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To determine efficiency of Ilizarov's circular external fixator in form of the bone outcome and functional outcome in treatment of femoral and tibial nonunions

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Abstract

Aim: planned to assess bone and functional outcome of Ilizarov's circular external fixator in treatment of femoral and tibial nonunion (infected and noninfected both).

Material and methods: The present study is clinical prospective type of study conducted at Dr Hardas Singh Orthopaedic Hospital & Superspeciality Research Centre, Amritsar, Punjab. The present study included 15 cases, all managed with Ilizarov circular external fixator for isolated femoral or tibial nonunion after obtaining informed consent, clinical and radiological examination during a period of 24 months. After removal of frame, patient followed up regularly every month and we assessed them for bony and functional outcome.

Results: The age of patients in present study was 22 to 55 years with mean age of 39.4 years. There were 3 (20%) femoral and 12 (80%) tibial nonunions that were operated with Ilizarov's circular external fixator using ilizarov method's. Road traffic accidents were the most common mode of injury accounting for 11 cases (73.3%). Fourteen patients had undergone fixation previously (plate osteosynthesis = 7, external fixators of the AO tubular type = 7) and one patient had been treated by traditional bonesetter bandages. According to ASAMI guidelines, bone outcome was excellent in 7 cases (46.6%), good in 5 cases (33.3%), fair in 2 (13.3%) cases and poor in 1 case (6.7%). Functional outcome was excellent in 3 cases (20%), good in 11 cases (73.3%), fair in no case and poor in 1 case (6.7%). But no patient required amputation.

Conclusion: Ilizarov technique using circular external fixator is a good salvage operation for infected and noninfected nonunion of the femur and tibia both. Functional results can be improved by the early use of the Ilizarov technique.

Keywords: Ilizarov technique, femur, tibia, outcome

Introduction

Injuries are predicted to become the leading cause of disability over the next few decades eventually rising to the level of a substantial global burden in which musculoskeletal injuries including long bone fractures play a major part ^[1, 2].

One of the complications that occur due to fractures is nonunion. The rate of fracture nonunion is estimated to be between 5%³ and 10%^[4], and the rate of nonunion may be increasing as the survival rate for patients with severe injuries improves ^[5].

There is currently no one accepted standardized definition of fracture nonunion among orthopaedic surgeons. According to the current definition from European society of tissue regeneration in orthopaedics and traumatology (ESTROT), a non-union is a fracture that does not heal without further intervention, independent of the length of treatment ^[6].

The US Food and Drugs Administration (US-FDA) defines a nonunion as a fractured bone that has not completely healed within 9 months of injury and that has not shown progression towards healing over 3 consecutive months on serial radiographs ^[7].

Although the exact causes of delayed union and non-union are unknown, both systemic and local factors are thought to contribute to its development. Systemic factors include the patient's metabolic and nutritional status, general health, and activity level. The use of the use of tobacco has been implicated in the development of nonunions ^[8]. Nicotine has been shown

experimentally to affect union rate and fracture callus strength [9].

The severity of the trauma, open infected injuries, an unfractured fibula¹⁰, and fracture in the lower third of the tibia etc. also are other causes of nonunion.

Stability and vitality of the bone, are the cornerstone of bone healing as they provide a favourable platform on which new bone can be formed. Internal fixation is not favourable in case of infected nonunion for the fear of persistence or recurrence of infection. According to AO manual, External fixator is considered as the standard method of fixation in infected nonunion [11].

Circular external fixators uses 'the concept of shared stability' [12] and were identified as the ideal fixation devices to fulfil all requirements for non-union management. These devices could be applied with limited iatrogenic injury to the soft tissue envelope and with preservation of the existing blood supply to the nonunion site. Their mechanical characteristics also assist with creating the optimal biomechanical milieu for fracture union.

Gavril Abramovich Ilizarov popularised the use of fine wire circular external fixators [13]. In the following three decades there was a dramatic increase in the use of fine wire external fixators, with a growing number of applications in elective and trauma orthopaedic surgery. The Ilizarov system and the Ilizarov principles of distraction osteogenesis have been subsequently become indispensable in limb reconstruction surgery.

