



Ilizarov External Fixator Versus Orthofix LRS in Management of Femoral Osteomyelitis: A Propensity Score Matched Analysis

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Received: 8 December 2023 / Accepted: 18 June 2024 / Published online: 7 July 2024
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Abstract

Purpose Treatment of osteomyelitis (OM) is challenging. Ilizarov bone transport is a commonly used technique for management of OM. The recently introduced limb reconstruction system (LRS) has been effectively used for management of OM. It was suggested to be easier in use and less invasive. The present retrospective study aimed to compare LRS and Ilizarov bone transport in management of femoral OM using a propensity score matched analysis.

Methods The present retrospective study included 80 consecutive patients with femoral OM. The studied patients were managed either using Ilizarov external fixator ($n=40$) or Orthofix LRS ($n=40$). The clinical outcome measurements included union time, limb length discrepancy, additional operative procedures, refracture and infection.

Results Patients in the LRS group were exposed to significantly higher frequency of bone transport (30.0 versus 15.0%) and lower frequency of acute compression and lengthening (10.0 versus 32.5%). Patients in Ilizarov group had significantly higher frequency of tobramycin pellets as compared to their counterparts. The studied groups were comparable regarding the operative complications including pin-tract infection, non-union at docking site and refracture. Patients in the Ilizarov had significantly shorter time to union (8.2 ± 3.2 versus 11.0 ± 5.6 months, $p=0.012$). No statistically significant differences were found between the studied groups regarding the quality-of-life domains.

Conclusions Use of Ilizarov external fixator and Orthofix LRS devices proved to be effective and reliable. Their influences on patients' quality appear to be comparable.

Keywords Ilizarov external fixator · Orthofix · Limb reconstruction system · Femoral osteomyelitis

Introduction

Osteomyelitis (OM) describes a wide spectrum of inflammatory bone conditions mostly caused by microbial invasion. The pathologic concepts explaining OM continue to evolve.

In general, the process is elicited by microbial invasion resulting in bone tissue destruction and biofilm formation. The ensuing immune response produces profound increase in inflammatory cytokines in the local milieu and induction of osteoclastogenesis. Ultimately, proapoptotic mediators promote dramatic diminution of bone remodeling [1].

Treatment of OM remains challenging. Essential elements of treatment include removal of infected tissue, dead-space management and antibiotic therapy [2]. In spite of the continuous advances in surgical and medical treatment of OM, the long-term recurrence rate remains around 20.0% [3]. Moreover, many aspects of management lack standardization with insufficient clinical evidence [4, 5].

Ilizarov bone transport is a commonly used technique for management of OM. Whatever, the associated soft tissue problems, the technique proved to be effective and economic particularly when applied early. The infections recurrence

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rate is estimated to be around 11.0% [6]. The technique was successfully used in management of ankle [7, 8], fibula [9], tibia [10–12], femur [13] and shoulder [14] in children and adults either as a single procedure or in combination with other techniques [12, 15].

The recently introduced limb reconstruction system (LRS) or rail fixator was developed to provide a simple, less invasive and effective tool for management of multiple orthopedic conditions [16–18]. In OM, the device was successfully used for management of the bony defect [19, 20].

Unfortunately, few studies assessed use of LRS in OM and only one study compared it to Ilizarov bone transport in tibial OM [19]. The present retrospective study aimed to compare LRS and Ilizarov bone transport in management of femoral OM using a propensity score matched analysis.

Patients and Methods

The present retrospective study protocol was approved by the local ethical committee. Patients provided consent to anonymously use their clinical data for research purposes in line with the recommendations of Helsinki Declaration on clinical research involving human subjects.

The study included 80 consecutive patients with femoral OM. Infection was diagnosed on the basis of history and physical examination and was confirmed during operation with evidence of pus or positive culture from bacteriological tests. Type of OM was identified according to the clinical staging system for OM suggested by Cierny et al. [21]. Patients were excluded if they had other active systemic infections or immunocompromised states.

The studied patients were managed either using Ilizarov external fixator ($n = 40$) or Orthofix LRS ($n = 40$). Patients in the studied groups were selected using a propensity score calculated by logistic regression with 1:1 ratio. Factors included in the propensity score were age, sex, type of OM, size of the defect, classification, location, and limb discrepancy.

