Outcomes of Complex Humeral Fractures Treated with Limb Reconstruction System External Fixator: A Case Series Review

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Abstract: ***Background**: Humeral shaft fractures HSFs are common and can be particularly challenging to treat in complex cases. This study evaluates the union rate and functional outcomes of HSFs treated with a monorail unilateral limb reconstruction system (LRS). **Methods**: We retrospectively reviewed six patients with HSFs treated with LRS from November 2019 to March 2021. Indications included AO 12A, 12B, 12C fractures, open fractures, poor soft tissue conditions, and fracture - related infections. Functional outcomes were assessed using the DASH score, shoulder and elbow range of motion (ROM), and the ROWE score. Radiological union was evaluated using the modified Radiological Union Score for Tibia (mRUST). **Results**: This case series reviews the outcomes of six patients with HSFs treated using the Limb Reconstruction System LRS. The study retrospectively evaluates the union rate, functional recovery, and complications. A 100% union rate was achieved within a mean time of 4.5 months, with significant improvements in DASH scores from 69.9 preoperatively to 6.7 postoperatively (p < 0.00001). **Conclusion**: Monorail unilateral LRS demonstrated high union rates and significant functional improvement in treating humeral shaft fractures. The LRS proved effective in managing complex humeral fractures, combining conservative and surgical approaches without infection recurrence.***

Keywords: Fracture Related Infection, Humeral shaft fracture, Limb Reconstruction System, DASH score, complex fracture, case series

1. Introduction

The humeral shaft extends from the proximal border of the pectoralis major insertion to the supracondylar ridge. Humeral shaft fractures (HSFs) are relatively common injuries, accounting for approximately 1% to 5% of all adult fractures and 20% of upper extremity fractures. [1] [2] [3] The average incidence of HSFs is about 14 per 100, 000 individuals annually. [4] Traditionally, non - operative treatment has been the preferred method for managing these fractures due to the humeral's strong healing potential, rapid fracture healing rates, and the fact that precise anatomical restoration is not always necessary for a favorable functional outcome. [5] Furthermore, non - surgical management avoids the risks associated with surgery, such as iatrogenic radial nerve palsy, postoperative infections, and implant failure. However, while landmark studies in the 1970s and 1980s, such as those by Sarmiento, reported very good outcomes with functional bracing, subsequent studies have struggled to replicate these results consistently. [6]

When non - operative treatment fails, the current gold - standard treatment involves revision surgery, which typically includes debridement of the non - union site, rigid internal fixation, and potentially the use of cancellous bone grafts. [7] [8] [9] [10] [11] However, there is ongoing debate regarding the optimal surgical sequence, type of fixation, and whether to use autologous bone grafts or other substitutes. [12] [13] The reported failure rates for surgical intervention range from 2% to 30%, with complication rates between 8% and 20%. One notable complication is radial nerve palsy, which occurs in approximately 6% of cases. [14] [15]

In the late 1970s, the introduction of a new unilateral external fixator represented an advancement over the technically challenging application of three - dimensional fixators. This new method did not compromise the principles of stabilization, while also expanding the range of indications to include both complex and simple closed fractures. External fixation works by stabilizing fractures at a distance, preserving the fracture hematoma and reducing infection risk, similar to conservative treatment. It offers effective reduction and retention of the fracture without compromising joint motion, allowing sufficient stability for early physiotherapy and unrestricted mobility of the adjacent joints. Unilateral external axial dynamic fixation combines the benefits of both conservative and operative therapies, offering a minimally invasive stabilization technique. [16]

One of the key advantages of this method is the option for axial dynamization, which applies axial forces at the fracture site through muscle tension, potentially enhancing callus formation and promoting healing. However, a major drawback of external fixation is the need for screw insertion through the soft tissue into the bone. This insertion can lead to mechanical irritation due to shearing forces between muscles and bone during joint movement, potentially restricting shoulder and elbow mobility. Such irritation increases the risk of pin - track infections. If these infections progress into the bone, they can lead to pin loosening and local osteitis. To mitigate this risk, strict adherence to therapy principles is crucial, including timely removal or replacement of loose pins and proper pin placement to minimize mechanical irritation. It is advised to insert the pins where there is minimal muscle and bone movement during elbow and shoulder motion, ideally distal to the deltoid muscle for the proximal pin group and between the lower part of the lateral intermuscular septum and the radial epicondyle for the distal pin group. A minimum distance of 3 cm from the fracture line is recommended to avoid creating an access point for potential infection through the pin track. [16]

