Implantable Direct-Current Bone Stimulators in High-Risk and Revision Foot and Ankle Surgery: A Retrospective Analysis With Outcome Assessment

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Abstract

Efficacy and morbidity of a surgically implanted direct-current bone stimulator were evaluated in 38 patients (40 feet) with fracture nonunion or at high risk for nonunion; 14 of these patients had Charcot (diabetic) neuroarthropathy. Union occurred in 26 (65%) of the 40 feet; complications other than nonunion occurred in 16 feet (40%). Two amputations (5%) were performed in cases of intractable neuritis and deep infection. Of the 6 cases of deep infection (15%), 5 resolved with device removal, and the sixth case required below-knee amputation. Use of a bone stimulator in patients with diabetes may be problematic, but the device did not have any adverse effects in other high-risk patients.

In patients at risk for nonunion, orthopedists strive to improve biological and mechanical conditions to gain improved results. An implantable electric bone stimulator has been found to enhance the bone-healing environment biologically[1-4] by stimulating production of numerous growth factors, such as bone morphogenetic proteins, transforming growth factors, and insulinlike growth factor 2. Use of a surgically implanted direct-current (DC) stimulator in treating fracture nonunion and spinal fusions has been reported,[5-7] but bone stimulators were not used in foot and ankle surgery until recently. Possible advantages include continuous treatment for up to 6 months and a mesh cathode applied directly to the fracture or arthrodesis site, which maximizes the area of exposure to the electromagnetic field.

Previous investigators have had good results using bone stimulators in foot and ankle surgery. Successful treatment of a first metatarsal-cuneiform nonunion was reported with an implanted bone stimulator used in conjunction with bone grafting and internal fixation.[5] Other investigators have reported success using implantable bone stimulators with surgical treatment for nonunion of ankle arthrodesis[8] or with major risk factors for nonunion of ankle or hindfoot arthrodesis.[9] Outcome data are needed to begin to understand this complex treatment scenario.

In the investigation reported here, we retrospectively reviewed a series of patients at high risk for failed treatment (for whom bone stimulators were used as part of end-stage salvage treatment), including numerous patients with diabetes and Charcot neuroarthropathy. To determine whether use of bone stimulators is associated with adverse results, we compared these patients with similar patients (from previous studies at our institution) whose treatment did not include use of bone stimulators.

"Possible advantages include continuous treatment for up to 6 months..."

Materials and Methods

We identified 47 patients who had been treated with implantable DC stimulators by Drs. Myerson and Schon between 2000 and 2001. After obtaining study approval from our institutional review board, we contacted patients with a minimum follow-up of 12 weeks and obtained informed consent for study participation. Of these 47 patients, 9 were excluded (1 died, 2 had follow-up of fewer than 12 weeks, and 6 could not be contacted for follow-up, and either their x-rays or their chart was incomplete). The remaining 38 patients (22 men, 16 women; age range, 28-75 years) were eligible for study participation. Forty surgical procedures were performed with implantable DC stimulators. Eighteen patients (20 surgical procedures) were evaluated with physical examination and functional and radiographic assessment; for the other 20 patients (20 surgical procedures), who could not be contacted, charts and x-rays were reviewed. Charts were reviewed for demographic data, including age, sex, risk factors, diagnosis, surgical approach, use of bone autograft/allograft, clinical

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Table I. Procedures Reviewed, With Rates of Union and Nonunion

Procedure	Union	Nonunion	Total
Ankle arthrodesis	1	2	3
Midfoot arthrodesis	4	2	6
Other (pantalar, ankle + subtalar)	0	2	2
Subtalar arthrodesis	6	2	8
Tibial osteotomy	1	1	2
Triple arthrodesis	5	1	6
Tibiotalocalcaneal arthrodesis	9	4	13
Total	**26**	**14**	**40**

and radiographic union, and any associated postoperative complications or morbidity.

Fifteen patients (17 feet) were assessed with the Short Form Health Survey (SF-36),[10] a generic validated outcome score. Three patients did not answer one or more questions on this global instrument, and their forms were not assessed. Site-specific outcome scores used included American Orthopaedic Foot and Ankle Society (AOFAS) foot and ankle scores,[11] Ankle Osteoarthritis Scale (AOS) ankle scores,[12] and Foot Function Index (FFI) foot scores.[13] The AOS and the FFI are valid site-specific outcome measures. Standard x-rays of operated regions were also reviewed. Clinical success was defined as stable and nontender physical examination; stable x-ray with trabeculae crossing the fracture, arthrodesis, or osteotomy site; and no change in hardware position.

A short questionnaire was used to assess patient functional improvement and satisfaction. The questionnaire asked patients to evaluate whether they were functionally improved, were satisfied with the operation, would undergo the operation again, and would recommend the operation to a friend with a similar problem. Patients were asked if they noticed a prominence over the surgery site, if the prominence was painful, and, if painful, what its pain rating was based on a scale ranging from 1 (no pain) to 10 (severe pain). Patients with neuropathy were able to respond about pain because they were not numb to pain in general and because the area in question may have been above the neuropathy level.

