# Ilizarov Treatment of Infected Nonunions of the Distal Humerus After Failure of Internal Fixation: An Outcomes Study

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**Objective:** To report the functional outcomes of Ilizarov treatment of infected nonunion of the distal humerus.

**Design:** Prospective case series.

**Setting:** Tertiary referral center.

**Patients:** Between July 1998 and August 2003, 6 consecutive patients (age 33 to 73 years) were referred to us with an infected nonunion of the distal humerus following failure of open reduction and internal fixation. The average time from initial injury to presentation with the nonunion was 27 months (range, 6 to 99 months). The average number of prior surgeries was 2.8 (range, 1 to 4).

**Intervention:** Hardware removal, ulnar nerve neurolysis, 1 stage debridement, autogenous bone grafting, and application of an Ilizarov external fixator with acute compression in the operating room followed by slow gradual compression (0.25–0.50 mm per day) for several weeks postoperatively.

**Measurements:** Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire; SF-12 Physical Component Scale (PCS); Brief Pain Inventory; quality-adjusted life years.

**Results:** All patients attained bony union. One patient refractured 3 weeks after removal of the external fixator following a fall and ultimately underwent total elbow arthroplasty. At an average follow-up of 4.1 years (range, 2 to 7 years), none of the remaining 5 patients had undergone any additional surgery on their arm and all were free of infection. For these 5 patients, significant improvements were seen in standardized DASH scores (42% initially to 78% at follow-up, $P = 0.017$), worst pain intensity ratings (5.4 initially to 0.8 at follow-up, $P = 0.007$), and SF-12 PCS scores (37 initially to 44 at follow-up, $P = 0.041$). On average, the pretreatment to posttreatment improvement was equivalent to 3.8 quality-adjusted life years.

**Conclusions:** Ilizarov treatment of infected distal humeral nonunions that have failed internal fixation restores function, decreases pain, and improves quality of life. The Ilizarov method should be considered a primary treatment option for this disabling and difficult clinical problem.

**Key Words:** fracture, ununited, external fixation, internal fixation, outcomes

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## INTRODUCTION

Distal humeral fractures account for approximately 4% of all fractures.[1] Approximately 2% to 5% of these fractures progress to nonunion.[2,3] Distal humerus fractures that progress to nonunion tend to be difficult to bring to union.[4–6]

Failure of bony union following a distal humerus fracture is painful and disabling. Patients are unable to use the limb for loaded activities and often have intractable pain. A distal humerus nonunion can persist for years despite appropriate medical and surgical care.[5,7] The presence of infection with a distal humeral nonunion increases the treatment challenge and is associated with lower rates of successful bony union, limited fixation options, and worse functional outcomes.[8,9]

The purpose of this study was to report the outcomes of the Ilizarov method in the treatment of infected nonunions of the distal humerus that have failed 1 or more prior attempts at open reduction and internal fixation (ORIF). The Ilizarov method has been shown to be effective in the treatment of nonunions of the humeral diaphysis.[10] The Ilizarov method has also been used in the treatment of supracondylar fractures[11–13] and in the treatment of cubitus varus and valgus deformities.[14] To the best of our knowledge, a consecutive series of infected distal humeral nonunions treated using the Ilizarov method has not previously been reported in the English language medical literature.

## PATIENTS AND METHODS

The patients included in this study had infected distal humeral nonunions that had failed 1 or more attempts at ORIF. Between July 1, 1998 and August 4, 2003, 19 consecutive patients were referred to our center with nonunions of the

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distal humerus. Thirteen patients had aseptic nonunions and were excluded from the current study.

The study group of the current investigation was 6 consecutive patients with infected distal humeral nonunions who had failed 1 or more attempts at ORIF. All 6 nonunions were extraarticular. All 6 patients were prospectively enrolled into this outcomes study and underwent Ilizarov treatment at our facility. There were 4 women and 2 men with an average age of 49.9 years (range, 33 to 73 years). The nonunion was in the left arm in 3 patients. The patients were referred to us an average of 27 months (range, 6 to 99 months) after their initial injuries. This study was approved by our facility's Institutional Review Board, and all subjects consented to participate.

The patients had undergone an average of 2.8 (range, 1 to 4) previous surgical procedures (Table 1). Five of the 6 patients had sustained an open distal humerus fracture at the time of the original injury. One of the patients (Case 2) had been injured at work. None of the patients had pending litigation regarding their injury.

