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Case Series

Prospective evaluation of the role of limb reconstruction system in fracture non-union of femur: a case series

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ABSTRACT

Traditionally the Ilizarov's ring fixator was used in the management of non-union of long bones, especially in the cases with infection. But limb reconstruction system (LRS) is a viable lightweight, technically easier alternative for the same. The aim of this study was to assess the functional outcome, the radiological outcome and the complications associated with the management of fracture non-union femur treated with LRS. A prospective case series was undertaken comprising of 10 patients. Both infected and non-infected shaft of femur fractures were enrolled. Patients underwent debridement, implant removal and definitive fixation with LRS. Post-operative radiological outcome and functional outcome using the ASAMI (Association for the Study and Application of the Method of Ilizarov group) score. In 70% cases the mechanism of injury was road traffic accident. Mean period of non-union before admission was 11.9 months, mean time for union was 10.10 months, with 90.0% cases successfully uniting. 70% cases underwent lengthening following Ilizarov's principles. ASAMI radiological outcome was excellent in 70%, good in 10%, fair in 10% and poor in 10% cases. ASAMI functional outcome was excellent in 60%, good in 10%, fair in 10% and poor in 20% cases. Pin tract infection was the most common problem at 70.0% while knee stiffness at 40% was the most common true complication. Thus by this study it can be expressed that LRS is a feasible alternative to ring fixators for the management of fracture non-union shaft of femur.

Keywords: Fracture non-union, Femur, Limb reconstruction system, ASAMI, LRS

INTRODUCTION

In recent times, there has been an increasing number of open femur fractures due to the high incidence of road traffic incidents. Femur fractures are frequently associated with high velocity injuries and are often severe in nature. This is further compounded when there is an open injury, which often has to be fixed by a two-staged procedure at the minimum, further increasing the morbidity of the patients. Often these open fractures have to be operated several times in order to completely eliminate the infection and in order to proceed with definitive fixation.

A number of these open fractures in spite of the best efforts of orthopaedic surgeons often proceed to non-union either due to remnant deep seated infection or due to devitalized fracture ends, resulting in sub-optimal callus formation. These non-unions often present a wide array of problems such as associated limb length discrepancy, joint stiffness, disuse osteopenia, limb angulation etc.

Non-unions of long bones can be managed with debridement in case of presence of infection, excision of devitalized fracture ends, external fixation and bone transport if need be.[1,2] Traditionally, the Ilizarov's ring external fixator is the ideal implant for the management of infected non-union of long bones, using the principles of distraction osteogenesis to even correct limb length discrepancy as well as angular deformity.[3] But with its many advantages the Ilizarov's ring fixator has a number

of disadvantages as well, which includes neuro-vascular impingement when inserted at the diaphysis of the femur, trans fixation of soft tissues which impedes any further plastic surgery intervention, bulky frame is often poorly tolerated by patients and high technical expertise for the application of the same.[4,5] In contrast, a mono-lateral external fixator, in this case a limb reconstruction system (LRS) or a rail-road external fixator has the advantage of being present at one side of the patient's limb, is less bulky and thus has a far greater patient acceptance, requires far less surgical expertise and has a shorter learning curve when compared to the Ilizarov's ring Fixator.[6] This study focuses on the management of non-union fracture femur fixed definitively with mono-lateral limb reconstruction system.

The primary objective of this study is to determine the functional and radiological outcome of the patients of fracture non-union femur treated with LRS, and as a secondary objective the complications associated with the procedure are also noted. As there is significant controversy, associated with the management of fracture non-union of femur, starting from debridement and exchange nailing, ring external fixators to LRS, this series will shed some light upon the effective use of LRS in the management of the same.

METHODS

A prospective case series was undertaken at R.G. Kar Medical College, Kolkata, India, during the study period May 2020 to June 2022. The final sample size was 10, after 2 patients were lost to follow-up, and since this was a time bound single centre study with no financial funding, a non-random convenience sampling technique was chosen.

Samples were selected from the patients admitted in the inpatient and visiting the outpatient department of the Department of Orthopaedics, R. G. Kar Medical College. Inclusion criteria was all patients with fractures of the femur which had failed to unite by at least 6 months, according to radiological evidence. This included both infected and non-infected non-unions. Any patient with associated pathological fracture causing non-union, non-unions due to congenital disorder, intra-articular fractures and moribund unfit patients were excluded from the study. After pre-operative assessment, radiographs of the affected femur were taken in AP, lateral views, while culture and sensitivity testing was done for infected non-union patients.