To determine the effectiveness of implanted DC stimulators, we compared the treatment group with a control group of patients (data from the database of Drs. Myerson and Schon) with identical demographics, diagnosis, and treatment but not the implanted stimulator. Chi-square analysis was used to determine which factors affected union and complication rates. Student *t* test was used to determine which outcome instruments were affected by union/nonunion or complication. Significance was set at $P \leq .05$.

Results

Mean age was 51 years (range, 28-75 years). Mean follow-up was 37.4 weeks (range, 12-90 weeks). Each procedure had a mean of 2.1 preoperative risk factors for nonunion (range, 1-5), and 14 procedures (35%) were revisions.

Reviewed risk factors for nonunion included worker's compensation (6), smoking (13), infection (0), previous nonunion (19), medical morbidity (5), steroid use (4), rheumatoid arthritis (3), diabetes mellitus (15), Charcot (diabetic) neuroarthropathy (14), avascular necrosis of talus (6), tibiotalar cysts (1), and nondiabetic neuroarthropathy (3).

Surgeries consisted of ankle arthrodesis (3), midfoot arthrodesis (6), subtalar arthrodesis (8), triple arthrodesis (6), and tibiotalocalcaneal arthrodesis (13), plus procedures such as tibial osteotomy (2) and other fusions (2).

All patients received an implantable DC bone stimulator, which in 31 cases was supplemented with autograft (17) or allograft (14); bone graft was not used in 9 cases. Union was reported in 26 cases (65%) (Table I). Union was not significantly affected by any single risk factor or by attending surgeon ($P = .51$), worker's compensation status ($P = 1.000$), revision surgery ($P = .730$), or surgery type ($P = .474$).

Complications, excluding nonunion, occurred in 16 cases (40%). Two amputations were performed (5%), in 1 case of intractable neuritis and 1 case of deep infection. Deep infection was reported in 6 cases: Infection resolved with removal of the bone stimulator in 5 of these cases; 1 required below-knee amputation. The 6 patients with these infections had a mean of 2.3 preoperative risk factors (range, 2-4 risk factors): 3 patients were smokers, and 3 had diabetes and Charcot neuroarthropathy. One patient with diabetes and Charcot neuroarthropathy required amputation. Painful or prominent bone stimulators were removed in 5 cases, and routine removal was performed in 12 cases.

Other complications included 2 malunions of arthrodesis, distal tibia stress fracture after distal tibial osteotomy (1), deep venous thrombosis (1), superficial wound infection (1), ulcer due to cast immobilization (1), postoperative neuroma (1), excessive bleeding (1), and wound breakdown requiring a rotational flap (1).

At follow-up, scores for the 15 patients (17 feet) with complete SF-36 data were significantly lower than those of the standardized age-matched group: physical function ($P < .001$), role physical ($P = .0029$), bodily pain ($P < .001$), social function ($P < .001$), role emotional ($P = .0357$). Bodily pain scores were significantly worse for the 5 patients with nonunion than for the 11 patients with union ($P = .027$) and for the 8 patients with complications than for the 8 patients without complications ($P = .0172$).

Each of the 2 patients with bilateral surgery was counted once if both feet had the same outcome in terms or union or complications, or twice if one foot had a complication (failure) and the other foot did not (success).

AOS (pain, $P = .297$; function, $P = .357$), FFI (pain, $P = .614$; function, $P = .079$; physical limitations, $P =$

Table II. Preoperative Risk Factors

Study	Cases (n)	Procedure (n)	Risk Factors (n)	Union Rate	Complications
Cohen et al (1993)	1	Midfoot arthrodesis (1)	Charcot (1) Diabetes mellitus (1) Nonunion (1)	100% (1/1)	0
Midis & Conti (2002)	10	Ankle arthrodesis (10)	Nonunion (10) Smokers (4) Other (<2)	100% (10/10)	0
Donley & Ward (2002)	13	Ankle arthrodesis (3) Subtalar arthrodesis (2) Tibiotalocalcaneal arthrodesis (6) Tibiocalcaneal arthrodesis (2)	Smoking (11) Nonunion (7) Major medical (4) Other (1)	92% (12/13)	Superficial infection (4) Prominent battery (5)
Current study	40	Ankle arthrodesis (3) Subtalar arthrodesis (8) Tibiotalocalcaneal arthrodesis (13) Midfoot arthrodesis (6) Tibial osteotomy (2) Triple arthrodesis (6) Other fusions (2)	Nonunion (19) Diabetes mellitus (15) Charcot neuroarthropathy (14) Smoking (13) Other (<6)	65% (26/40)	Deep infection (6) Amputations (2) Superficial infection (1) Prominent battery (5)

.608), and AOFAS (ankle/hindfoot, $P = .347$; midfoot, $P = .995$) scores were not significantly different for patients with union versus patients with nonunion. Score differences between patients with and without complications were also not significant. Of the 18 patients who completed the questionnaire, 14 (78%) were functionally improved, and 16 (89%) were satisfied.