As this technique is not much old, results of this technique needed to be find out. In existent literature, almost all studies includes either only infected or only noninfected cases, either includes only femoral nonunion or only tibial nonunion. Study including all variables infected, noninfected, femoral nonunion, tibial nonunion and their treatment with circular external fixator by same surgeon in same facility should be carried out to find out uniform outcome. This clinical prospective study was planned to assess bone and functional outcome of Ilizarov's circular external fixator in treatment of femoral and tibial nonunion (infected and noninfected both).

Materials and Methods

The present study is clinical prospective type of study conducted at Dr Hardas Singh Orthopaedic Hospital & Superspeciality Research Centre, 882, circular road, Amritsar, Punjab.

The present study included 15 cases, all managed with Ilizarov circular external fixator for isolated femoral or tibial nonunion after obtaining informed consent, clinical and radiological examination during a period of 24 months from April 2016 to April 2018.

Inclusion Criteria

- All Patients who have been diagnosed for nonunion of either femoral shaft or tibial shaft and have been operated with Ilizarov's circular external fixator.
- All Patients giving consent to be part of the study, aged 18 years and above.

Exclusion Criteria

1. Patient not willing to participate in the study.
2. Patients presenting with complex nonunion due to congenital disorders and following pathological fractures were excluded from the study.
3. Patients of nonunion with intramedullary nail in situ were automatically excluded from this study as protocol of our institute is to treat these patients by exchange nailing or

reosteosynthesis with plating over nailing.

Methodology

Some of our nonunion patients were managed in our institute previously. Others were referred from elsewhere.

A detailed history was taken relating to age, sex, mode of injury, previous surgery done or not, time since previous surgery, h/o fever, past and associated medical illness etc. Then thorough clinical examination was done to notice temperature, tenderness, signs of infection including sinus discharge, abnormal mobility at fracture site etc.

Plain radiographs of AP and lateral view of leg with knee and ankle or thigh with hip and knee were done accordingly to confirm the nonunion and its type.

When nonunion was confirmed with signs of infection clinically and radiologically, it was classified according to AO classification in infected draining nonunion or infected nondraining nonunion.

When there was no signs of infection i.e. when noninfected nonunion was diagnosed, it was further classified to atrophic, oligotrophic or hypertrophic nonunion (Weber's types). Hematological investigations like ESR, TLC, DLC and CRP were also used to rule out infection.

Operative procedure

Implants used are full ring, half ring, 5/8th ring, cannulated wire fixation bolt, threaded rod, Schanz pin, male post, female post, male hinge, female hinge, long connection plate, short connection plate, twisted plate, threaded socket, bushing, washer, slotted washer, bolt, nut, Ilizarov wire, Ilizarov wire with stopper, dynamometric wire tensioner, wrench, tubular angulated wrench, Italian arch, oblique support, drill bit sleeve etc.

Surgical technique

Modified Ilizarov frames (stainless steel, Pitkar) were used in all cases.

1. For femur we had three patients of Femoral nonunion. Type was oligotrophic, noninfected in all three cases. Patients were operated under spinal anaesthesia. Supine position was given. After suitable incision and exposing nonunion site, existing implants (if present) were removed and debridement of nonviable fibrous tissues was done. The medullary canal was opened on both sides. Freshening of bone ends was done using nibbler and sharp osteotome. From iliac crest, bone graft was taken. Bone grafting was done at site of freshened bone ends. Then site was closed. The Preconstructed sterilised Ilizarov frame was applied after debridement of sclerotic bone and dead tissues. Rings were fixed to the bone, distally first, then to the middle and proximal sections to maintain the mechanical axis of the femur by keeping the rings parallel to the tibial articular surface of the knee joint. Moreover, adjustment of the proximal construct after fixation of the middle and distal rings is easier than the converse sequence. Full rings of the middle and distal constructs were reinforced with tensioned 1.8-mm olive wires through the rings; Schanz screws were applied for additional stability when required, especially in osteoporotic bone. To avoid damage to vital structures, wires were inserted according to the level of the femur and were directly guided by the goniometric atlas of the Association for the Study and Application of the Method of Ilizarov (ASAMI) [14, 15].

The proximal construct was completed with 3 to 5 bicortical Schanz screws through pin fixation bolts. The Schanz screws were inserted after predrilling drill bit. The screws were fixed through the fixation bolts in the arch in a multiplanar way within the safe corridor of the proximal femur from 30° to 150° laterally.

