Do Successful Surgical Results after Operative Treatment of Long-bone Nonunions Correlate with Outcomes?

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Abstract There has been increased emphasis on validated, patient-reported functional outcomes after orthopaedic interventions for various conditions. The few reports on these types of outcomes after treatment of fracture nonunions are limited to specific anatomic sites, limited by small numbers, and retrospective. To determine whether successful healing of established long-bone nonunions resulted in improved functional outcomes and reduction in patient-reported pain scores, we prospectively followed 80 patients. These patients had a mean of 1.4 surgical procedures before enrollment and a mean of 18 months had elapsed from previous surgery until enrollment. Baseline data and functional scores were obtained before intervention. Seventeen of the 80 patients (21%) had positive intraoperative cultures. At a mean of 18.7 months (range, 12–36 months), 72 (90%) nonunions

had healed. Patients with healed nonunions scored better on the Short Musculoskeletal Functional Assessment. Pain scores among all patients improved compared with baseline, but to a greater degree in patients who achieved healing by final followup. Our data suggest improvement in pain scores is seen in all patients after surgery, whereas successful internal fixation leads to improved function.

Level of Evidence: Level III, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Much has been written about the development, classification, and treatment of fracture nonunions [4, 5, 8, 10–13, 15–17, 20–30, 33–36]. Nonunion of a fracture is a known complication that has varying incidence depending on fracture type, location, and baseline patient factors. Factors such as excessive motion, avascularity, gap, and infection have been implicated as causes for development of an ununited fracture. Fracture nonunions of the upper and lower extremities typically are associated with pain and functional disturbance. Although functional outcomes have been well studied in various acute fracture patterns, relatively little information exists regarding the functional outcomes of patients who have fracture nonunions develop [3, 18, 19, 36]. When reported, some of the outcomes used are not validated or they address one joint and not the entire patient.

Several recent studies [2, 3, 31, 32, 36, 38] have reported patients with specific fracture nonunions with respect to treatment success and functional outcome. All of these studies had small numbers of patients and used various outcome measures to assess the effects of treatment.

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at NYU Hospital for Joint Diseases and The Jamaica Hospital Medical center.

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Ring et al. [36] reported improvement in shoulder Constant and Murley scores [6] after treating atrophic humeral nonunions with locked plates. In a small study of 11 patients, Reed and Mormino [31] reported improvements in American Orthopaedic Foot and Ankle Society scores from 29 to 89 points after plating of distal tibial nonunions. Brinker and O'Connor [3] reported 80% good or excellent results based on SF-12 [39] and American Academy of Orthopaedic Surgeons lower limb scores [14] after treatment of tibial nonunions with an Ilizarov apparatus. Although each of these studies had reasonable functional outcomes reported, none obtained pretreatment baseline levels of function to control for other factors seen in these patients and all used population norms for posttreatment comparison of function rather than the preinjury function of the patient.

To corroborate previous findings using retrospective data, we sought to determine whether there is a correlation between successful internal fixation of long-bone nonunions and improvement in pain scores and validated functional outcomes. We hypothesized (1) patient-reported functional and (2) pain scores would improve with successful healing after surgery for an established long-bone nonunion, and (3) certain patient demographics such as age, gender, infection status, or history of smoking could predict either success or failure with healing or recovery of function.

Materials and Methods

Between September 2004 and October 2006, we identified all 91 patients with long-bone nonunions in a prospective database. We excluded 11 patients, three who did not return after the index procedure and eight who had less than 12 months followup or with incomplete followup. This left 80 patients (88%), 21 (27%) with nonunions of upper extremity fractures and 59 (73%) with nonunions of lower extremity fractures. There were 40 female (50%) and 40 male (50%) patients. The mean age for these patients was 49 years (range, 18–86 years) and the mean body mass index of the cohort was 30 kg/m² (range, 19–46 kg/m²). Twenty-three cases were initially open fractures. The patients had a mean of 1.4 surgical procedures (range, 0–10) previously. A mean of 18 months (range, 2–204 months) elapsed from prior surgery to enrollment at our facility. Forty-five patients were treated at outside institutions (30 surgically and 15 nonoperatively) before presentation to our institution. Thirty-five patients were treated for an index fracture at our institution surgically (30 by a fellowship-trained trauma surgeon and five by other staff). Nonunion sites included 39 tibia or fibula (48.5%), 20 femur (25%), 12 humerus (15%), six forearm (7.5%), and

three clavicle (4%) fractures. Seventeen of these cases (21.3%) had positive intraoperative cultures at the time of surgery at our institution. The minimum followup was 12 months (mean, 18.7 months; range, 12–36 months). Our study consisted of a chart and radiographic review of prospectively collected data.

