

A Prospective Study of Analysis of the Treatment of Infected Nonunion of Long Bones Using Monolateral External Fixator

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ABSTRACT

The purpose of the study is to analyze the outcome of treatment of complex infected Non-unions of long bones using the Monolateral external fixator (The dynamic external fixation system and Rail fixation system) and to establish its efficacy in order to bring about sound union and at the same time being able to correct any bone length discrepancy. The Monolateral external fixator is variable telescopic device that can be locked for rigid fixation or unlocked to permit load sharing and dynamization. Being light weight and patient friendly the patients can perform day to day activities with the fixator in situ, Since the pins are unilateral it is much more comfortable for the patients, hence joint mobilization can be done simultaneously with the fixator in situ. Being rigid, early weight bearing can be allowed with the device. Patient themselves can be taught how to take care of pin and fixator hygiene and also do the lengthening procedure themselves.

Key words: Monolateral external fixator, Limb reconstruction system (LRS), Avascular, Osteogenesis, Orthofix, corticotomy

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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. Infected non-union can develop after an open fracture after a previous open reduction and internal fixation (ORIF) or as sequele to chronic hematogenous osteomyelitis. The incidence also seems to be increasing especially in view of increasing high velocity trauma which is more frequently treated with internal fixation. It is difficult to treat infected non-union because of the following reasons. previous surgeries would have resulted in cicatrization of the soft tissue with an avascular environment around the fracture site. The sinus tract formation leading on to the fracture site indicating dead bone or sequestrum inside. Necrosis of bone near the

non-union site, to a considerable distance, due to thrombosis of blood vessels of the haversian canals. Prolonged immobilization, multiple surgeries with fibrosis of the muscles leading on to a stiffening of adjoining which is frequently referred to as fracture disease.

The microorganism may have developed resistance to the previous antibiotic therapies and poses a problem in the control of infection. These factors make an unfavourable milieu for the fracture union to proceed harmoniously even after prolonged treatment and repeated surgeries to correct this problem, the outcome is unpredictable, and amputation may sometimes be the only option left. Bone union is not usually obtained until the infection has been eradicated. The method known as the distraction osteogenesis simultaneously addresses deformity, shortening, loss of bone function, osteoporosis, and soft tissue atrophy. The cornerstones of 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.

According to AO manual, external fixator is considered as the standard method of fixation in infected non-union. The Limb Reconstruction System (LRS) is a series of modulator monolateral external fixators to be used in reconstructive procedures for the treatment of limb length discrepancy, bone loss, open fractures, non-union and angular deformities. Many years of clinical experience have confirmed the efficacy of the device, providing good outcomes for the above indications. The innovation in the advanced LRS has produced improved efficiency, increasing its ease of application in deformity correction, joint contracture and bone transport with short segments. This has expanded the available choices for the surgeon as there is now a system of external fixation for the effective treatment of deformity and bone defects that is better tolerated by the patient. Management of these complex non - unions in the presence of infection, angular deformity, limb length discrepancy and multiple previous surgery is a challenging orthopaedic task, that the surgeon faces. The disadvantages of ilizarov ring fixator are that it has a poor patient compliance and requires frequent surgeon monitoring. This limb reconstruction system (LRS) on the other hand are uni-planar, less bulky, and less cumbersome, further it allows for distraction at one site and compression at the other site. It further permits for dynamization of treatment of fracture non-union site, which is the essence of the principle of treatment of non-union. The present study incorporates non-union resulting from non-unions of long bones viz; tibia, femur and the humerus, which are of infective origin.

In the process of lengthening of bone LRS has a distinct advantage in allowing for both mono-focal and bi- focal lengthening. Here it is important to emphasize that bone transport differs from lengthening. Since, instead of the bone and soft tissues maintaining a relatively fixed relationship to one another, the bone sides in the soft tissue envelope, rather like a lift max lift the shaft. The technique of standard osteotomies for bone transport were perfected. The application of the callotasis technique was perfected. Once transport has brought the two segments into contact, union is achieved by compression alone a compression distraction combination. Thus, LRS is very versatile surgical instrumentation in restoring the limb length [1-36]

MATERIALS AND METHODS

MATERIALS

This is a prospective study conducted at Balaji Medical College and Hospital, Chrompet, Chennai. The recruitment of patients started in March 2017 and recruitment stopped in February 2018 (12 months). The follow-up continued till October 2018. So that there was the minimum follow-up period was of 8 months (range 8 to 20 months).