The anatomical and mechanical axes were corrected at the time of frame application. Remaining corrections were gradually done during postoperative period. Biomechanical principle followed throughout the fixation. Gradual compression advised in later follow-ups if needed according to x-rays.

Out of three patients, two had postoperative shortening of >2.5cm. We offered corticotomy and limb lengthening in different setting but refused by patients. (As we did not have cases of gap nonunion femur, we did not use corticotomy and bone transport in cases of femur).

2. For tibia In surgery for tibia, mechanical principles of fixation remains same as femur. ASAMI guidelines for tibia were followed for wire and pin insertion.

We had total 12 patients of tibial nonunion from which four were atrophic noninfected type, two were oligotrophic noninfected type and six were infected type.

- In cases of atrophic and oligotrophic tibial nonunion: After suitable incision and exposing nonunion site, existing implants (if present) were removed and debridement of nonviable soft tissues was done. The medullary canal was opened on both sides. Freshening of bone ends was done using nibbler and sharp osteotome. From iliac crest, bone graft was taken. Bone grafting was done for biological augmentation at site of fractured bone ends. Then site was closed. Maintaining normal mechanical axis, Ilizarov fixation was done. Bone ends were kept in close contact without any gap.

Among these six patients, two patients had postoperative shortening of >2.5 cm. We offered corticotomy and limb lengthening in different setting but refused by patients.

- In cases of infected nonunion, balanced resection of infected necrotic bone was the key step in our surgery. Punctate cortical bleeding (paprika sign) was used to determine the completeness of bone debridement.
- i. In four cases, when resection was done, larger gap of >5 cm was created. Acute docking should not be done in this much gap. So, we used bone transport method in such cases. A corticotomy at the distal metaphyseal-diaphyseal created a mobile bone segment with good vascularity that can be transported linearly along the gap by transverse wire fixation. Distraction osteogenesis filled the gap while the non-union was united by compression on bone contact. Transportation was carried out at 1 mm per day, and the non-union was compressed at ¼ mm every three days to maintain stability until the callus is visible. Distraction was continued till desired length achieved.
 - ii. In two cases, created gap after resection was <5cm. Acute docking was done in these cases. Maintaining normal mechanical axis, Ilizarov fixation was done. Bone ends were kept in close contact as much as possible. Bone grafting was needed in later setting. It was done when infection was completely eliminated. Gradual compression

was also used when needed according to follow-up X-rays. Corticotomy and Limb lengthening had been planned later in these two patients, but were refused by patients.

Postoperative care and rehabilitation

Patients were put through a stringent postoperative protocol with a suitable diet. Post-operative pain and inflammation were managed using anti-inflammatory analgesics for minimal period. All patients with noninfected nonunion were given intravenous antibiotic (ceftriaxone 1gm + sulbactam 0.5gm) twice daily for 3 days and followed by oral antibiotics like cefexime 200mg twice daily. In cases of infected nonunions, systemic i.v. antibiotics for 6 weeks according to culture/sensitivity results, and wound care was done.

Affected limb was kept elevated and patients were asked to perform active movements of toes, ankle, knee and hip from day one. A physical therapist actively participated in all stages of the treatment.

Patients were discharged after two days with routine instructions and exercises. Patients were followed up after 15 days. In cases where corticotomy was done, Patients were discharged after having learnt the method of distraction and so long as wound healing had started.

The apparatus was regularly checked for loosening and the wire was retensioned if required.

Immediate post-operative check X-rays were taken in both anteroposterior (AP) and lateral views. Reduction of nonunion site, joint alignment, fixation of schanz pin and k-wires, parallelization of k-wires were confirmed. As all of our patients from remote areas, subsequent radiograph taken at monthly interval. In cases where distraction was advised, X-rays were taken every 3 weeks. Patients were called for follow-up every 1 month. Cases in distraction phase were called every 20 days.

Weight bearing with crutches/walker was started as soon as tolerated. Foot drop splint was used in all patients Femur and Tibia nonunion.

Final Bone and Functional Outcome Assessment

- ❖ A.S.A.M.I. grading was used for final bone and functional outcome.
 - ❖ For final bone results cases were assessed for:
 - Union/refracture,
 - Final LLD,
 - Residual deformity,
 - Infection present or not at fracture site.
1. Union or refracture were confirmed clinically and radiologically.
 2. Measurement of limb length – noted for discrepancy (shortening)

Statistical Analysis

The results of this clinical observational prospective study has been given in the percentage and their association with various variables has been calculated using descriptive statistical method chi-square test. SPSS (17 ver.) software has been used.

