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A COMPARATIVE STUDY OF ILIZAROV RING FIXATOR AND LIMB RECONSTRUCTION SYSTEM IN MANAGEMENT OF INFECTED NON UNION OF LONG BONES

Orthopaedics

Dr. Amar	Junior Resident, Department Of Orthopaedics, Hind Institute Of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh
Dr. Manish Kumar Maurya	Assistant Professor, Department Of Orthopaedics, Hind Institute Of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh
Dr. Sanjay Srivastava	Assistant Professor, Department Of Orthopaedics, Hind Institute Of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh
Dr. Deepak Srivastav	Professor And Head Of Department, Department Of Orthopaedics, Hind Institute Of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh
Dr. Ashish Jain	Associate Professor, Department Of Orthopaedics, Hind Institute Of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh
Dr. Jai Kumar Singh	Associate Professor, Department Of Orthopaedics, Hind Institute Of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh
Dr. Saifer Khan	Associate Professor, Department Of Orthopaedics, Hind Institute Of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh

ABSTRACT

Background: Traumatic injuries are a significant global health concern, with India reporting over 4.5 million open fractures annually. Non-union of long bone fractures, defined as fracture which persists for 9 months, without any visible signs of healing for last 3 consecutive months, account for 2% to 7% of these cases. These infections pose severe challenges to orthopaedic surgeons, leading to functional impairments and considerable economic and social burdens. **Objectives:** This study aims to compare the radiological and functional outcome and complication rates between Ilizarov ring fixator and Limb Reconstruction System (LRS) in managing infected non-unions of long bones. **Methodology:** An analytical prospective study of 40 patients with infected non-unions of long bones is performed, treated using either the Ilizarov ring fixator or LRS, allotted by consecutive sampling and followed up for 18 months. The outcome measured were the bone union rate, complication rate and functional status assessed according to ASAMI criteria. SPSS software was used for statistical analysis. **Results:** Most were in age group 31-50 years males. Pin tract infection was the most complication. The majority of LRS patients (80%) underwent treatment for 9-12 months, whereas the majority of Ilizarov patients (40%) received treatment for 14-17 months. In the Ilizarov group, 25% of patients achieved excellent, 35% had good, 35% had fair, and 5% had poor outcomes. Similarly, in the LRS group, 40% of patients achieved excellent, 45% had good, 15% had fair, and no patients had poor outcome. Bony union was achieved in 100% of the patients. Treatment index was 60.6 days/cm ± 16.5 days/cm for Ilizarov group and 56.7 days/cm ± 14.1 days/cm for LRS group. **Conclusion:** Both the Ilizarov ring fixator and LRS are effective in managing infected non-union of long bones, with high union rates and favorable functional outcomes. LRS offers a shorter treatment duration and slightly better functional results. Individual patient factors should guide the choice of treatment modality, and further research is needed to optimize strategies.

KEYWORDS

Infected non-union, long bones, Ilizarov ring fixator, Limb Reconstruction System, orthopaedic surgery, distraction osteogenesis.

INTRODUCTION:

Each year, the incidence of open fractures in India exceeds 4.5 million cases, contributing significantly to the worldwide statistics **[1]**. Among these injuries, long bone fractures pose a particularly severe challenge, with 2% to 7% resulting in non-union**[2]**. The United States Food and Drug Administration (FDA) defines non-union as the absence of visible healing over a period of three consecutive months following a fracture that has persisted for nine months **[3]**. This complication is exacerbated by the rising incidence of high-velocity motor vehicle collisions, leading to an increase in complex limb injuries and consequently, a surge in cases of infected non-unions **[4]**.

These infections often stem from open fractures, prior surgical interventions, or as a complication of osteomyelitis. For decades, orthopedic surgeons have faced significant hurdles in managing infected non-unions due to various factors, including scar tissue formation, inadequate blood supply, chronic sinus due to persistent infection, and necrosis of fracture ends caused by blood vessel thrombosis. **[5]**.

Managing infected non-union requires addressing both soft tissue and bone end infections, necessitating extensive debridement that creates substantial gaps in bone and soft tissue **[4]**. Traditional approaches to managing these complex fractures include debridement, provisional stabilization using external fixators, wound care, and definitive management. However, distraction osteogenesis might be the only reliable method to bridge these bone gaps **[6]**.

