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Study of limb reconstruction system in infected and gap nonunion: At tertiary care centre

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Abstract

Background: Management of nonunion with bone loss of long bones is a matter of debate. The treatment options range from external fixator, Masquelet technique, nailing, ring fixator, bone grafting with or without plastic reconstruction. All the procedures have their own set of complications like acute docking problems, shortening, difficulty in soft tissue management, chronic infection, increased morbidity, multiple surgeries, longer hospital stay, malunion, nonunion and higher patient dissatisfaction. We evaluated the outcome of the limb reconstruction system (LRS) in the treatment of infected non union and bone loss of long bones as a definitive mode of treatment to achieve union as well as eradication of simultaneously.

Aim: The aim of the study is to analyze the outcome of treatment of Infected and Gap Nonunion of long bones by using Limb Reconstruction System (The dynamic external fixation system and Rail fixation system) and reveal its real usefulness.

Method and Materials: In this study, we included 21cases of infected non-union with age range from 16 yrs to 65 yrs (with a mean age of 37.5 yrs) of which 19 males (90.47%) and 2 females (9.53%) using AO classification for infected nonunion categorized them into Infected non-draining nonunion (Active/Quiescent) and Infected draining nonunion treated them with limb reconstruction system (LRS).

Results: 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. Of the 21patients union achieved in 18 patients (85.7%). Union time ranged from 4 to 9 months (mean 5.9months). Sinus tract got cleared in all cases except 3 where the sinus tracts were multiple and there was no progression towards union in those three cases. Out of 21 cases 11 cases had pin tract infection (52.3%) which was most common problem in this study.

Conclusion: The limb reconstruction system is uniplanar and less bulky. Use of limb reconstruction system is convenient and effective method for the treatment of infected and gap nonunion of long bones. This can also be used to correct the limb length discrepancies simultaneously.

Keywords: Infected nonunion, gap nonunion, limb reconstruction system (LRS)

Introduction

Ununited fractures of long bones are not only a complex surgical problem but also a chronic and at times debilitating condition. Infected non-union^[1, 2] has been defined as a state of failure of union for 6 to 8 months with persistent infection at the fracture site. Infected and gap nonunion can develop after an open fracture, after a previous open reduction and internal fixation (ORIF). The incidence also seems to be increasing especially in view of increasing high velocity trauma, which is more frequently treated with internal fixation. Soft tissue loss with multiple sinuses^[3, 4], osteomyelitis, osteoporosis, complex deformities with limb length inequality, stiffness of the adjacent joints and multidrug resistant infection all complicate treatment and recovery. These factors make an unfavourable milieu for fracture union.

Bone union is not usually obtained until the infection has been eradicated. There are various option for treatment for infected and gap nonunion, but simultaneously all problems of nonunion like deformity, shortening, infection and abnormal mobility were managed. The cornerstones for successful bone healing are Bio-mechanical stability and biological vitality of the bone, as they provide an environment in which new bone can be formed by distraction osteogenesis^[3]. Distraction osteogenesis simultaneously addresses deformity, shortening, loss of bone function, osteoporosis and soft tissue atrophy.

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According to the AO manual [5], External fixator is considered as the standard method of fixation in infected non-union. The dynamic external fixator system is a unilateral external fixator system. With the frequent association of infection, bone loss, limb shortening, deformity and soft tissue problems with atrophic non-union makes external fixator an attractive option for skeletal stabilization and bone transport simultaneously.

Materials and Methods

This is a prospective analytical study which consists of 21 cases with infected and gap non-union of long bones in the age range from 16 yrs to 65 yrs (mean 37.5 yrs). There were 19 males (90.47%) and 2 females (9.53%) in this study who were treated at our institution from July 2015 to July 2018. Our institution approved our treatment protocols and all patients gave written informed consent. Patients who were lost to follow up were not included in this study.