All patients were followed to determine resolution of their fracture nonunion. We collected: dates and anatomic sites of initial injury; documentation of initial soft tissue injury (open fracture or compartment syndrome); a detailed history of previous surgery, if present; history of previous infection; nonoperative modalities used; age; medical comorbidities; smoking status and history; and medications used. Each patient filled out a baseline Short Musculoskeletal Functional Assessment [37] (SMFA) form. Physical examination focused on the injured extremity. We examined the soft tissue envelope for integrity. The suspected nonunion site was palpated for areas of tenderness and gross motion and we used the standard visual analog scale (VAS) for pain on each patient.

We evaluated all patients with plain radiographs of the affected extremity and classified the nonunion according to the system of Weber and Cech as described by Brinker [1]. Fifty-three patients (66%) were classified as atrophic and 27 (34%) were classified as hypertrophic. We obtained computed tomography (CT) scans to confirm the nonunion in 24 patients (30%) when the diagnosis was not clear from plain radiographs and clinical examination. In addition, one patient was referred with MRI scans confirming nonunion. We evaluated all 65 patients (81%) with a history of previous surgery using baseline laboratory values that included erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and leukocyte count. In eight patients in whom infection was suspected owing to elevated serologies, a labeled nuclear study was obtained [7]. In all cases of revision surgery (65 nonunions), we obtained intraoperative cultures. We treated positive cultures with organism-specific antibiotics and obtained an infectious disease consultation.

All patients were treated surgically for their fracture nonunion. The method of treatment was left to the treating surgeon and based on personal preference. The following general principles were followed: patients were treated with internal fixation (if no previous surgery), revision internal fixation (if previous fixation was present) (Fig. 1), external fixation (if major deformity was present or if there was a preoperative suspicion for an infected nonunion), and some type of graft procedure, whether autogenous iliac crest or iliac crest aspirate with adjunct bone morphogenetic protein and an appropriate carrier [2, 9, 12, 13, 27, 29]. Although the definition of major deformity was somewhat subjective and depended on the anatomic site, we defined it as limb deformity that was grossly visible. In the cohort of patients

Fig. 1A–D A 32-year-old male pedestrian was struck by a motor vehicle and sustained an open tibial fracture. He was treated with an external fixator for the bony injury and a gastrocnemius flap for soft tissue coverage. He presented to us 8 months postsurgery with an atrophic tibial nonunion. The (A) AP and (B) lateral projections of the nonunion are shown. The patient underwent removal of the external fixator and wore a cast until the pin sites closed. Three weeks later, he underwent open reduction and internal fixation with an autogenous iliac crest bone graft and an implantable bone stimulator. Radiographs obtained at the 1-year followup reveal a healed nonunion. The (C) AP and (D) lateral projections of the healed nonunion are shown. The patient had an excellent clinical and functional result.

who did not have prior surgery, 60% had gross deformity, 66.7% had some motion at the nonunion site, and 100% had tenderness to palpation or motion at the nonunion site. In the cohort of patients who had previous surgery: 31% had gross deformity, 34% had some motion at the nonunion site, and 83% had tenderness to palpation or motion at the nonunion site. Two patients received an implantable bone stimulator as part of their surgery. Nineteen other patients were prescribed an external electrical bone stimulator for use after surgery. Compliance using this device was measured by verbal confirmation only.

Postoperatively, all patients with positive intraoperative cultures were treated with 6 weeks of organism-specific antibiotics under the care of an infectious disease specialist. Patients were followed with infection-specific laboratory tests, including ESR and CRP, until normalized as a measure of response to antibiotic treatment.

Patients were followed at routine postoperative intervals. We obtained followup functional scores at 3, 6, and 12 months after surgery with longer followup if possible. Complications were recorded. We considered a major complication as one requiring a return to the operating room.