Antibiotic Protocol

If given, antibiotics were stopped 14 days preoperatively. Intraoperative specimens were sent for bacteriological studies and antibiotics were given on the basis of culture and sensitivity. Antibiotics were given intravenously for 2 weeks followed by oral form for 4 weeks. Tobramycin pellets 4.0% (Wright Medical Technology, Inc, Arlington, TN 38002 USA) or custom-made gentamycin beads (40 g of cement powder mixed with 2 g of vancomycin and made into beads connected to each other by suture) were used as appropriate.

Ilizarov External Fixator Insertion

External fixator was mounted according to the length of the bone defect and the surrounding soft tissue condition, minimal invasive Gigli saw osteotomy was applied to protect the periosteum as much as possible. For bone defects larger than 8 cm or more than 40% of the original bone length, bifocal (double level) bone transport was adopted.

LRS Insertion

LRS insertion and corticotomy were done according to the technique described by Nayagam [22]. Corticotomy and bone transport were performed after control of infection. Bone transport was initiated after 1-week latency period. Transport was done at the rate of a quarter turn three times daily. Bone grafting was done when docking of the transported segment has been achieved. Distraction is continued until equal length to the contra-lateral femur was achieved. Physiotherapy was started as soon as the patient tolerates usually on the second postoperative day. Patients were encouraged to have partial weight bearing to prevent disuse osteoporosis and stimulate bone healing.

Postoperative Evaluation

Radiographic evaluation was performed every 2 weeks during distraction phase and every 2–4 weeks during the consolidation phase. Consolidation was diagnosed radiographically with ossification of at least three cortices and clinically when there is no pain on full weight bearing with a loosened frame. To avoid refracture from premature removal of frame, the frame was dynamized first by removing the screw that fixes the proximal clamp to the rail. Then, patients were allowed to fully weight bear without support for six weeks before removing the whole frame.

Surgical Outcome

The clinical outcome measurements included union time, limb length discrepancy, additional operative procedures, refracture and infection. Patients' quality of life was evaluated using the validated Arabic version of the SF-36 questionnaire [23]. Patients were followed up for an average duration of 10.1 ± 4.9 months.

Statistical Analysis

Data obtained from the present study are expressed as number and percent or mean and standard deviation (SD). Categorical variables were compared using chi-square test

while numerical variables were compared using student *t* test. Times to union were compared using Kaplan Meier test with log-rank comparison. All statistical calculations were computed using SPSS 27.0 and *p* value less than 0.05 was considered statistically significant.

Table 1 Baseline characteristics in the studied groups

	LRS N=40	Ilizarov N=40	<i>p</i> value
Age (years) mean ± SD	25.2 ± 9.8	28.6 ± 14.2	0.22
Male/female <i>n</i>	35/5	37/3	0.46
Associated morbidities <i>n</i> (%)			
Diabetes mellitus	2 (5.0)	1 (2.5)	0.56
Hypertension	1 (2.5)	2 (5.0)	0.56
Paraplegia	1 (2.5)	-	0.31
Hepatitis C	1 (2.5)	1 (2.5)	NA
Pulmonary TB	1 (2.5)	-	0.31
Etiology <i>n</i> (%)			
Hematogenous	7 (17.5)	9 (22.5)	0.58
Posttraumatic	33 (82.5)	31 (77.5)	
Location <i>n</i> (%)			
Proximal third	2 (5.0)	2 (5.0)	0.73
Midshaft	30 (75.0)	27 (67.5)	
Distal third	8 (20.0)	11 (27.5)	
Cierny Mader classification <i>n</i> (%)			
IVA	33 (82.5)	36 (90.0)	0.33
IVB	7 (17.5)	4 (10.0)	
Isolated pathogens <i>n</i> (%)			
Single pathogen	25 (62.5)	23 (57.5)	0.75
Two pathogens	10 (25.0)	13 (32.5)	
Multiple pathogens	5 (12.5)	4 (10.0)	
Bone defect (cm) mean ± SD	4.2 ± 3.4	4.9 ± 0.8	0.19
Lower limb discrepancy	2.4 ± 2.3	2.8 ± 1.4	0.35

