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# **Evaluation of Results of Ilizarov Fixator and Methodology in Tibial** Non-Union

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## ABSTRACT

Background: Treatment of non-union of tibial diaphyseal fractures has always posed a formidable challenge to surgeons. Persistant infection, deformity, bone loss, stiffness of joints and disability complicate the problem further. Ilizarov methodology tackles all the above problems simultaneously and offers a solution for non-union. Progressive new bone formation and increased vascularity following corticotomy and bone transport helps in filling bone gaps and promoting fracture union. Stability of the fixation allows early weight bearing, ambulation and joint mobilization. To evaluate the results of Ilizarov fixator in treating tibial non-union. Methods: This retrospective hospital study was conducted at Ramakrishna Mission Seva Pratishthan, Kolkata, India from August 2009 to February 2012. Forty two patients treated at this hospital between August 1994 and August 2011 with a minimum of 12 months follow up were included. The results were analysed on the outcome of bone and functional score using the Association for the Study and Application of the Method of Ilizarov (ASAMI) scoring system. Results: Of the 42 patients in this study, there were 28 (66.7%) excellent, 6 (14.3%) good, 5 (11.9%) fair and 3(7.1%) poor bone results and 17(40.5%) excellent, 20(47.6%) good, 2(4.8%) fair and 3(7.1%) poor functional results. Conclusions: Treatment of tibial non-unions with Ilizarov fixator is effective but not without considerable amount of complications and morbidity associated with it. The functional outcome was largely multifactorial and dependent on the final joint function, soft tissue condition and ability of the patient to return to activity.

Keywords: ilizarov fixator; osteomyelitis; tibial non-union.

#### **INTRODUCTION**

The substantial incidence of tibial diaphyseal fractures continues in the face of changing pattern of injuries, from 14<sup>th</sup> Century warfare to the modern age high velocity road traffic accidents.<sup>1</sup> Subcutaneous position of the tibia results in high incidence of open fractures along with soft tissue damage resulting in impaired bone vascularity. The presence of infection, bone loss, excessive gap with soft tissue interposition, fracture site mobility and impaired bone vascularity increases the incidence of tibial non-union.<sup>1</sup> In 1986, for testing bone-healing devices, a U.S. Food and Drug Administration panel defined non-union as, "established when a minimum of 9 months has elapsed since injury and the fracture shows no visible progressive signs of healing for 3 months". Multiple factors complicate long standing tibial non-union such as scarring of surrounding soft from multiple surgeries, chronic tissues with multiple osteomyelitis drug resistant microorganisms, stiffness, deformity, bone gaps, draining sinuses and disuse osteoporosis.<sup>2</sup>

Conventional treatment of infected non-unions includes extensive debridement with use of flaps or skin grafts, antibiotic bead packing, Papineau open cancellous grafting, tibiofibular synostosis and free tissue transfer including bone transplants. Secondary procedures are often required for correction of bone defects and deformity. Results are multiple surgeries with joint stiffness and oedema, interfering with optimal limb function.<sup>3</sup> Prof. Ilizarov employed biological techniques and a system of external fixation as a multimodal approach to the management of non-union. Any size of defect can be regenerated by progressive histiogenesis at the corticotomy site by Ilizarov technique. Because the level at which the regenerate bone is formed is healthy, infection can be eradicated at one site while the bone is regenerated at another site, which not only saves time but also significantly increases local vascularity.<sup>4</sup> The use of a highly modular apparatus allows an assembly of an unlimited number of configurations. The frame can be used

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to overcome deformities while at the same time permitting weight bearing ambulation and joint mobilization.<sup>5</sup> The objective of this study is to evaluate the results of Ilizarov fixator and methodology in treating tibial non-union by assessment of bone healing and functional results according to a modified Association for the Study and Application of the Method of Ilizarov Foundation (ASAMI) criteria.<sup>3,4</sup>

