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Use of the limb reconstruction system for the management of non-union of the tibia: A prospective case series

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Abstract
Introduction: Management of fracture non-unions of the tibia are demanding due to the hampered vascular supply, poor bone quality and the deficient soft tissue cover. Instead of the traditional Ilizarov's ring fixator which is bulky, technically demanding and has a poor patient compliance, the Limb Reconstruction System (LRS) is a viable alternative. The aim of this study is to assess the functional and radiological outcome and the complications associated with the management of fracture non-union tibia treated with LRS.
Method: A prospective case series was undertaken comprising of 20 patients. Both infected and non-infected shaft of tibia fractures were enrolled. Patients underwent debridement, implant removal and definitive fixation with LRS. Radiological and functional outcome were assessed using the ASAMI (Association for the Study and Application of the Method of Ilizarov Group) score.
Results: In 90% cases the mechanism of injury was road traffic accident. Mean period of non-union before admission was 12.85 months, mean time for union was 9.30 months, with 95.0% cases successfully uniting. 55% cases underwent lengthening following Ilizarov's principles. ASAMI Radiological outcome was Excellent in 80%, Good in 15% and Poor in 5% cases. ASAMI Functional outcome was Excellent in 40%, Good in 50% and Poor in 10% cases. Pin tract infection was the most common problem at 70.0% while ankle stiffness at 35% was the most common true complication.
Conclusion: 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 tibia.

Keywords: Fracture non-union, tibia, limb reconstruction system, ASAMI, LRS

Introduction
Expansion in the road network, a surge in motorization and rising population in the country contribute toward the increasing number of road accidents, leading to injuries and fatalities [1]. Selected patients among the victims of road traffic accident with fractures of the tibia are operated upon several times for stabilization or to eradicate infection, which in turn produces scarring of the soft tissues and devitalization of any surviving bone [2]. They present with indolent infection, which is almost always associated with deformity, limb length discrepancy, joint stiffness, disuse osteoporosis and soft tissue atrophy [3]. There is a significant controversy in the treatment of non-union of fracture shaft of tibia, regarding use of devices. Various devices used in treatment of non-union are Ilizarov's external fixator, intramedullary nails, limb reconstruction system (LRS) etc. The requirements common to all successful techniques are absolute biomechanical stability and biological vitality of bones which is very well provided by external fixators of sufficient strength [4, 6]. Initially complex non unions were managed by the Ilizarov ring fixators. But, as per some researchers, it is cumbersome and complicated, from point of view of patient-education, patient-profile, institution-set-up & expertise of the concerned surgeon [7]. Complex non-union is defined as an established non-union (of at least 6 months) with one or more of the following criteria:
(a) Infection at the site of non-union;
(b) A bone defect of more than 4 cm (defect non-union);
(c) An attempt to achieve union that failed to heal after at least one supplementary intervention, for example, bone grafting or exchange nailing [8].

Limb Reconstruction System is relatively less cumbersome, relatively less complicated with respect to above mentioned points or factors and also allows dynamization of the fracture site which is the essential principle in the treatment of non-unions [8]. Also, LRS external fixator is one of the simplest and effective device with good union rates and also unlike Ilizarov's external fixator, LRS is easy to construct the frame and less cumbersome to the patient. Most modern unilateral fixator (LRS) also has facility to distract or compress fractures and also allows the dynamization of the fractures which are the essential principles in the treatment of non-union [9]. This study was undertaken with the primary objective of analysing the functional outcome and radiological outcome in the management of fracture non-union of shaft of tibia with LRS. Also as a secondary objective, complications associated with the procedure was also evaluated. As there is still a controversy about union rates and complications associated with LRS in the treatment of non-union [10], this study is being conducted to assess the union rates, infection control, lengthening and the complications associated with LRS.

The rationale for using external fixation techniques for tibial fracture management includes [11]:

1. Compression, neutralization or fixed distraction of the fracture fragment is possible.
2. Immediate motion of the proximal and distal joints is allowed.
3. The methods offer stable fixation with adjunctive wound care.
4. Early dynamization or gradual frame disassembly should be performed which helps in callus formation.
5. External fixation does not cause additional disruption of soft tissue envelope or vascularity of fracture fragments.
6. Associated treatment can be undertaken in open injuries like dressing change, skin grafting, bone grafting and irrigation.
7. Rigid fixation can be used in infected, acute fracture or non-union.

Materials and 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 20, after 3 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 shaft of tibia 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 tibia 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, under 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 if needed which were impregnated with vancomycin. After 8 weeks, cement beads were removed and definitive fixation was done with LRS. In cases where the fibula might pose a hindrance to the union, mid shaft fibulectomy was also done. 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). The limb was protected with POP cast for 3-4 weeks in most of the cases after LRS removal. Active and passive mobilization of adjacent joint that is knee and ankle 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 [7] as problem, obstacle or true complication. 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) [12]. 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 & experience of past work.