The Ilizarov ring fixator is a pivotal device in orthopedic surgery for treating various bone and joint conditions, particularly complex fractures, limb length discrepancies, and deformities. Its external nature reduces the risk of infection compared to internal fixation methods, allowing for thorough debridement and irrigation. This device provides stability and precise control over bone alignment, promoting healing through techniques like bone transport, which stimulates new bone tissue formation. Similarly, the Limb Reconstruction System (LRS) is a minimally invasive fixator which is easy to handle and apply, compatible, have a lightweight and simple design, and has a short learning curve for application that enables early weight-bearing, effective wound management, and limb elongation using the compression-distraction osteogenesis principle **[7,8]**.

However, literature lacks comprehensive comparative studies on the functional and radiological outcomes of the Ilizarov ring fixator versus LRS. This study aims to assess and compare the radiological and functional outcome and also the difficulties during limb lengthening where required and complications between Ilizarov ring fixator (IRF) and Limb reconstruction system (LRS) for the management of infected nonunion of long bones.

MATERIALS & METHOD:

This analytical prospective study was conducted over 18 months between 2022-2024 at the Orthopaedics Department of Hind Institute of Medical Sciences, Barabanki, UP, focusing on patients with infected non-union of long bones. An active infection was considered if there was a discharging sinus or if the causative organism was isolated from the wound. A consecutive sampling technique was employed, with a calculated sample size of 40 patients who met the inclusion criteria:

aged 30-60 years, previously treated with nailing or plating, and presenting with infected long bone fractures and bone loss. Patients with pathological fractures, conditions affecting bone healing, segment transport associated with tumor resection, epiphyseal or metaphyseal fractures, or those unfit for surgery were excluded. The study received ethical clearance from the Institutional Ethics Committee (HIMS).

Intraoperative procedures for the Ilizarov Ring Fixator involved percutaneous insertion of 1.5 mm diameter wires into the bones, secured to rings and interconnected with threaded rods for stability. A corticotomy followed to allow for controlled compression or distraction between bone ends. For the Limb Reconstruction System (LRS), 4 mm diameter pins were placed proximally and distally to the fracture site. The LRS rail and clamps were secured, and Compression-Distraction units were applied.

Postoperative management included instructing patients on distraction at a rate of 1 mm/day in four increments and pin tract care. Patients not requiring corticotomy and bone lengthening began weight-bearing on postoperative day one, while those requiring bone transport started weight-bearing post-docking. Following confirmation of union, the frame bolts were loosened and the patient was instructed to walk in the dynamic fixator frame for 15 days without experiencing any pain. Following this, the frame was removed and a plaster of Paris cast (or patellar tendon bearing cast for tibia) was applied for a duration of 1 month.

Analysis Of Outcome

Association for the Study and Application of the Methods of Ilizarov (ASAMI) Criteria based on Radiological and Functional results

RESULT	RADIOLOGICAL CRITERIA	FUNCTIONAL CRITERIA
Excellent	Union, no infection, Deformity < 7°, Limb length discrepancy (LLD) < 2.5 cm	Active, no limp, minimum stiffness (loss of <15° knee extension/ < 15°ankle dorsiflexion), no reflex sympathetic dystrophy (RSD), insignificant pain
Good	Union + any two of the following: Absence of infection, < 7° deformity, LLD < 2.5 cm	Active with one or two of the following: limp, stiffness, RSD, significant pain
Fair	Union + any one of the following: Absence of infection, < 7° deformity, LLD < 2.5 cm	Active with three or all of the following: limp, stiffness, RSD, significant pain
Poor	Non-union/refracture/ union + infection + deformity > 7° + LLD > 2.5 cm	Inactive (unemployment or inability to return to daily activities because of injury)
Failure	Not applicable	Amputation

Statistical Analysis:

The information was input into Microsoft Excel and analysed version 26 of the statistical software SPSS (SPSS Inc., Chicago, IL, USA). Utilizing chi-square, the dichotomous variables were analysed in number/frequency format. A p-value of less than 0.05 or 0.001 was considered to indicate statistical significance.

RESULTS:

This analytical prospective study aimed to perform a comparative study of Ilizarov ring fixator and limb reconstruction system in management of infected non-union of long bones.

The age distribution among patients was fairly balanced, with the majority falling within the 31-50 age range for both ILIZAROV (45%) and LRS (30%) groups. There was no significant difference in age distribution between the groups (p=0.905). Similarly, sex distribution was predominantly male (90% in ILIZAROV and 85% in LRS), with no significant difference (p=0.633). Laterality and site of infection also showed no significant differences between groups, indicating a comparable baseline for both treatment modalities **(Table 1).**

The majority of patients had prior treatment with external fixators (55% ILIZAROV, 50% LRS), with a similar distribution in pre-treatment history (p=0.933). The incidence of corticotomy was higher in the ILIZAROV group (70% vs. 60% in LRS), though not significantly different (p=0.507) **(Table 2)**.

