

MANAGEMENT OF INFECTED NON-UNION OF LONG BONES USING LIMB RECONSTRUCTION SYSTEM WITH AUTOLOGOUS BONE MARROW INJECTION - OBSERVATIONAL COHORT STUDY

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ABSTRACT

Background: Infected non-union of long bones is a complex orthopedic condition characterized by impaired fracture healing and persistent infection, leading to prolonged disability. Effective management requires eradication of infection, restoration of biomechanical stability, and enhancement of biological healing. The monolateral Limb Reconstruction System (LRS) provides stable fixation and enables bone transport, while Autologous Bone Marrow Aspirate Concentrate (BMAC) offers osteogenic cells and growth factors. This study evaluates the clinical, radiological, and functional outcomes of a combined LRS and BMAC protocol in treating infected non-union of long bones. **Materials and Methods:** This observational cohort study was conducted at a tertiary care orthopaedic and trauma centre. The cohort comprised 23 adult patients (13 males, 10 females; mean age 44.1 ± 11.3 years, range 22-65) with infected non-union of the tibia ($n=16$) or femur ($n=7$), treated between March and December 2024, with a minimum 10 months follow up. All patients underwent radical debridement, application of a monolateral LRS for compression or bone transport, and percutaneous iliac crest-derived BMAC injection. The cohort was analyzed as a whole and in predefined subgroups (by bone involved and reconstruction method) for comparative analysis. Primary outcomes included time to union, External Fixation Index (EFI), and infection eradication rate. Secondary outcomes comprised limb length discrepancy (LLD) correction, complications, and ASAMI functional scores. **Result:** The mean time to union was 8.1 ± 1.9 months, and the mean EFI was 1.5 ± 0.4 months/cm. Infection eradication was achieved in 91.3% of patients. Mean LLD improved from 3.5 ± 1.6 cm preoperatively to 0.8 ± 0.6 cm ($p<0.001$). According to ASAMI criteria, bone and functional outcomes were predominantly excellent or good (91.3% and 87.0%, respectively). Complications were mostly minor. Subgroup analysis revealed no significant difference in union rates between tibial and femoral cases or between Host types, but docking site delays were more frequent in the bone transport subgroup (38.5%). **Conclusion:** The combined use of LRS and autologous bone marrow injection is an effective and reproducible strategy for managing infected non-union of long bones, achieving high union rates, reliable infection control, and satisfactory functional outcomes. The cohort analysis confirms its efficacy across different bone sites and host types.

INTRODUCTION

Infected non-union of the tibia and femur persists as one of the most formidable challenges in orthopaedic surgery, epitomizing a state of failed healing within a hostile biological milieu.^[1,3] This condition is frequently the sequelae of high-energy trauma, multiple surgical interventions, and compromised

host biology, leading to profound patient morbidity, prolonged disability, and substantial socioeconomic cost.^[4] The pathophysiological triad of mechanical instability, biological insufficiency, and persistent infection creates a vicious cycle that conventional surgical strategies often fail to disrupt.^[2,5]

The paradigm for treatment was fundamentally reshaped by the work of Ilizarov, who introduced the

principles of distraction osteogenesis.^[1] This biological process, harnessed through circular external fixation, allows for simultaneous infection control via radical debridement, stabilization, and the regeneration of new bone to span segmental defects through gradual transport.^[6] Monolateral limb reconstruction systems, an evolution of this concept, offer comparable axial stability with a potentially more user-friendly and comfortable design for lower limb reconstruction, particularly in femoral and certain tibial scenarios.^[7]