Those patients were included in study having Gap and infected nonunion of long bones and Patient willing to give written informed consent. Those Excluded who having Non unions due to congenital disorders, All pathological fractures with nonunion, Hypertrophic nonunion, Articular and periarticular nonunion (within 2cm from joint) [22] and Aseptic nonunion.

In this study, infected and gap nonunion were categorized by the AO classification [4, 5]. According to this classification, Patients with wounds that had no discharge for 3 months were called as non-draining (Quiescent).

AO Classification [4, 5]

1. Infected non-draining nonunion. (Active/Quiescent)
2. Infected draining nonunion.

6 patients had infected nonunion of femur, 14 patients had infected nonunion of tibia and 1 patients had infected nonunion of humerus. Of the 21 patients 11 (52%) patients developed infected nonunion following open fracture and 10 patients (48%) developed infected nonunion following surgeries (implant in situ) for closed fractures.

• Treatment Protocol

The patients were admitted from OPD and casualty. Detailed history was taken. Thorough clinical examination and Local examination including swelling, tenderness, discharge, deformity and distal neurovascular status were assessed. Radiological examination including antero-posterior and lateral view of the affected limb was taken. A routine blood investigation for anaesthesia fitness was done and posted for surgery as early as possible. Patients were operated after taking written informed consent.

The appropriate parenteral antibiotics, which the patient has been taking preoperatively for infection (according to culture and sensitivity report) are administered before the start of the surgery and in post operatively continued in case negative culture report otherwise according to culture and sensitivity report. Through previous incision scar, implant removal done. Most cases of infected nonunion have component of infection in soft tissue and bone ends. Both have to be debrided extensively till fresh bleeding appeared (Paprika sign) [6] was done. This creates gap in the soft tissue and bone. Tourniquet was not used in any surgery. The sinus tract, infected soft

tissue, unhealthy granulation tissue was excised and sent for culture studies. The medullary canal was opened on either side or Monolateral external fixator was applied following this. In some cases acute docking (shortening less than 4 cm) was done at the nonunion site and compression given. For femur the fixator was always applied to the lateral aspect, for the tibia the fixator was always applied to the medial aspect and for the humerus the fixator was applied to the lateral aspect [3, 7].

An open approach is made to perform corticotomy, which is actually a low energy osteotomy made by connecting multiple through and through 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 [2, 7]. In case of humerus nonunion the shortening that resulted from debridement was acceptable [16] which was 3 cm.

In the wards the distraction was done by the surgeon and after discharge from the hospital this was done by the patient or his relatives. All patients had considerable bone loss after through debridement from 1.5 cm to 5cm (mean 3.2 cm). 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 5cm (Mean 4.2 cm). In some of the cases supplementary procedures like skin grafting, flap cover, revision of pins and bone grafting were done. In spite of thorough debridement and antibiotics, infection would not be controlled in 3 patients.

Follow Up Protocol: Radiograph was taken every week during the initial period of distraction (after corticotomy then after 1 week, at 3week) and at monthly interval thereafter. Before discharge, all patients were taught about pin site care, hygiene and the rhythm of distraction where lengthening procedure was carried out. The patients were followed in the out patient 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 nonunion site was maintained till union.

Poor consolidation of the regenerate (2 cases) was treated by encouraging weight bearing and alternate compression – distraction (Accordion technique) [2, 25]. 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. In three cases, in spite of successful docking and control of infection, there were no signs of radiological union; iliac grafting was done at the docking site. Our criteria for radiological union [13] are the presence of bony consolidation in three out of four cortices in AP and Lateral x-rays. When this was achieved, the patient was examined clinically and the fixator was removed. After removal of the fixator patient was advised to use functional cast brace for upper limb and crutches for lower limb for a period of 6 weeks during which the patient was gradually mobilized to full weight bearing.

Asami Score: (Association for the study and application of methods of Ilizarov) [7].

