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Outcomes of mono-lateral limb reconstruction system in infected non-union of long bones

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ABSTRACT

Background: We planned to evaluate functional and radiological outcomes of mono-lateral limb reconstruction system for infected non-union of long bones and to analyse its complications occurring.

Methods: It was a prospective study, conducted during period of September 2015 to August 2017 and consisted of 73 cases of these 60 cases were available for final assessment. This infected non-union were classified by AO classification and were treated with mono lateral limb reconstruction system. All the cases were evaluated by ASAMI criteria for bony and functional outcomes. Our mean follow up period was 16.8 months.

Results: Among 60 cases of infected non-union with mono-lateral external fixator were followed for mean 16.8 months. According to these ASAMI criteria in our study 26.6% had excellent; 46.6% had good; 16.6% fair; and 10% poor bony outcome. And the functional outcomes were 13.3%, 60%, 16.6%, 10% were excellent, good, fair and poor respectively. Among the cases 50% had pin tract infections and loosening. Two cases pin revision was done. Sinus tract got cleared in all cases except 6 where multiple sinus tracts were present and healing did not occur. There were no infections at the corticotomy site. Delay in the consolidation phase was present in all cases. There was no difficulty in transportation of bone. Post-operatively wound dehiscence in eight cases was managed with split skin graft cover. Limb length discrepancy upto 2.5 cms in lower limb was managed with modified footwear with heel and sole raise. Non-healing fractures united in mean 5.9 months after start of treatment. Non-union site united in 90% cases. **Conclusions:** Mono-lateral limb reconstruction system is efficient method for treatment of infected non-union of long bones. It has an additional advantage of correcting limb length discrepancies which sometimes occur during the course of treatment.

Keywords: Non-union, Infection, Long bones, Limb reconstruction system, External fixator

INTRODUCTION

Infected non-union has been defined as a state of failure of union for 6 to 8 months with persistent infection at the fracture site.¹⁻³ It can develop after an open fracture, after a previous open reduction and internal fixation, or as sequel to chronic haematogenous osteomyelitis.^{4,5} This is

complex surgical problem being debilitating and chronic in nature leading to social hardship and financial losses.

Treatment of infected non-union, is difficult due to various factors such as avascular environment around the fracture site due to previous surgeries, necrosis of bone near the non-union site, due to thrombosis of blood vessels and Haversian canals, sinus tract formation leading to the fracture site and sequestrum formation.^{6,7}

Fibrosis of muscles, joint stiffness and fracture disease is caused due to prolonged immobilization or multiple surgeries. Stiffness of the adjacent joints, micro-organism that may develop resistance to the antibiotic therapy, multi drug resistant infection, osteomyelitis, soft tissue loss with multiple sinuses, osteoporosis, complex deformities with limb length inequality, all complicate treatment and recovery.^{8,9} These factors make an unfavorable milieu for fracture union even after prolonged treatment and may require repeat surgeries to correct this problem.

There are various modalities of treatment for infected nonunion. The cornerstones for successful bone healing are biomechanical stability and biological vitality of the bone, as they provide an environment in which new bone can be formed. According to AO manual, external fixator is considered as the standard method of fixation in infected non-union and internal fixation is deferred for the fear of persistence/recurrence of infection.⁷

METHODS

It was a prospective study, conducted at Sri Ramachandra University, Chennai during the period of September 2015 to August 2017. Our follow-up period was with a minimum of 6 months and maximum of 28 months (mean 16.8 months). Cohort included skeletally matured patients with fracture non-union due to infection and excludes patients with signs of fracture healing or non-unions due to aetiology other than infection.

Diagnosis was established by history, physical examination and investigations like erythrocyte sedimentation, total and differential white blood cell count, pus culture sensitivity and standard AP, Lateral radiographs. Special attention was focused on limb length measurements, range of motion of the joints, neuromuscular status and distal vascularity.

These infected nonunion were classified accordingly by the AO classification into Quiescent non-draining, Active non-draining and draining.⁹ Patients with wounds that had no discharge for 3 months were labelled as non-draining (Quiescent) and was evident by local symptoms and signs like increase warmth, redness, sinus, fever, etc.

