system, was developed in order to perform multisegmental surgery, such as bone transport and bifocal lengthening. The design of this device has enabled screw placements very close to a corticotomy site providing additional stability. The advantage of LRS in the management of complex non-union is to provide stable fixation and lengthening in a simpler manner than with the Ilizarov fixator and with a higher degree of patient acceptability.[1]

Attempting limb reconstruction in the presence of bone loss and infection involves surgery which is technically demanding, time consuming for the surgeon and physically and psychologically demanding for the patient with no guarantee of a satisfactory outcome. Even after prolonged treatment and repeated surgeries outcome is unsure and amputation may be the only option left at last. Hence, present study is undertaken to evaluate union rates with rail fixator in the treatment of complex non-union of long bones and to study the complications associated with this treatment modality.

MATERIALS AND METHODS

The current clinical prospective study was conducted at Department of Orthopaedic Surgery, North DMC Medical College & Hindu Rao Hospital, New Delhi (India) among 42 patients with complex non-union having infection at the site of non-union or a bone defect of more than 4 cm or cases with an attempt to achieve union that failed to heal after at least one supplementary intervention. All data consisting of patient details, presenting symptoms and duration, medical history, clinical details, deformity, function and neurovascular status of the nearby joints were recorded on a preformed proforma. Radiological examinations of the involved part as well as routine investigations were done. Full informed consent was taken from each patient regarding the intervention performed, its complications and drawbacks. Pre-operative assessment of soft tissue defect and planning for subsequent reconstruction was done. Under appropriate anaesthesia, any implant present in situ was removed first. All the dead bone were resected and the infected scarred soft tissues and sinus tracts were debrided adequately. Cortical bleeding was considered the end point of bone resection. Resultant bone gap was measured intra operatively with a sterile scale. Injectable antibiotics) were started empirically.

Fixation was performed using a monolateral external fixator (Rail External Fixator System). 300 mm fixator was used for humerus and ulna, 350 mm or 400 mm for tibia and femur. In the post-operative period, IV antibiotics were given for initial 4 days and thereafter oral antibiotics were given till stitch removal. Antibiotics were continued for 6 weeks if infection was present. Wound inspection was done on the fourth day of operation and was repeated if required. In case soft tissue reconstruction was performed, viability of flap or graft was checked and managed accordingly by plastic surgeons.

Stitch removal was done after 12 days. Pin tract hygiene and dressing of pin tract was taught to each and every patient. Patient was discharged only after patient became familiar with the process of distraction (Half circle twice a day). Distraction was started on 7th post-operative day. Physiotherapy of the adjacent joints and non-weight bearing walk was started from the next postoperative day as tolerated by the patient.

Patients were followed up regularly in OPD every two weeks for the first two months and thereafter every month till docking of the fracture fragments was achieved. Patients were allowed to walk bearing full weight once docking of the bone fragments was achieved to enhance union. Patients were reviewed thereafter every two months till there was union. Parameters assessed at every follow up consists of clinical i.e. pain (significant / insignificant), gait (present / absent limp), activities of patient, movement of adjacent joints, pin tract infection, loosening of pins, local skin condition, shortening, limb length discrepancy, reflex sympathetic dystrophy and radiological parameters include gap at fracture site, callus formation, regenerate (patients in whom distraction osteogenesis is carried out), features of osteomyelitis (at fracture site and at pin site), deformities (angle). Complications were classified according to the Paley classification as problem, obstacle, or true complication (minor or major). Problems represented difficulties that required no operative intervention to resolve. Obstacles represented difficulties that required an operative intervention. All intra-operative injuries and difficulties during limb lengthening that were not resolved before the end of treatment were considered true complications. Results were calculated and graded as excellent, good, fair and poor based on ASAMI Scoring System (table 1,2).

Table 1: Bone results using ASAMI scoring system

Bone results	Description
Excellent	Union, no infection, deformity < 7°, limb length discrepancy < 2.5 cm
Good	Union + any two of the following: Absence of infection <7° deformity and limb length inequality of < 2.5 cm
Fair	Union + only one of the following: Absence of infection, deformity < 7° and limb length inequality < 2.5 cm
Poor	Non-union/ refracture/ union+infection+deformity > 7° + limb length inequality>2.5 cm

ASAMI: According to the Association for the Study and Application of Methods of Ilizarov