Bone result		Functional result	
Excellent		Bone union, no infection deformity <7° Ability to perform previous activities of daily living (ADL), no pain or mild pain No limp, no soft tissue sympathetic dystrophy knee or ankle joint contracture <5° Loss of ankle or knee motion <15°	
Good	Bone union, failure to meet one of the other criteria	Almost all ADL with minimal difficulty No pain or mild pain, failure to meet one of the other criteria	
Fair	Bone union, failure to meet two of the other criteria	Most ADL with minimal difficulty No pain or mild pain, failure to meet two of the other criteria	
Poor	Nonunion or refracture, failure to meet three of the other criteria	Significantly limited ADL Significantly pain requiring narcotics, failure to meet three of the other criteria	

Fig 1.

Results

We had the opportunity to treat 21 cases of infected non-union with monolateral external fixator. Our average follow up time 16.8 months (6 to 28 months). Union time 5.9months (4 to 9 months) seen in all but 3 cases out of 21 (85.7%). Average lengthening of 3 to 5cm (Mean 4.2 cm). Mean limb length discrepancy was 2.06 cm in this study. Sinus tract got cleared in all cases except 3 where the sinus tracts were multiple and there was no progression towards union in those cases. There was considerable delay in the consolidation phase in all cases. Out of 21 cases 11 cases had pin tract infection (52.3%). During transportation phase in bone lengthening procedure there was pin tract infection and loosening in two cases for which pin revision was done.

For wound dehiscence in the post operative period, split skin graft cover was given in one case. In three patients bone grafting required at nonunion site. In all cases there were no infection at the corticotomy site. After a period of waiting for consolidation to occur, final result of the healing of the osteotomy was adequate in all cases. Patients with limb length discrepancy up to 2 cm in lower limb managed with modified footwear with shoe raise. The results were divided into bony results and functional results, according to the classification of the ASAMI [4, 7] (Association for the study and application of the method of Ilizarov). ASAMI'S criteria were used to analyze the results in our study.

The fracture was considered to be united when it appeared so radiographically, when there was no motion at the site of the nonunion after loosening all nuts in the apparatus and the patient was able to walk without pain and had a feeling of solidity of the limb. The functional results of the limb were determined by assessing pain, range of movements and strength of joint, there was no neurological or vascular injury as a result of instrumentation. The Bone healing index [9]

(days of fixator use/centimeters of length gain) was 1.51month/cm (4 to 9 months).

	Bony Union	Functional Results
Excellent	7	3
Good	9	13
Fair	2	2
Poor	3	3

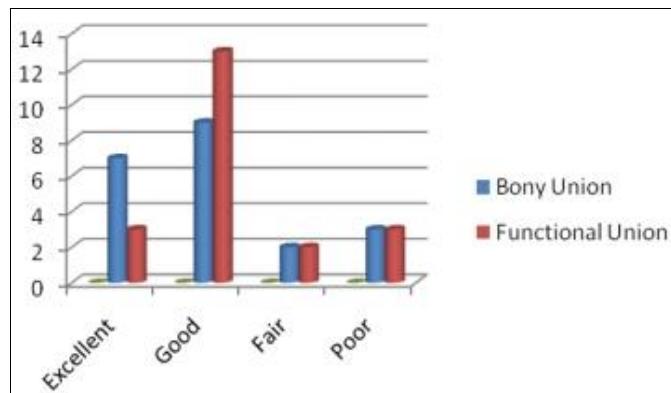


Fig 2.

Complications

We encountered certain complications and these complications were grouped into following categories as recommended by Paley [9, 10]. Problems -represent minor complications that were treated non-operatively without resorting to any anaesthesia. Obstacles -were complications that were resolved by operative means. True complications-were residual permanent deficits at the end of the treatment period.

Table 1.

S. No.	Problems	Obstacles	True Complications
1	Superficial pin tract infection 11 of 21 cases (52.3%)	Pin loosening 2 of 21 (9.5%)	Malunion 4 of 21 (19.04%)
2		Non union 2 of 21 (9.5%) requiring bone grafting	Persistent nonunion 3 of 21 (14.28%)

Discussion

The overall goal in the reconstruction of an infected ununited

long bone fracture involves more than control of infection and includes creation of a healed aligned and drainage free limb

which is functionally better. Several factors must be considered in reconstruction of bone including the patient's age, metabolic status, mobility of joints, integrity of neurovascular structures and importantly the patient's motivation.