Results

Table 1: clinio-demographic profile of the study population

Parameters	Number of patients	Percentage
Age		
21-30	3	20%
31-40	6	40%
41-50	2	13.3%
>50	4	26.6%
Gender		
Male	15	100%
Female	0	0%
Side		
Right	8	53.3%
Left	7	46.7%
Bone		
Femur	3	20%
Tibia	12	80%
Mode of injury		
RTA	11	73.3%
Fall from height	3	20%
Gunshot injury	1	6.7%
Total	15	100%

Table 2: association of close and open fracture type with development of infected vs noninfected non-union

Bone	Type of fracture	Type of nonunion developed	No of patients (N=15)	P value
Femur	close	Infected nonunion	0	0.014; significant
		Noninfected nonunion	3	
	open	Infected nonunion	0	
		Noninfected nonunion	0	
Tibia	close	Infected nonunion	2	
		Noninfected nonunion	6	
	open	Infected nonunion	4	
		Noninfected nonunion	0	

Test applied: chi-square test

Table 3: outcomes of different A.S.A.M.I. grade variables in study

No	ASAMI variable Results	No. of patients	
1	Union	Yes	14 (93.3%)
		No	1 (6.7%)
2	Infection	No	15 (100%)
		Yes	0
3	Final deformity	<7 degree	12 (80%)
		>7 degree	3 (20%)
4	Final LLD	<2.5 cm	7 (46.7%)
		>2.5 cm	8 (53.3%)
5	Activity	Present	14 (93.3%)
		Absent	1 (6.7%)
6	Limp	No	7 (46.7%)
		Yes	8 (53.3%)
7	Loss of ankle dorsiflexion	<15 degree	6 (40%)
		>15 degree	9 (60%)
8	Loss of knee extension	<15 degree	12 (80%)
		>15 degree	3 (20%)
9	Pain in late follow-ups	No	14 (93.3%)
		Yes	1 (6.7%)

Table 4: association between bone and functional outcome

Bone findings	No of patients	Functional grading				P value
		Excellent	Good	Fair	Poor	
Final LLD < 2.5 cm	7	3	4	0	0	0.092; NS
Final LLD > 2.5 cm	8	0	7	0	1	
Final Deformity <7 degree	12	3	9	0	0	0.092; NS
Final Deformity >7 degree	3	0	2	0	1	
Union	14	3	11	0	0	0.001*
Nonunion/refracture	1	0	0	0	1	

* $p < 0.05$; Significant

Table 5: list of complications

No	Complications	No of patients
1	Pin tract infections	10
2	Pain	15
3	Loss of ankle movements	11
4	Loss of knee movements	3
5	Significant deformity (>7degree)	2
6	Hardware failure	1
7	Over lengthening	1

Discussion

The results of conventional treatment of nonunion of the femur and the tibia can be poor, due to high velocity primary trauma, multiple surgeries, late presentation, bone and soft tissue infection, bone loss, osteoporosis, dystrophy, poor vascularity, associated deformities, and shortening. The Ilizarov technique based on "tension-stress effect" is a salvage procedure for these difficulties.

In the present study, 15 patients with lower limb (femur and tibia) posttraumatic nonunion treated with Ilizarov's modified circular external fixator. Range of age was 22 to 55 year with mean age 39.4 years. The average mean age in our study is comparable to studies of Mohammad Shahid *et al.* (2013) [16] and T. Bauer *et al.* (2017) [17] who had an average age of 43.3 years and 37 years respectively.

In our study, all 15 patients with lower limb nonunion were male. Male preponderance was also consistent in study of Mohammad Shahid *et al.* (2013) [16] with 10 males and 2 females. Increased incidence of lower limb nonunions in males is probably due to their involvement in outdoor activities, riding vehicles and heavy manual labour which consequently leads to premature weight bearing and re-trauma in previously treated limb. Both right (8 cases) and left (7 cases) side were involved almost equally in the present study.