Inclusion criteria

Only infective non-unions of long bones were included in the study.

Both male and female in the age group 26 to 45 years were included in the study.

Exclusion criteria

Fracture non-unions resulting from metabolic and congenital causes were excluded.

Fracture non-union occurring in pathological bones were excluded.

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 X-rays. History was taken from the patient including the date of injury, details of the original accident and subsequent stages of treatment. Special attention was focused on limb length measurements, range of motion of the joints, neuro-muscular status and distal vascularity.

METHOD

The cost of the original orthofix is high. The price is beyond the reach of our patients. Various Indian versions of Orthofix have been introduced in the recent past, which is much cheaper than the original and is available at an affordable price for the patients. We did not come across gross deformity as most of the cases in our study have had previous surgeries and the problem was mainly infected non-union with minimal deformity.

Surgical protocol

Anaesthesia

For upper limb, the surgery was performed under general anaesthesia and for the lower limb the surgery was performed under spinal

anaesthesia. The appropriate parenteral antibiotics, which the patient has been taking pre-operatively for infection, are administered before the start of the surgery and continued post-operatively. Through previous scar, if surgery has been done already, metal exit was done, through wound debridement and excision of the infected soft tissue and necrotic bone till fresh bleeding appeared (Paprika sign.) 39, was done. The sinus tract, infected soft tissue, and unhealthy granulation tissue was all excised and sent for histo-pathological and culture study.

The medullary canal was reamed opened on either side. Monolateral external fixator was applied following this. 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. In some of the cases drain was kept, which was removed on POD 2.

In order to compensate for the bone loss, corticotomy was done with a separate set of instruments either at the proximal metaphyseal area for tibia or the distal supracondylar area for the femur.

An open approach was made to perform the corticotomy, which is 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 distraction osteogenesis.

Segmental resection of fibula was done in the leg to allow for acute docking. Distraction was started on the POD 7,32. In case of humerus non-unions the shortening that resulted from debridement was accepted 22, as limb length discrepancy does not grossly affect the functional ability in case of upper limb.

For femur, the fixator was always applied [37] 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 posterolateral aspect. 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. Distraction was done at the rate of one-fourth of a mm in 4 instalments during the waking hours of the patients (6 am to 10 pm) (Figure 1).

Post-operative protocol

Post-operatively, the limb is kept elevated to reduce the post-operative edema. The ankle is splinted in neutral position. Drain is removed on POD 2. Parenteral antibiotics were continued for 2 weeks post-operatively or till the subsidence of infection and then oral antibiotics were given for an additional period of 2 weeks. Joint motion exercises and non-weight bearing was 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 POD 7. Radiograph was taken every week during the initial period of distraction and then at monthly intervals.

On discharge, all patients were taught about pin site care, hygiene and the rhythm of distraction



Figure 1: The LRS fixator.

where the lengthening procedure was being 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 sound union. Poor consolidation of the regenerate was treated by encouraging weight bearing and alternate compression-distraction (Accordion technique) 32. The distraction was stopped when sufficient gain of length had been achieved. The fixator was left in position for a further period of 8 to 12 weeks to allow for the consolidation of the callus.

Usually, the consolidation phase is 2 times the duration that it looks to distract. Our criteria for radiological union 22 was the presence of bony consolidation in three out of four cortices in AP and Lateral x-rays.

RESULT

Results are explained in the tabular form Tables 1-6.

Bone results

The bone results were determined according to ASAMI'S criteria as follows:

Union

Infection (3) Deformity.

Table 1: Age and sex distribution of cases.