#### **METHODS**

This was a retrospective hospital based study conducted at Ramakrishna Mission Seva Pratishthan, Kolkata, India from August 2009 to February 2012. Forty two patients treated at this hospital between August 1994 and August 2011 with a minimum of 12 months follow up with Ilizarov fixator for tibial diaphyseal non-union were included. While the inclusion criteria involved established tibial non-union with a bone gap of 2cm or more, the exclusion criteria included patients with less than 12 months follow up or with inadequate clinical records or who opted for fixator removal prior to completion or who underwent limb amputation. Additionally, the operative technique and follow-up included several steps as elaborated next. All unhealthy fibrous tissues and bone were excised. The resultant gap was measured and decision made regarding acute docking and or bone grafting. The assembly was opened like clam shell and brought around the limb. The main proximal frame supporting ring was stationary. The stabilizing frame supporting ring was applied most distally. The pusher- puller ring was applied distal to fracture-osteotomynonunion site. The reference ring was used as a reference for supporting rings or distraction compression rings. Wires were tensioned by tensioner at 130 kgs for wires fixed to full rings and 90 kgs for half rings. Stopper wires were used for cancellous bone, osteoporotic bones, and correction and deformity inter-fragmentary compression. Corticotomy was performed at metaphyseo-diaphyseal junction in cases intended for bifocal compression along with fibular osteotomy. Distraction / compression started after 5 - 7 days of operation. Rate was kept at 0.25 to 0.5 mm each time, 4 times per day. If laxity was more than 7 degrees, then hypertrophic nonunion was first compressed for 2-3 weeks followed by gradual distraction. If end to end bone contact was satisfactory following docking then bone ends were compressed for 2- 3 weeks followed by Post operatively, knee and ankle distraction. exercises were initiated and walking with support

started as soon as tolerated. X-rays of the limb were obtained after 7 to 10 days to confirm distraction. Patients were discharged on 14 to 21 days of operation and were called back every 3 weeks during compression distraction phase and every 4 weeks during consolidation phase. Patients were followed up in the outpatients department. Pin tracts were checked for infection. Transfixion wires were checked for loosening and re-tensioned accordingly. Frame was removed after radiological union in 3 of 4 cortices and no fracture site movement. The limb was put in a patella tendon bearing cast and allowed full weight bearing and final x-rays obtained after 6 to 8 weeks before removal of cast. Patients were further followed up for a minimum period of 12 months addressing joint stiffness, pain and complaints regarding any discharge or soft tissue ailments.

### RESULTS

Forty two cases were evaluated in this study and the results are indicated. The patient characteristics are described in (Table 1). Six cases of bifocal treatment had delayed

Table 1. Characteristics of the 42 patients			
involved in this study			
Parameters	Value(N=42)		
Age, y(mean ± SD, range)	35.8±14.4(7-66)		
Gender (M:F)	34:8(81%, 19%)		
Site of initial fracture	Diaphyseal lower1/3-7		
	(16.7%)		
	Diaphyseal Middle third-		
	26(61.9%)		
	Diaphyseal upper third- 9		
(21.4%) Comorbidities Diabetic-3, smoker-17			
	,		
Type of initial injury	Closed fracture $-13(31\%)$		
Maghanism of injumy	Open fracture-29(69%) RTA (59.5%), fall from a		
Mechanism of injury	height (23.8%), crush		
	(7.1%), gunshot $(2.4%)$ ,		
	industrial accident (4.8%),		
	natural disaster (2.4%)		
Prior surgery	Plating 5(11.96%), exter-		
	nal fixator 28(66.67%)		
	plaster cast immobilization		
	2(4.76%) or nailing 7		
	(16.67%)		
Type of Non- union	Atrophic- 69%, hypertro-		
<b>D</b> (* * 6 (*	phic- 31%		
Pre-operative infection	Absent- 18(42.9%), Pre- sent- 24(57.1%)		
Paley's type of Non-	B1- 10(23%), B2- 24		
union	(57%), B3- 8(19%)		
Average Injury to	45.9 weeks (36-84 weeks)		
llizarov fixator interval			
Average bone gap(mean,	4.1 cm (2-15 cm)		
range)	× , , ,		