Table 2: Functional results using ASAMI scoring system

Functional Results	Description
Excellent	Active, no limp, minimum stiffness (loss of < 15° knee extension/ < 15° dorsiflexion of ankle), no RSD, insignificant pain
Good	Active, with one or two of the following: Limp, stiffness, RSD, significant pain
Fair	Active, with three or all of the following: Limp, stiffness, RSD, significant pain
Poor	Poor inactive (unemployment or inability to perform daily activities because of injury)
Failure	Amputation

ASAMI: According to the Association for the Study and Application of Methods of Ilizarov, RSD: Reflex sympathetic dystrophy

RESULTS

A total of 42 patients were treated during the study period. Out of the 42 patients studied 38(90%) were male and 4(10%) were female with a male female ratio of 9.5:1. Average age of the patients included in the study was 31 years ranging from 13-62 years. Tibia was involved in 22 (52%) patients, femur in 16 (38%) patients, humerus in 3(7%) patient and ulna in 1(3%) patient (figure 2).Results were calculated according to ASAMI scoring system which includes various clinical and radiological parameters. Bone results were excellent in 12 (54.5%), good in 4 (18.18%), fair in 3(13.6%) and poor in 3(13.6%). Functional results were excellent in 10 (45.45%), good in 5 (22.72%), fair in 4 (18.18%). Three cases were declared failure.

1 patient of complex non-union of tibia failed to show consolidation of regenerate even after 14 months of treatment with loosening of multiple pins and infection. Patient was kept on long leg slab after fixator removal. Patient insisted for amputation and ultimately below knee amputation was done. In one patient a PRPP injection was given at the docking site to achieve union but it ultimately failed to unite. So fixator was removed and patient was put on PTB calliper and waiting for secondary procedure. In one patient of tibia, there was malalignment of fragments with soft tissue interposition in between and bad skin condition. Fixator was removed and long leg slab was applied. Patient is awaiting secondary procedure.

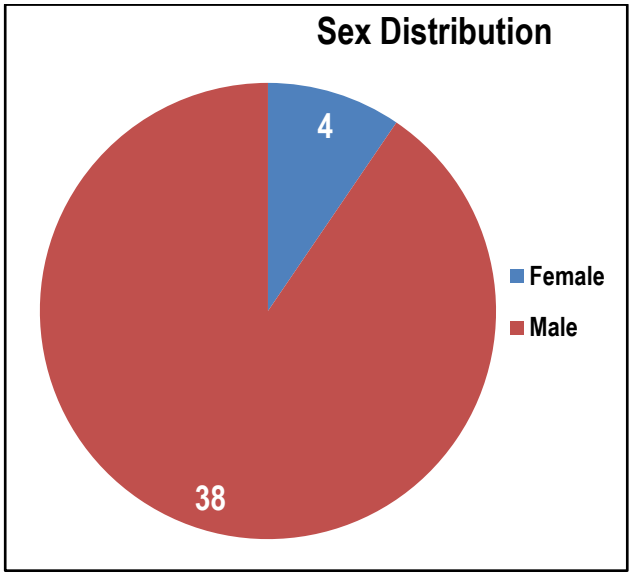

Figure 1: Sex Distribution

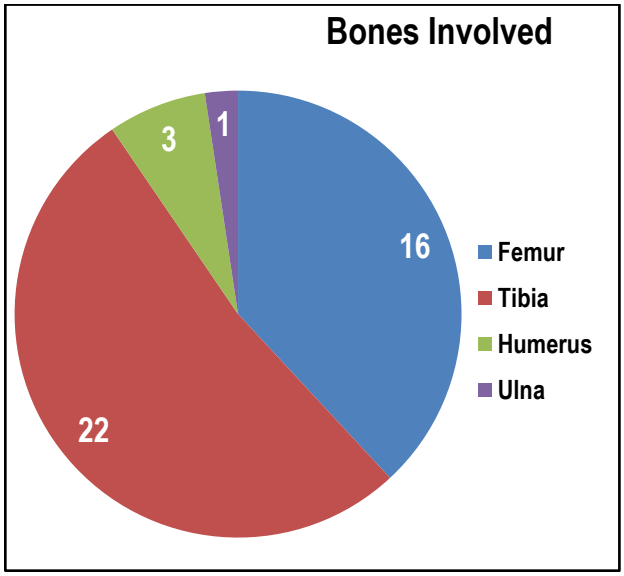

Figure 2: Bones Involved

Pre-Op X-Ray | Post-Op X-Ray | At 12 Months | After Removal of Fixator

At 6 Months Follow-Up | After Freshening of Bone ends and remanipulation (at 8 Months) | Functional Results

Figure 3: Non-union case showing functional results

Complications

Complications were classified according to Paley classification as problem, obstacle or true complication. Problem represented difficulties that required no operative intervention to resolve. Obstacles represented difficulties that required an operative intervention.