Age in years	Male 'n' (% age)	Female 'n' (% age)	Total 'n' % age
26-30	12 (46.15)	3 (11.54)	15(57.69)
31-35	5 (19.23)	1 (3.84)	6 (23.07)
36-40	2 (7.7)	0 (0)	2 (7.7)
41-45	2 (7.69)	1 (3.85)	3 (11.54)
Total	21 (80.77)	5 (19.23)	26 (100)

Table 2: Patient particulars.

Characteristics	No: of Patients 'n'	% age
Gender	Male	21
	Female	5
Sidedness of fracture	Left	6
	Right	20
Original nature of fracture	Closed	8
	Open	18
Mode of injury	RTA	20
	Fall from height	4
	Fall from Ladder	2

Table 3: Nature and anatomical site of the infected nonunion.

Characteristics	'n' no: of patients	% age
Level of non-union	Upper 1/3rd	2
	Middle 1/3rd	5
	Lower 1/3rd	19
Nature of infective non-union	Infected quiescent non-draining	4
	Infected active non- draining	6
	Infected draining	16

Table 4: Characteristics of the non-union and usage mode of orthofix.

Particulars	Data	n	% age
Mean duration of infective non- union	6-7 months	4	
	8-9 months	19	
	10-11 months	3	
Long bone involvement	Humerus	3	
	Femur	6	
	Tibia	17	
LRS usage mode	Compression	3	
	Compression and distraction	3	
	Compression and bone transport	20	

Table 5: Complications encountered.

Problem encountered	n' no: of patients	% age
Pin tract infection	9	34.62
Pin loosening	4	15.38
Joint stiffness	10	38.46
Premature union of cortkotomysite	2	7.69
Per sistent Discharge	2	7.69
Equinus	7	26.92
Cases requiring plate Augmentation and bone grafting	1	3.84
Deformity >7 degrees	0	0
Shortening > 2.5cm	0	0
Refracture	0	0

Table 6: Mean period taken for femoral distraction and then subsequent fracture healing.

Shortening in mm	Femur		
	'n' no: of patients	d' Mean days taken for distraction	M' Mean months needed for consolidation
20-24	1	35	5.2
25-29	0	0	0
30-34	1	51	6.2
35-39	1	58	6.8
40-44	3	66	7.3

(4) Leg length discrepancy.

The fracture was considered to be united when it appeared so roentgenographically, 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. According to the protocol of the ASAMI1, 15, a bone result cannot be graded excellent unless union was achieved without the use of the bone graft.

Bone union results

E-Excellent-Union+No Infection+Deformity<7degrees+Shortening <2.5cms.

G-Good-Union+any TWO of the above factors.

F-Fair-Union+any ONE of the above factors.

P-Poor-No union / Refracture / none of the above factors.

According to these criteria the bone result in our study was.

Excellent-6 cases.

Good-8 cases.

Fair-2 cases.

Poor-3 cases.

Functional results

The functional results were based on five criteria [38]

A noteworthy limp.

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).

Soft tissue sympathetic dystrophy.

Pain that reduced activity or disturbed sleep and Inactivity (unemployment or an inability to return to daily activities because of injury).

Functional results-limp, equines, ankle rigidity, soft tissue deformity, pain & inactivity

Excellent-active+no other

Good-active+1 or 2

Fair-active+ 3 or 4

Poor-inactive irrespective of whether other criteria were applicable.

According to these criteria the functional result was Excellent-3 cases.

Good-11 cases.

Fair-2 cases.

Poor-3 cases.

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 nonunion of humerus, at follow up there was no pain/limitation of movements of elbow or shoulder and the strength was adequate. There was no neurological or vascular injury because of instrumentation.

The Bone healing index 11 (days of fixator use/centimeters of length gain) was 47.1 days/cm. The bone union results and their functional outcome, based on ASAMI criteria. It was found that even when the bone results were on the deficient grade, ultimately the evaluation of the functional results at the end of 8 months, were found to be on the superior grading. Hence, it has to be taken cognizance of the fact that bony grading in ASAMI criteria, need not reflect the final functional outcome ASAMI score.