Among 15 cases of lower limb nonunions, twelve cases (80%) were of tibia and three cases (20%) were of femur. In our study, femoral nonunions involving distal 1/3rd accounted for all 3 cases (100%). Tibial nonunions involving proximal 1/3rd accounted for 4 cases (33.3%), middle 1/3rd accounted for 1 case (8.3%) and distal 1/3rd accounted for 7 cases (58.3%). Statistically, it was not significant (P=0.392). In study of 30 cases by H kumar *et al.* (2013) [18], site was proximal 1/3rd in 6 cases, middle 1/3rd in 13 cases and distal 1/3rd in 11 cases.

Road traffic accidents were the most common mode of injury the time of fracture. 11 cases (73.3%) accounted for road traffic accidents, 2 cases (20%) accounted for fall from height and 1 case (6.5%) for gunshot injury. This is comparable to the study of Krishnan A *et al.* [19] The reason of RTA being a the most common mode of injury in nonunion cases may be due to its high velocity forces leading to open injury, high comminution, massive soft tissue stripping and bone loss.

In the present study, there were 6 cases of infected nonunion and 9 cases of noninfected nonunion. In femur, all 3 cases were oligotrophic type. There was no infected nonunion in femur. In tibia, there were 6 cases of infected nonunion, 4 cases of atrophic nonunion, 2 cases of oligotrophic nonunion.

In the study, all 3 cases of femur nonunions were close type fracture at the time of injury. Among cases of tibia, 8 cases were close type and 4 cases were open type. These all four cases of open fracture in tibia were developed into infected nonunion. It was statistically significant with p value 0.014.

In the present study, 14 patients had undergone fixation previously (plate osteosynthesis = 7, external fixators of the AO tubular type = 7) and 1 patient had been treated conservatively

by traditional bonesetter bandages. Among these, all three patients of femur nonunion were operated previously for open reduction and plating. While Five cases of tibia were operated for open reduction and plating. Six cases of tibia were operated for monolateral tubular external fixation. One case of tibia nonunion was managed conservatively. In this study, there was no significant association (P=0.194) found between different modality of previous treatment with development of nonunion.

In this study, distraction histiogenesis method in form of bone transport has been used in four patients. In all four patients, time needed for consolidation was almost twice the distraction time. In our study, distraction-consolidation time had a direct linear relationship with the magnitude of the distraction gap. This observation was consistent in the study of Fischgrund J *et al.* [20] Overlengthening (3.5cm) was also a complication in one poor compliant patient. He came very late for follow up while distraction was continued without consultant's advice. He was treated conservatively by giving shoe raise on opposite limb. Compliance of patient finds to be very important factor to achieve better results.

During the study it was noted that pain tolerance and psychological profile of these patients were very important for the implementation of ambulation and physiotherapy. Two patients were engaged in light occupations, while on treatment.

The multiple scars were cosmetically acceptable to all patients. After follow-up it was noted that ankle movements never returned to normal in 11 cases. This was probably due to soft tissue contracture following prolonged immobilization prior to treatment and poor compliance with weight bearing and physiotherapy.

Bone outcome assessment and functional outcome assessment were done by ASAMI guidelines. Bone outcome was excellent in 7 cases (46.6%), good in 5 cases (33.3%), fair in 2 (13.3%) cases and poor in 1 case (6.7%). Functional outcome was excellent in 3 cases (20%), good in 11 cases (73.3%), fair in no case and poor in 1 case (6.7%). No patient required amputation. Our outcome was slightly poorer than studies by Krishnan A *et al.* [19] in which the bone results were excellent in 13 patients, good in 4, fair in one, poor in one and treatment failed (amputation) in one. The functional results were excellent in 3 patients, good in 9, fair in 3, poor in 4, and failed in one.

Conclusion

Ilizarov technique using circular external fixator is a good salvage operation for infected and noninfected nonunion of the femur and tibia both. The bone results are usually superior to the functional results. Functional results can be improved by the early use of the Ilizarov technique. Limb salvage is always preferable to a prosthesis, so long as the limb is viable, adequately innervated and the patient is committed to the financial and psychological demands of the procedure.

It is suggested that, a further long term study with large number of patients and comparison with other treatment modalities are needed to establish efficiency and superiority of this technique especially in noninfected nonunion. In infected nonunion, we consider this treatment method is gold standard due to biomechanical superiority and high versatility.

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