Our criteria for radiological union are the presence of bony consolidation in three out of four cortices in AP and lateral x-rays.¹⁰

According to ASAMI'S criteria the clinical/bony outcomes were determined as follows.¹¹

1. Union 2. Infection 3. Deformity 4. Leg length discrepancy and were graded into;

- Excellent- union + no infection + deformity <7 degrees + no bone graft + shortening <2.5 cms.
- Good- union + any TWO of the above factors.
- Fair- union+ any ONE of the above factors.
- Poor- no union/refracture/none of the above factors

The functional results were based on five criteria.^{9,11}

1. A noteworthy limp, 2. Stiffness of either the knee or ankle (loss of more than 15 degrees of full extension of the knee or of 15 degrees of dorsiflexion of the ankle in comparison with the normal contra lateral side), 3. Soft tissue sympathetic dystrophy, 4. Pain that reduced activity or disturbed sleep and 5. Inactivity (unemployment or an inability to return to daily activities because of injury.)

According to this criteria the result were graded into;

- Excellent- active + none of above criteria,
- Good- active + 1 or 2,
- Fair- active + 3 or 4 and
- Poor- 'inactive' irrespective of whether other criteria were applicable

Surgical protocol

General anaesthesia for upper limb and Spinal anaesthesia for lower limb was preferred. Antibiotics were administered pre-operatively, intra-operatively and continued post-operatively.

Thorough wound debridement and excision of the infected soft tissue and necrotic bone till fresh bleeding appeared (Paprika sign) was done.¹² The sinus tract (in toto), infected soft tissue, and unhealthy granulation tissue was excised and sent for histopathological and culture study. If patient had undergone surgery before, in addition to above, implant exit was done through previous surgical scar.

The medullary canal was opened on either side by gentle reaming. Mono-lateral external fixator was applied on femur - lateral aspect, fortibia - medial aspect and for humerus - postero-lateral aspect.¹³⁻¹⁵ The most distal and the proximal screws were applied first and tightened after making sure that the limb is in proper alignment and rotation, remaining screws were passed subsequently. In all the cases acute docking was done at the non-union site and compression given. The operative field was thoroughly irrigated and wound closed by stay sutures.

An open approach is made to perform corticotomy, which is actually a low energy osteotomy made by connecting multiple drill holes with an osteotome. Attention should be paid to preserving periosteum because it has a major role in osteogenesis. Segmental resection of fibula was done in leg to allow acute docking. Distraction was started on the 7th post-operative day.¹¹

Post-operative protocol

Post operatively, the limb is kept elevated to reduce the post-operative edema. The ankle is splinted in neutral position. In cases were drain was kept, it was removed after 48 hrs. Parenteral antibiotics were continued for 2 weeks post-operatively or till the subsidence of infection and then oral antibiotics were given for an additional of 2 weeks. Joint motion exercises and non-weight bearing followed for 4 weeks and then partial weight bearing was advised. Distraction was carried at the rate of 0.25 mm four times a day, which was started from the 7th postoperative days.^{2,11} Radiograph was taken every week during the initial period of distraction and at monthly interval thereafter.

Distraction was carried on for a period of minimum 34 days to a maximum of 58 days (mean 46.6 days). The length of bone gained was from 3 to 5 cms (mean 4.2 cms.).¹⁶ In the hospital the distraction was done by the surgeon and after discharge from the hospital this was done by the patient or his relatives. On discharge, all patients were taught about pin site care, hygiene and rhythm of distraction where lengthening procedure was carried out.

The patients were followed in the outpatient department, where assessment of clinical and radiological progress was made. The rate of distraction was altered based on the radiographic appearance of the regenerate. In all cases compression at the non-union site was maintained till union. The distraction was stopped when sufficient gain of length has been achieved. The fixator was left in position for a further period to allow consolidation of callus.

When radiological union is achieved, the patient is examined clinically and the fixator is removed. After removal of the fixator patient is advised to use functional cast brace for upper limb and crutches for lower limb for a period of 6 weeks during which the patient is gradually mobilized to full weight bearing.

RESULTS

73 cases were identified for this study, patients who were lost in follow up were not included in this study thus 60 cases (50 males and 10 females) in age group of 20 to 65 years with a mean age of 37.5 years were available for final assessment.

		Humerus	Femur	Tibia
Infected non union		10	34	16
Post	Open fracture	04	12	08
	Closed fracture	06	22	08
	POP			04
Previously treated with	Ex fix		04	02
	Plate osteosynthesis	10	08	
	Nailing		10	08
	Native treatment		12	02

In this cohort, 10 patients had infected non-union of humerus, 34 patients had infected non-union of femur and 16 patients had infected non-union of tibia.

Humerus

Of 10 cases of humerus, 6 patients with septic non-union resulted after ORIF with plating for closed fractures. And 4 patients of infected non-union after open fracture.