Initially after proper positioning, we managed the patient with implant removal if previously operated, radical debridement and fixed the non-union with the LRS in operation theatre under all aseptic condition under suitable anaesthesia and under the facility of an image intensifier if it was a case of non-infected non-union. In case of infected non-unions, after implant removal and radical debridement, bone cement (poly methyl methacrylate) beads were inserted which were impregnated with vancomycin.

After 8 weeks, cement beads were removed and definitive fixation was done with LRS. In most cases, after removal of the de-vitalized bone ends, shortening was obtained in the leg. Shortening of up to 2 mm is tolerated by the patient and correctable by heels, and thus was managed by compression only. Shortening up to 2 cm were treated by compression and distraction where the distal segment underwent compression while a proximal osteotomy was done to distract the proximal fragment. Shortening above 2 cm were treated by compression and bone transport where 2 osteotomies were done proximally and distally and bone was gradually transported to achieve compression at the centre. LRS was maintained till radiological sign of union was obtained (at least three out of four cortices united). Active and passive mobilization of adjacent joint that is hip and knee was encouraged the day following operation. Ambulation and partial weight bearing was started on second or third postoperative day depending on patient's compliance, pain, local soft tissue condition and quality of bone. Distraction at corticotomy site was started on the seventh postoperative day. We distracted corticotomy site at the rate of 1 mm/day, preferably in four increments a day till desired length was reached. Patients were discharged and asked to follow-up at 4, 8 and 4 weeks onwards till completion of treatment on the OPD basis. Patients were educated about pin tract hygiene, regular dressing, cleaning of external fixator and compression-distraction.

Complications were classified according to Paley's classification as problem, obstacle or true complication.[7] Problem represented difficulties that required no operative intervention to resolve. Obstacles represented difficulties that required an operative intervention to resolve. All intraoperative injuries and difficulties during limb lengthening that were not resolved before the end of treatment were considered true complications.

At each follow-up appointment, problems of pin tract infection, loosening of pins, bolts, clamps were addressed by thorough debridement and tightening. Check X-ray was taken at each follow-up appointment. Once radiological union of fracture site was visualized, 4 weeks were given for the consolidation and at the same time the corticotomy site was assessed. LRS was removed as office procedure in minor operation theatre under intravenous sedation. Post op functional and radiological outcome was assessed by using ASAMI Score (Association for the Study and Application of Methods of Ilizarov).[8] When it came to radiological outcome Excellent is defined as Union with no infection and deformity less than 7° and limb length discrepancy of less than 2.5 cm. Good is defined as Union with any two of the above three criteria. Fair is defined as union with any one of the above three criteria, while Poor is when none of the four criteria are met. Functional outcome is defined as Excellent when the patient is active with no limp and minimum stiffness and no reflex

sympathetic dystrophy and insignificant pain. Good is defined as active with 1 or 2 of the following: limp, stiffness, reflex sympathetic dystrophy, significant pain while fair is when 3 or all of the following is present along with an active patient. Poor is defined as an inactive patient while failure is defined as a patient who has undergone amputation. All data was collected, compiled and subjected to suitable statistical analysis using appropriate methods. Also, informed consent was undertaken by all the patients participating in the study.

The IBM SPSS 25 was used for data analysis and MS excel 2016 was used for data entry and grand chart creation. Results were discussed on the background of present knowledge and experience of past work.

CASE SERIES

The final sample size was 10 cases of fracture non-union of femur. Among the 10 patients, 9 were males and 1 was female, with the mean age being 28.80 years (SD=10.82). The mechanism of injury was road traffic accidents in 7 cases, occupational injury in 1 case, domestic injury in 2 cases. Most patients presented with an open fracture at 6 cases and closed injuries at 4. 8 patients had at least one surgery prior to admission. Only 2 cases of fresh non-union without any surgical intervention presented to us. The mean period of non-union before admission to the study was 11.90 months (SD=2.76), with the maximum being 17 months before presentation. The level of non-union was upper one third in 1 case, mid-shaft in 5 cases and lower one third of the diaphysis in 4 cases. 9 patients of infected non-union presented to us with only 1 patient being cases of non-infected non-union. Among the 9 patients of infected non-union, 3 patients were implanted with vancomycin impregnated poly-methyl methacrylate cement beads and after 8 weeks the beads were removed and these patients were fitted with LRS.