Unilateral external fixation serves as a definitive operative treatment, often eliminating the need for secondary interventions. Once the fracture has healed, the fixator can be removed in a "test" manner. If the bone remains stable, the screws can be removed in an outpatient setting without anesthesia or analgesia. [16]

Table 1: Patient Demographic Data
MVA – Motor Vehicle Accident

Case No.	Sex	Age	Co-morbidities	Date of trauma	Mechanism	Diagnosis	AO Classification	Diagnosis during presentation	Date of definitive surgery	Time from Injury Until Definitive Procedure
1	M	42	nil	21.10.2020	MVA	Closed fracture mid-shaft right humeral	A1	Infected non-union post plating	17.12.2021	14 months
2	M	40	nil	24.10.2019	MVA	Closed fracture distal 3rd left humeral	C1	Closed fracture distal 3rd left humeral with severe soft tissue injury	19.11.2019	2 months
3	M	20	nil	29.4.2020	MVA	Closed fracture right humeral	B2	Infected non-union post plating	24.2.2021	10 months
4	M	28	nil	20.7.2020	MVA	Closed fracture right humeral	A2	Infected non-union post plating	29.4.2021	9 months
5	M	22	nil	11.11.2020	MVA	Open fracture grade 3B right humeral	B2	Open fracture grade 3B right humeral	7.1.2021	2 months
6	M	37	nil	14.1.2021	MVA	Open fracture grade 3C right humeral	B3	Open Fracture grade 3C right humeral	19.3.2021	3 months

The aim of this study is to evaluate and critically analyze the union rate and functional outcomes in the treatment of humeral shaft fractures using a monorail unilateral limb reconstruction system at our center. By examining this case series, we seek to provide insights into the effectiveness and potential complications of this treatment method, offering valuable information for the management of HSFs.

2. Methods

This study reviewed six patients with humeral fractures who underwent surgery using the Limb Reconstruction System (LRS) from November 2019 to March 2021. The inclusion criteria for LRS management included humeral shaft fractures classified as AO 12A, 12B, or 12C, open fractures, closed fractures with compromised soft tissue envelopes, and fractures associated with infection. Patients were excluded if they had humeral shaft fractures with intraarticular involvement of the proximal or distal joints, or if they required conversion from LRS to another fixation method. (Table 1)

Demographic data, including age, sex, race, baseline comorbidities, and mechanism of injury, were recorded for each patient. Surgical data collected included the time from initial injury to definitive fixation with LRS, AO fracture classification, Gustilo - Anderson classification of long bone fractures, and surgery duration. (Table 1)

Preoperative and postoperative x - rays were evaluated by two experienced surgeons to assess fracture healing and complications. The radiographic assessments focused on fracture pattern, implant loosening, loss of reduction, angular deformity, implant failure, and nonunion. Associated injuries prior to LRS fixation, revisions using other implants, and post - fixation complications were also documented.

Initially, the ROWE score was utilized to assess upper limb function post - fixation, with a focus on shoulder outcomes. [17] However, it was later determined that the Disabilities of the Arm, Shoulder, and Hand (DASH) score would provide a more comprehensive evaluation of clinical recovery. [18] Additionally, the range of motion (ROM) for the shoulder and elbow of the affected limb was measured to further evaluate fixation outcomes. [19] Patient satisfaction was assessed, and patients were asked if they would recommend the treatment. Informed consent was obtained from all participants included in the study. [20]

Radiological evaluation of bone union was conducted using the modified Radiological Union Score for Tibia (mRUST). Although the original RUST score was developed to evaluate tibial diaphyseal union with interlocking nails, the mRUST score has been adapted for use in other long bones, such as the femur and humeral. [21] [22] The union was assessed at intervals of 3 weeks, 6 weeks, 3 months, 6 months, and 12 months during clinic visits. The LRS was removed once bony union was evident in at least 3 out of 4 cortices with an mRUST score greater than 12. [23]

A Pediatric Limb Reconstruction System (LRS) was used for all patients. This system included a Pediatric LRS rail, available in lengths of 250mm or 200mm, and two Pediatric LRS straight clamps—one for the proximal fragment and one for the distal fragment. The system, manufactured using an aluminum alloy, ensured a lightweight construct. To achieve optimal compression at the fracture site, a Pediatric LRS Compression - Distraction (CD) unit, capable of extending up to 5cm, was used. This unit was removed after the desired compression was achieved, and the straight clamps were tightened. (Figure 1)

Stainless steel, tapered, hydroxyapatite - coated Schanz pins with self - tapping flutes were used for fixation. The pins had a shaft diameter of 6mm, with the threaded area tapering from

4.5mm to 3.5mm. (Figure 2) The length of the pins was determined by soft tissue thickness, with the most common lengths being 110mm and 120mm. Each fracture segment was stabilized using three pins, in line with findings by Hiranya Kumar et al., who reported that two pins per segment can provide adequate stability for union with LRS. [24].