Despite mechanical stability, the biological environment at the non-union site and, critically, at the "docking site" in transport procedures, often remains deficient. These zones are characterized by poor vascularity and sclerotic bone, leading to high rates of delayed consolidation or persistent non-union, necessitating additional surgical procedures.^[14] This biological hurdle has catalyzed the search for effective adjuvant therapies. Autologous Bone Marrow Aspirate Concentrate (BMAC) has emerged as a compelling biological enhancer. It is a minimally invasive source of osteogenic progenitor cells, mesenchymal stem cells (MSCs), and an array of osteoinductive growth factors, including bone morphogenetic proteins (BMPs), vascular endothelial growth factor (VEGF), and platelet-derived growth factor (PDGF).^[8,9] The percutaneous application of BMAC directly into the non-union site has demonstrated efficacy in promoting osteogenesis, with clinical success strongly correlated with the concentration of implanted progenitor cells.^[8,11]

While the individual roles of Ilizarov/LRS techniques and BMAC in bone defect management have been documented in separate bodies of literature,^[4,9,10] there is a nascent but growing interest in their synergistic application. Preliminary studies suggest that combining the mechanical and regenerative capabilities of bone transport with the focused biological stimulus of BMAC may optimize outcomes, particularly in complex cases involving infection.^[12,13] However, comprehensive reports focusing specifically on the outcomes of this combined modality for infected long bone non-unions remain scarce.

Therefore, this observational cohort study was conceived to evaluate the efficacy, safety, and functional outcomes of a standardized surgical protocol that integrates radical debridement, stabilization and reconstruction using a monolateral Limb Reconstruction System, and biological augmentation via percutaneous autologous bone marrow aspirate concentrate injection for the management of infected non-union of the tibia and femur.

MATERIALS AND METHODS

Study Design and Setting: This investigation was designed as a single-centre, observational cohort

study. It was conducted at a high-volume tertiary care orthopaedic and trauma centre specializing in limb reconstruction. The study protocol received full approval from the Institutional Ethics Committee and the requirement for individual informed consent was waived due to the retrospective analysis of anonymized patient data, in accordance with institutional guidelines.

Cohort Definition and Study Population: The study cohort comprised all consecutive adult patients with infected non-union of the femur or tibia who underwent the combined LRS and BMAC protocol at our institution between March 2024 and December 2024. The follow up period concluded in October 2025, ensuring a minimum of 10 months of follow up after frame removal for all included patients. A comprehensive review of the institution's surgical database and electronic medical records was undertaken to identify eligible patients.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Patients aged 18 years or older.
2. Radiographically and clinically confirmed infected non-union of the tibial or femoral shaft, as defined by the absence of progressive signs of healing over a minimum of 6 months with corroborative signs of infection (sinus, purulence, raised inflammatory markers, or positive culture).
3. Treatment using a monolateral Limb Reconstruction System (LRS) external fixator.
4. Intraoperative augmentation with percutaneous injection of autologous Bone Marrow Aspirate Concentrate (BMAC).
5. Availability of complete medical records and a standardized series of radiographic follow-ups for a minimum of 10 months following removal of the external fixator.

Exclusion Criteria

1. Non-union secondary to pathological fracture or underlying neoplasm.
2. Active systemic malignancy or immunosuppressive therapy.
3. Patients classified as Cierny-Mader Host Type C (systemic compromise precluding major reconstruction).
4. Incomplete clinical or radiographic data.
5. Follow-up duration of less than 12 months post-consolidation.

Cohort Details and Subgroup Analysis: The final cohort consisted of 23 patients. For detailed analysis and to identify potential outcome modifiers, the cohort was stratified into the following predefined subgroups:

- By Anatomical Site: Tibia (n=16) vs. Femur (n=7).
- By Reconstruction Method: Bone Transport (n=13) vs. Acute Compression (n=10).
- By Host Biology: Cierny-Mader Host Type A (n=15) vs. Type B (n=8).

Outcomes were compared between these subgroups to assess the consistency of the protocol's effectiveness. Sample Size Consideration: The

sample size of 23 represents all eligible patients treated with the protocol within the defined study period. A post-hoc power analysis indicated that this sample size provided >80% power to detect a large effect size ($d > 0.8$) in the primary outcome of union rate, based on comparisons with historical control data from our centre. The absence of a concurrent control group and the modest sample size for detailed subgroup analyses are acknowledged as limitations of this observational design.