Table 2 Operative and postoperative data in the studied groups

	LRS N=40	Ilizarov N=40	<i>p</i> value
Operative duration (min.)	136.4 ± 24.9	141.7 ± 26.9	0.36
Bone reconstruction approach <i>n</i> (%)			
Acute compression	24 (60.0)	21 (52.5)	0.031
Acute compression and lengthening	4 (10.0)	13 (32.5)	
Bone transport	12 (30.0)	6 (15.0)	
Antibiotics <i>n</i> (%)			
Tobramycin pellets	14 (35.0)	25 (62.5)	0.028
Gentamycin beads	2 (5.0)	-	
Complications <i>n</i> (%)			
Pin-tract infection	5 (12.5)	8 (20.0)	0.36
Non-union at docking site	6 (15.0)	2 (5.0)	0.14
Refracture	7 (17.5)	2 (5.0)	0.08
Time to union (months) mean ± SD	11.0 ± 5.6	8.2 ± 3.2	0.012

Results

The present study included 40 patients submitted to Ilizarov external fixator and 40 patients submitted to Orthofix LRS for management of femoral OM. Comparison between the studied groups regarding baseline data revealed no statistically significant differences regarding age, sex distribution, associated morbidities, cause of OM, location of OM, Cierny Mader classification, isolated pathogens, bone defect, and lower limb discrepancy (Table 1).

Regarding the operative and postoperative data, it was shown that both groups were comparable regarding operative time (136.4 ± 24.9 min. versus 141.7 ± 26.9, *p* = 0.36). However, patients in the LRS group were exposed to significantly higher frequency of bone transport (30.0 versus 15.0%) and lower frequency of acute compression and lengthening (10.0 versus 32.5%). Patients in Ilizarov group had significantly higher frequency of Tobramycin pellets as compared to their counterparts. The studied groups were comparable regarding the operative complications including pin-tract infection, non-union at docking site and refracture. Patients in the Ilizarov had significantly shorter time to union (8.2 ± 3.2 versus 11.0 ± 5.6 months, *p* = 0.012) (Table 2, Fig. 1).

No statistically significant differences were found between the studied groups regarding the quality-of-life domains (Table 3).

Discussion

The present study compared the outcome of Ilizarov external fixator and Orthofix LRS in patients with femoral OM. In spite of the fact that both techniques were reported to be reliably used for management of bone defects related to OM, a

Fig. 1 Time to union in the studied groups

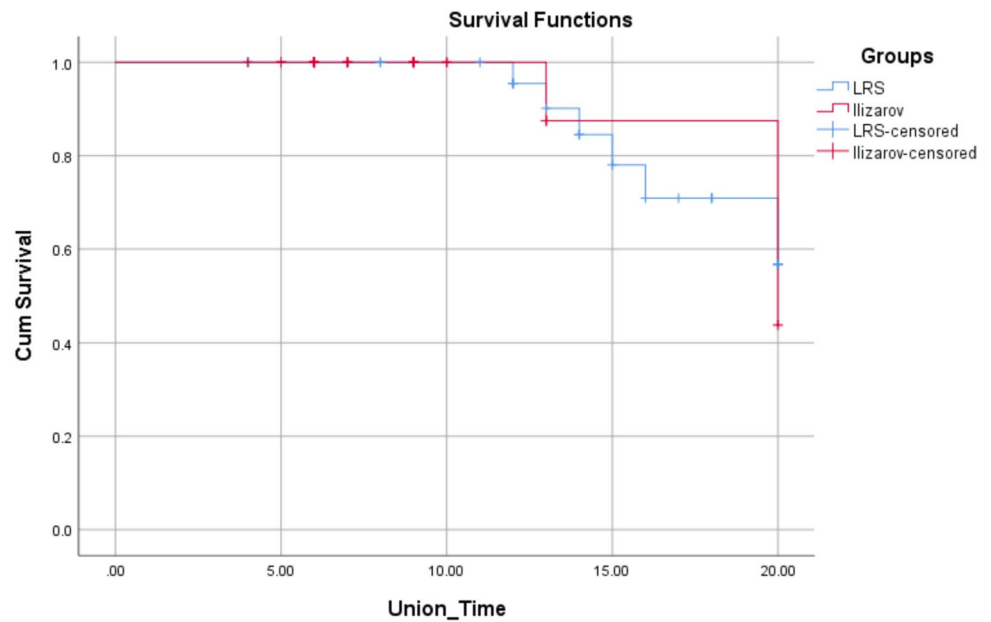


Table 3 Comparison between the studied groups regarding SF-36 questionnaire domains

