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Original Research

Management of bone gap/ nonunion by the use of limb reconstruction system or rail fixator in long bones: A prospective study

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ABSTRACT:
Introduction: The present study aimed at management of Bone Gap/ Non union of long bones of lower limb using Limb Reconstruction System (LRS) with primary objectives of reconstruction of bone gap, to restore limb function to normal as early as possible and to assess patient compliance. **Methodology:** The present study was conducted at Guru Nanak Dev Hospital, of Government Medical College Amritsar. This study was conducted after taking permission from Thesis Committee and Institutional Ethic Committee, Govt. Medical Collage Amritsar. 25 cases of infected nonunions involving tibia and femur were treated by LRS fixators after debridement of the infected nonunion site. Flap cover procedure was done as per necessity. Bone gaps and limb length discrepancies were dealt with bone transport or limb lengthening by the LRS instrument. **Results:** we observed 100% success rate of union in all the cases of gap/non union fractures of long bones using Limb Reconstruction System. Good to excellent results were observed in 64% cases while fair results were observed in 36% cases.It was observed to be well-tolerated by all patients as well. **Conclusion:** This study concludes that in cases of gap non-union and infected non-union of long bones, rail fixator is a good option to achieve union and to restore limb length and function.
Keywords: Limb Reconstruction System (LRS),fractures, non-unions

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INTRODUCTION

Fracture healing is a complex physiological process caused by the interaction of cellular elements that are activated and controlled by an array of cytokines and signalling proteins[1]. This process is both temporal and spatial in nature and usually results in the formation of new bone, which is structurally and mechanically similar to the pre-fracture state[2]. For a lot of reasons this process can fail and result in non-union of bone in 10%-20% of all fractures.

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[3-5]. 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. Today open fractures with infection are perhaps the most common causes of nonunion[6].Various factors like: 1) soft tissue loss with multiple sinuses, 2) osteomyelitis, osteoporosis, complex deformities with limb length inequality, 3) stiffness of the adjacent joints due to prolonged immobilization, multiple surgeries with fibrosis of the muscles resulting in stiffness of adjacent joints, and 4) multidrug resistant infections, 5) variable degree of soft tissue loss or defects requiring multiple sessions of plastic surgical reconstructions, all complicate treatment and recovery and hereby make an unfavorable milieu for fracture union[7,8].

The present study aimed at management of these cases using Limb Reconstruction System (LRS) with primary objectives of reconstruction of bone gap, to restore limb function to normal as early as possible and to assess patient compliance.

METHODS AND MATERIAL

The present study was conducted at Guru Nanak Dev Hospital, Amritsar/ Government Medical College Amritsar. This study was conducted after taking permission from Thesis Committee and Institutional Ethic Committee, Govt. Medical Collage Amritsar. Detailed history and medical examination was done and date was recorded as per proforma attached. 25 patients with Compound fractures of femur and tibia with bone loss or Non union femur and/or tibia fractures with or without bone loss were included in the study. Patients having closed diaphyseal fractures, pathological fractures, long bones fractures with intra articular extension and compound diaphyseal fractures of long bones without bone loss were exluded from the study

APPROACH TO CASE

Following admission of the patient, orthogonal radiographs of the affected extremity were taken and routine investigations were done for pre-anesthetic checkup. Appropriate size rail fixator was selected pre-operatively.

The Rail fixator was designed specially to address the problems inherent in classic external fixator technique and thereby to widen applicability of this form of treatment. The basic principal is to enhance the natural physiological process of fracture healing which demands rigidity in early stages and a degree of movement at fracture site in later stages of healing process.

PRE OPERATIVE PLANNING

The device is normally mounted anteriorly and laterally in the femur and in tibia it was mounted anteriorly and medially taking into consideration the safety of soft tissues. Since the saphenous vein and nerve are superficial to the subcutaneous border in the lower third of tibia, careful stab skin incision and deep dissection are required in order to avoid damage to these structures.

AP and lateral view of affected bone was taken. The length of the limb on normal side was measured. This enabled planning of pin fixation and selection of correct length of rail respectively. When an unstable segment is present care was taken while handling the limb. The image intensifier was used to identify important bony land marks & to define the axis of bone. This axis was parallel to final position of fixator. The position of defect was also marked.