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. Through wound debridement and removal of the doubtful bone and soft tissues to keep the area totally devoid of non viable tissue is essential for achieving bony union. The patient must be cooperative and understand the length of time the frame has to be worn and complications requiring pin revision are a probability. In elective situations the patients can be made to meet similar patients, who have undergone through this process, have preoperative teaching and elect this treatment protocol. Patients may accept these techniques better when they have chosen it as an elective reconstruction rather than when it is inflicted on them. Patients require adequate nutrition, exercise, and encouragement to stop smoking. Although distraction osteogenesis is associated with marked improvement of the blood supply, good vascularization is necessary to obtain bone healing especially in patients with infected nonunion. Before the surgery it is necessary to plan the procedure adequately.

As in other series functional results were inferior to bony results. An excellent bone results does not guarantee a good

functional result [4]. As to the 11 cases where there was rigidity of ankle/knee, it must be noted that eight were preexistent and 3 were post treatment. The functional result is affected by the condition of the nerves, muscles, vessels, joints, and to a lesser extent bone.

At nonunion site, union seen 18 (85.3%) in all but 3 cases (14.3%) out of 21, which is comparable to the study conducted by Hiranya kumar *et al.* [17] in 2016(93%), Seenappa *et al.* [19] (89%), Harshwal *et al.* [18] in 2014(91.9%), Eduardo Garcia *et al.* [10] in 2004 (86.7%), Antonio Biasibetti [11] (93%). Infected nonunion of humerus are rare yet challenging problem to treat. In our study 1 patient with infected nonunion of humerus was treated with implant removal, debridement and stabilization in compression with external fixator. The resultant shortening was accepted. One of our humeral fractures healed by 5 months which compares well with the series of Seenappa *et al.* [19] where it was reported as 6.2 months and Nirup NC [20] it (5.8 month). Since the nonunion was in the diaphyseal region and because of the co-operative mobilization exercises carried out by the patients there was not much of impairment of range of movements in joints for the case. The results were excellent for both functional aspect as well as bony union. In long-term study of tibial fractures, Merchant and dietz [12] determined that angular deformities of 10 to 15 degrees are well tolerated. Leg length discrepancy of up to 2.5 cms does not require any treatment, 5 to 6 degrees of angulation is acceptable.

Table 2.

Bony Union					
In this study	Hiranya kumar <i>et al.</i> [17]	Seenappa <i>et al.</i> [19]	Harshwal <i>et al.</i> [18]	Antonio Biasibetti [11]	Eduardo Garcia <i>et al.</i> [10]
85.3%	93%	89%	91.9%	93%	86.7%

Pin tract infection occurred in 11out of 21cases (52.3%), which is comparable to the study conducted by Qun Zhang *et al.* [20] in 2017(56%), Nirup NC *et al.* [20] in 2018 (32%), Gopal S *et al.* [13] (53%), kumar *et al.* [17] (83%). Hence the rate of pin tract infection remained high in Bone transport

resulted in a better restoration of limb length discrepancy in lower limbs. Some of the patients who had shortening of more than 2 cm of lower limb did not give consent for limb lengthening procedure which was planned after evidence of union at the nonunion site managed conservatively.

Table 3.

Pin Tract Infection				
In this study	Qun Zhang <i>et al.</i> [20] in 2017	Nirup NC <i>et al.</i> [20] in 2018	Gopal S <i>et al.</i> [13]	kumar <i>et al.</i> [17]
52.3%	56%	32%	53%	83%

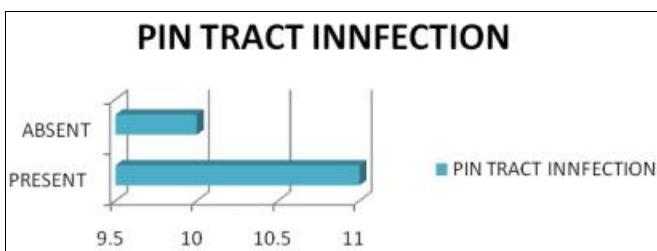


Fig 3.