All intra operative injuries and difficulties during limb lengthening that were not resolved before the end of treatment were considered true complications. Pin tract infection (*n* = 13, 59.1%) and pain during distraction were the most common problem, pin loosening (*n* = 4, 18.18%) was the most common obstacle and joint stiffness (*n* = 2, 9.1%) was most common true complication. In our study at completion of treatment, there was no significant angular deviation (>15 degree) in any case.

Eighteen cases (81.8%) had no angulation, while one case (4.54%) had angulation less than 5 degree. Neurovascular complications, joint subluxation or fracture of regenerate was not seen in any of the cases. Delayed union at the docking site was encountered in few cases. In 3(13.6%) cases secondary procedures were done. Freshening of bone ends was done in 1 patient (4.54%) to achieve union. Freshening of bone ends with bone grafting was done in 2 patients (9.1%) to achieve union. Delayed maturation of regenerate was dealt with slowing or stopping the distraction for few days. Figure 2 shows functional results.

Table 3: Results (As Per ASAMI Score)

Bone Results	
Excellent	12 (54.54%)
Good	04 (18.18%)
Fair	03 (13.64%)
Poor	03 (13.64%)
Functional Results	
Excellent	10 (45.45%)
Good	05 (22.72%)
Fair	04 (18.18%)
Poor	0
Failure	03 (13.64%)

Out of 42 Patients, Result was calculated in 22 Patients as in 19 Patients treatment is still continuing. 1case was lost to follow up.

DISCUSSION

Autogeneous cancellous bone grafts have been used to manage bone defects of 6-10 cm and results have been good but limited availability of graft material is a check step in using this technique to treat large gap non unions of long bones. A long period of corticallization is generally required and weight bearing on the effected limb is not possible before that. Stress fractures may develop at the graft site. Non-union at the bone graft junction has also been reported leading to delay in completion of treatment. Grafts of cortical bone vascularise slowly and incompletely and also there is substantial risk of infection. Delayed union, non-union and fracture through the graft are common. Bone graft expanders can also be added to autogeneous bone graft to fill large bone defects. Their function is chiefly osteoconduction. Examples include ceramics such as calcium phosphate, hydroxyapetite, tricalciumphosphate or calcium sulphate.[4,5] Bioactive active substances such as bone morphogenetic protein and platelet rich plasma preparations may have a role in dealing these difficult situations.[6,7] Allografts can be used to fill voids in segmental bone defects. The advantages of allograft are unlimited supply, no size restriction and they can include joint surfaces. The disadvantages are risk of infection (about 5-12%), incomplete incorporation, healing problems and risk of disease transmission. The risk of viral transmission from allograft is 1 in 600,000.[8]

Non-vascularised fibula grafting- Reconstruction using a non-vascularised fibular graft is relatively easy compared to other techniques. However it revascularises very slowly. The slow progress of this process means that the graft gets weaker initially as it increases in porosity and this weakness may persist for months with the risk of stress fracture which is related to the length of graft. It cannot be done if vascularization of bed site is not good, there is infection at the bed site, soft tissue coverage is inadequate or bone defect is larger than 6 cm.[9]

Free vascularised bone grafts have been used to treat segmental bone defects since 1970s and mean success rates reported with procedure is 69%. Secondary surgical procedures have been done in additional 15% of cases. Vascularised bone grafts from tibia or iliac crest can be used and union rate of 40% has been reported in the presence of infection. This mode of treatment requires microsurgical techniques, long term immobilization and bracing. The surgical expertise and equipments needed are not readily available in every hospital. Additional disadvantages of the method are non-union at bone graft interface and stress fracture in graft. Some studies have reported that the graft may take upto 3 years to consolidate.[10-14]

Masquelet et al[15] reported a series of 35 cases of bone reconstruction of large diaphyseal defects performed in two stages. In weight bearing on diaphyseal segments normal walking was possible at 8.5 months on average. Recently developed techniques such as LON and intramedullary elongation devices (motorized nail) require surgical expertise which is available in only few centers around the world. Moreover in third world countries like ours, motorized nails are still not easily available to patients due to economic reasons. Additionally, patients with active intramedullary infections are not ideal candidates for LON or motorized nails.[16]

In the present study, a total of 42 patients with complex non-union of long bones were included in the study. The average age of the patients is 31 years, ranging from 13 years to 62 years. Majority of the patients are in the age group of 20-35 years. This could be because young patients have more outdoor activities and hence more prone to injury. 35 out of 42 patients developed complex non-union following RTA and 34 are males (97%) because of more outdoor activities and high speed driving predisposing them to trauma. Tibia is the bone involved in 22 out of 42 patients (52%) in our study.