The surgery was a 1-stage procedure that involved the following: (1) harvesting bone graft from the posterior iliac crest; (2) exploration and neurolysis of the ulnar nerve; (3) removal of retained hardware; (4) obtaining deep cultures; (5) debridement of the nonunion site including pulsed lavage irrigation (6 liters of normal saline); (6) iliac crest autogenous bone grafting of the nonunion site; (7) wound closure; (8) application of the Ilizarov external fixator (Fig. 1A); and (9) acute shortening of up to 2.0 cm via the Ilizarov fixator with immediate bone-to-bone contact at the nonunion site. Surgical exposure in all cases was performed using the prior incisions. Following debridement, none of the resulting segmental defects were larger than 2.0 cm; therefore shortening was acceptable in all cases.[15,16]

The Ilizarov external fixator configuration included a proximal arc fixed to the humeral diaphysis using 2 half pins; a full ring fixed to the distal humeral diaphysis–metaphysis using 1 half pin and one 1.8 mm olive wire; and a 5/8 ring fixed to the distal metaphyseal or epiphyseal fragment using three 1.8 mm olive wires. The open portion of the 5/8 ring was positioned anteriorly to facilitate active elbow range of motion (Fig. 1).

We did use special precautions to avoid injuries to nerves. No paralytic agents were used during the operative procedure. When placing Ilizarov transosseous implants, care was taken to look for motor flickers to the wrist, hand, and fingers, indicating proximity to a nerve. If motor flickers

**TABLE 1.** Patient Demographics and Comorbidities

| Case Number | Sex | Age (yr) | Original Injury Open | Time from Injury to Presentation (months) | Number of Previous Surgical Procedures | Comorbidities | Infectious Organism at Nonunion Site at Presentation | Ulnar Neuropathy at Presentation | Time in Ilizarov External Fixation |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Female | 47 | Yes | 7 | 4 | • None | *Enterococcus faecalis* | Yes | 5.2 months |
| 2 | Male | 73 | Yes | 6 | 3 | • Hypertension<br>• Mitral valve prolapse | *Staphylococcus aureus* | No | 7.6 months |
| 3 | Male | 33 | Yes | 35 | 4 | • Radial nerve transected at injury, underwent graft during initial injury surgery | *Staphylococcus aureus* | Yes | 7.4 months |
| 4* | Female | 52 | Yes | 99 | 4 | • Hypertension<br>• Clinical depression<br>• History of smoking (25 pack-years)<br>• Chronic obstructive pulmonary disease<br>• Lung cancer | *Staphylococcus aureus* | No | 1. 6.8 months<br>2. 11.7 months |
| 5 | Female | 61 | Yes | 7 | 1 | • Coronary artery disease<br>• Hypertension<br>• Hypothyroidism | *Blastomyces dermatitidis* | No | 4.7 months |
| 6 | Female | 34 | No | 6 | 1 | • None | *Staphylococcus aureus* | Yes | 6.4 months |

| Case Number | Follow-up After Removal of Ilizarov External Fixator | Brief Pain Inventory Intensity | | Brief Pain Inventory Interference | | Standardized DASH Score | | SF-12 Physical Component Summary Score | |
|---|---|---|---|---|---|---|---|---|---|
| | | Presentation | Final | Presentation | Final | Presentation | Final | Presentation | Final |
| 1 | 82.7 months | 4.0 | 1.0 | 4.4 | 0 | 57% | 93% | 41.3 | 50.1 |
| 2 | 42.2 months | 0.8 | 0.0 | 2.9 | 0 | 51% | 50% | 38.7 | 33.8 |
| 3 | 42.7 months | 1.5 | 0.3 | 3.7 | 0.3 | 51% | 81% | 30.6 | 40.2 |
| 4* | 53.9 months | 6.3 | NA | 8.6 | NA | 35% | NA | 23.0 | NA |
| 5 | 24.2 months | 4.8 | 0.0 | 6.4 | 0 | 41% | 83% | 40.4 | 53.4 |
| 6 | 54.8 months | 6.0 | 1.0 | 8.1 | 0.9 | 13% | 82% | 35.1 | 44.5 |

*Case 4 ultimately required a total elbow arthroplasty.
NA, Not applicable.