The mean limb length discrepancy noted in our study was 2.06 cm. In a study of 26 cases of infected nonunion

conducted by Eduardo *et al.* [10] the mean limb length discrepancy noted was 2.03cm, in study done by Hiranya kumar *et al.* [17] it was 1.36cm and study by Srikanth M. [23] (1.04cm). 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 as quoted in the literature [11].

The Bone healing index (BHI) [14] in our study was 47.1days/cm, which is high when compared with that reported in the literature like in study by Harshwal *et al.* [18] in 2014 (BHI- 44days/cm), study by Srikanth M [23]-56.9 days/cm, P Megas *et al.* [22] in 2009 (BHI- 32 days/cm), Aldegheri [15] mean BHI of 39 days/cm.

Table 4.

Bone healing index (BHI)				
In this study	Harshwal <i>et al.</i> [18]	P Megas <i>et al.</i> [22]	Aldegheri [15]	Srikanth M [23]
BHI- 47.1days/cm	BHI- 44days/cm	BHI- 32 days/cm	BHI- 39 days/cm	BHI- 56.9 days/cm

The Monolateral external fixator is a telescopic device that can be locked for rigid fixation or unlocked to permit load sharing. Even though the cost of the fixator is high the patients because of the following reasons accept it: Light weight, patient friendly, day to-day activities can be done easily, Since the pins are unilateral it is much more comfortable for the patients, hence joint mobilization can be done with ease. Being rigid [16] early weight bearing can be allowed with the device. Patient themselves can tolerate. Moreover plastic surgery procedures like cross leg flap, Fascio-cutaneous flap and skin grafting can be done comfortably. Once the patients have been taught about the distraction procedure they are advised to come for review once in 7days to asses the length gained and also to asses the quality of the regenerate. Moreover the fixator (other than the tapered half pins) can be reused for another patient provided there is no damage to the apparatus.

The disadvantages include the high cost of the system,

inability to use the apparatus for correction of infected nonunion with gross deformity, in severe osteoporosis, stabilization very close to a joint for which Ilizarov fixator could be a better option. The cost factor has been reasonably managed by the introduction of Indian version of LRS. Compared with the Ilizarov ring fixator [9] the unilateral external fixator is simpler to apply and better tolerated by the patients. The learning curve for implementation of the unilateral fixator is less steep than that encountered with the Ilizarov fixator.

Case 1: 22 yr male with closed Shaft tibia, fibula # with Tibia Nailing done. After 6 month, there was quiescent infection with nonunion Implant removal and Fixation done with LRS and debridement of necrosed bone and acute Docking done. After docking pt had shortening of 6 cm which is corrected with LRS.



Pre operative clinical photo



intra operative photo



Above x ray film showing Pre operative image, immediate post operative, x ray after 12 weeks and x ray after removal of LRS



Above images showing clinical outcome after removal of LRS

Case 2: 36 yr male Closed distal 3rd Tibia # with IMIL Tibia Nailing done. After 7 month pt had quiescent Infected non union Implant removal done and LRS fixation and Docking done. Lengthening 3cm done with distraction osteogenesis.



Clinical image of operated case of tibia IMIL nailing with infection



Intra operative image of LRS fixation



Above images of x ray shows Pre operative, immediate post operative, after 12 weeks with LRS and after Removal of LRS