	procedures and outcome.		
Procedure/	No. of cases (N=42)		
Outcome			
Type of compres-	Monofocal- 23(54%), bifocal- 19 $(45.29)$		
sion/distraction	(45.2%)*		
Bone grafting	13(31%)-12 iliac, 1 fibular		
Acute docking	30(71.4%)		
Corticotomy	Distal- 7(16%)		
	Proximal-26(62%)		
<b>T</b> T •	None-9(21.4%)		
Union 41(97.6%)			
Return to activity	Previous activity-16(38%)		
	Alternative activity- 23(55%)		
	Unemployed-3(7%)		
Average duration	38.1 weeks		
of compression	70.2 1		
Average duration 78.3 weeks			
of distraction(n=19)	4(0.50/)		
Residual infection	4(9.5%)		
Average frame	7.3 months(3.5-21 months)		
duration	1.0 $(1.5.2$ $(1.5.2)$		
Average plaster cast duration	1.9 months(1.5-3 months)		
	57.14 months		
Average follow up			
Complications	Pin tract infection- 40(95%), refrac- ture-1(12%), nerve palsy-3(7.1%),		
	reflex sympathetic dystrophy-9.5%,		
	ankle stiffness-7(17%), knee stiff-		
	ness-5(11.9%), subtalar joint stiff-		
	ness-26(62%)		
Average Patient	76±24.8		
satisfaction on 0- 100 VAS			
*monofocal- compression followed by distraction at docking,			

\*monofocal- compression followed by distraction at docking, bifocal- distraction at corticotomy and compression at nonunion site.

Table 3. Limb movement and deformity.					
Parameter	Initial		Final	Final	
	mean±	Rang	m e a	Ran	val
	SD	e	n±S	ge	ue
Limb length	2.2±2.	0-11	<b>D</b> 1±1.	0-3.5	0.0
discrepancy	6		2		08*
(cm)					
Angular	12.5±1	0-34	$4.3\pm$	0-12	0.0
deformity	1.3	(26	6.2	(12	001
(degrees)		pa-		pa-	*
		tients		tients	
		>7		>7	
TICC (	01.013	deg)	2012	deg)	0.2
Effective	81.8±3	15-	89±2	20-	0.2
knee ROM	2.9	130	9.7	130	9
(deg)					
Effective	35.7±1	0-55	$42 \pm 1$	0-65	0.0
ankle ROM	6		8.2		9*
(deg)					
<i>*significant at p-value&lt;0.05</i>					

consolidation at distraction site. Four cases had delayed non-union site consolidation out of which 1 failed to unite after 18 months. Repeat corticotomy was done in 3 out of 33 patients.

Table 4. Results using Association for theStudy and Application of the Methods ofIlizarov (ASAMI) scoring system.<sup>3,4</sup>

	ý <b>č</b> .			
A. Bone Re	A. Bone Results			
Condition	Description	No.		
Excellent	Union, No infection, Deformity <7°, Limb Length Discrepancy <2.5 cm	28		
Good	Union + any two of the following; Ab- sence of infection, $< 7$ deg deformity and limb length discrepancy of $< 2.5$ cm	6		
Fair	Union plus one of the following; Absence of infection, $< 7$ deg deformity and limb length discrepancy of $< 2.5$ cm	5		
Poor	Nonunion/ refracture/ union plus infec- tion plus deformity>7 deg and limb length discrepancy> 2.5 cm	3		
Total		42		

## 5. Functional Results.

Condition	Description	No.
Excellent	Active*, no limp, minimum stiffness [Loss < 15 deg knee extension/< 15 degrees dorsiflexion of ankle], No reflex sympathetic dystrophy [RSD], insignifi- cant pain	17
Good	Active* with one or two of the follow- ing: limp, stiffness, RSD, significant pain	20
Fair	Active* with three or all of the follow- ing; limp, stiffness, RSD, significant pain	2
Poor	Inactive [Unemployment or inability to return to daily activities due to injury]	3
Total		42
*Active= Patient returning to his previous activity level or		

\*Active= Patient returning to his previous activity level or finding an alternative activity to sustain a livelihood, was considered active.