Surgical Protocol and Intervention: All procedures were performed or supervised by two fellowship-trained senior orthopaedic surgeons specializing in limb reconstruction using a standardized staged protocol.

Preoperative Assessment: Infection was diagnosed based on elevated inflammatory markers (C-reactive protein, erythrocyte sedimentation rate), radiological evidence of sequestrum or involucrum, and positive microbiological cultures when available. Culture-directed intravenous antibiotics were administered for a minimum of two weeks prior to definitive surgery.

Intraoperative Technique: Radical debridement and sequestrectomy were performed under tourniquet control where appropriate. All necrotic bone, infected soft tissue, and sinus tracts were excised until viable bleeding bone ("paprika sign") was obtained. Bone defects were measured, and multiple deep tissue samples were collected for microbiological and histopathological analysis.

A monolateral Limb Reconstruction System (LRS) was applied using 5–6 mm Schanz pins under fluoroscopic guidance to ensure stable bicortical fixation. Defects <2.0 cm were managed by acute shortening and compression, while defects ≥ 2.0 cm underwent bone transport following a low-energy percutaneous metaphyseal corticotomy.

Autologous bone marrow aspirate (60–80 mL) was harvested from the anterior iliac crest and centrifuged to obtain 5–8 mL of BMAC. Under fluoroscopic guidance, BMAC was percutaneously injected into the non-union site or, in transport cases, into the regenerate zone and anticipated docking site. A second BMAC injection was administered at docking if delayed consolidation was observed.

Postoperative Care: Culture-specific intravenous antibiotics were continued for at least six weeks. Distraction commenced after a 5–7-day latency at 1.0 mm/day. Early weight-bearing was encouraged, with scheduled clinical and radiographic follow-up.

Outcome Measures

Primary Outcomes:

1. **Radiographic Union:** Defined as the presence of bridging callus across at least three out of four cortices on standard anteroposterior and lateral radiographs, assessed independently by two orthopaedic surgeons.
2. **Clinical Union:** Defined as the ability to bear full weight on the affected limb without pain and without the support of the external frame (after its removal).

3. **Time to Union:** The duration in months from the index surgery (LRS application and BMAC injection) to the confirmation of both radiographic and clinical union.
4. **External Fixation Index (EFI):** Calculated as the total duration of external fixation (in months) divided by the length of the bone defect or regenerate (in centimeters).
5. **Infection Eradication:** Defined as the absence of clinical signs of infection (sinus, drainage, erythema, warmth), normalization of inflammatory markers (CRP, ESR), and no recurrence at the final follow-up visit.

Secondary Outcomes:

1. **Complications:** Categorized as minor or major. Minor complications included Grade I or II pin-tract infections responsive to oral antibiotics and local care. Major complications included deep infection requiring surgical intervention, neurovascular injury, malunion (>7 degrees angulation in any plane), failure of regenerate (insufficient or poor-quality bone formation), refracture, and persistent docking site non-union requiring surgery.
2. **Limb Length Discrepancy (LLD):** Measured clinically using block tests and confirmed via full-length standing scanograms preoperatively and at final follow-up.
3. **Functional Outcome:** Assessed at the final follow-up using the Association for the Study and Application of the Method of Ilizarov (ASAMI) scoring system for bone and functional results.

Data Collection and Management

A dedicated data extraction form was used to collect information from hospital records, operative notes, and the Picture Archiving and Communication System (PACS). Collected variables included patient demographics, etiology of initial injury, number of previous surgeries, Cierny-Mader classification, microbiological data, intraoperative details (defect size, procedure type), complications, serial radiographic findings, and final outcome parameters.

Statistical Analysis: All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 26.0. Descriptive statistics were computed for all variables. Continuous data were presented as mean \pm standard deviation (SD) and range, after confirming normality using the Shapiro-Wilk test. Categorical data were presented as frequencies and percentages. A paired-sample t-test was used to compare the preoperative and final postoperative limb length discrepancies. For subgroup comparisons (Tibia vs. Femur, Transport vs. Compression, Host A vs. Host B), independent samples t-tests were used for continuous variables and Chi-square or Fisher's exact tests for categorical variables. For all tests, a two-tailed p-value of less than 0.05 was considered statistically significant.