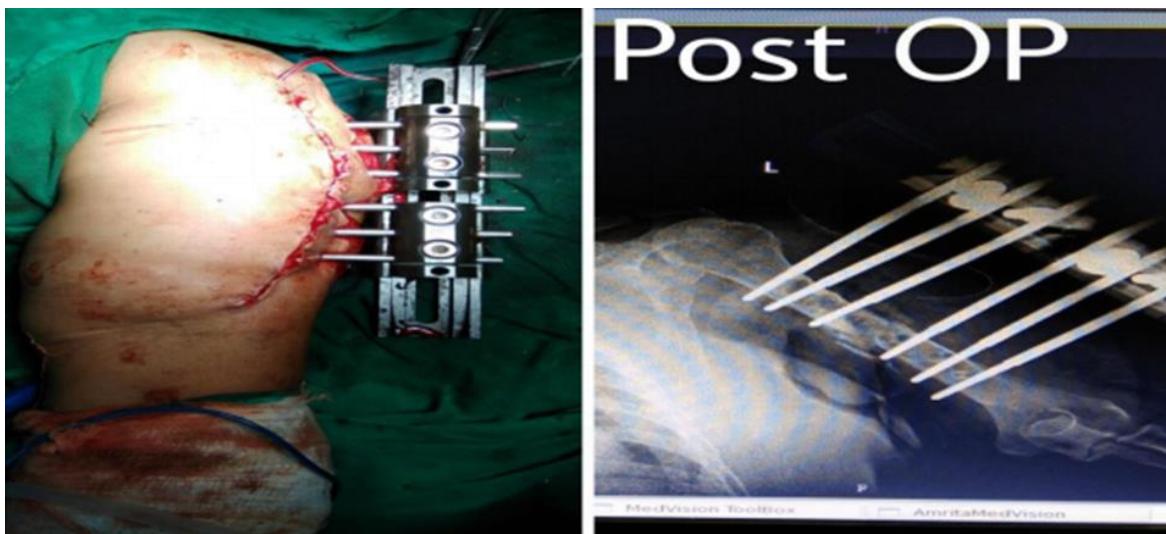


Clinical outcome with LRS and after removal of LRS.

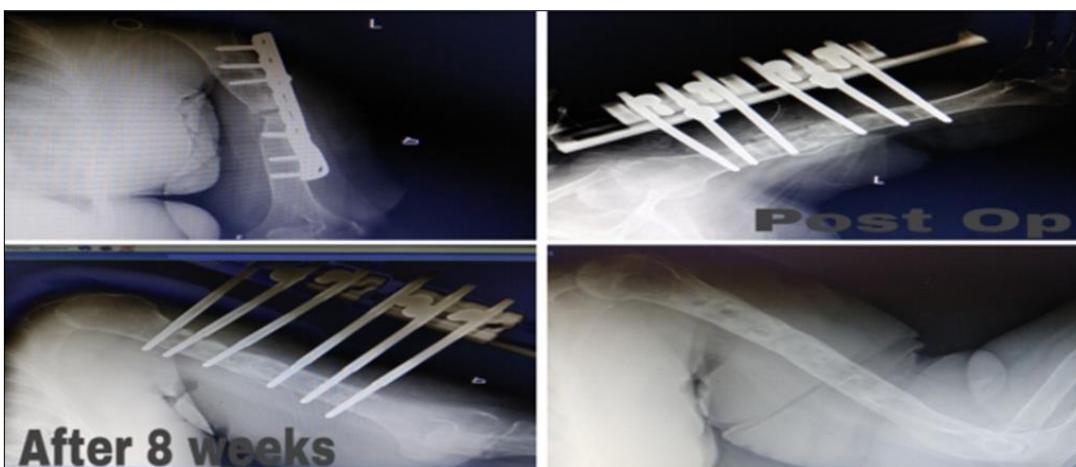
Case 3: 56 yr female with closed shaft humerus # with nailing done 10 yr back, patient is known case of uncontrolled DM. She had nonunion of humerus, she was operated with implant removal and orif with humerus DCP plating with bone grafting. she still had Non union at # site, Implant removal and LRS fixator applied with compression at # site done after refreshing # edges. After which she had 2 cm of shortening which acceptable.



