



Risk Factors Associated With Nonunion After Elective Foot and Ankle Reconstruction: A Case-Control Study



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ABSTRACT

Postoperative nonunion is not uncommon in the lower extremity, and significant morbidity can be associated with nonunion of the foot and ankle after surgical reconstruction. For the purposes of the present study, we retrospectively reviewed and compared a cohort of patients who had undergone elective foot and ankle reconstruction to better assess the modifiable risk factors associated with postoperative nonunion. We hypothesized that the presence of endocrine and metabolic abnormalities are often associated with nonunion after foot and ankle surgical reconstruction. We formulated a matched case-control study that included 29 patients with nonunion and a control group of 29 patients with successful fusion to assess the prevalence of certain modifiable risk factors known to have an association with nonunion after foot and ankle arthrodesis. The modifiable risk factors assessed included body mass index, tobacco use, diabetes mellitus, vitamin D abnormality, thyroid dysfunction, and parathyroid disease. A statistically significant ($p < .05$) difference was found between the 2 groups for endocrine and metabolic disease diagnoses in the medical records of the 58 patients identified. Thus, 76% versus 26% ($p < .05$) of patients experienced nonunion in the endocrine disease group versus the nonendocrine disease group, respectively. Patients with vitamin D deficiency or insufficiency were 8.1 times more likely to experience nonunion (95% confidence interval 1.996 to 32.787). No statistically significant differences were found between the groups in terms of age, sex, tobacco use, body mass index, or procedure selection ($p = .56$, $p = .43$, $p = .81$, $p = .28$, and $p = 1.0$, respectively). A greater prevalence of endocrine abnormalities, in particular, vitamin D deficiency and insufficiency, was associated with nonunion after elective foot and ankle reconstruction. Patients with such abnormalities appear to have a greater risk of developing nonunion after arthrodesis procedures.

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Arthrodesis is a commonly performed procedure in the foot and ankle. Elective arthrodesis is performed by surgeons to address varying degrees of deformity and degenerative joint disease. The specific indications, techniques, and complications related to arthrodesis have been well described for the anatomic zones of the lower extremity, including the forefoot, midfoot, hindfoot, and ankle (1–13). A specific complication that remains one of the most challenging dilemmas after attempted arthrodesis is postoperative nonunion. The development of nonunion after elective foot and ankle

reconstruction can lead to significant patient morbidity and has been shown to increase the usage of costly healthcare resources (14). Frequently, such patients require additional nonoperative and surgical therapeutic interventions to promote healing of the arthrodesis site (Fig. 1). Patients can experience physical, emotional, and financial sequelae and require extended convalescence resulting from treatment of a painful nonunion.

Preventative screening algorithms and formalized assessments that recognize patient risk factors are frequently reported topics in medical studies (15,16). Preoperative screening affords an opportunity to identify and correct certain modifiable factors before the associated complications can occur. Some published data have focused on nonunion of the lower extremity and described modifiable risk factors that can be screened and optimized before reconstruction is attempted (17,18). Tobacco use, diabetes mellitus, nutritional deficiencies, poor vascularity, and certain pharmaceutical regimens have

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Fig. 1. (Top) Nonunion occurring after ankle joint arthrodesis for severe tibiotalar arthritis and deformity in a patient with juvenile rheumatoid arthritis. (Bottom) Revision in the form of tibiotalarcalcanal arthrodesis and endocrinology-guided medical optimization was performed.

been shown to potentiate a patient's risk for complications after lower extremity surgery (13,14,17–25).

We performed a case-control study of patients who had undergone elective foot and ankle reconstruction by way of arthrodesis at our institution from 2011 to 2014. The purpose of the present study was to compare the prevalence of certain frequently cited modifiable risk factors such as body mass index (BMI), tobacco use, and endocrine disease, including diabetes mellitus, vitamin D abnormality, thyroid dysfunction, and parathyroid disease, in subjects who had either experienced postoperative nonunion or successful arthrodesis. We hypothesized that the prevalence of endocrine disease (vitamin D abnormality, thyroid dysfunction, parathyroid disease, and diabetes mellitus) would be high in the medical records of our nonunion group, with a significantly greater prevalence of such factors compared with the successful arthrodesis group.

Patients and Methods

We used an institutional clinical practice database and the appropriate International Classification of Diseases, 9th revision, and Common Procedural Terminology codes to identify patients who had undergone arthrodesis procedures of the foot and/or ankle and experienced postoperative nonunion from January 1, 2011 to December 31, 2014. Additionally, we identified a cohort of patients from the same clinical practice database who had undergone arthrodesis procedures of the foot and/or ankle during the study period but had not developed nonunion as the control group. The control group patients were chosen at random in a 1:1 ratio for comparison with the case group. Verification of procedure selection, the presence of nonunion, progression to successful union, medical and social history, and postoperative course was confirmed by a comprehensive review of the hardcopy and electronic medical records for all evaluated subjects. The institutional review board of our institution approved the present study.