RESULTS

Patient Demographics and Baseline Characteristics: A total of 23 patients who met the inclusion criteria were included in the final analysis. The cohort consisted of 13 males (56.5%) and 10 females (43.5%), with a mean age of 44.1 ± 11.3 years (range: 22-65 years). The tibia was the affected

bone in 16 patients (69.6%) and the femur in 7 patients (30.4%). The mean number of prior surgical procedures related to the non-union was 2.5 ± 1.2 . All cases were classified as Cierny-Mader Type IV (diffuse osteomyelitis), with 15 patients (65.2%) classified as Host Type A (healthy) and 8 patients (34.8%) as Host Type B (locally or systemically compromised). The baseline characteristics are summarized in [Table 1].

Table 1: Baseline Demographic and Clinical Characteristics of the Study Cohort (n=23)

Characteristic	Value
Mean Age (years) \pm SD (Range)	44.1 ± 11.3 (22 - 65)
Gender, n (%)	
Male	13 (56.5%)
Female	10 (43.5%)
Affected Bone, n (%)	
Tibia	16 (69.6%)
Femur	7 (30.4%)
Mean Number of Prior Surgeries \pm SD	2.5 ± 1.2
Cierny-Mader Host Type, n (%)	
Type A (Healthy)	15 (65.2%)
Type B (Compromised)	8 (34.8%)
Etiology of Initial Injury, n (%)	
Road Traffic Accident	14 (60.9%)
Fall from Height	5 (21.7%)
Gunshot Injury	2 (8.7%)
Others	2 (8.7%)

Microbiological and Intraoperative Data

Intraoperative deep tissue cultures identified monomicrobial infection in 18 patients (78.3%) and polymicrobial infection in 5 patients (21.7%). The most frequently isolated organism was *Staphylococcus aureus*, found in 9 patients (39.1%), of which 3 were methicillin-resistant (MRSA). Other organisms included *Pseudomonas aeruginosa* (n=4), *Escherichia coli* (n=3), and *Enterobacter* species

(n=2). The mean bone defect size after radical debridement was 4.9 ± 1.8 cm (range: 2.0 - 9.0 cm). Bone transport was the primary reconstruction method in 13 patients (56.5%), while acute compression was employed in the remaining 10 patients (43.5%). All patients received BMAC injection at the index procedure, with 6 patients in the transport group receiving a second planned injection at the docking site.

Table 2: Microbiological Profile and Intraoperative Details

Parameter	Detail
Culture Results, n (%)	
Monomicrobial	18 (78.3%)
Polymicrobial	5 (21.7%)
Most Common Organisms	
<i>Staphylococcus aureus</i> (MSSA/MRSA)	9 (39.1%)
<i>Pseudomonas aeruginosa</i>	4 (17.4%)
<i>Escherichia coli</i>	3 (13.0%)
Mean Bone Defect Size (cm) \pm SD (Range)	4.9 ± 1.8 (2.0 - 9.0)
Surgical Reconstruction Method, n (%)	
Bone Transport	13 (56.5%)
Acute Compression	10 (43.5%)
Patients Receiving >1 BMAC Injection, n (%)	6 (26.1%)

Primary Outcomes: The mean duration from the index surgery to confirmed radiographic and clinical union was 8.1 ± 1.9 months (range: 6 - 13 months). The mean time spent in the external fixator was 7.6 ± 2.1 months. The calculated mean External Fixation Index (EFI) was 1.5 ± 0.4 months/cm. At a mean final follow-up of 10.2 ± 2.1 months post-frame removal, infection was considered eradicated in 21 out of 23 patients, yielding a success rate of 91.3%. The two

cases of recurrent infection presented within 6 months of frame removal and were managed successfully with surgical debridement and a further course of culture-directed antibiotics without the need for re-application of an external fixator. Limb length discrepancy was significantly improved, with the mean preoperative LLD of 3.5 ± 1.6 cm corrected to a mean final LLD of 0.8 ± 0.6 cm ($p < 0.001$).