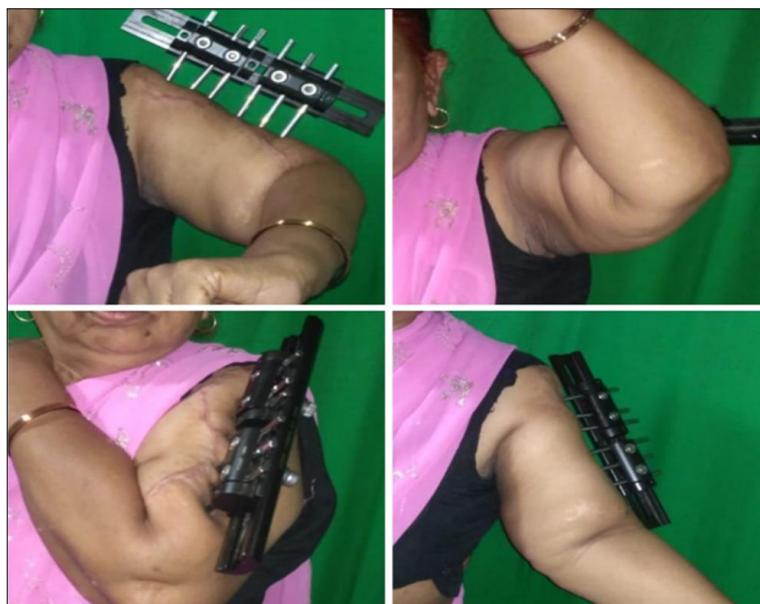
Pre operative clinical image showing previous surgical scar



Above images showing intra operative and immediate post operative x-ray



Above images showing pre operative x ray, immediate post operative, x ray after 8 weeks of LRS and x ray after removal of LRS



Above images show clinical outcome of patient with LRS

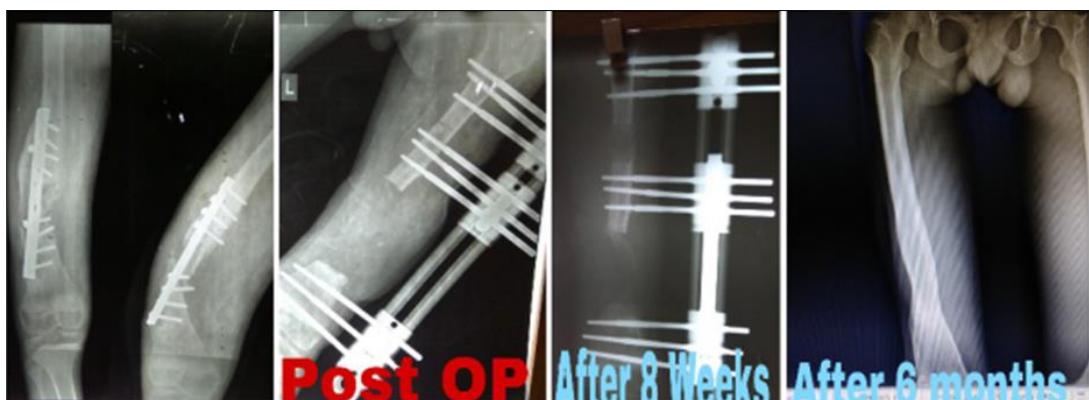
Case 4: 19 yrs male pt with operated case of shaft femur fracture with ORIF with plating with quiescent infection with implant failure with implant removal and LRS fixotor applied and multiple times debridement done. After debridement there was 12 cm of bone loss. Bone transport of 12 cm done and union achieved withthe help of LRS.



Operated case of shaft femur plating with infection, image after implant removal and multiple debridement before application of LRS



Intra operative image of LRS application for femur



Above x ray images shows pre operative implant failure with non-union, immediate post operative debridement and excision of necrotic bone, x ray after 8 weeks after LRS and After removal of LRS

Case 5: 44 yr male with H/O RTA with compound grade 3 B distal femur # with bone loss with closed shaft tibia #(which is managed with nailing. For compound femur # through debridement done and Limb Reconstruction System (LRS) applied after infection subside corticotomy was done and regular distraction started. But pt had pin tract infection which required regular debridement and removal of LRS before achieving bony union and length. At the end of treatment patient had 8 cm of Shortening and stiff knee joint and Radiological Nonunion.