Treatment duration varied significantly between groups, with LRS patients predominantly completing treatment within 9-12 months (80%), whereas ILIZAROV patients had a longer treatment duration, with 40% undergoing therapy for 13-15 and 16-18 months each (p=0.0003). This indicates a quicker resolution with LRS therapy **(Table 3)**.

Both groups achieved a 100% union rate, demonstrating the effectiveness of both treatments. However, complications varied, with ILIZAROV patients experiencing more joint stiffness (30%) and LRS patients having more pin tract infections (40%), though these differences were not statistically significant (p=0.076) **(Table 4)**.

Functional outcomes assessed by the ASAMI criteria showed that in the ILIZAROV group, 25% achieved excellent results, 35% good, 35% fair, and 5% poor. In contrast, the LRS group had 40% excellent, 45% good, 15% fair, and no poor outcomes. While both groups had favorable outcomes, the LRS group had a higher proportion of excellent results, but the difference was not statistically significant (p=0.3437). Treatment index was 60.6 days/cm ± 16.5 days/cm for Ilizarov group and 56.7 days/cm ± 14.1 days/cm for LRS group. (**Figure 1, Figure 2, Figure 3**).

DISCUSSION:

In the present study, a total of 40 patients were enrolled and randomly divided into two treatment group: Group-ILIZAROV (Patients treated with Ilizarov ring fixator) and Group-LRS (patients treated with limb reconstruction system). The majority of the patients in the ILIZAROV group were aged (years) between 41-50 (45.00%), followed by 31-40 (25.00%), 18-30 (15.00%), 51-60 (10.00%) and >60 (5.00%). Similar pattern was noted in the LRS group, where the most common age group was 41-50 (30.00%), 31-40 (30.00%), 18-30 (20.00%), 51-60 (15.00%) and >60 (5.00%). Regarding the gender, male predominance was reported in both ILIZAROV and LRS groups (90.00% and 85.00%, respectively). No difference was recorded in the age (p=0.905) and gender (p=0.633) distribution of the patients in both groups. In a similar vein, **Pal C et al. [4]** conducted a study involving 32 patients, evenly divided into two groups, with 16 cases in each group. Among the 32 patients included in the study, 26 were males and 6 were females, indicating a higher level of activity and mobility among males. This gender distribution aligns with the broader pattern observed in orthopaedic patient populations, where males often exhibit increased engagement in physically demanding activities, potentially leading to a higher incidence of orthopaedic injuries requiring treatment with fixators. Further, **Lone A et al.** investigated a cohort of 40 patients **[9]**. Twenty patients were assigned to Group A, which received treatment using limb reconstruction system fixators (LRS). In contrast, twenty patients were operated on in Group B using Ilizarov ring fixators. It is worth noting that a significant proportion of the subjects (45%) were between the ages of 28 and 37, and men made up the plurality (65%). In a similar vein, **Hussain A. et al. [10]** investigated forty patients, observing that the average age was 27±2.5 years, with a range of 20 to 47 years. Additionally, **Bakshi A et al. [11]** explored a cohort of 40 patients. They observed that 50% of patients in Group A were aged 41 to 60 years, while 50% in Group B were aged 21 to 40 years, with a male predominance in both groups. **Bhardwaj R et al. [7]** investigated fifty cases of infected nonunion of long bones, dividing them into two groups of 25 each based on treatment modality. Likewise, **Chahar H et al.** enrolled 14 patients aged 20 to 70 years. They observed that fractures were most common in the 31–40 age group (35.71%), predominantly among males (85.72%) **[12]**. **Kumar A et al.** included 30 patients with a mean age of 35.75 years. A significant proportion of the patients belonged to distinct age groups: thirteen were between the ages of 21 and 31, eight were between the ages of 32 and 42, six were between the ages of 43 and 53, two were between the ages of 54 and 64, and one was over the age of 65. Of these, 24 were male, and 6 were female **[13]**.

In the present study, regarding the pre-treatment, most of the patients in ILIZAROV group and LRS group had external fixator (55.00% and 50.00%, respectively), followed by Intramedullary (IMIL) nailing (25.00% and 30.00%, respectively). Plating was reported by 20.00% in each group. Most ILIZAROV patients (70%) underwent corticotomy compared to LRS patients (60%). However, this difference is not statistically significant (p = 0.507). According to the findings of **Bakshi A et al.**, open reduction with internal fixation (ORIF) with intra-medullary nail was reported by 30% of the patients in both groups. ORIF with plating was followed by 25% in each group. Debridement with external fixator was experienced by 25% of the

group ACIIN (antibiotic-coated intramedullary interlocking nail) and 10% of the group LRS/ILIZAROV **[11]**. **Seenappa H et al.** had performed six cases requiring bifocal corticotomy **[14]**. In 8 out of 14 cases, corticotomy was conducted, according to **Chahar H et al. [12]** Further, **Pal C et al. [4]** determined that ten patients, five in each cohort, required corticotomy.