According to site of defect, appropriate corticotomies in respective directions was done. Numbers of corticotomies were done at single level and at double level if the gap is more than 5 cm. The clamp templates were first assembled on the rail with their locking screw loosened to allow free movement.

Placement of the pins were decided depending upon the bone loss and gap to be reconstructed.

OPERATIVE TECHNIQUE

The appropriate parenteral/oral antibiotics, which the patient has been taking pre-operatively for infection, are administered before the start of the surgery and continued post operatively. Patient was put on operation table in supine position. Surgical site was prepared. If surgery has been done already, implant removal was done, through wound debridement and excision of infected soft tissue and necrotic bone till fresh bleeding appeared (Paprika sign)[9]. The sinus tract, infected soft tissue, and unhealthy granulation tissue was excised and sent for histopathological and culture study. A stab skin incision was given, proximal to wound, parallel to joint. The appropriate length screw guide was selected and inserted into the incision using the trocar to locate the midpoint of bone.

In most cases "three clamps LRS" construct was used, with two clamps in the segment where corticotomy was planned. All screws were fixed. After fixing the screws, the template is removed and the clamp was locked on the tapered screw. Now the non union site was opened and bone ends were freshened and debrided which may create a bone gap. Then incision was given over the proposed corticotomy site, after soft tissue dissection corticotomy was done. Wound was closed in layers. With the clamps locked into position on the rail, the CD (compression distraction) unit was placed between the appropriate clamps depending upon the corticotomy site. The central clamp was loosened and 3 to 4 mm of distraction was applied. The end point reached when firm resistance was met on turning the Allen key. This represents the first stage of tension corticotomy.

POST OPERATIVE MANAGEMENT

Segmental transport was commenced after 5 to 7 days. It was shorter in children and longer in older, infected cases and patients with more scarring. The middle clamp locking screw and its washer was loosened and distraction wascarried out by turning CD unit anticlockwise 90 degree every six hours. In practice after opening an initial gap, the rate of transport may be adjusted to 0.75 mm or 1.25 mm a day, according to quality of bone judged by its appearance on X-ray. At the conclusion of transport the defect was closed with varying degree of contact between the bone ends. The middle clamp should be locked on the rail. Depending upon the quality of bone formed and extent of contact achieved, various measures may be required to stimulate union. Consolidation of docking site is monitored by serial AP X-ray.If needed, bone grafting was done by taking graft form iliac bone.

Dynamization of newly formed segment is done when required. Clamp and tapered threaded pins are removed when 4 distinct and complete cortices evident on X-Ray.

Patients were called regularly at interval of one month in orthopaedics O.P.D in Guru Nanak dev Hospital,

Amritsar for regular follow up which will be done with checking of the:-

1. X –ray of patient
2. Assessing the progression of distraction histogenesis
3. Filling up of bone gap.

The results will be graded as per ASAMI classification (1995)

STATISTICAL ANALYSIS

The collected data was analyzed using SPSS statistics software 21. Version. To describe the data descriptive statistics frequency analysis, percentage analysis was used for categorical variables and the mean & S.D were used for continuous variables.

RESULTS AND OBSERVATIONS

In the present study mean age of the study sample came to be 36.36±12.54 years with 96% of patients being males tibia was involved the most and most of the patients had previously underwent treatment by External Fixator(76%).14 (56%) of cases had a duration of 4-5 months of LRS use. Corticotomy was performed in all 25 (100%) cases and was done on diaphyseal side in 14 (56%) cases, while on metaphyseal side it was done on 11(44%) cases. 19 (76%) cases had duration of distraction between 2 to 4 months.(table 1). Mean bone gap observed in the present study was 7.90 cm . Mean consolidation time observed was 13.64 days and Mean union time in the present study was 16.88 months with a minimum of 9 months and a maximum of 28 months(table 2).

Pin tract infection was the most common problem in 12 (48%) cases, followed by equines foot in 6 (24%) cases, knee joint stiffness in 4 cases (16%), loosening of pins in 3 (12%) cases , discharging sinus in 1 (4%) cases.

In the present study limb length discrepancy was observed in 4 (16%) cases. Average limb length discrepancy (LLD) was 1.25 cm (range 1-1.5 cm)(Table 4).