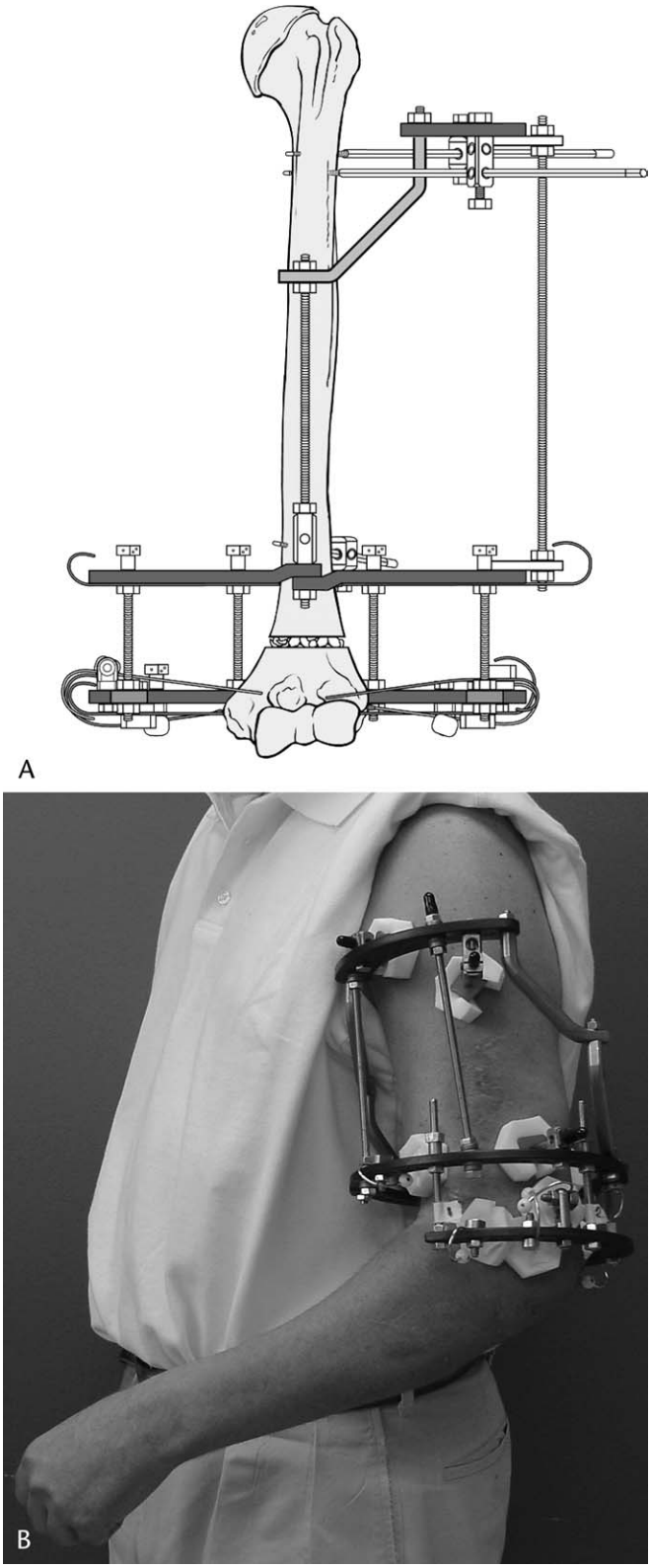


**FIGURE 1.** Illustration (A) and clinical photograph (B) of a patient (Case 3) showing the configuration of the Ilizarov external fixator for treatment of infected nonunion of the distal humerus.

occurred during drilling, the implant was removed and repositioned.

Postoperatively, all patients were administered 6 weeks of intravenous antibiotics as per the outcomes of the intraoperative cultures (Table 1). The Ilizarov external fixator was used to apply monofocal compression at an initial rate of 0.25 mm to 0.50 mm per day for 2 to 4 weeks. Following this, the rate was decreased to 0.25 mm 1 to 3 times per week.

Patients and their families were instructed in pin care cleaning and hygiene. Each pin site was cleaned once or twice daily with a 0.5% chlorhexidine solution. The pin sites were covered with sterile dressings, which were changed after pin cleaning or showering. The pin sites were inspected at each clinical visit, and patients were instructed to call the office immediately if swelling, erythema, purulent drainage, or severe pain was noted at any pin site.