Pre operative clinical image



Intra operative image



Above x ray images shows preoperative bone loss, 2nd images shows 8 weeks with LRS 3rd images after removal LRS due to infection and 4th images shows non-union after 8 months



Above image shows clinical outcome after 8 months, pt having discharging sinuses and stiff knee

- **Clinical photos of patients showing complications**



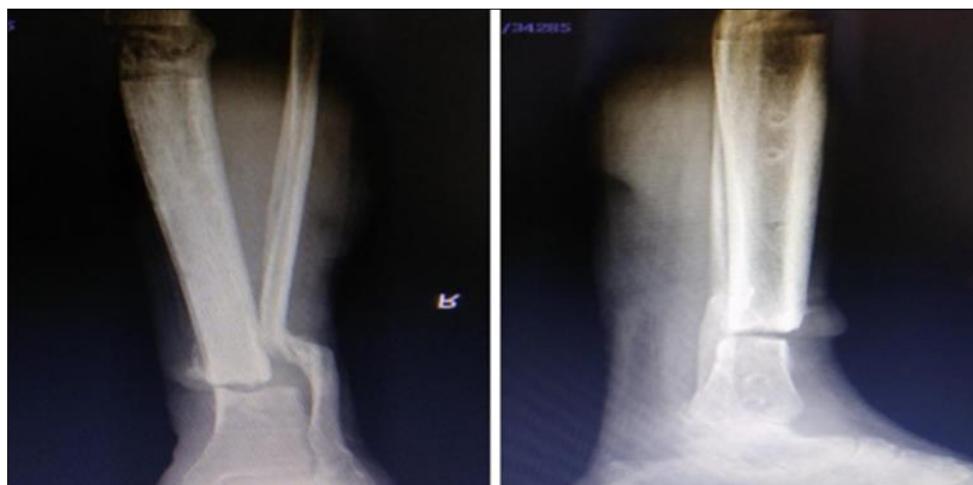
Above images shows discharging sinus after removal LRS



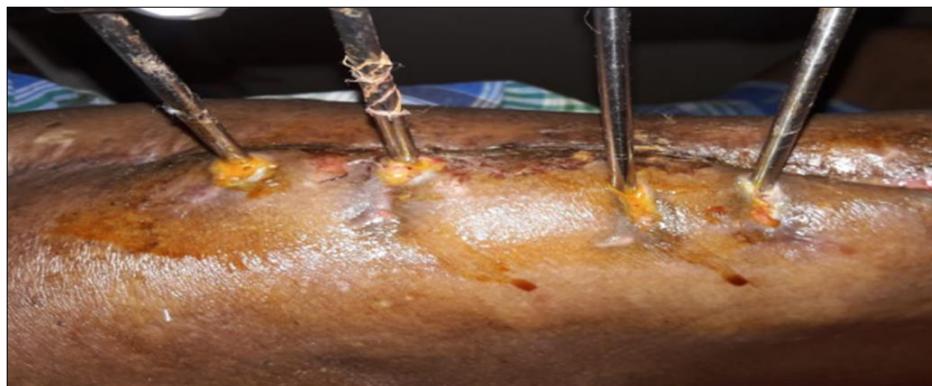
Malunion



Equines deformity



Non union



Pin track infection

Conclusion

In this study we conducted, we could achieve a success rate of 86%, giving good encouraging results to most of our patients. Hence we conclude that Limb Reconstruction System (monolateral external fixation system) is effective and convenient method for the treatment of infected and gap nonunion of long bones. This can also be used to correct the limb length discrepancies simultaneously, which can arise during the course of the treatment, also learning curve is less, Easy and Simple Technique, Less cumbersome to patients, Less hospital stay. Patient with poor cooperation are not good candidates for this technique, which requires wearing the frame for a long time, with probably additional secondary surgical procedure.

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