Figure 1: Pediatric Limb Reconstruction System with Straight Clamps and Compression and Distraction (CD) unit

Figure 2: Tapered Hydroxyapatite (HA) coated pins

Intraoperatively, patients were positioned supine on a radiolucent table with the injured arm abducted to 90 degrees and the elbow fully extended. A radiolucent arm board supported the injured limb. General anesthesia was administered due to the proximity of the procedure to the patient, which could induce anxiety and discomfort if performed under local anesthesia. To enhance postoperative pain control, the anesthesia team also provided regional anesthesia, such as an interscalene block or supraclavicular brachial plexus block, covering the entire humeral. The combination of general and regional anesthesia facilitated immediate passive mobilization of the operated segment.

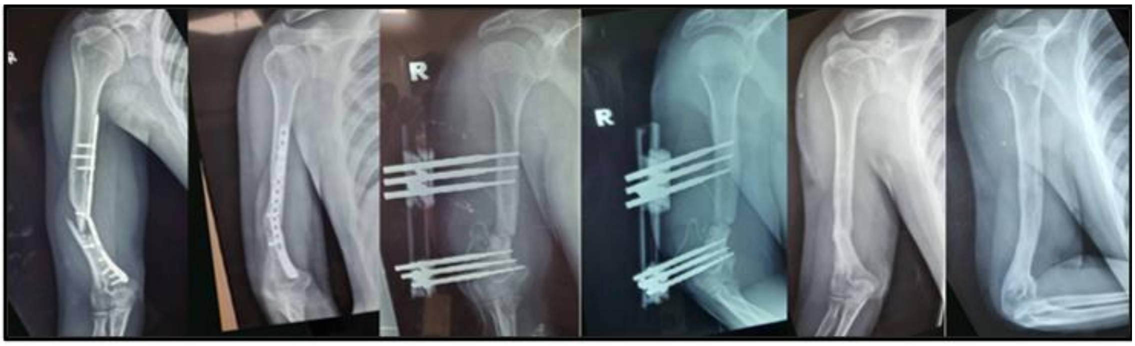

Figure 3: Series of X-ray from one of the patients

Surgical procedures typically involved open reduction, hardware removal, bone resection, acute docking, and monorail LRS fixation. The anterolateral approach to the humeral was the preferred surgical technique, allowing direct access to the fracture site for reduction or bone resection. Bone and soft tissue samples were collected for culture and sensitivity analysis. Reduction was temporarily maintained using two crossed K - wires (2.0mm or 1.8mm). Preoperative planning guided the pin placement, generally in a true lateral position relative to the humeral and perpendicular to the humeral axis. Care was taken to avoid critical structures such as the axillary nerve, located 5 - 7cm from the acromion process, and the radial nerve, which crosses anteriorly at the middle third of the humeral. Pins were inserted in a manner that avoided the olecranon fossa to prevent blocking elbow extension during rehabilitation.

Postoperatively, wounds were inspected on day 3. While awaiting culture and sensitivity results, patients were encouraged to begin early mobilization with active - assisted range of motion (ROM) exercises as tolerated. Pin insertion sites were cleaned daily and covered with saline - soaked gauze. In cases of suspected infection, povidone - iodine solution was used for dressing. Patients and their families were educated on pin care and hygiene, with instructions to promptly report any signs of infection, such as swelling, erythema, purulent discharge, or severe pain at the pin site. Patients with positive culture results were treated with antibiotics for 6 weeks, starting with a 2 - week intravenous course followed by oral administration. Follow - up was conducted weekly for the first month to ensure proper wound and pin site care, then at intervals of 6 weeks, 3 months, 6 months, and 12 months for radiological assessment. After initial rehabilitation in the ward, patients were instructed to continue with active and passive ROM exercises of the shoulder and elbow 3 to 4 weeks postoperatively. Gradual strengthening exercises for the shoulder, elbow, wrist, and hand were introduced as tolerated. Ideally, physiotherapy sessions were scheduled 2 to 3 times per week; however, due to the high patient volume in the outpatient physiotherapy department, sessions were limited to once every 2 weeks. Patients were advised to perform home - based physiotherapy exercises twice daily, in the morning and evening.