Figure 1. Infected non-union of tibia in a 7yr old male patient: a) Pre-operative radiographs of nonunion tibia with intramedullary implants insitu, b) Postoperative radiographs on day 64 showing evidence of early union, and c) Radiographs at 12 months showing a complete union of tibia.



Figure 2. Gap non union in fracture tibia with significant bone loss: a) Pre-operative X ray with 15 cm bone loss, b) Follow up at 8 months with distraction at proximal corticotomy site with bone regeneration and compression at distal nonunion site, and c) Follow up at 18 months showing complete union of tibia with consolidation of the regenerate.

## DISCUSSION

Ilizarov fixator and its methodology allow the treating surgeon an opportunity to overcome the factors to reach the desired goal. Recycling of rings and undamaged components between patients, as in other studies<sup>6</sup> helped in bringing down the financial burden. Adequate glycaemic control in 3 diabetic patients was undertaken prior to treatment procedures. High incidences of smokers was noted in the study population and were actively discouraged during treatment. Smoking has has been shown to lengthen treatment time.<sup>7</sup> Twenty four patients had infection at the non-union site as compared to 50 % of patients in series by Paley et al<sup>4</sup>. This indicates that infection is not only the cause but also a principal element to consider eradication for union to take place. There was an improvement in the limb length discrepancy and deformity in the final outcome. The final effective range of movement of knee and ankle showed overall improvement. Subtalar joint stiffness if present before treatment persisted so after treatment. The mean time interval from injury to Ilizarov was 11.5 months compared to 7.8 months in series by Madhusudhan et al.<sup>3</sup> and 3.5 years in series by Paley et al.<sup>4</sup> All type B1 underwent bifocal treatment, 23 of type B2 had monofocal and 1 underwent bifocal treatment and all of B3 underwent bifocal treatment. In Paley's series 6 patients with B1 had bifocal treatment, 10 patients with type B2 had bifocal treatment and 3 had monofocal treatment and 3 of B3 had bifocal treatment with internal and external lengthening, 1 had trifocal treatment and 2 had bifocal treatment with internal lengthening<sup>4</sup>.Acute docking of non-union site was done wherever possible except in large gaps. Gene D. Bobroff has advocated bone grafting as an additional procedure in the docking area in case of delayed consolidation

to shorten fixator duration.<sup>8</sup>The total treatment period lasted over a mean period of 9.0 months. Paley et al in their study had a mean total treatment period of 10.6 months in patients undergone bifocal treatment.<sup>4</sup> In our study, we considered an active individual to be inclusive of patients who returned to previous activity as well as finding an alternative activity to sustain a livelihood. In our country with no social benefits, patients had to return to their job at the earliest or search for a less demanding one. Limp in patients with shortening of 2cm or more was well compensated by shoe raise. The mean overall satisfaction was 76%. The result was comparable with the study by Sanders et al who demonstrated 77% overall satisfaction in their series.<sup>12</sup>