Among the 9 cases, 6 cases had a draining sinus while 3 had deep seated infection with quiescent sinuses, detected by raised inflammatory markers and intra-operative bio-film found in the implant. The one case of non-infected non-union had a fibrous septa connecting the two fracture ends. The mean time for union was 10.10 months (SD=3.63) with 1 case (10.0%) going into non-union. Those with more than 6 months in union time were subjected to secondary procedures like bone marrow injection, early mobilization, dynamization of the frame and teriparatide injection as adjuvants. 3 (40.0%) were treated with compression only while the rest 7 (70.0%) patients were treated with compression and bone transport.

Shortening up to 2 mm was treated with compression. Among the 7 patients who underwent lengthening, 3 patients did not have any residual limb length discrepancy (LLD). In 2 patients the range was from 0.1 to 1 cm, and in 1 patient it was 1.6 cm, the rest 1 patient underwent non-union. All residual limb length discrepancy was corrected with heels as prosthetics. Among the complications classified according to Paley et al, pin tract infection (n=7, 70.0%) was the most common problem, pin loosening (n=3, 30%) was the most common obstacle and knee stiffness (n=4, 40.0%) was most common true complication.[7] Pin tract infections were managed with pin tract debridement and a course of oral antibiotics, however 3 cases progressed to pin loosening, which was then taken up in the operation theatre and the loosened pins were re-fixed. Pain was another problem, often encountered in patients who under-went compression and bone transport that is 7 cases. Among the other obstacles faced were 3 cases of persistent drainage, out of which 2 were resolved with aggressive debridement and intra-venous antibiotics. But 1 case was not resolved and eventually resulted in non-union.

One case of re-fracture occurred, which was then again aligned under fluoroscopy and went on to unite. Among the 4 cases of knee stiffness, one had a flexion contracture. These were not resolved even after aggressive physiotherapy support. The other true complication faced was, 1 case of angulation of 7.5°. So to summarize complete union was achieved in 9 (90.0%) out of the 10 cases and out of the 9 cases of infected non-union, complete eradication of infection was achieved in 8 cases (88.8%) while 1 went into non-union again, this patient refused any further intervention. When it came to radiological outcomes by the ASAMI score, 7 cases had excellent outcome, 1 case had good outcome, 1 case had a fair outcome and 1 case had a poor outcome. Poor outcome was noted in the one singular case of non-union.[8] When it came to functional outcome by the ASAMI score, 6 cases had an excellent outcome, 1 cases had a good outcome, 1 case had a fair outcome and 2 cases had a poor outcome.[8] These were inactive patients where 1 had a non-union and 1 had a fixed flexion contracture of the knee joint. This study was not funded and did not have any conflict of interest.

Table 1: Comparison of ASAMI Functional outcome of different studies.

ASAMI functional	This study (%)	Arora et al[13] (%)	Kumar et al[14] (%)	Chahar et al[16] (%)
Excellent	60	33.33	40	71.43
Good	10	53.33	50	14.28
Fair	10	13.33	0	14.28
Poor	20	0	10	0

Table 2: Comparison of ASAMI radiological outcome of different studies.

ASAMI radiological	This study (%)	Arora et al[13] (%)	Kumar et al[14] (%)	Chahar et al[16] (%)
Excellent	70	80	86.66	85.72
Good	10	20	0	7.14
Fair	10	0	0	0
Poor	10	0	10	7.14

DISCUSSION

Non-union of the femur, whether infected or non-infected is a technical challenge for orthopaedic surgeons, due to the devitalized fracture ends, remnant infective foci, bio-film formation over the previous implant, severe surrounding soft tissue fibrosis. These fractures have to be managed by controlling the previous infection by debridement and removal of previous implant, freshening of the fracture ends, and removal of sequestrum till the arrival of bleeding points or paprika sign followed by intra-venous antibiotics. Then they can be managed either in a single stage procedure or a two-staged procedure. Any two staged procedure tends to increase the morbidity of the patient due to multiple interventions involved such as repeat nailing after the infection has subsided. Thus the Ilizarov's ring fixator came in to vogue. Ilizarov described his method of distraction osteogenesis, where by a low energy corticotomy, distraction of the bone was done in a controlled manner which provided the stimulus needed for new bone formation inside the intact periosteal sleeve. Ilizarov's ring fixator provides an end all solution in case of infected long bone non-union, where the fixator provides rigid stability necessary for union, at the same time being an external fixator mitigates the chance of bio-film formation or spread of infection. Thus it can be done as a final procedure in case of non-unions. But in case of femur fractures, the Ilizarov's ring fixator provides several technical difficulties in application including the risk of neuro-vascular injury.[9]