Determination of healing clinically was made by the treating surgeon and based on clinical parameters, such as the absence of pain on weightbearing at the nonunion site if a lower extremity site, and radiographic criteria, defined as bridging of three of four cortices on orthogonal radiographic views at a particular followup. For upper extremity sites, the same radiographic criteria held with the absence of pain at the site with use of the extremity. In cases in which radiographic and clinical union were equivocal, we obtained a CT scan to confirm healing at the site. Fifteen of the 80 patients (19%) had postoperative CT scans to confirm union or nonunion. Of the 15 postoperative CT scans,

eight confirmed union whereas seven confirmed nonunion. For purposes of this study, healing was determined by the treating physician (NCT, KAE) based on radiographic and clinical parameters and supported by documentation from an attending radiologist's report. To confirm concordance of the diagnosis of radiographic union, all radiographs immediately postoperative through the latest followup were reviewed in a blinded fashion by the two senior authors (NCT, KAE), and two physicians (one attending orthopaedic traumatologist [RID] and one musculoskeletal radiologist [LR]) not associated with this article. Radiographic healing was reported as occurring by 3, 6, 12, 18, or 24 months, or not healed. We used Kappa statistics to assess the interrater agreement in the radiographic determination of healing. The kappa statistic for fractures that ultimately healed was 0.78). For fractures considered healed in less than 3 months the kappa was 0.41, for those considered healed in 3–6 months the kappa was 0.53, for those healed in 6–12 months the kappa was 0.44, and for those with longer healing times (12–24 months) the kappa was 0.27.

We used linear regression to compare the difference in pain (VAS) and function (SMFA) between patients who achieved healing and those who did not at each followup while simultaneously controlling for the baseline scores to account for baseline differences in pain and function. The regression coefficients for each covariate are presented along with their associated p values. Additionally, we controlled for the other covariates (nonunion type, age, use of a bone stimulator, and previous deformity) in these regression models. Patient observations were independent, and pain and function as described by the VAS and SMFA, respectively, were distributed normally. Stata® 10 statistical software (StataCorp LP, College Station, TX) was used for all analyses.

Results

The 72 patients (90%) who achieved healing and union did so by a mean of at least 5.8 months (range, 3–23 months) after surgery, with upper extremity nonunions documented as healed at a mean of at least 5.5 months (range, 3–12 months) and lower extremity nonunions documented as healed at a mean of at least 5.9 months (range, 3–23 months). Six lower extremity nonunions and two upper extremity nonunions (10%) failed to heal at an average followup of 15.8 months. Fifty-nine of the 72 patients (82%) who achieved healing did so after one procedure and 13 of 72 (18%) who eventually achieved healing did so after multiple interventions.

Overall function (SMFA) improved ($p < 0.0001$) in patients who ultimately achieved healing (Table 1).

Table 1. Pain and function scores

Outcome	Baseline	Followup	p Value
Pain (VAS; mm)			
All	5.2 (2.2)	3.0 (2.5)	< 0.0001
Union	4.9 (2.2)	2.8 (2.5)	< 0.0001
No union	6.7 (2.0)	4.0 (2.9)	0.004
Function (SMFA; points)			
All	39.0 (23.4)	25.7 (20.6)	< 0.0001
Union	36.7 (22.1)	22.9 (18.5)	< 0.0001
No union	57.2 (26.3)	47.7 (23.4)	0.28

Values are expressed as means, with standard deviations in parentheses; VAS = visual analog scale; SMFA = Short Musculoskeletal Functional Assessment.

Table 2. Change in SMFA function scores (regression coefficient) by risk factors

Risk factor	Regression coefficient	p Value
Healed (vs not healed)	−19.1	0.005
Upper extremity (vs lower extremity)	−11.9	0.016
Closed wound (vs open wound)	−4.7	0.321
Male (vs female)	−1.02	0.815
Compartment syndrome (vs its absence)	19.4	0.158
Nerve injury (vs no injury)	4.3	0.549
Smoker (vs nonsmoker)	−7.4	0.113

SMFA = Short Musculoskeletal Functional Assessment.