DISCUSSION

The incidence of open fractures of long bones have been increasing due to increase in RTA. These patients are usually operated upon several times for stabilization (and healing) or to eradicate infection, which in turn produces scarring of the soft tissues and devitalization of any of the surviving bone [39]. As a result, it is considered to be one of the most complex and challenging orthopaedic situations to manage [40]. External fixation is able to address these problems simultaneously [41,42]. Traditionally complex infective non-unions are managed by the illizarov ring fixators. But they are cumbersome, heavy and complicated both for the operating surgeon and the patient [43]. The Indian orthofix or the limb reconstruction system (LRS, pitkar, pune) is uniplanar and less bulky. It has the advantage of allowing distraction at fracture site. It also allows dynamization of the fracture site which is the essential principle in the treatment of non-unions [44].

The aim of reconstructive surgery in an infective non-union of a longbone, involves not just getting control of infection and achieving a sound union, but also to correct any deformity or length discrepancy (especially in the lower limbs), so that the resultant limb can restore good limb functionality and restore the pre-injury quality of life. A multitude of factors play a crucial role in this humungous task, viz; the patient's age, metabolic status, mobility of the foot and ankle, integrity of the neuro-vascular structures, health of the muscles and tendon causing the movements and above all the patient's own patience and motivation. The non-union site is addressed primarily depending on its active or quiescent infective status. If the infection is active the prior to definitive treatment with the fixator, after through debridement and resection of non-

union site, until punctuate bony bleeding points are seen are followed by application of antibiotic impregnated beads (usually gentamycin, vancomycin or cephalosporins). This is held in situ for about 4-to-6-weeks, until active discharge stops. In the meanwhile, based on the intra-operative culture sensitivity report appropriate antibiotics are initiated and maintained for 2 weeks parentally and thereafter for 4 weeks orally. Once it is evident that the infection is under satisfactory control and the fracture is no more draining of pus, then the definitive procedure of LRS (orthofix) is initiated. The next step is to decide on the amount of limb shortening, we need to correct. If distraction is contemplated, then the appropriate diaphyseal-metaphyseal junction is chosen and the corticotomy performed with a distinct set of instruments. Care is taken to preserve the periosteum, to the extent possible circumferentially, as the play a vital role in osteogenesis. The non-union site is then visited, fracture ends are freshened, antibiotic beads of already in place removed and bone grafting if deemed necessary, is harvested from the ipsi-lateral iliac crest, by a separate team with separate instruments. Muscle and tendons, adhering to the bone are elevated and sinus tract if any are excised. Acute docking of the non-union site is done. The non-union site is compressed from POD 1 at the rate of 0.25mm/day for 2 to 3 weeks. Rarely the "Accordion" method of alternate compression and distraction is employed at the acutely docked non-union site. The distraction at the corticotomy site is begun on POD 7 and proceeds at the rate of 1mm/day (0.25mm in four minutes during the waking hours of the patient, viz; 6 am to 10 pm).

In the 12 months of recruitment, we had 26 cases of infective non-unions of long bones of these 80.77 (n=21) were male and 19.23 (n=5) were female patients. Majority of these patients 57.69% (n=15) cases were in the age group 26 to 30 years followed by 23.07 % (n=6) cases in the age group 31 to 35 years. Our mean age group in males was 31.05 years (range 26 to 45 years) and in the females was 29.5 years (range 26 to 45 years). The average shortening was 4.96 cm (range 2 to 6.2 cm). Of the 26 cases, except the 3 which belonged to humerus, all 23 cases underwent corticotomy. Since we did not have cases of shortening beyond 7cm, bifocal corticotomy was not performed in any of our