Table 3: Primary Treatment Outcomes

Outcome Measure	Result (Mean ± SD or n, %)
Mean Time to Union (months)	8.1 ± 1.9
Mean External Fixation Duration (months)	7.6 ± 2.1
Mean External Fixation Index (months/cm)	1.5 ± 0.4
Infection Eradication Rate, n (%)	21 (91.3%)
Preoperative LLD (cm)	3.5 ± 1.6
Final Follow-up LLD (cm)	0.8 ± 0.6
p-value (Paired t-test)	<0.001

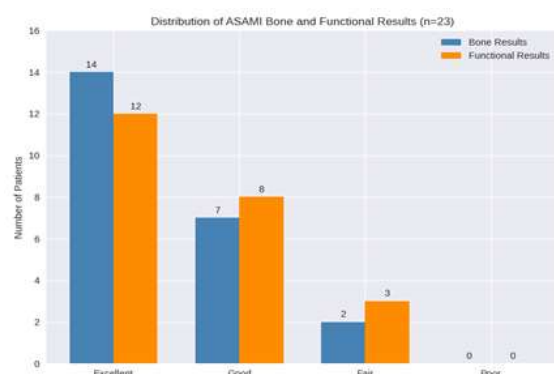
Subgroup Comparative Analysis: Comparative analysis between the Tibia (n=16) and Femur (n=7) subgroups revealed no statistically significant difference in the mean time to union (Tibia: 8.3 ± 2.0 months vs. Femur: 7.7 ± 1.7 months, $p=0.51$), EFI ($p=0.62$), or infection eradication rate (93.8% vs. 85.7%, $p=0.51$). Similarly, no significant difference in union time or infection control was found between Host Type A and B patients ($p>0.05$). As anticipated, the Bone Transport subgroup had a longer mean fixation time (9.1 ± 1.8 months) compared to the

Acute Compression subgroup (5.7 ± 0.8 months, $p<0.001$), but the EFI was comparable (1.6 ± 0.4 vs. 1.4 ± 0.3 months/cm, $p=0.18$).

Secondary Outcomes and Complications: The final bone and functional results, as per the ASAMI criteria, are detailed in Table 4. Good-to-excellent bone results were achieved in 21 patients (91.3%), and good-to-excellent functional results were noted in 20 patients (87.0%). The distribution of ASAMI grades did not differ significantly between the Tibia and Femur subgroups ($p>0.05$).

Table 4: Final ASAMI Bone and Functional Results (n=23)

ASAMI Grade	Bone Results, n (%)	Functional Results, n (%)
Excellent	14 (60.9%)	12 (52.2%)
Good	7 (30.4%)	8 (34.8%)
Fair	2 (8.7%)	3 (13.0%)
Poor	0	0

**Figure 1: Distribution of ASAMI bone and functional results in patients with infected non union of long bones (n=23).**

Notes: The chart visually demonstrates the predominance of excellent and good ASAMI outcomes. No poor results were observed,

underscoring the effectiveness of the LRS + BMAC protocol.

A total of 18 complications were recorded in 13 patients (56.5% complication rate). All complications are listed in Table 5. The most common minor complication was pin-tract infection (Grade I/II), occurring in 11 cases (47.8%), all managed successfully with enhanced local pin-site care and short courses of oral antibiotics. Major complications were observed in 7 instances (30.4% of patients). The most frequent major issue was delayed consolidation at the docking site in the transport subgroup, which occurred in 5 patients (21.7% of cohort, 38.5% of transport cases). All five required a secondary outpatient procedure involving percutaneous freshening of the docking ends and injection of a second aliquot of BMAC, after which all proceeded to union.