Discussion

Use of implantable DC stimulators in orthopedic surgery has been well described for fracture nonunion and spinal arthrodesis.[5-7] A few investigators have used a surgically implanted DC stimulator in high-risk foot and ankle surgery with good results.[5,8,9] Cohen and colleagues[5] described using an implantable DC stimulator with bone grafting to successfully treat a nonunion of the first metatarsal cuneiform joint 8 months after attempted Lisfranc joint fusion for Charcot neuroarthropathy of the midfoot. Midis and Conti,[8] using an implantable stimulator in treatment for aseptic nonunion of ankle arthrodesis, reported successful union and high patient satisfaction in the 10 patients treated. Two complications were noted, but neither was related to use of the implantable device. Donley and Ward[9] used an implantable electrical stimulator and bone graft in 13 patients (≥2 major risk factors for nonunion) undergoing ankle or hindfoot arthrodesis. They found that fusion occurred in 12 (92%) of the 13 patients, and there were no infections.

In comparison with these previous studies, patients in our series had a lower union rate (65%, 26/40 procedures) and a higher complication rate (40%, 16/40 procedures). These discrepancies are likely related to our including a substantial number of patients with neuroarthropathy and diabetes mellitus in our study (Table II). Previous studies used bone stimulators in patients with high-risk factors, such as nonunion, smoking, and major medical comorbidities, including 1 case of neuropathy.[8,9] Our study included 15 patients with diabetes and 14 with Charcot (diabetic) neuroarthropathy—patients at higher risk for nonunion than patients with other high-risk factors.[14-16]

Union was not significantly affected by any single risk factor in these high-risk patients, likely because of the small number of patients involved. However, 6 deep infections occurred, in patients who smoked (3) or in patients with diabetes and Charcot neuroarthropathy (3). For 5 of these patients, the infection resolved with battery-pack removal; 1 patient (with Charcot neuroarthropathy) required amputation. The cause of infection and amputation was felt to be multifactorial in these high-risk patients, and we do not believe that deep infection can be attributed to use of the stimulator alone. Most cases in this study were considered extremely high risk, and this treatment was a last resort before amputation. Our data show that implantable DC stimulators were not associated with adverse results in foot and ankle surgery in high-risk patients, but we add a caveat regarding use of this treatment in patients with Charcot neuroarthropathy.

In a study involving 174 patients with isolated subtalar arthrodesis (but no implantable bone stimulators), Easley and colleagues[17] reported that revision surgery was performed for 28 nonunions and that 21 of these cases had local avascular necrosis. The union rate was 71% at a mean of 15 weeks. In the current study, 8 patients had a revision subtalar fusion with an implantable bone stimulator for nonunion (7) and avascular necrosis (1), with mean time to union of 7.8 weeks. The current union rate of 75% (6/8 patients) is comparable to that of the Easley and colleagues[17] series, which did not involve implantable bone stimulators, but mean time to union was substantially shorter in the current study.

In a series of severe midfoot and hindfoot reconstructions, including surgeries for 38 (63%) of 60 feet with neuroarthropathy, Schon[18] found that 55 (92%) of these feet united without an implantable bone stimula-

tor, and there were 18 complications and a mean time to union of 4 months. A later study of lateral column lengthening (fourth-fifth metatarsal cuboid fusion) in 28 neuroarthropathic feet without bone stimulators found a union rate of 93% (26/28 feet).[19] The union rate of 83% (5/6 feet) with neuroarthropathic midfoot reconstruction in the current study is comparable to those in these previous studies, which did not involve implantable bone stimulators. Larger retrospective studies with validated outcome measures testing the use of bone stimulators in this select group could provide more information on the efficacy of this device. Prospective studies may be able to establish whether implantable bone stimulators produce faster healing and improved union in patients with diabetes or in high-risk patients, though the multiple variables inherent in treatment of these high-risk patients may make prospective studies with specific inclusion and exclusion criteria difficult to perform.

The validated outcome measures available for 15 patients (17 feet) provide some interesting findings. Despite the relatively high number of complications and nonunions, 16 (89%) of 18 patients were satisfied, according to questionnaire responses. Because use of bone stimulators did not substantially affect results in comparison with those from similar studies not involving bone stimulators, these outcome data provide baseline outcomes for high-risk patients undergoing surgical foot and ankle salvage surgery. The findings add to the complexity of this treatment scenario in that high patient satisfaction was not strictly associated with union or lack of complications. Further study with validated outcomes in these patients may facilitate comparing results across studies and disease types.

Lack of a control group in the current study is a limitation that could be rectified in future investigations. Two patients at the low end of the follow-up time range had relatively short follow-up, but the mean follow-up time of all patients was 37 weeks. Our being unable to use 3 of the SF-36 forms (because of missing answers) is another limitation. Patients may leave a question unanswered in this global health survey if the answer they would provide is not related to the outcome of their recent surgery. We have observed this difficulty in other studies using the SF-36. In addition, though typical of retrospective studies in general, our low outcome data collection rate of 50% (20/40 feet) could be improved.

Bone stimulators are relatively expensive, approximately $5000 each. However, the current study suggests that this device can be added to the treatment choices for these challenging high-risk patients, with appropriate caution in using it in patients with diabetes and Charcot neuroarthropathy.

Authors' Disclosure Statement

The authors report no actual or potential conflict of interest in relation to this article.

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