Most of the studies discussed in literature about distraction histogenesis are on tibia. This could be because of subcutaneous position of tibia which predisposes it to open fractures and bone loss ultimately leading to delayed union, non-union, infection and osteomyelitis.

Our overall bone results were excellent in 12 (54.5%), good in 4 (18.18%), fair in 3(13.6%) and poor in 3(13.6%) cases. Functional results were excellent in 10 (45.45%), good in 5 (22.72%), fair in 4 (18.18%). Three cases (13.6%) were declared failure. Study done by Patil et al[17] using Ilizarov fixator had 41% excellent, 34% good,

10% fair and 15% poor bone results whereas functional results were excellent in 39%, good in 39%, fair in 5% and poor in 5% cases. 6% of cases were declared failure.

Another study done using Ilizarov fixator by Rose et al[18] reported 17% excellent, 49% good, 17% fair and 17% poor bone results and functional results were excellent in 17% cases, good in 50% and poor in 33% cases. Results of our study are clearly better than above mentioned studies.

Sangkaew C[19] reported 81% excellent, 14.3% good and 4.7% poor results. A study done by Mugadum et al[20] in a study of 25 infected tibial non-unions had 19 (76%) excellent, five (20%) good and one (4%) poor while functional results excellent in 15 (60%), good in eight (32%), one fair (4%) and one poor (4%). Bone results, in a study done by Hiranya et al[1] regarding management of complex non-union of long bones using Rail fixator reported 79% excellent, 11% good and 10% poor. Functional results were excellent in 40% patients, good in 50% and in 10% cases treatment was declared failure.

Study done by Hashmi et al[21] reported 61% excellent, 35% good and 3% fair bone results whereas functional results were excellent in 42% cases, good in 50% cases and fair in 4% cases. 5% cases were declared failure.

Dendrinos et al[22] had in a study of 28 infected tibial non-unions 14 (50%) excellent, Eight (28.5%) good, one (3.5%) fair and five (18%) poor results. Sanders et al[23] reported 48% excellent, 21% good, 5% fair and 26% poor results in his study.

Sahibzada AS et al[24] had 60% excellent results, 10% good results, 15% fair results and 15% poor results. These results are comparable to our results.

In our study, patients were treated by either compression-distraction or bone transport technique. Compression distraction was found simpler than bone transport and should be used wherever applicable to close the defect. Defect is closed instantly and there is no problem related to translation. Good bone apposition is obtained at once and healing starts. When bone transport is used, necrotic or infected bone ends should be resected and fashioned to facilitate docking. Bone transport is more complicated than compression distraction, with longer treatment time and more need for secondary procedures. Because the defect is closed gradually, there is delay in bone contact and compression. On occasions the transported segment may deviate as it passes through soft tissues leading to translation at the docking site.

Fixator manipulation and bone grafting at the docking site should be performed early, when necessary. Limiting factors are union at the docking site after transport and consolidation of the lengthening site after compression distraction.

Limitations of this study included the absence of a control group. With this method of treatment of complex non unions, we can obtain biological bone consolidation with no requirement of immobilization. Patients with Monorail fixator show better compliance as compared to Ilizarov fixator. The patient can wear clothes over the Monorail fixator (especially tradition Indian dresses) in a better way than Ilizarov system. The Monorail fixator technique is easier to learn than Ilizarov system. A single stage surgery can address both alignment and length. No further major surgical procedures are needed after application of monorail fixator, though adjustments in alignment may be needed. Monorail fixator is also low in cost as compared to ring fixator.

CONCLUSION

We are of the opinion that in badly infected wound with bone loss and in cases where extensive soft tissue damage is there, rail fixator is a good choice to save the limb, to achieve union and to restore limb length. Patient can be allowed early weight bearing without any adverse effect on bone union, alignment and quality of regenerate. Successful treatment depends on proper wound care instructions, active participation, and careful monitoring. Collaboration with a physiotherapist is also important.

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Source of Support: Nil.

Conflict of Interest: None Declared.

Cite this article as: Ritesh Kumar, Awadhesh Bhati, Vinod Kumar Anand. Complications and Functional Outcome in Patients with Limb Reconstruction System: An Institutional Based Study. Int J Med Res Prof. 2018 Sept; 4(5):12-17.
DOI:10.21276/ijmrp.2018.4.5.004