3. Result

The study cohort consisted of six patients, with a median age of 32.5 years and an average age of 32.17 years, ranging from

20 to 42 years. All patients were right - hand dominant, with five sustaining fractures on the right humeral and one on the left. Each injury resulted from a motor vehicle accident.

Of the six fractures, two were open fractures at the time of injury, while the remaining four were closed fractures. Additionally, half of the patients (50%) had undergone prior internal fixation with plates and screws. This subgroup included three patients who required secondary intervention following initial treatment failure. The cohort also comprised an equal distribution of acute fractures and non - unions, with three cases of acute fractures and three cases of non - union managed during this series.

Union Rates and Infection

Union was achieved in all six patients (100%), including those with associated infections, all of whom were successfully cured. In every case, the wounds were closed primarily and healed well without complications. The mean time to union was 4.5 months, with a range of 3 to 6 months following the application of the LRS.

The mean duration for frame removal was 8.42 months, ranging from 5 to 16 months, which is notably longer compared to other studies that report an average of 5.5 months. There are two main reasons for this extended duration. First, follow - up appointments were not conducted on a monthly basis, particularly after the third clinic visit. To optimize outcomes, more frequent follow - up, ideally on a monthly basis with radiological assessments, is recommended. Second, some patients requested to delay the removal of the LRS due to concerns about the potential risk of refracture.

In terms of infection management, success was defined by the absence of recurrent infections or sinus discharge throughout a follow - up period that extended from 12 to 40 months. Given the uncertainty surrounding the potential for future infection reactivation, the absence of a discharging sinus for at least 12 months was considered a successful outcome.

Figure 3: Example one of the patients with LRS in-situ without any problem with range of motion

Functional Outcome

This study evaluates the functional outcomes of patients following treatment, using three primary assessment tools: the range of motion (ROM) of the shoulder and elbow, the ROWE score for shoulder function, and the DASH (Disabilities of the Arm, Shoulder, and Hand) score for overall upper limb assessment. The ROM was assessed post - treatment, with full ROM defined as the ability to move the joint through its entire expected range. Patients who did not achieve this standard were recorded as having movement limitations. [19] The ROWE score was utilized for shoulder function assessment, as described by Rowe et al. (1988), categorizing outcomes as excellent (85 - 100 points), good (70 - 84 points), fair (50 - 69 points), and poor (<50 points). [25] The DASH score, a 30 - item self - reported questionnaire, was employed to assess the ability to perform various upper extremity activities, with patients rating their difficulty and interference with daily life on a 5 - point Likert scale. [26] This tool, validated in multiple languages and for various upper extremity disorders, provided comprehensive insights into upper limb function. [27] Assessments were conducted both before the definitive fixation with the LRS and after the completion of the rehabilitation regimen.

Results revealed notable improvements in both shoulder and elbow ROM. Specifically, after the removal of the LRS, 4 out of 6 patients (67%) regained full shoulder ROM, while the remaining 2 patients (33%) experienced restricted abduction and forward flexion (90 - 100 degrees) and limited extension (30 degrees). Similarly, in terms of elbow ROM, 4 patients (67%) achieved full ROM. Among the 2 patients who did not, one was unable to fully extend the elbow, and the other exhibited significant limitations, with flexion restricted to 90 degrees and limited internal and external rotation. These findings highlight the overall positive impact of the intervention on joint mobility.

Further, the ROWE score assessments indicated that 4 patients (67%) achieved an "excellent" outcome, with 1 patient (17%) falling into the "good" category. Only 1 patient (17%) scored in the "poor" category. These results suggest that 83% of patients exhibited outcomes rated as "good" or better, demonstrating the intervention's efficacy in improving shoulder function. The DASH score provided a more holistic view of upper limb functionality. The mean pre - operative DASH score was 69.9 units (range: 56 - 88), and post - treatment, this score improved significantly to 6.7 units (range: 0 - 17.5). The mean difference between pre - and post - treatment scores was 63.25 units, indicating substantial improvement in upper limb function.