Femur

Of 34 cases of femur in which, 18 had infected non-union after ORIF with nail/pate for closed fractures, 12 had infected non-union which occurred after open fractures and subsequent native treatment, and 4 had infected nonunion following treatment of open fracture with AO external fixator system.

Tibia

Of 16 cases, 8 patients had infected non-union after ORIF for closed fracture, 8 infected nonunion occurred after open fracture managed with ex fix two cases, POP two cases and POP four cases.

These infected nonunion were classified accordingly by the AO Classification, viz. Quiescent non-draining 12; Active non-draining 8; draining 40 cases.⁹ The most common organism isolated from draining nonunion was staphylococcus, others were *Pseudomonas*, *Proteus*, *Klebsiella*. We did not have MRSA (methicillin resistant *S. aureus*) infection. Appropriate antibiotics administered based on culture report.

All patients had considerable bone loss after thorough debridement, from 1.5 cms to 5 cms (mean 3.2 cms). In cases after debridement acute docking was done at the

nonunion sites, as the maximum amount of bone loss we encountered was 5 cms. Acute docking was done at the debrided site and osteotomy was performed distal to the tibial tuberosity at the proximal metaphyseal area for tibia (10 cases) and distal supracondylar osteotomy for femur (6 cases) by means of separate set of instruments so as to prevent introducing infection at the osteotomy site. In four cases, in spite of successful docking and control of infection, there were no signs of radiological union; iliac crest graft was applied at the docking site. In 16 of our cases shortening was from 3 to 5 cms (mean 4.2 cms).

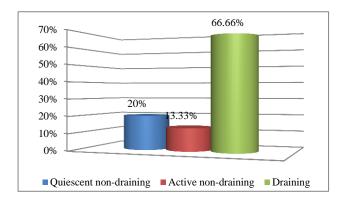


Figure 1: Showing AO classified infected nonunion.

Poor consolidation of the regenerate (4 cases) was treated by encouraging weight bearing and alternate compression –distraction (accordion technique).²

In case of humerus nonunion the shortening that resulted from debridement was accepted.¹⁰ In one case the shortening was 1 cm and in other it was 2 cms. The functional results of the upper limb were determined by assessing pain, shoulder and elbow range of movements and strength. In the cases of infected non-union of humerus, at follow up there was no pain/limitation of movements of elbow or shoulder and the strength was adequate. The Bone healing index, (days of fixator use/centimeters of length gain) was 47.1 days/cm.¹³

In 6 case of septic nonunion of femur supracondylar corticotomy was done and distraction was carried out from below upwards. In some of the cases supplementary procedures like skin grafting, flap cover, revision of pins and bone grafting were carried out.

Inspite of thorough debridement and antibiotics, infection did not get controlled in 6 cases. In cases of wound dehiscence, after the formation of healthy granulation tissue skin grafting was done.

10 cases of infected non-union had knee stiffness, 6 cases had ankle stiffness.

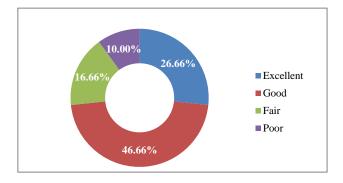


Figure 2: Showing clinical/bony outcome as per ASAMI criteria.

According to ASAMI'S criteria we had excellent - 16 cases, good – 28 cases, fair - 10 cases and poor - 6 cases of clinical/bony outcomes (Figure 2).

Table 2: Showing certain complications we encountered, which were grouped into following categories.

1	Troubles	Minor complications that were treated non-operatively without resorting to any anaesthesia. Superficial pin tract infection (according to DHAL's classification. ¹⁷) was found in 30 of the 60 cases (50%). All superficial pin tract infection responded to intravenous or oral antibiotics, except in two cases where the infection persisted. Mild edema was frequently present and got resolved after removal of fixator except in 10 cases, which persisted even after removal of fixator, such patients were advised full weight bearing with crepe bandage in the daytime and limb elevation in the night time for variable period of time.	
2	Hurdles	Complications that were resolved by operative means. During distraction in four cases metaphyseal pins got loosened which were readjusted in the operation theatre. Equinus correction was done by secondary surgical procedure like Achilles lengthening in four cases and triple arthrodesis in two cases. In four cases iliac bone grafting was done at the non-union site at the end of 4 months when there was insufficient evidence of bony union, to aid in union.	
3	True complications	Residual permanent deficits at the end of the treatment period. Mal-union beyond the limits of acceptability occurred in eight cases. Persisting non-union of the previous non-united site occurred in six cases.	