According to ASAMI Criteria excellent radiological results were present in 15 (60%) cases, good results were found in 9 (36%) cases and fair results were found in 1(4%). Overall, we achieved 100% union in all the cases. Base on ASAMI grading system good to excellent results were observed in 64% cases while fair results were observed in 36% cases(table 5).

Table 1: Shows the various baseline parameters

Mean Age	36.36±12.54
Males	24(96%)
BONE INVOLVED	
TIBIA	22
FEMUR	3
TOTAL	25
Previous Operation	
External Fixator	19(76%)
Open Reduction And Internal Fixation	4(16%)
Plaster Of Paris Splint	2(8%)
Duration Of LRS (Months)	
4-5months	14(56%)
6-7months	9(36%)
8-9 Months	2(8%)
Corticotomy Site	
Diaphyseal	14(56%)
Metaphyseal	11(44%)
Duration Of Distraction	
2.1-4 Months	19(76%)
4.1-6 Months	4(16%)
6.1-8 Months	2(8%)

Table 2: shows the mean values of different parameters assessed

Parameter	MEAN	SD	RANGE
Mean Bone Gap	7.90cm	2.69	5-15 cm
Mean Consolidation Time	13.64 days	4.77	7.5-28 days
Mean Time Of Union	16.88 months	4.41	9-28 months

Table 3: Complications

COMPLICATION	FREQUENCY %Age
Pin Tract Infection	12 (48%)
Equinus Foot	6 (24%)
Knee Joint Stiffness	4 (16%)
Loosening Of Pin	3 (12 %)
Discharging Sinus	1 (4%)
Fracture In Regenerate	1 (4%)
Angulation	1 (4%)
Soft Tissue Swelling	1(4%)
Premature Union Of Corticotomy	1(4%)

Table 4: Limb Length Discrepancy

Limb Length Discrepancy	Frequency	Percentage
No	21	84%
Yes	4	16%
Total	25	100%
Average Lengthening Achieved	1.25 Cm Range: 1-1.5 Cm	

Table 5: Results Based On As Per Asami Scoring System

	Radiological Bone Results		Clinical/Functional Results	
	N	%	N	%
Excellent	15	60%	10	40%
Good	9	36%	9	36%
Fair	1	4%	6	24%
Poor	0	0	0	0
Total	25	100%	25	100%

DISCUSSION

Non-union is a complex clinical concern that frequently results from serious limb injury. It can have a troubling effect on the social and financial status of patients. These patients are usually operated on several times for either stabilization and recovery or infection eradication, resulting in soft tissue scarring and devitalization of any remaining bone.

The present prospective study was undertaken with a total sample of 25 cases of long bones with non-union and gap non-union due to any reason admitted in Department of Orthopaedics, Guru Nanak Dev Hospital / Government Medical College, Amritsar. The study aimed at management of these cases using Limb Reconstruction System (LRS) with primary objectives of reconstruction of bone gap, to restore limb function to normal as early as possible and to assess patient compliance.

In the present study mean age of the study population came to be 36.36±12.54 years with male predominance (96%). Most commonly involved bone was tibia (88%), as it is more prone to injury due to its subcutaneous location, while femur fracture was observed 12% cases. In consensus with our findings, Ibad Sha I et al[10] also reported that majority of the cases in their study were in the age group of 25-50 years with male predominance. Tibia was the commonest long bone presented with non-union. In similarity, B. Sharma et al[11] also reported male predominance, and most common bone being treated was tibia. Lakhani A et al[12] also reported tibia as the most common bone involve in their study.

In the present study, at the time of presentation and based on previous operations, 76% patients presented with external fixator, similar findings were observed by Ibad Sha I et al[10]. 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 the present study, majority of cases i.e. 56% of cases had a duration of 4-5 months of LRS treatment.

For decades, the beneficial impact of corticotomy on the vascularity of the entire limb has also been a matter of concern. The effect of corticotomy on bone healing is also explained in microangiographic studies by the intact supply of intramedullary blood. By the distraction force at the corticotomy site, the lining cells covering the bone ends are able to differentiate into osteogenic and chondrogenic cells under adequate force.[13] In the present study, corticotomy was performed in all 100% cases. Corticotomy was done on diaphyseal side in 56% cases, while on metaphyseal side it was done on 44% cases.