Patients who achieved healing of their nonunions scored a mean 19.1 points better on the SMFA than those who did not (Table 2). Patients with an upper extremity nonunion scored a mean 11.9 points better ($p = 0.16$) on the SMFA than patients who had a lower extremity nonunion.

Patient self-reported pain scores improved ($p < 0.0001$) from a mean of 5.2 to 3.0 at latest followup for all patients. Compared with baseline the pain score was improved regardless whether patients achieved healing of their nonunion (Table 1). Of the factors studied, only male gender independently predicted improved ($p = 0.02$) pain scores (Table 3).

Of the 17 patients with positive intraoperative cultures, 14 (82%) were treated successfully with intravenous antibiotics. The three patients in whom treatment of infections failed underwent removal of implants after healing and intravenous antibiotics. One patient was treated unsuccessfully and the infection is chronically suppressed with oral antibiotics and periodic débridement. When controlling for baseline pain and functional scores, patients treated for infected nonunions (positive cultures) had worse SMFA scores than those without infection: the bother index and function index were worse ($P = 0.004$ and 0.001 ,

Table 3. Change in VAS pain scores (regression coefficient) by risk factors

Risk factor	Regression coefficient	p Value
Healed (vs not healed)	−0.68	0.44
Upper extremity (vs lower extremity)	−0.81	0.22
Closed wound (vs open wound)	0.61	0.32
Male (vs female)	−1.32	0.02
Compartment syndrome (vs its absence)	1.45	0.42
Nerve injury (vs no injury)	0.60	0.52
Smoker (vs nonsmoker)	−0.93	0.13

VAS = visual analog scale.

respectively) in these patients at 1 year. In addition, long-term subjective pain was greater in the subset of patients with infected nonunions (Table 4).

We found no associations between tobacco use, patient age, body mass index, history of a previously open fracture, use of a bone stimulator, limb deformity, and nonunion classification with nonunion healing. Four of the eight patients (50%) who did achieve union at the latest followup had a history of infection at some point during their treatment. In addition, this group had a mean 3.4 previous procedures (range, 0–10 procedures).

Complications occurred in both groups. We performed 14 additional unplanned procedures in the patients who did not achieve union. Major complications in the group that did not achieve union included development of a neuropathic ankle in a patient treated for a fibular nonunion and below-knee amputations in two patients in whom attempts failed for limb salvage for chronic tibial nonunion. Thirteen of the 72 patients (18%) who did achieve union required more than one procedure to gain union. In the group who achieved healing, the following major complications were seen: one hematoma from the iliac crest site in a patient treated with an autogenous bone graft to a tibial nonunion that required irrigation and débridement; and two postoperative wound infections (one femur and one fibula), both having negative intraoperative cultures and requiring additional surgery. Complication rates between patients who achieved healing and those who did not were similar.

Discussion

There has been an increased emphasis on validated, patient-reported functional outcomes after orthopaedic interventions for various conditions. Although current orthopaedic literature has some reports of these types of outcomes after treatment of fracture nonunions, these studies are limited to specific anatomic sites, limited by small numbers, and retrospective. To determine whether patient-reported outcomes of function and pain were related to success of operative treatment of fracture nonunions or how these outcomes were affected by patient demographics and the development of complications, we examined two cohorts of patients at a similar time in their disease process.

The following limitations of our study must be considered. (1) The study lacked preinjury baseline functional scores. This information might have revealed that these patients did not get back to their preinjury level of function. These data, however, would be impossible to obtain and were not the focus of this study. (2) It is possible additional breakdown of the subgroups into bony segments might have further implications for outcomes related to the specific injury. We could not break down our functional outcomes by anatomic site because there would not have been enough patients in all groups to perform a meaningful analysis. (3) Not all nonunions are the same, as different anatomic locations may have certain implications. For instance, metaphyseal nonunions may have more impact on the joint than diaphyseal nonunions. We performed an analysis of these subgroups for pain and function at presentation by anatomic site. There were no differences for pain (VAS) and function (SMFA) based on baseline scores by anatomic site, nor were there differences in outcomes by anatomic site. (4) Longer followup might have shown a reduction in pain scores in patients who did not achieve healing or a decay in other outcomes with time. Our minimum of 1 year for all patients is accepted followup in a trauma population. As with acute fractures, once healed, there are few changes in function with time. As none of these nonunions was intraarticular, functional status attributable to arthritic change was unlikely. (5) We were limited somewhat in our ability to strictly identify patients we considered healed. This definition is somewhat subjective and based on