Functional outcomes were as follows; excellent- 8 cases, good- 36 cases, fair- 10 cases, poor- 6 cases (Figure 3).

There were no infections at the corticotomy site. Osteotomy site healed adequately. Delay in the consolidation phase was seen in all cases. There was no difficulty in transportation of bone. Post-operatively wound dehiscence in 8 cases was managed with split skin graft cover after confirmation of healthy granulation tissue. Limb length discrepancy upto 2.5 cms in lower limb was managed with modified footwear with heel and sole raise. Non-healing fractures united in 4 to 9 months (mean 5.9 months) after start of treatment. The nonunion site united in 54 out of 60 cases which were 90%.

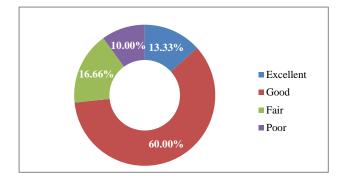


Figure 3: Showing functional outcomes as per ASAMI criteria.

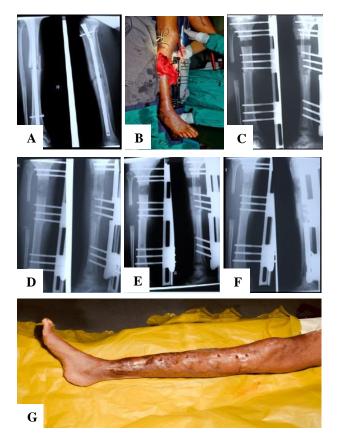


Figure 4: Showing radiographs and intra-operative pictures representing mono-lateral external fixation system applied for the infected non-union of tibia.

(A) Infected nonunion of tibia, (B) Intra operative picture Implant exit, wound debribment, (C) Corticotomy, LRS application, distraction docking, (D) 5 week distraction, (E) 10 week distraction, (F) Consolidation, (G) Following removal of LRS.

DISCUSSION

Reconstruction of infected non-union of long bone fracture involves more than control of infection and includes establishment of a healed, aligned and drainage free limb which is functionally better than that which could have been achieved by amputation or prosthetic fittings. 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.

In our study the nonunion site united in 54 cases that is 90% successful unions, which is comparable to the study conducted by Garcia et al wherein the bony union result was 86.7% and Biasibetti et al where in his study had a success rate of 93%.^{18,19} Functional outcomes were in accordance with bony union we assume it was due to site of non-union's which was in the diaphyseal region in all the cases, and because of the co-operative mobilization exercises carried out by the patients, there was not much of impairment of range of movements.

The patient must be co-operative and understand the long duration of time the frame will have to be worn and probability of complications requiring pin revision. In our study pin tract infection occurred in 30 out of 60 cases (50%), which is comparable to the study done by Gopal et al, where the reported pin tract infection was 10 out of 19 cases (53%).²⁰

Another aggrieving complication was limb length discrepancy, in a study of 26 cases of infected nonunion conducted by García-Cimbrelo et al the mean limb length discrepancy noted was 2.03 cms.¹⁸ Bone grafts can be added, after infection settles at the nonunion site. Graft can also be added to the regenerate site if progression towards consolidation is slow. The mean limb length discrepancy noted in our study was 2.06 cms. Some of the patients who had shortening of more than 1 cm of lower limb did not give consent for limb lengthening procedure which was planned after evidence of union at the nonunion site. Bone transport resulted in a better restoration of limb length discrepancy in lower limbs whereas larger bone defects can be tackled with two level corticotomy. Limb length discrepancy in lower limb were managed adequately with modified footwear with heel and sole raise.

In our study 10 patients of infected nonunion of humerus who were treated with hardware removal, debridement and stabilization in compression with external fixator there was evidence of good bony union in 5 months (range 4 to 6 months), which is comparable to study conducted by Gualdrini et al where the reported union time was 5.5 months after infected nonunion of humerus and 4 months in study done by Biasibetti et al.^{19,21} Since the nonunion was in the diaphyseal region in all the cases, and because of the co-operative mobilization exercises carried out by the patients there was not much

of impairment of range of movements in shoulder/elbow joints in these cases. The results were excellent in both functional as well as union of fracture.

CONCLUSION

Mono-lateral limb reconstruction system is efficient method for treatment of infected non-union of long bones. It has an additional advantage of correcting limb length discrepancies which sometimes occur during the course of treatment. Non-cooperative patient must be excluded as it requires wearing frame for a long time and may lead to poor outcomes.

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