Results

The final sample size was 20 cases of fracture non-union of tibia. Among the 20 patients, 18 were males and 2 were female, with the mean age being 43.0 years (SD=11.46). The mechanism of injury was road traffic accidents in 18 cases, occupational injury in 2 cases. Most patients presented with an open fracture at 18 cases and closed injuries at 2. 18 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 number of surgeries prior to fixation with LRS was 2.0 (SD=1.29). The mean period of non-union before admission to the study was 12.85 months (SD=2.81), with the maximum being 19 months before presentation. The level of non-union was upper one third in 5 cases, mid-shaft in 8 cases and lower one third of the diaphysis in 7 cases. 17 patients of infected non-union presented to us with only 3 patients being cases of non-infected non-union. Among the 17 patients of infected non-union, 5 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 17 cases, 13 cases had a draining sinus while 5 had deep seated infection with quiescent sinuses, detected by raised inflammatory markers and intra-operative bio-film found in the implant. The three cases of non-infected non-union one had a fibrous septa connecting the two fracture ends, one had a bone defect while the other was a case of oligotrophic non-union. The mean time for union was 9.30 months (SD=3.51) with 1 case (5.0%) 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. 9 (45.0%) were treated with compression only, 2 (5.0%) were treated with compression and distraction while the rest 9 (45.0%) patients were treated with compression and bone transport. Shortening up to 2 mm was treated with compression, and any residual discrepancy was corrected with heels. Among the 11 patients who underwent lengthening, 5 patients did not have any residual limb length discrepancy (LLD). In 3 patients the range was from 0.1 to 1 cm, and in 2 patients it ranged from 1.1 to 2 cm, the rest 1 patient underwent non-union. Almost all patients had some amount of pain during the lengthening phase, which however was resolved once the distraction was stopped.

Among the complications classified according to Paley *et al.* [7], pin tract infection (n=14, 70.0%) was the most common problem, pin loosening (n=6, 30.0%) was the most common obstacle and ankle stiffness (n=7, 35.0%) was most common true complication. Pin tract infections were managed with pin tract debridement and a course of oral antibiotics, however 6 cases progressed to pin loosening, which was then taken up in the operation theatre and the loosened pins were re-fixed. Among the other obstacles faced were 4 cases of persistent drainage, out of which 3 were resolved with aggressive debridement and intra-venous antibiotics. But 1 case was not resolved and eventually resulted in non-union. One case of premature union of corticotomy site occurred, which was then again revised under fluoroscopy. Among the 7 cases of ankle stiffness, 6 cases had a mobile equinus deformity and only 1 case had a rigid equinus. The other true complication faced was, 4 cases of angulation above 7° and one case of reflex sympathetic dystrophy with oedema of the feet. These were not resolved even after aggressive physiotherapy support. So to summarize complete union was achieved in 19 (95.0%) out of the 20 cases and out of the 17 cases of infected non-union, complete eradication of infection was achieved in 16 cases (94.11%) while 1 went into non-union again. When it came to radiological outcomes by the ASAMI score [12], 16 cases had excellent outcome, 3 cases had a good outcome and 1 case had a poor outcome. Poor outcome was noted in the one singular case of non-union. This singular case of non-union was then subjected to re-surgery by a two-staged procedure, and after the subsidence of infection, intra-medullary nailing was done which helped the fracture to finally unite. When it came to functional outcome by the ASAMI score [12], 8 cases had an excellent outcome, 10 cases had a good outcome and 2 cases had a poor outcome. These were inactive patients where 1 had a non-union and 1 had a rigid equinus contracture with more than 8° of angulation. These patients were thus unable to join back in the work force. This study was not funded and did not have any conflict of interest.