Postoperative rehabilitation included active and active-assisted range of motion beginning on the first postoperative morning. Passive range-of-motion exercises and joint mobilization of the elbow were incorporated into the rehabilitation program as tolerated, usually within the first 2 weeks following surgery. Physical therapy modalities were used to manage symptoms. Gradual strengthening exercises for the hand, wrist, elbow, and shoulder were added during the outpatient rehabilitation during the compression and consolidation phases of treatment. All patients attended regular therapy sessions, usually 2 to 3 days per week, and were instructed to perform a home exercise program twice a day.

Patients returned to the clinic every 2 to 4 weeks for monitoring of compression rate and bony healing. The Ilizarov external fixator was removed when there was evidence of bony union. Healing occurs during Ilizarov compression via direct osteonal healing and medullary healing, without visible callus formation. In addition, the radiopaque external fixator construct often obscures the nonunion site on plain radiographs. Consequently, it was often difficult to assess healing on 3 of 4 cortices, as described by Heckman and colleagues.[17] Thus, computed tomography (CT) scans were obtained every 45 to 90 days, depending on the progression of bony healing. Bony union was defined as bridging of greater than 25% of the cross-sectional area of the nonunion site.[15] We usually removed the external fixator 30 to 45 days after the CT scan showed bridging of greater than 25% of the cross-sectional area. Our conservative approach to frame removal is driven by our belief that it is better to leave the frame on for a few days too long than to remove it 1 day too early.

## PATIENT EVALUATION

Patients were evaluated by clinical examination and with outcomes surveys. As part of an ongoing outcomes initiative at our facility, all patients had been enrolled in this study and evaluated prospectively at presentation and at follow-up using clinical information and outcomes questionnaires. The most recent follow-up was an average of 4.1 years (range, 2 to 7 years) after removal of the Ilizarov external fixator.

The subjects completed 5 outcomes surveys: the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire;[18,19] the Brief Pain Inventory;[20] the Medical

Outcomes Survey Short Form 12 (SF-12);[21,22] the Quality of Life rating scale; and the Time Trade-Off questionnaire.[23] The outcomes data were collected using a computer system in the clinic of the treating orthopaedic surgeon.

The clinical and radiographic evaluation was performed at the most recent follow-up visit to the clinic. The clinical measures were evaluated and recorded by the treating orthopaedic surgeon. Active range of motion of the elbow was recorded. Anteroposterior (AP) and lateral radiographic views of the entire humerus were obtained and evaluated to assess healing at the injury site. Radiographic healing at follow-up was determined by (1) absence of a radiolucent line at the original fracture site and (2) healing on at least 3 of the 4 cortices as described by Heckman.[17]

Descriptive statistics were computed for all variables. Repeated measures analysis of variance was used to determine whether improvement had occurred in the outcomes ratings from before Ilizarov treatment to final follow-up. Utilities and improvement in quality-adjusted life years (QALY) was computed using the Time Trade-Off ratings and the patients' life expectancies, as estimated from standard life tables for the U.S. population.[24] Utilities are statistics that represent an individual's preference for a particular outcome as expressed in a scale bounded by 0 for death and 1 for perfect health.[23,25] All analyses were performed with Microsoft Excel 2002 (Microsoft, Redmond, Washington) and SPSS 14.0 (SPSS, Chicago, Illinois). Statistical significance was set at $P = 0.05$.

## RESULTS

All patients achieved bony union. All patients were free of infection at the most recent follow-up. None of the patients have been lost to follow-up.

One patient (Case 4), who presented having failed 3 previous attempts at internal fixation, fractured through the nonunion site during a fall 3 weeks after removal of the initial Ilizarov external fixator. A second Ilizarov external fixator was placed and compression was applied until solid bony union was again obtained. This patient ultimately required a total elbow arthroplasty for severe and painful posttraumatic arthritis 20 months after the second Ilizarov external fixator had been removed. This patient's final outcomes survey data were not included in the group analysis because those measures would reflect an outcome of total elbow arthroplasty, which was not the purpose of this study. No other patient was excluded from the outcomes portion of our study.

No other patient had complications during treatment. There were no cases of pin site infection that required antibiotics or hospital admission, no instances of pin or wire breakage, no other refractures, and no clinical or radiographic evidence of recurrence or reactivation of the original infections.