The wires in Ilizarov's fixator often fix the soft tissue such that it can lead to severe limitation of movements on part of the patient. At the same time, it is often cumbersome for patients to commit to the lifestyle change and often times the compliance is poor. LRS is uniplanar dynamized external fixator that is light weight, easy to construct frame with short learning curve and based on same basic principle of Ilizarov. It provides stable external fixation with the capacity to change the stiffness of fixation, and therefore, the fracture environment can be more precisely controlled. Limb lengthening can be achieved by bone transport. LRS is mechanically very stable because of the robust construct and variable spread of fixation by the use of sliding clamps. But it is difficult to correct three-dimensional deformities with uniplanar external fixator LRS unlike Ilizarov fixator. A few studies have been done in the past where bone transport has been done using the limb reconstruction system in case of infected non-unions over an intra-medullary nail.[10,11]

But this involved significant risks such as a possibility of the spread of infection along the bone with the use of intra-medullary devices. At the same time this would involve increasing the treatment duration, performing the procedure of nailing when the infection subsides, application of the fixator, performing the corticotomy, then performing the distraction and then locking the nail in a separate sitting. This would involve severe financial costs and would require significant man power resources, thus was not used in our set up. In literature, there is a paucity of studies which discuss the management of non-union shaft of femur fractures managed by limb reconstruction system, mainly due to the smaller number cases available and the fact that LRS is a fairly recent advancement.

A study conducted at Sheffield, UK by Hashmi et al showed that Mono- LRS can provide stable fixation for the treatment of established non-unions. The fracture environment may be carefully controlled and angulation and length corrected simultaneously.[12] 90.0% of the patients in our study had an infected non-union, which encases the main cause of non-union in operated shaft of femur fractures. Similar results were obtained by Arora et al.[13] 70.0% of our patients had to undergo lengthening, whereas in Kumar et al study 46.7% patients had to undergo lengthening.[14] 90.0% of our patients achieved bony union after non-union shaft of femur with LRS, which is in agreement with previous studies. The mean time for union was 10.10 months (SD=3.63) with 1 case (10.0%) going into non-union in our study. This is similar to the study by Banks et al where 13 out of the 14 patients achieved union by LRS.[15] In the study by Arora et al all patients achieved union with a mean treatment duration of 7.3 months. However, Kumar et al's study had a 16% non-union rate. When it came to complications, 70.0% patients developed pin tract infection in our study, in contrast to

Arora et al where only 33.3% patients developed pin tract infections. However, the rate of knee stiffness was similar in both studies at 40.0%. Kumar et al noted, pin tract infection at 73%, pin loosening 26% and knee stiffness 33%, which is similar to our study.[14] The study by Banks et al surprisingly had no cases of pin tract infections.[15] Chahar et al reported however an alarming 80% incidence of knee stiffness, but only 14.29% incidence of pin tract infections.[16] According to the ASAMI score, comparison of our study to other studies in literature is given in Table 1 and 2. As in other studies, in our study the functional results were inferior to the radiological outcome. To prevent any poor outcome for the patient, especially since they are undergoing such prolonged treatment, collaboration and expert aggressive physiotherapy is a must in order to properly mobilize the knee joint. This will further help in the patient's rehabilitation as well.

Limitation

Limitation of our study includes the lack of a control group or a comparison treatment group that does not allow the development of true evidence-based guidelines for the optimal treatment of this group of patients. Additionally, our study includes a small sample size and thus results may not be extrapolated to the broader population.

CONCLUSION

Thus non-union of fracture shaft of femur can be effectively managed with LRS. It is an alternative to

Ilizarov fixation in management of complex non-union of long bones. Even though it is costlier, in general it is a light weight apparatus, allowing easy mobilization of joints, allows plastic surgery interventions, provides rigid frame for non-union management, technically easier and has a better patient compliance. Active involvement and participation of the patients is necessary for successful LRS treatment. Patient should be involved in daily adjustment of the apparatus. The co-operation of the physical therapist and patient is also important, since the patient must exercise the limb and joints. Nearly all of our patients were able to stand and walk with partial weight bearing immediately after LRS application. This is considered the most essential part of this method of treatment.

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