Discussion

The goal of management of non-union of the tibia, is to provide the patient with a functional limb post treatment, which is stable with no deformity, pain free, allows them ambulation and at the same time restores their livelihood. However, most fracture non-union of the tibia, are a technically difficult to manage. This is because tibia being a sub-cutaneous bone, has a relatively deficient blood supply once the surrounding skin is exposed, which it is prone to. This makes the salvage difficult in most patients with open fracture of the tibia, and also in patients which has undergone more than one operative intervention in the bone. Usually patients with fracture non-union of the tibia, has one or more than one prior surgeries, which in turn hamper the vulnerable blood supply of the bone. When plastic surgery interventions such as muscle flaps are under taken to cover the defects, this in turn makes an open reduction and internal fixation procedure technically challenging. The Ilizarov's method of fixation was devised for the treatment of chronic osteomyelitis of long bones with bone defects [13]. The Ilizarov's method focuses on the creation of a low energy corticotomy in the hyper-vascular metaphyseal region and then uses distraction osteogenesis to create new bone in the periosteal sleeve and thus bridging the gap defect. It is a highly effective single stage procedure, where internal fixation is contra-indicated such as in infected non-union. Infected bone when subjected to internal fixation will result in transmission of the infection along the medullary canal, and thus is more amenable to a staged procedure where after the infection has subsided the bone is subjected to a definitive fixation. This increases the number of surgical interventions being done in the patient as a result increasing their morbidity. In these scenarios, Ilizarov's ring fixator provides an excellent alternative as an end all procedure. But at the same time, it has to be considered that the procedure has a steep learning curve, the implant is bulky, prevents any plastic surgical interventions and has a poor compliance. LRS on the other hand provides a similar rigidity, offers the option of distraction osteogenesis under the same principles as Ilizarov, is much light weight, has a shorter learning curve and is widely accepted by patients. To achieve the desired length of

the limb, two methods can be used that is, compression and distraction or compression and bone transport. Acute docking and lengthening or compression and distraction is suitable for defect of 3 cm for tibia and 5 cm for femur [5]. The same principle was used in our study and any residual defect was corrected by heeled shoes. In literature, there is a dearth of studies which discuss exclusively the management of non-union shaft of tibia fractures managed by limb reconstruction system. A study conducted at Sheffield, UK by Hashmi *et al*. showed that Mono-lateral external fixation(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 [10]. The mean period of non-union before admission to the study was 12.85 months (SD=2.81), this was similar to Jilani *et al.* [14] study where the mean time of non-union was 1.8 years. In Singh *et al*. [15] study this gap was 9.4 months. 45.0% of our patients had to undergo lengthening by compression and bone transport while 5.0% underwent compression and distraction, whereas in Jilani *et al*. [14] study 63.6% patients had to undergo lengthening by compression and distraction and 36.3% underwent compression and bone transport. 95.0% of our patients achieved bony union after non-union shaft of tibia with LRS, which is in agreement with previous studies. The mean time for union was 9.30 months (SD=3.51) with 1 case (5.0%) going into non-union in our study. This is similar to the study by Jilani *et al*. [14] where 20 out of the 22 patients achieved union by LRS. In the study by Gupta *et al*. [16] 94.4% patients achieved union with a mean time of union of 9.7 months (SD=1.7). However, in Kushwaha *et al*. [17] study all patients achieved bony union. When it came to complications, 70.0% patients developed pin tract infection in our study, similar to Jilani *et al*. where 59.1% patients developed pin tract infections, Gupta *et al*. had a 33.3% incidence. Our study had a 30.0% incidence of pin loosening while Jilani *et al*. study had a 18.18% incidence. The incidence of joint stiffness was 35.0% in our study, it was 22.2% in Singh *et al*. study, while Jilani *et al*. had a 9.1% incidence and Gupta *et al* had a 11.1% incidence.

According to the ASAMI score, comparison of our study to other studies in literature is given in Table 1 & 2. As in other studies, in our study the functional results were inferior to the radiological outcome. Excellent bony results of treatment accompanied by resolution of infection does not guarantee a good functional result. The functional result depended primarily on the existing damage of nerves, muscles, vessels, joints and to a lesser extent bones. To prevent any poor outcome for the patient, since they are undergoing such prolonged treatment, expert aggressive physiotherapy is a must in order to properly mobilize the adjacent joint. This will further help in the patient's rehabilitation as well.

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.

Table 1: Comparison of ASAMI Functional outcome of different studies

ASAMI Functional	This study	Jilani *et al.* [14]	Gupta *et al.* [16]	Kushwaha *et al.* [17]
Excellent	40%	50%	66.7%	52.38%
Good	50%	22.72%	27.8%	42.85%
Fair	0%	18.18%	0%	4.76%
Poor	10%	9%	5.55%	0%

Table 2: Comparison of ASAMI Radiological outcome of different studies

ASAMI Radiological	This study	Jilani *et al.* [14]	Gupta *et al.* [16]	Kushwara *et al.* [17]
Excellent	80%	54.5%	83.3%	42.85%
Good	15%	22.7%	11.1%	47.61%
Fair	0%	13.6%	0%	9.52%
Poor	5%	9.1%	5.55%	0%

Conclusion

Complex non-unions of the tibia can thus be managed satisfactorily with LRS. It is an alternative to Ilizarov fixation in management of complex non-union of long bones due to its design and ease of use. 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 crucial part of this method of treatment.