Other than Case 4, no patient has had any type of humerus or elbow surgery or contracture release since discharge from our care. The average time of Ilizarov external fixation was 192 days (range, 144 to 232 days). Standardized DASH scores improved significantly from 42.5% (range, 13% to 57%) at presentation to 77.5% (range, 50% to 93%) at the most recent follow-up ($P = 0.017$) (Table 1). Before Ilizarov treatment, the average reported worst pain was 5.4 out of a possible 10; at the most recent follow-up, the average reported worst pain was 0.8 ($P = 0.007$). The average of the Brief Pain Inventory's "intensity" items decreased from 3.4 out of 10 to 0.5 ($P = 0.014$); the average of the Brief Pain Inventory's "interference" items decreased from 5.1 out of 10 to 0.2 ($P = 0.002$) (Table 1).

The average SF-12 Physical Component Summary (PCS) scores improved from 37.2 points (range, 31 to 41) to 44.4 points (range, 34 to 53) ($P = 0.041$) (Table 1). Four of the 5 patients had improvements larger than the suggested threshold for a meaningful change in scores for individuals (5.3 points).[21]

Before Ilizarov treatment, the patients indicated that they would be willing to trade an average of 12% of their remaining lifespan in exchange for perfect health. This equates to a utility state of 0.88 (ie, 100%−12% = 88% = 0.88) for the quality of life in the nonunion state. At the most recent follow-up, none of the patients would trade any of their remaining lifespan in exchange for perfect health; the utility state for the quality of life after treatment was 1.00. Thus, the treatment improved quality of life by 12% (increase in utility as a result of treatment = 0.12). Using the patients' projected life expectancies, this pretreatment to posttreatment difference was equivalent to 3.8 quality-adjusted life years per patient—that is, on average each patient gained the equivalent of an additional 3.8 years of perfect health after undergoing treatment with the Ilizarov method (Fig. 2).

The arc of elbow range of motion improved from a pretreatment average of 67 degrees (range, 55 to 75) to a posttreatment average of 81 degrees (range, 70 to 100). Four of the 5 patients gained motion, and 1 patient had no change in motion. All patients had at least 95 degrees of flexion, and all but 1 patient had extension to 30 degrees or better; 1 patient had an extension lag of 45 degrees.

Three patients had clinical signs of ulnar neuropathy on presentation, including weakness of the intrinsic muscles of the hand, paresthesia of the fourth and fifth digits, Tinel's sign elicited by tapping at the medial elbow, or abnormal nerve conduction velocity. Following our treatment protocol, these 3 patients had complete resolution of the signs and symptoms associated with ulnar nerve involvement.

## DISCUSSION

In the current series, all patients achieved bony union, decreased pain, and had after treatment with the Ilizarov method for infected distal humeral nonunion. The group of patients also had improvement in upper-extremity function and health-related quality of life. One patient refractured after removal of the initial Ilizarov external fixator and ultimately required total elbow arthroplasty following successful union in a second Ilizarov fixator. No other patient has undergone any additional surgical procedures.

Treatment of infected nonunions, particularly those that have failed multiple attempts at internal fixation or that have significant deformity, is complex.[16,26] Distal humeral nonunions are often complicated by elbow contracture, articular deterioration, poor bone stock, retained hardware, and ulnar nerve problems.[9,13,16] Infected humeral nonunions present many challenges relative to uninfected cases, including lower rates of