In the present study, we observed a mean bone gap of 7.90 cm with a min of 5 cm and maximum of 15 cm, mean consolidation time was 13.64 days with a min of 7.5 days and a maximum of 28 days. Mean union time in the present study was between 9 to 28 months with a mean of 16.88 months. In similarity with our findings, Milind V Ingle et al[14] reported Union time of 5.9months (4 to 9 months) seen in 85.7% cases in their study. They also observed an average lengthening of 3 to 5cm (Mean 4.2 cm).B. Sharma et al[11] also reported that union time in their study was between 4 and 11 months but the maximum union was achieved in 7-9 months in 53.33% cases.

Next In the present study, during transportation phase during procedure, Pin tract infection was the most common problem encountered in 48% of the cases . Literature reveals that rate of pin tract infection usually remained high in Bone transport and is thus the most common complication encountered with LRS. Kumar et al.[15] reported 83% cases of pin tract infection, Milind V Ingle et al[14] reported 52.3% cases of pin tract infection, Nirup NC et al[16] with 32% cases, Vinod Kumar Anand et al[17] reported 59.1% cases, Gopal S et al[18] with 53% cases, Hiranya Kumar S et al[19] reported 73% and Iqbal, A et al[20] reported 40.2% cases.

In the present study limb length discrepancy was observed in 4 (16%) cases. Average LLD was 1.25 cm (range 1-1.5 cm). Other authors like Tang Liu et al[21]reported a mean lengthening was 9.3 cm (range, 5.8-12.1cm) in their study. Hiranya Kumar S et al[19] mentioned that finally there was no limb length discrepancy in 62% of cases, in 24% of cases it was 0.5-1 cm and in 14% of cases it was 1.1-2 cm. There was no significant difference in preoperative and post treatment joint movements as well. Similarly, Milind V Ingle et al[14] noted a mean limb length discrepancy of 2.06 cm while Mudiganty S et al.[22] reported a mean limb length discrepancy of 1.04cm in their respective studies. 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.

After treatment in the present study, limp was observed in 6 (24%) cases while it was absent in 19 (76%) cases. In similarity with our findings, Ibad Sha I et al[10] reported that 80 % of subjects in their study had no limping. This suggests that the fracture environment can be carefully controlled and angulations and length can be corrected simultaneously with External fixator (LRS).

Girish Kumar K et al[23] the residual limb length discrepancy was 0.5-1 cm. There was no significant angulation more than 15 degrees in any cases, two cases had angulation of about 8 degrees (femur) and remaining cases did not have any angulation. Infection was eradicated in all of their cases.

According to ASAMI Criteria excellent radiological results were present in 15 (60%) cases, good results were found in 9 (36%) cases and fair results were found in 1(4%). Excellent functional results were observed in 10 cases (40%) and good results were found in 9(36%) cases and fair results were observed in 6 (24%).

In similarity to our results, B. Sharma et al[11]in their study also reported 100% union achieved in all cases. According to ASAMI Criteria excellent radiological results were present in 11 (73.33%) cases, good results were found in 4 (26.67%) cases and excellent functional results were observed in 7 cases (46.67%) and good results were found in 8 (53.33%) cases. Infection was cured in all patients and did not recur till the last follow-up.

Similarly, Girish Kumar K et al[23] also achieved union in 100% of their cases.. Even, Lavini F et al[24] achieved union in all 100% patients in a mean time of 4.9 months. Hiranya Kumar S et al[15] reported that complete union was attained in 84% and eradication of infection in 96.5% of cases in their study. It is believe that this method is reliable, effective and low risk provided that the patient is cooperative; furthermore, the monolateral axial external fixator is tolerated well and allows movement of the shoulder and elbow throughout the period of treatment

In yet another study by Vijay C et al.[25] on the management of open tibia fractures with rail fixators, overall 90% of the fractures united well excellent to good results were seen in 72% cases, fair in 18%, and poor in 10% cases and Hashmi et al.[26] had 90% union rates with the use of rail fixators.

Hence, our results suggest that in cases of open non union fractures and infected nonunion, rail fixator presents to be a good option to achieve union and to restore limb length and function.

CONCLUSION

Limb Reconstruction System is found to be successful in managing infected non union in long bones due to its simplicity, short learning curve, ease of use with improved patient compliance. However, prior to deciding to go ahead with this procedure, patient education for compliance is important, as this method is time consuming and may take several months to achieve the required results.

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