A paired t - test was performed to evaluate the statistical significance of the change in DASH scores. The t - statistic was 21.29, with a p - value of 0.00000424, which indicates a statistically significant improvement ($p < 0.05$). Therefore, the results provide strong evidence that the intervention using LRS had a significant positive impact on patient outcomes as measured by the DASH score. To further determine the clinical significance of the observed changes, the Minimal Clinically Important Difference (MCID) was estimated using both distribution - and anchor - based approaches. The distribution - based approaches included the effect size method, which suggested an MCID of 6.20 points, and the Standard Error of Measurement (SEM), which indicated an MCID of 3.92 points. An anchor - based approach, using a commonly accepted threshold for the DASH score, suggested an MCID of approximately 10 points. By triangulating these approaches, the estimated MCID for the DASH score was 6.71 points. Given that the mean difference between pre - and post - treatment scores (63.25) substantially exceeds this MCID, it can be concluded that the changes observed are not only statistically significant but also clinically meaningful.

4. Discussion

This study demonstrated a 100% union rate in patients with complex humeral fractures managed using the Limb Reconstruction System (LRS), with a mean time to union of 4.5 months. Functional outcomes assessed via the DASH and ROWE scores showed significant improvements, with the mean DASH score decreasing from 69.9 pre - operatively to 6.7 post - treatment, indicating a substantial enhancement in upper limb functionality. These findings underscore the potential effectiveness of LRS in managing complex humeral fractures.

The union rate observed in this study aligns with previous reports on external fixation methods for humeral fractures. While traditional methods like plate fixation and intramedullary nailing have reported union rates ranging between 80 - 95%, [28] our 100% success rate suggests that LRS may offer an advantage in cases with complex presentations, such as open fractures or infections.

Atalar et al. performed a retrospective analysis of 80 patients with humeral non - union who were treated using circular external fixators (35 patients), unilateral external fixators (24 patients), or plates (21 patients). Of the 52 patients who had previously undergone surgical management, 22 were treated with circular external fixators, 19 with unilateral external fixators, and 11 with plate fixation. Non - union was observed in one patient from each external fixation group, while no cases of non - union occurred among the patients treated with plates. [29]

Other option of treatment using Ilizarov external fixator reported by Tomic et al. reported on 28 cases of humeral non - union, including 21 patients with previously failed fixation. Following treatment with Ilizarov external fixation, all patients successfully achieved bone union.

The use of LRS in this case series was associated with a high rate of fracture union and significant functional improvement. The external fixator's ability to stabilize the fracture while allowing for axial dynamization seems to promote callus formation, contributing to the observed union rates. Furthermore, the LRS system facilitated early mobilization, which is crucial in preventing joint stiffness and promoting a return to function. In cases where internal fixation might pose a risk of infection or where the soft tissue envelope is compromised, LRS serves as a viable alternative, combining the benefits of both conservative and operative approaches.

One of the potential complications of external fixation is the risk of pin - track infections. However, in this series, no recurrent infections were observed during the follow - up period of 12 to 40 months. Strict adherence to pin care and hygiene protocols likely contributed to this outcome. Despite the extended mean duration for frame removal (8.42 months), patients did not exhibit signs of implant failure or non - union. The decision to prolong the duration of fixation was influenced by patient and clinical factors, including the desire to minimize the risk of refracture. Although longer fixation periods may increase the risk of complications such as pin loosening, careful follow - up and patient education on pin care played a pivotal role in minimizing adverse outcomes.

The high union rate and significant functional recovery observed in this study suggest that LRS is an effective option for managing complex humeral fractures, particularly in cases where traditional methods are contraindicated. The ability to maintain fracture alignment while permitting early joint mobilization addresses a key challenge in humeral fracture management. Additionally, the minimally invasive nature of LRS offers an advantage in reducing the risk of iatrogenic complications commonly associated with open surgical procedures, such as radial nerve palsy and surgical site infections.

This study's strengths include the use of validated functional outcome measures and a comprehensive follow - up period to assess both union rates and long - term functional outcomes. However, the small sample size and the retrospective design limit the generalizability of the findings. Additionally, the absence of a control group makes it challenging to directly compare the outcomes of LRS with other fixation methods. Future prospective studies with larger cohorts are necessary to confirm these findings and establish LRS as a standard treatment modality for complex humeral fractures.

5. Conclusion

In conclusion, the treatment resulted in significant improvements in shoulder and elbow function, as evidenced by the ROM, ROWE, and DASH scores. Both statistical and clinical analyses confirmed the effectiveness of the intervention, with the change in DASH scores far surpassing the estimated MCID. This study contributes valuable insights into the efficacy of LRS in managing complex humerus fractures, particularly in cases complicated by infection or failed prior interventions, offering an alternative to more invasive surgical methods.

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