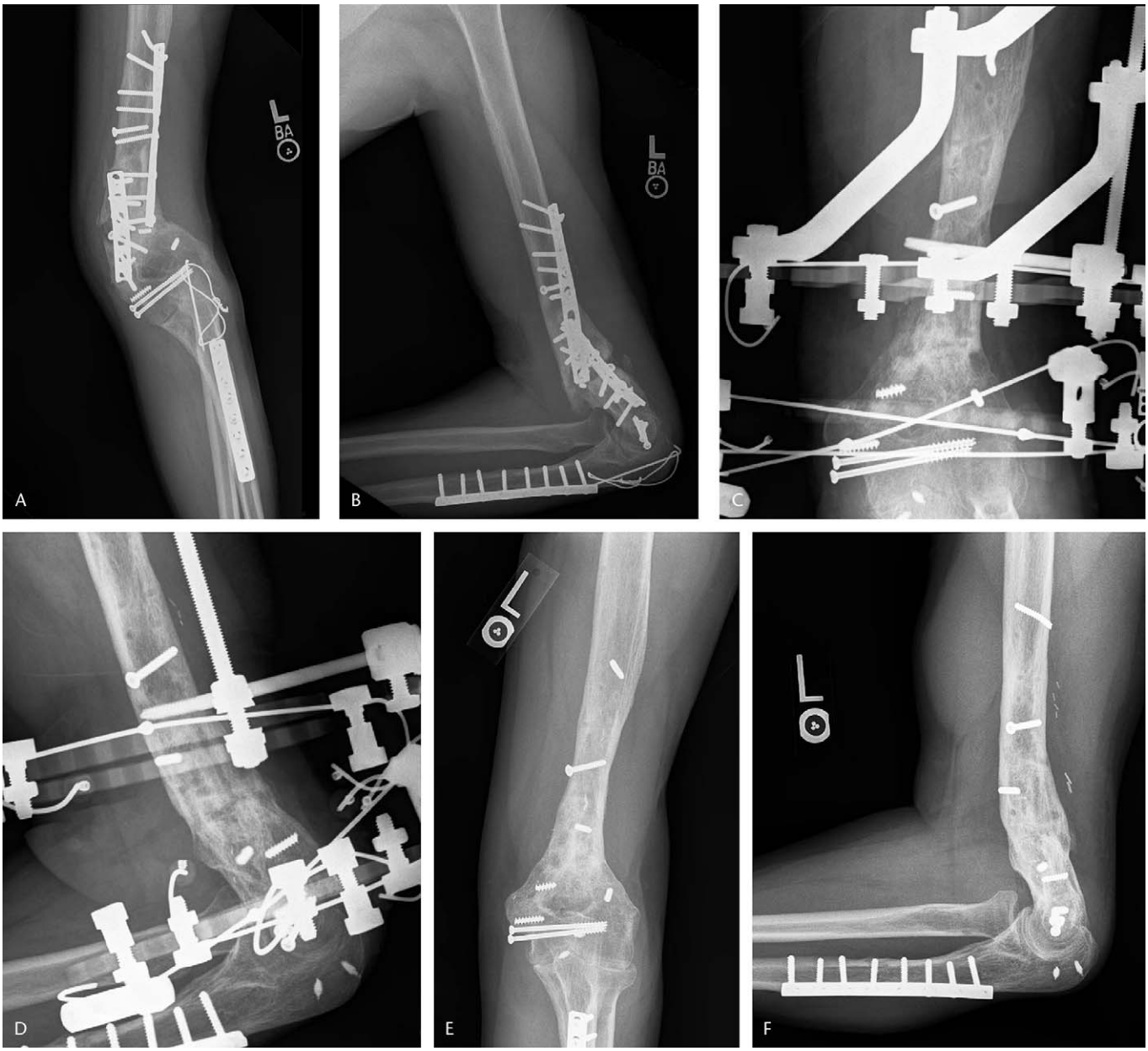


**FIGURE 2.** A and B, Presenting anteroposterior and lateral radiographs of an infected (grossly purulent) nonunion of a 33-year-old man (Case 3) 35 months after an open fracture of the distal humerus that was initially treated elsewhere by plate and screw fixation. The patient had undergone 1 attempt at plate and screw fixation and 1 bone graft procedure for treatment of his nonunion prior to being referred to us. At presentation, he rated his maximum pain as 6/10, had a DASH score of 51%, and self-rated his quality of life as ''good.'' C and D, Radiograph during treatment showing compression at the nonunion site. E and F, Final radiographic result showing bony union following 224 days of Ilizarov external fixation. At 42 months follow-up, the patient had a 90 degree arc of motion with flexion to 110 degrees, no evidence of infection, a maximum pain of 1/10, a DASH score of 81%, and self-rated his quality of life as ''very good'' with a gain of 4 quality-adjusted life years.

successful bony union, joint proximity, limited fixation options, and lower functional outcome.[8,9]

There is an acknowledged lack of information in the medical literature regarding clinical decision-making in the treatment of supracondylar humeral nonuions.[9] Many treatment options have been described, including ORIF with plates and screws,[2,3,27–29] intramedullary nailing with interfragmentary wiring,[30] elbow arthroplasty,[31] and free vascularized bone grafting.[32]

ORIF is generally recommended for treatment of uninfected nonunions in younger, more active patients who have good bone stock at the injury site.[4,16,31] We use plate and screw fixation for cases that have not had prior operative treatment or cases that have had prior operative treatment but

are free of infection and have fracture fragments that are amenable to plate and screw techniques. ORIF may be contraindicated in infected cases, thus limiting the available treatment options.