Table 4. Function and pain by infection status

Outcome*	No infection	Infection	p Value†
Followup SMFA function (points)	22.8 (18.8)	31.0 (20.3)	0.004
Followup SMFA bother index (points)	23.2 (24.7)	39.8 (34.7)	0.001
Postoperative pain (VAS; mm)	2.8 (2.5)	3.9 (2.8)	0.001

Values are expressed as means, with standard deviations in parentheses; * followup outcomes are adjusted for baseline outcomes; †p values from adjusted means are presented; SMFA = Short Musculoskeletal Functional Assessment; VAS = visual analog scale.

Table 5. Literature comparison

Study	Site	Number of patients	Outcomes used	Results	Mean length of followup (months)
Tomic et al. [38]	Humerus	28	Lammens system	28 good/excellent results regarding pain and function; healing times increased in women	76
Brinker and O'Connor [3]	Tibia	23 elderly (> 60 years)	SF-12 Brief Pain Inventory	80% of patients showed functional and pain improvements	38
Reed and Mormino [31]	Tibia	11	AOFAS score	All patients achieved healing; hindfoot scores increased from 29 to 89	22
Richmond et al. [32]	Tibia	32	None	29 ultimately achieved healing; no other outcomes reported	25
Ring et al. [36]	Humerus	24 elderly	Constant and Murley score	22 good/excellent results; all achieved union	12
Current study	Multiple	80	SMFA, VAS for pain	90% achieved healing; improvement in function and pain	18

AOFAS = American Orthopaedic Foot and ankle society; SMFA = Short Musculoskeletal Functional Assessment; VAS = visual analog scale.

individual practitioner guidelines. Numerous factors must be considered. We chose to accept the treating physicians' classification of healing based on their management of the patient's clinical history. We attempted to control for this by performing an interrater reliability measure of radiographic healing using blinded reviewers. The strengths of this study include the large number of patients identified at the same time of their disease state and extremity function-specific patient-reported outcomes.

We found all patients experienced a reduction in pain compared with preintervention levels regardless of healing status. In multivariate analysis, we found men to have reduced pain relative to women. Function as measured by the SMFA improved substantially in patients who achieved healing of their nonunions. Only site of injury was associated with improvement, as upper extremity nonunions improved more than lower extremity nonunions. Finally, presence of positive cultures (infected nonunion) was associated with worse pain and function scores.

Overall, 90% of patients achieved healing with established long-bone nonunions. We found a correlation between successful treatment of long-bone nonunions and improved functional outcome and patient-reported pain. Patients who were treated surgically for their long-bone nonunion had improvements in patient-reported pain regardless of nonunion healing status. In addition, all patients who achieved healing of their nonunion had improved functional scores as measured by the SMFA; those who did not achieve healing of their nonunions had an insignificant trend toward improvement. Finally, poorer functional scores and higher pain scores were associated with the presence of an infected nonunion. Although there is some evidence that correlates improved function with successful internal fixation, most are based on specific

anatomic sites in series with small numbers and without validated outcome measures (Table 5).

We cannot be sure why there was a reduction in pain experienced by patients who did not achieve healing of their nonunion. It may be that the effect of bony stabilization with an implant reduces enough motion at the nonunion site to effect a reduction in perceived pain. It also is possible a placebo effect after surgery may play a role in diminished pain scores. If either of these plays a role, the effect seen may diminish with time with further followup.

Our data corroborate those from the most recent studies of long-bone nonunions and suggest successful internal fixation of these injuries can lead to improved objective outcomes (radiographs) and improvement in patient-reported pain and level of function. The goal of surgery for a fracture nonunion is to achieve bony healing and restore the preinjury level of function for patients. We believe successful union is associated with improved function. However, decreased pain in patients who present with a symptomatic long-bone nonunion may occur regardless of final healing status of the bone. Men seem to identify pain relief in these cases more than women, and the presence of infection at any point in the patient's history portends failure of successful union.

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