In the present study, the majority of LRS patients (80%) underwent treatment for 9-12 months, followed by 13-15 months (20.00%), whereas the majority of ILIZAROV patients received treatment for 13-15 (40%) and 16-18 months (40%). Only 20.00% of the patients in ILIZAROV group had treatment duration of 9-12 months. All patients in both ILIZAROV and LRS groups achieved union, indicating successful treatment outcomes without significant differences between the two groups. They also reported a 100% bony union rate in both groups. Further, **Kumar A et al.** reported a mean duration of 7.8 months for Ilizarov external fixator employment in their study, with a minimum duration of 4 months and a maximum of 12 months **[13]**. According to the findings of **Seenappa H et al.** [83] the humerus required a reduced average treatment duration (mean 6.2 months) than the femur (mean 9.3 months) and tibia (mean 10.2 months) **[14]**. In a similar vein, **Pal C et al.** noted that the LRS fixator group removed the fixator at 21-28 weeks (50 percent), whereas the Ilizarov ring fixator group removed the fixator at 29-36 weeks (50 percent) **[4]**. In contrast to the Ilizarov ring fixator group, the majority of patients in the LRS group attained outstanding bony outcomes, according to the comparison of bony outcomes.

In the present study, concerning the complications, several complications were noted, including adjacent joint stiffness, Pin Tract Infection, inactivity, limping, chronic pain or reflex sympathetic dystrophy (RSD), and no complications. However, it is noteworthy that 15.00% within the ILIZAROV group experienced no complications, while 40.00% within the LRS group exhibited no complications. Statistical analysis revealed no significant difference (p= 0.076). **Lone A et al.** observed a higher incidence of postoperative complications in the ilizarov ring fixator group compared to the LRS group. Pin tract infection was the most common complication, reported in 15% of the ilizarov group compared to 5% in the LRS group **[9]**. Similarly, **Hussain A et al.** reported PTI as the most common complication in the ilizarov ring fixator group (25%), followed by superficial skin infection (15%) and chronic osteomyelitis (5%) **[10]**. These findings align with previous studies **[16,17]**. 15% of patients experienced pin loosening, 30% developed pin infection, and 25% experienced joint stiffness, according to **Bakshi A et al. [11]** PTI was identified as the most prevalent complication in both groups by **Bhardwaj R et al. [7]**. **Chahar H et al.** noted deep infection in 7.14% of cases and slight restriction of knee movement in 14.28% **[12]**.

In the present study, the analysis of functional outcomes revealed that the majority of patients in the ILIZAROV group exhibited good (35.00%) and fair outcomes (35.00%), with lesser proportions achieving excellent (25.00%) and poor outcomes (5.00%). Conversely, within the LRS group, most patients showed good (45.00%) and excellent outcomes (40.00%), followed by fair outcomes (15.00%), and notably, no patients in this group experienced poor outcomes. However, it is important to note that the statistical difference observed was insignificant (p=0.3437). Similarly, **Lone A et al.** conducted a comparison of functional outcomes according to ASAMI score, revealing that a higher percentage of patients in the LRS group (60%) achieved excellent functional outcomes compared to the Ilizarov ring fixator group (45%) **[9]**. Furthermore, **Bhardwaj R et al.** recorded that 36% of the ilizarov group had fair outcomes, followed by excellent and good outcomes (32% each), while in the rail(LRS) group, 52% of patients had good outcomes, followed by an excellent result (32%) **[7]**. **Chahar H et al.** observed that 71.43% of patients had excellent outcomes, followed by good and fair outcomes (28.57%) **[12]**. **Kumar et al.** documented the following in their study results: fifteen patients demonstrated exceptional functional outcomes, six patients were classified as good, five patients attained acceptable functional results, and four patients encountered poor functional outcomes **[13]**. Furthermore, operational outcomes were deemed adequate in 75.00% of instances and unsatisfactory in 25.00% of instances **[4].** Similarly, **Seenappa H et al.** observed good functional outcomes in 50% of patients, followed by excellent outcomes (40%) **[14]**. These findings underscore the importance of tailored treatment approaches in achieving optimal outcomes for patients with infected non-union of long bones, with a focus not only on infection control but also on functional restoration and patient well-being.