recruited cases. Active and passive mobilization of the adjacent joint was encouraged from the day following operation. Ambulation and partial weight bearing was started from POD 3; depending upon patient's compliance, pain, local soft tissue condition and the quality of the bone. Patients were discharged and asked to follow-up at bi-weekly intervals for the first two months and thereafter at monthly interval until bony union. Patients were educated about pin tract dressing, hygiene of the external fixator and the technique of compression and distraction. At each follow-up in the OPD problems of pin tract infection, loosening of pins, bolts, clamps were addressed. X-rays were taken at monthly intervals until bony regenerate was formed. Thereafter twice the distraction time were given for consolidation. The average duration of time for union was less for humerus (mean 6.4 months) compared to femur (mean 10.4 months). These are in closed comparison to those to Seenappa et al. [45] whose study reported mean humeral time to be 6.2 months, for femur 9.3 months and tibia 10.2 months. In the study by Seenappa et al. [46] the incidence of complex non-union was common in the third (40%) decade with male preponderance (93%) and RTA (83%) was the most common mechanism of injury. In our study the incidence of infective non-union was in the late 2nd decade (26 to 30 years, 57.6%). The male preponderance in our study was 80.77% RTA constituted for 76.92% of all cases as mechanism of injury in our study. Their study had 10.72% (n=3) of failure to achieve union, whereas in our study 11.54% (n=2) required plate augmentation and bone grafting. We had pin tract infection (34.62%) and joint stiffness 38.46% as our majority of complication which settled with regular dressing and physiotherapy. 26.92% (n=7) case of tibial non-union had equinus deformity of ankle requiring TA surgical procedures. 7.69% of premature union of corticotomy, required surgical re-corticotomy as the proximal and of the distraction site in Tibia and the distal end of the distraction site in the femur.

Our 15.38% (n=4) cases of pin loosening were managed with pin exchange. 7.69% (n=2) cases of persistent discharge were managed with Ilizarov fixator and ultimately union achieved. One case of failure to achieve union was addressed by plate augmentation and bone

grafting. Thus, our union rate primarily with LRS alone was 88.46% which is better comparable to the study of Coarcia et al. 86.7% [47] but our union rates were poorer compared to the union rates (93%). Good humeral union rates were observed to be in the average of 6.4 months, in study by Gualdrini et al. [48] it was 5.5 months and the study conducted by Biasibetti et al. [49] it was 4 months.

In the long term study of tibial infective non-union fractures, Merchant et al. [42] determined that angular deformities of 10 to 15 degrees are well tolerated. Also they concluded that LLD up to 2.5 cm does not require any treatment. In our series we had no cases of either angular deformity exceeding 7 degrees nor any case of shortening beyond 2.5 cm. In our series pin tract infection constituted 34.62% (n=9) of all cases, which performed better than the series of Gopal et al; who reported this complication in 53% (n=10) of all cases. Our study closely matches the study by J.R Coll et al; who reported pin tract infection in 30% of the cases.

CONCLUSION

Plastic surgery procedures like cross leg flap, Fascio-cutaneous flap and skin grafting can be done comfortably. Furthermore, the fixator (other than the tapered half pins) can be reused for another patient provided there is no damage to the apparatus. The disadvantages of the monolateral external fixator include the inability to use the apparatus for correction of infected nonunion with very gross deformity, in a several by osteoporotic bone and to achieve stabilization awfully 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 orthofix. Compared with the Ilizarov ring fixator 11 the unilateral external fixator is simpler to apply and better tolerated by the patients. The learning curve for surgical implement of the unilateral fixator is less steep than that encountered with the Ilizarov fixator, even for the operating orthopaedic surgeon.

In our relatively short period of study spread over 21 months, we could recruit 26 cases of infective non-union of long bones conforming to our inclusion criteria. We could achieve sound union primarily only with LRS in 88.47% (n=23) of cases and even in the remaining 11.53%

(n=3) with additional surgery like augmentative plating, bone grafting or by changing over to the Ilizarov ring fixator, we could ultimately achieve union. That brings in our study a net union rate terminally to 100%, which is the primary goal in treating infective non-unions. Hence the study concludes and recommends use of LRS (MLEF) for treating infective Nonunion of long bones, after preliminarily controlling the infection. However, its short-coming is that it cannot be deployed when there are gross deformities and in instances where shortening exceeds 7 cm necessitating bifocal lengthening. In these situations, the role of the ilizarov ring fixators cannot be undermined.

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ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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