Our clinical outcomes with the Ilizarov method in infected cases are comparable to those of ORIF in uninfected cases. The rate of bony union following ORIF in the treatment of uninfected distal humeral nonunions has been reported to range from 64% to 100%.[4,6,28–30,33–35] Our results are in stark contrast to those of Ring and colleagues, who reported on 5 patients with infected distal humerus fractures who were treated with static compression using a thin-wire external fixator; 1 patient had also received a vascularized fibular bone graft.[13] Four of the 5 patients in their series required a second operative procedure (ORIF, bone graft, or both) to achieve bony union; the fifth patient did not achieve bony union and refused further operative intervention.[13] All 6 patients in our series achieved bony union after treatment with Ilizarov gradual compression. Ilizarov treatment of distal humeral nonunions is technically demanding and is dependent on proper frame construction and mounting, implant selection and placement, preparation of the bony surfaces, and the application of slow gradual compression. It is likely that some or all of these factors contributed to the differences in results between our series and those of Ring et al.[13]

The arc of elbow motion following ORIF has been reported to range from 76 to 97 degrees.[4,6,28,29,33,34] The average arc of motion in our patients at follow-up was 81 degrees.

Many of the patients in the published ORIF studies underwent multiple contracture releases, sometimes in staged procedures, to attain their final range of motion. To date, none of our patients have elected to undergo contracture release to improve range of motion at the elbow. Our patients maintained elbow range of motion without having undergone soft-tissue releases. The use of a 5/8 distal ring on the Ilizarov external fixator allowed our patients to perform elbow range-of-motion exercises immediately after surgery.

Functional outcomes following treatment of infected distal humeral nonunions with the Ilizarov method were also comparable to those reported for treatment of uninfected cases by ORIF. Most previous studies report a relatively large increase in functional ability and decrease in pain, with 50% to 83% of patients having "excellent" or "good" subjective results.[4,6,33,34] Our patients also had large improvements in upper-extremity function, as indicated by the DASH, and overall physical health, as indicated by the SF-12 PCS scores. Pain intensity decreased substantially and no longer interfered with daily activities.

Our patients also experienced an improvement in health-related quality of life, a finding that to our knowledge has not been previously reported for distal humeral nonunions. Our patients' average improvement in quality of life was a gain of 0.12 from an initial utility state of 0.88 with nonunion to a final utility state after treatment with the Ilizarov method of 1.00. For perspective, the improvement in quality of life following total hip arthroplasty in 1 recent report was a gain of 0.36 from a baseline utility state of 0.50 to a final utility state after treatment of 0.86.[36] The final utility state of anterior cruciate ligament reconstruction averaged over a 7 year period has been reported to be 0.86, compared with the final utility state of 0.57 for nonoperative management of an anterior cruciate injury over the same time span, for a 0.29 difference in quality of life between operative and nonoperative management.[37] Utility state values can be used to estimate quality-adjusted life years and cost effectiveness of various treatments for a given condition, which can be used to assist in clinical decision-making.

The amount of foreshortening following treatment in our patients was less than 2.0 cm in all cases. Acute shortening of the upper extremity of 3 to 4 cm is generally well tolerated.[15,16] The relatively small amount of shortening in our patients did not appear to affect their clinical or functional outcomes.

ORIF techniques often include bone grafting, neurolysis, contracture release, or a combination of these adjunctive procedures.[6,28–30,34] Bone grafting stimulates the biology of the nonunion site. Neurolysis releases constrictions that may cause sensory or motor neuropathies, which are common in supracondylar nonunions. We also used autogenous bone grafting and neurolysis of the ulnar nerve in conjunction with Ilizarov external fixation. Contracture release is often used to facilitate restoration of elbow range of motion. We did not perform soft-tissue releases, either in conjunction with or following Ilizarov external fixation. All of the patients in the current series were treated with aggressive debridement and irrigation followed by bone grafting, wound closure, and Ilizarov application, all during the same trip to the operating room. An alternative approach might be several successive trips to the operating room for serial debridement, with bone grafting and Ilizarov application being performed on the final operative procedure. Although we cannot find fault with this alternative approach, we did not find it necessary in the current series.

In conclusion, Ilizarov treatment of infected distal humeral nonunion has been shown to restore function, decrease pain, and improve quality of life. At an average follow-up of 4.1 years, only 1 of the 6 patients in the current series has required later total elbow arthroplasty for severe arthritis. The Ilizarov method should be considered a primary treatment option for this disabling and difficult clinical problem.

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