The prevalence of patient-related variables and modifiable risk factors assessed between the 2 groups included age, BMI, tobacco use, and endocrine disease (i.e., vitamin D abnormality, thyroid dysfunction, parathyroid disease, diabetes mellitus).

The inclusion criteria were as follows: adult subjects aged >18 years; surgical procedures occurring from January 1, 2011 to December 31, 2014; a minimum of 1 year of follow-up data available from the surgery date; and surgical reconstruction of foot and ankle pathology (deformity, instability, primary and secondary arthritis) in the form of joint arthrodesis. The exclusion criteria were as follows: subjects not meeting the inclusion criteria; incomplete medical and/or surgical records; and deformity caused by Charcot neuroarthropathy.

The basic guidelines set forth by the Food and Drug Administration were used for clinical identification of those with nonunion. These included the absence of bony trabeculation across a surgically fractured surface for 9 months or the lack of progressive signs of healing for 3 consecutive months (19). Nonunion was diagnosed from serial plain film radiographs and advanced imaging modalities such as computed tomography scanning. Also, the senior authors (K.R.S., A.R.C.) consistently used a set range of 8 to 12 weeks to define “successful, uncomplicated” radiographic union in their practices. A combination of plain film radiographs and computed tomography were used to determine osseous bridging across the arthrodesis site. Successful union in the clinical setting was determined in all cases by the senior authors (K.R.S., A.R.C.).

The fixation techniques consisted of compression screws, locking plates and screws, and intramedullary nails. Autogenous bone grafts, allogenic bone grafts, and orthobiologic agents (e.g., demineralized bone matrix, bone marrow aspirate, platelet-rich plasma, osteogenic/osteoprogenitor stem cells, bone morphogenic proteins) were used indiscriminately between the 2 groups assessed in the present study.

The characteristics and other variables obtained from the review of the 2 groups were analyzed using appropriate statistical methods (e.g., Fisher's exact test, paired *t* test, Pearson's chi-square test, Mann-Whitney *U* test, likelihood ratio test) with the assistance of a professional research statistician. Statistical significance was set at $p < .05$ for the reported data. These data are presented in Tables 1, 2, and 3.

Results

We identified a total of 34 adult male and female patients aged >18 years who had undergone foot and ankle reconstruction during the 3-year period and had developed nonunion. Of these 34 patients, 5 were excluded because they did not have 1-year postoperative follow-up data available. The remaining 29 patients (15 males and 14 females) met the inclusion criteria and their records were assessed further. The nonunion group was then matched against a control group of 29 randomly selected adult patients (12 males and 17 females) who met the inclusion criteria and had undergone foot and ankle reconstruction by way of arthrodesis with successful union. The total patient population included 58 patients (27 males and 31 females), matched 1:1 for 2 groups.

The mean age of the 58 patients was 54.5 ± 14.0 (median age 57.5, range 19 to 86) years. Of the 58 patients, 27 were male (46.6%) and 31 were female (53.4%). The female patients were slightly, but not significantly, older than the male patients (56 years versus 53 years).

The full assessment of the clinical, surgical, and radiographic records of the 2 groups revealed a statistically significant ($p < .05$) difference between the 2 groups for a diagnosis of an endocrine disease reported in the medical records. Of the 29 nonunion patients evaluated, 22 (76%) had an active diagnosis of endocrine disease, including vitamin D insufficiency or deficiency in 14, hypothyroidism in 2, and diabetes mellitus in 6. Of the 29 successful union patients (control group), 8 (26%) had an active diagnosis of endocrine disease, including vitamin D insufficiency or deficiency in 3, hypothyroidism in 4, and diabetes mellitus in 1. No patient in either group had a diagnosis of parathyroid disease reported in their medical record. Overall, 76% of nonunion subjects versus 26% of successful union subjects had a diagnosis of endocrine disease reported in their medical record.

Further analysis was performed to better assess the endocrine dysfunctions individually to determine their association with the nonunion outcome. Of the 58 patients, 41 (70.7%) did not have a diagnosis of vitamin D abnormality, 10 (17.2%) had vitamin D deficiency, and 7 (12.1%) had vitamin D insufficiency. The presence of vitamin D deficiency or insufficiency was significantly associated with the outcome of nonunion [$\chi^2(1) = 10.1; p = .002$]. Of the 29 patients with nonunion, 14 (48.3%) had either vitamin D deficiency or insufficiency. Of the 29 patients with successful union, 3 (10.3%) had either

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