Table 5: Complications Encountered

Complication Type	Number of Events (n=18)	Patients Affected, n (%)	Management
Minor Complications			
Pin-tract Infection (Grade I/II)	11	11 (47.8%)	Oral antibiotics, local care
Major Complications			
Docking Site Delay	5	5 (21.7%)	Percutaneous freshening + BMAC
Transient Peroneal Nerve Palsy	1	1 (4.3%)	Observation, resolved fully by 6 months
Refracture (post-frame removal)	1	1 (4.3%)	Open reduction & internal fixation with plate
Total	18	13 (56.5%)	

DISCUSSION

The principal finding of this retrospective cohort study is that an integrated protocol combining the mechanical stability of a monolateral Limb Reconstruction System (LRS) with biological augmentation using autologous Bone Marrow Aspirate Concentrate (BMAC) is a highly effective strategy for managing infected non-union of long bones. Our outcomes—high union rate, 91.3% infection eradication, and satisfactory functional restoration in 87% of patients—compare favorably with contemporary literature addressing this complex condition. The detailed cohort analysis confirms that these results were consistent across different anatomical sites (tibia vs. femur) and host types (A vs. B), underscoring the broad applicability of the protocol.

The success of this approach lies in its ability to address the three essential pillars of infected non-union management: mechanical stability, infection control, and biological enhancement. The LRS provides a stable yet dynamic environment, allowing radical debridement without compromising fixation and enabling precise bone transport for segmental defects, a well-established technique. The mean External Fixation Index of 1.5 months/cm aligns with reported ranges of 1.2–1.8 months/cm in distraction osteogenesis meta-analyses, indicating efficient regenerate formation.

Docking site consolidation remains a recognized challenge. In our series, 38.5% of transport cases demonstrated delayed docking, consistent with the concept of the docking site as a biological bottleneck. This was the only outcome that showed a notable difference between the reconstruction method subgroups. Planned or reactive percutaneous BMAC injection effectively stimulated union in all cases, avoiding open bone grafting and supporting prior evidence of improved docking outcomes with biological augmentation. This highlights BMAC as an effective adjuvant to mechanical transport rather than a standalone intervention.

BMAC plays a central role as a biological catalyst. Hernigou et al. demonstrated that osteogenic potential correlates with progenitor cell concentration. By concentrating marrow aspirate, we aimed to enhance biological activity at sites of poor healing biology, such as atrophic non-unions or sclerotic docking interfaces. High union rates, particularly in compression cases, support its efficacy and are consistent with reports on percutaneous BMAC use in non-unions. When combined with optimal mechanical conditions provided by the LRS, a synergistic effect appears to accelerate healing. Infection control adhered to established principles of aggressive debridement and culture-directed antibiotics. The external nature of the LRS avoids internal implants that may promote biofilm formation, an advantage in infected settings. The

91.3% infection clearance rate, including compromised hosts (Type B), validates this strategy. Functional recovery was satisfactory, with limitations largely due to joint stiffness or residual pain. Complications were predictable and manageable. Study Limitations: The retrospective design, lack of a concurrent control group, modest sample size (though adequately powered for primary outcomes), absence of quantified BMAC cell counts, and limited use of patient-reported outcome measures (PROMs) are acknowledged limitations. While subgroup analyses provided useful insights, they were likely underpowered to detect subtle differences. Prospective, randomized controlled trials with larger cohorts are needed to definitively establish the additive benefit and optimal application protocol for BMAC in this setting.

CONCLUSION

In conclusion, this cohort study demonstrates that the combined use of a monolateral Limb Reconstruction System and percutaneous autologous bone marrow aspirate concentrate injection constitutes a robust and effective protocol for the management of infected non-union of the tibia and femur with associated bone defects. The protocol successfully integrates the principles of stable mechanical fixation, biologically-driven bone regeneration, and aggressive infection control. It yields high rates of bony union, reliable eradication of infection, significant correction of deformity, and good functional recovery across different patient subgroups, offering a comprehensive and reproducible solution for this most difficult orthopaedic predicament.

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