Table 5. Several authors have used modified criteria laid down by Association for the Study and Application of the Methods of Ilizarov Foundation (ASAMI) system and a comparison of the results is as follows:

as follows:				
Authors	Subjects studied	No. of pa- tients	ASAMI <sup>a</sup> Bone Scores, %E, G, F, P <sup>a</sup>	ASAMI <sup>a-</sup> Functional Scores, %E, G, F, P <sup>a</sup>
Dendri- nos et al. <sup>9</sup>	Infected tibial nonun- ion	27	50, 28, 4, 18	26, 41,15, 18
Maini et al. <sup>10</sup>	Infected nonunion	30	70, 10, 0, 20	27, 40,10, 23
Bobroff et al. <sup>8</sup>	Tibial non- union	12	50, 25, 0, 25	50, 16.6, 16.6, 16.6
Paley et al. <sup>4</sup>	Defect non- union > 1 cm	25	72, 20, 8, 0	64, 28, 4,4
Mad- husudha n et al. <sup>3</sup>	Recalcitrant infected tibial nonun- ion	22	23, 36, 23, 18	5, 18, 27, (32) 45
Far- manulla h et al. <sup>11</sup>	Tibial non- union	58	58.8, 20.68, 13.79, 8.62	33, 18, 4, 3
Present study	Tibial non- unions	42	66.7, 14.3, 11.9, 7.1	40.5, 47.6, 4.8, 7.1
<sup>a</sup> E- excellent, G-good, F-fair, P- poor				

## CONCLUSIONS

The author would like to thank all the patients for giving consent to participate in the study.Observations in this study suggest that Ilizarov ring fixator and methodology is an efficient device in treating established cases of tibial non-unions. The ability to achieve an excellent bony result does not mandate an excellent functional result. The resultant functional result is dependent on multiple factors including range of movement, neurovascular status and ability for the patient to return to activity. Patients who were already heavily burdened due to their socioeconomic status along with lost resources in previous surgeries and admissions found the results

### Ghosh et al. Evaluation of Results of Ilizarov Fixator and Methodology in Tibial..

to be satisfying but "union" came at a heavy price. procedure. А strategized postoperative rehabilitation program is followed in which the Hence patient selection and counseling is of paramount importance. Issues regarding the patient is an active participant. The key to success lengthy time of treatment, additional procedures lies in the proficiency of the surgeon, a thorough and considerable amount of complications must be knowledge of the anatomy, familiarization of fully explained by the surgeon and understood by components of the system and their multimodal the patient prior to commencement of treatment. utility, understanding the biology of nonunion, There are considerable amount of complications watchful documentation and individualized care of and morbidity associated with the treatment the patient. S, REFERENCES Ghosh Roy D. Ilizarov fixator in management of nonunited and infected tibial 1. Green DP, Bucholz RW, Heckman JD, Court-Brown CM. Fractures of Tibia and Fibula. shaft fractures. Med J Dr DY Patil Univ 2015;8 Rockwood and Green's Fractures in Adults: 6th (1):35.Ed. 2006; 2: Pg. 2079-2143. 8. Bobroff GD, Gold S, Zinar D, others. Ten year 2. Gustilo RB. Management of infected fractures. experience with use of Ilizarov bone transport Surgery of Musculoskeletal for tibial defects. Bulletin (Hospital for Joint System: C McCollister Evarts. II. 1990. Pg. 4429. Diseases (New York, NY)). 2003;61(3-4):101. 3. Madhusudhan TR, Ramesh B, Manjunath KS, 9. Dendrinos GK, Kontos S, Lyritsis E, others. Shah HM, Sundaresh DC, Krishnappa N. Use of the Ilizarov technique for treatment of Outcomes of Ilizarov ring fixation in non-union of the tibia associated with infection. recalcitrant infected tibial non-unions - a The Journal of bone and joint surgery. American volume. 1995;77(6):835 prospective study. Journal of Trauma Management & Outcomes. 2008 Jul 23;2(1) 10. Maini L, Chadha M, Vishwanath J, Kapoor S, 4. Paley D, Catagni MA, Argnani F, Villa A, Mehtani A, Dhaon BK. The Ilizarov method in Benedetti GB, Cattaneo R, et al. Ilizarov infected nonunion of fractures. Injury. 2000;31 treatment of tibial nonunions with bone loss. (7):509-17.Clinical orthopaedics and related research. 11. Farmanullah, Khan MS, Awais SM. Evaluation 1989;(241):146. of management of tibial non-union defect with

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