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None

Conflict of Interest

None

References

1. Transport Research Wing, Ministry of Road Transport and Highways. Road Accidents in India 2015. New Delhi: Ministry of Road Transport and Highways, Government of India; c2015.
2. Dendrinos GK, Kontos S, Lyritsis E. Use of the Ilizarov technique for treatment of non-union of the tibia associated with infection. J Bone Joint Surg Am. 1995 Jun;77(6):835-46. DOI: 10.2106/00004623-199506000-00004. PMID: 7782356.
3. Motsitsi NS. Management of infected nonunion of long bones: the last decade (1996-2006). Injury. 2008 Feb;39(2):155-60. DOI: 10.1016/j.injury.2007.08.032. Epub 2008 Jan 29. PMID: 18234202.
4. Saleh M, Royston S. Management of nonunion of fractures by distraction with correction of angulation and shortening. J Bone Joint Surg Br. 1996 Jan;78(1):105-9. PMID: 8898138.
5. Saleh M, Rees A. Bifocal surgery for deformity and bone loss after lower-limb fractures. Comparison of bone-transport and compression-distraction methods. J Bone Joint Surg Br. 1995 May;77(3):429-34. PMID: 7744930.
6. Cleveland Kevin B. Delayed Union and Non-union of Fractures, chapter 56, Campbell's Operative Orthopaedics: 11th edition, Mosby Elsevier, Philadelphia, Pennsylvania, USA. 2008;3:3533.
7. Paley D. Problems, obstacles, and complications of limb lengthening by the Ilizarov technique. Clin Orthop Relat Res. 1990 Jan;(250):81-104. PMID: 2403498.
8. Watson TJ. Principles of External Fixation. Chapter 8, Rockwood and Green's fracture in adults. 7th ed. Philladelphia USA: Lippincott Williams and Wilkins Publisher; c2010;1:191-243. Sec 1.
9. Charles M, Court- Brown, Ed. Fracture of The tibia and fibula; chapter 52, Rockwood and Green's fractures in

adults: 6th edition, Section 4, Lippincott Williams and Wilkins, Philadelphia, USA. 2006;2:2113.
10. Hashmi MA, Ali A, Saleh M. Management of non-unions with mono-lateral external fixation. Injury. 2001 Dec;32(4):SD30-4. DOI: 10.1016/s0020-1383(01)00162-0. PMID: 11812476.
11. Lavini F, Renzi Brivio L, Pizzoli A, Giotakis N, Bartolozzi P. Treatment of non-union of the humerus using the Orthofix external fixator. Injury. 2001 Dec;32(4):SD35-40. DOI: 10.1016/s0020-1383(01)00114-0. PMID: 11812477.
12. Paley D, Catagni MA, Argnani F, Villa A, Benedetti GB, Cattaneo R. Ilizarov treatment of tibial nonunions with bone loss. Clin Orthop Relat Res. 1989 Apr;(241):146-65. PMID: 2924458.
13. Ilizarov GA, Lediaev VI. Zameshchenie defektov dlinnykh trubchatykh kosteĭ za schet odnogo iz otlomkov [Replacement of defects of long tubular bones by means of one of their fragments]. Vestn Khir Im I I Grek. 1969 Jun;102(6):77-84. Russian. PMID: 4904826.
14. Jilani LZ, Shaan ZH, Ranjan R, Faizan M, Ahmad S, Asif N. Management of complex nonunion of tibia using rail external fixator. J Clin Orthop Trauma. 2020 Jul;11(4):S578-S584. DOI: 10.1016/j.jcot.2019.12.016. Epub 2019 Dec 31. PMID: 32774032; PMCID: PMC7394815.
15. Singh AK, Parihar M, Bokhari S. The Evaluation of the Radiological and Functional Outcome of Distraction Osteogenesis in Patients with Infected Gap Nonunions of Tibia Treated by Bone Transport. Open Access Maced J Med Sci. 2019 Feb 21;7(4):559-566. DOI: 10.3889/oamjms.2019.112. PMID: 30894912; PMCID: PMC6420925.
16. Gupta D, Akshay KS, Yadav AK, Shah NZ, Pandey S, Gop A. Infected non-union of tibia treated with limb reconstruction system (LRS): A prospective study. International Journal of Orthopaedics. 2021;7(2):805-11.
17. Kushwaha Ns, Mahendra M, Kumar S, Sinha S, Singh A, Sharma V. Infected Non-union of Tibia Managed by Limb Reconstruction System-A Prospective Cohort Study. Journal of Clinical & Diagnostic Research. 2020 Sep 1;14(9).