	LRS N=40	Ilizarov N=40	p value
Physical functioning	57.7 ± 12.0	53.9 ± 9.8	0.13
Role limitations due to physical health	55.0 ± 9.4	52.7 ± 11.8	0.35
Role limitations due to emotional problems	54.0 ± 10.9	50.7 ± 11.8	0.2
Energy/fatigue	61.2 ± 8.6	58.7 ± 9.9	0.22
Emotional well-being	56.5 ± 7.7	54.6 ± 8.3	0.28
Social functioning	62.8 ± 8.5	60.0 ± 10.4	0.2
Pain	52.5 ± 9.6	51.3 ± 12.0	0.62
General health	62.5 ± 7.4	60.2 ± 7.2	0.15

scarcity of studies made head-to-head comparison between them. To our knowledge, the current study is the first to conduct such comparison on exclusive cohort of femoral OM patients. To avoid the bias related to difference in baseline characteristics between the studied groups, we used a propensity score matching analysis. Factors included in the score were age, sex, type of OM, size of the defect, classification, location and limb discrepancy.

The study revealed that both groups were comparable regarding operative duration. However, in the LRS groups, more patients needed bone transport as compared to the Ilizarov group. In contrast, acute compression and lengthening was more frequently used in the Ilizarov group. Use of bone transport with both techniques for treatment of significant bone defects related to OM was previously reported. In the retrospective study of Pallaro et al. [24] on seven patients with femoral OM, use of LRS system with descending bone transport for management of infected femoral bone loss was found to be effective. In another 18-patient study affected by femoral and tibial OM, the procedure proved to be feasible

and effective [25]. Also, Ilizarov bone transport was recognized as an effective method for repairing and reconstructing infected bone defects of the lower limbs [26]. Interestingly, the study of Sen et al. [27] found that both bone transport and acute shortening and re-lengthening were comparable regarding the external fixation time and index and functional results.

Regarding the surgical outcome, the current study found that both techniques are generally safe and effective which is consistent with other studies. Ilizarov’s technique was successfully used in management of OM alone or with intramedullary lock nail [13]. It proved to be comparable to some other interventions e.g., Masquelet technique [28] and even better than others e.g., bone grafting techniques [29]. Likewise, rail fixators were efficiently used in management of bone gap due to chronic OM [30].

In addition, in the present study, it was shown that both groups were comparable regarding postoperative complications including pin-tract infection, non-union at docking site and refracture. The comparable outcomes of the two

interventions in the present study are in harmony with the study of Yilihamu et al. [19] who compared outcomes of post-traumatic tibial OM treated with an Orthofix LRS versus an Ilizarov external fixator. They found no significant differences between both approaches regarding docking site complications, bone healing index and postoperative X-ray findings.

Regarding the effect of both techniques on patients' quality of life, no significant differences were found between the studied groups in spite of the fact that patients in the LRS group expressed slightly better quality of life domains over their counterparts in the Ilizarov group. This finding may be supported by the conclusions of Abulaiti et al. [20] who noted that both Ilizarov and Orthofix LRS negatively affected patients' quality of life. However, Orthofix LRS had less severe impact in spite of the similar clinical outcomes.

Notably, patients in the Ilizarov group had significantly shorter time to union as compared to the Orthofix group. This may be explained by the fact that significantly lower frequency of patients in the Ilizarov group needed bone transport.

Findings of the present study may be limited by its retrospective design, the relatively small sample size and the short follow-up duration. However, the propensity score matching of the study groups helped to provide balanced evaluation of the operative interventions used and reduced the bias related to preoperative confounders. This can contribute to better build up of clinical evidence practice in management of chronic OM. Further studies with larger sample, longer follow-up duration, multicentric design and probably additional treatment options are recommended to confirm findings of the present study.

In conclusion, the present study found that use of Ilizarov external fixator and Orthofix LRS devices proved to be effective and reliable. However, use of Ilizarov external fixator was associated with significantly shorter time to union. Their influences on patients' quality appear to be comparable.

Acknowledgements We thank all patients participating in the study. In addition, the authors extend their appreciation to the Deputyship for Research & Innovation, Ministry of Education in Saudi Arabia for supporting this research work through the project number (IF2/PSAU/2022/03/21767).

Authors' Contributions All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or manuscript drafting, writing and revision. All authors approved the final version of the manuscript.

Funding None.

Data Availability Data of this research will be available upon reasonable request.

Declarations

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval The study protocol was approved by the ethical committee of Al-Azhar University Faculty of Medicine.

Consent for Publication For this type of study informed consent is not required.

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