CONCLUSION:

This analytical prospective study compared the Ilizarov ring fixator and the Limb Reconstruction System (LRS) in managing infected non-union of long bones. The findings revealed that all patients achieved successful union with both treatments. While LRS treatment duration was significantly shorter, both groups had comparable rates of complications, with joint stiffness more common in the ILIZAROV group and pin tract infections more prevalent in the LRS group. Functional outcomes were favorable in both groups, with a slight advantage for LRS. The study concludes that both treatment modalities are effective, with no statistically significant differences in outcomes. The insights from this study underscore the need to consider individual patient factors when choosing between these treatments and suggest further research to refine and optimize strategies for managing infected non-union of long bones.

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Consent: Written informed consent has been obtained from all participants in accordance with international or university standards and is maintained by the authors.
Ethical Approval: Ethical approval was granted in compliance with international or university standards, and the written approval is preserved by the authors.

Tables And Figures:

Table 1- General Parameters Of The Enrolled Patients Among The Different Treatment Groups.

PARAMETERS		GROUPS				Total	P-VALUE
		GROUP-ILIZ		GROUP-LRS			
		N	%	N	%		
AGE DISTRIBUTION [Years]	18-30	3	15.00%	4	20.00%	7	X=1.034 p=0.905
	31-40	5	25.00%	6	30.00%	11	
	41-50	9	45.00%	6	30.00%	15	
	51-60	2	10.00%	3	15.00%	5	
	>60	1	5.00%	1	5.00%	2	
	Total	**20**	**100.00%**	**20**	**100.00%**	**40**	
SEX DISTRIBUTION	Female	2	10.00%	3	15.00%	5	X=0.229 p=0.633
	Male	18	90.00%	17	85.00%	35	
	Total	**20**	**100.00%**	**20**	**100.00%**	**40**	
PRE-TREATMENT	EXT FIXATOR	11	55.00%	10	50.00%	21	X=0.139 p=0.933
	IMIL NAILING	5	25.00%	6	30.00%	11	
	PLATING	4	20.00%	4	20.00%	8	
	Total	**20**	**100.00%**	**20**	**100.00%**	**40**	

Table:2- Duration Of The Treatment And Corticotomy Of The Enrolled Patients Among The Different Treatment Groups.

		GROUPS				Total	P-VALUE
		GROUP-ILIZ		GROUP-LRS			
		N	%	N	%		
DURATION OF TREATMENT (Months)	9-12	4	20.00%	16	80.00%	20	X=16.53 **p=0.0003***
	13-15	8	40.00%	4	20.00%	12	
	16-18	8	40.00%	0	0.00%	8	
	TOTAL	**20**	**100.00%**	**20**	**100.00%**	**40**	
CORTICOTOMY	NO	6	30.00%	8	40.00%	14	
	YES	14	70.00%	12	60.00%	26	
	Total	**20**	**100.00%**	**20**	**100.00%**	**40**	

Table:3- Duration Of The Treatment Of The Enrolled Patients Among The Different Treatment Groups.

DURATION OF TREATMENT (Months)	GROUPS				Total	P-VALUE
	GROUP-ILIZ		GROUP-LRS			
	N	%	N	%		
9-12	4	20.00%	16	80.00%	20	X=16.53 **p=0.0003***
13-15	8	40.00%	4	20.00%	12	
16-18	8	40.00%	0	0.00%	8	
TOTAL	**20**	**100.00%**	**20**	**100.00%**	**40**	

Table:4- Status Of The Union And Complications Of The Enrolled Patients Among The Different Treatment Groups.

		GROUPS				Total	P-VALUE
		GROUP-ILIZ		GROUP-LRS			
		N	%	N	%		
STATUS OF UNION	YES	20	100.00%	20	100.00%	40	--
	TOTAL	**20**	**100.00%**	**20**	**100.00%**	**40**	
COMPLICATIONS	Joint stiffness	6	30.00%	0	0.00%	6	X=9.96 p=0.076
	Pin Tract Infection	5	25.00%	8	40.00%	13	
	Inactive	1	5.00%	1	5.00%	2	
	Limp	3	15.00%	1	5.00%	4	
	Chronic pain/RSD	2	10.00%	2	10.00%	4	

Figure-1: Graphical Representation Of Functional Outcome Among The Enrolled Patients In Both Groups.

Figure-2: Case Ilizarov X-ray And Clinical Photo

Figure-3: Case Lrs X-ray And Clinical Photo

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