Implantable Electrical Bone Stimulation for Arthrodeses of the Foot and Ankle in High-Risk Patients: A Multicenter Study

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This study assessed arthrodesis procedures performed in the foot and ankle of high-risk patients following implantation of an internal electrical bone stimulator. Criteria defining patients as "high risk" included diabetes, obesity, habitual tobacco and/or alcohol use, immunosuppressive therapy, and previous history of nonunion. Standard arthrodesis protocol of bone graft and internal fixation was supplemented with the implantable electrical bone stimulator. A retrospective, multicenter review was conducted of 26 patients (28 cases) who underwent 28 forefoot and hindfoot arthrodeses from 1998 to 2002. Complete fusion was defined as bony trabeculation across the joint, lack of motion across the joint, maintenance of hardware/fixation, and absence of radiographic signs of nonunion or pseudoarthrosis. Radiographic consolidation was achieved in 24 of the 28 cases at an average 10.3 ± 4.0 weeks. Followup averaged 27.2 months. Complications included 2 patients who sustained breakage of the cables to the bone stimulator. Five patients underwent additional surgery. Four of the 5 patients had additional surgery in order to achieve arthrodesis. All 4 went on to subsequent arthrodesis. This study demonstrates how arthrodesis of the foot and ankle may be enhanced by the use of implantable electrical bone stimulation.
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Electrical current stimulation to enhance bone growth has gone from an investigational modality to an accepted method of treatment over the past 50 years. Yasuda, in 1955, was the first to report new bone formation around the site of electronegative potential (1). Since that discovery studies have shown a successful association between electrical stimulation and bone growth (2, 3). Thus, it has been implemented in the healing of nonunions, especially in the long bones and the scaphoid (4–6).

The primary indications for the various types of electrical bone stimulation have been for nonunions and delayed unions, and to a lesser degree for failed arthrodesis. One study on spinal fusion showed a higher rate of fusion with an implantable electrical bone stimulator (7). This raises the possibility of utilizing internal electrical bone stimulation as an additional modality for other joint fusions in a high-risk patient population, as opposed to assuming the risk of a failed arthrodesis. It also emphasizes the need for considering which factors characterize the high-risk patient. Factors inclined to lead to a nonunion include smoking, immunosuppressive drugs for inflammatory arthroses patients, diabetes, obesity, alcoholism, and previous operations. Knowing the contribution of each factor to a chance of nonunion would assist in the decision process of utilizing adjunct electrical bone stimulation.

The rate of nonunion for subtalar joint arthrodesis has been reported between 0% and 16% (8, 9) while for nonunion of the ankle it has ranged from 0% to 41% (10, 11). However, there has been little written regarding the use of internal electrical bone stimulation in foot and ankle. Donley and Ward (12), in a series of 13 patients, demonstrated that internal bone stimulation in hindfoot arthrodesis could benefit high-risk patients. Prior to that study, Cohen et al (13) reported the first case of internal electrical bone stimulation for a nonunion in the foot.

The goal of this study was to assess arthrodesis procedures performed in the foot and the ankle of high-risk patients. These patients were treated with an implantable

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electrical bone stimulator in addition to the standard arthrodesis protocol of bone graft and internal fixation. Rates of union and complications using this technique were evaluated.

Materials and Methods

Twenty-six patients underwent 28 foot and ankle arthrodeses with placement of an implantable electrical bone stimulator (Osteogen; EBI, Parsippany, NJ) from 1998–2002 and were available for retrospective review. A minimum of 1-year followup was required. Inclusion criteria consisted of any or all of the following: diabetes, a BMI greater than 28, a history of previous failed arthrodeses, a history of smoking or alcohol abuse, or a history of immunosuppressive medications such as steroids.

Postoperatively, patients were assessed by an evaluator not involved with the surgery. Surgical technique for the arthrodeses was performed in standard fashion. Fixation for the arthrodesis was achieved with internal screws except in 2 cases; bioabsorbable screws and external fixation were each utilized in 1 case. The 1- or 2-lead cathode portion of the internal bone stimulator was imbedded in the arthrodesis site. Bone graft was placed in the arthrodesis sites, often entwined within the cathode, with care taken that it did not have contact with any metallic fixation. The anode portion of the internal bone stimulator was placed in the posterior aspect of the ankle, generally deep to the posterior tibial muscle.

Each patient's postoperative regimen was determined by the involved joint and included non–weight bearing for 6–8 weeks in a below-knee cast or boot. Following this, the below-knee boot was utilized until 10–12 weeks postoperatively or until fusion was achieved. Radiographs were taken at 1 month postoperatively, and approximately every 2 weeks thereafter (varying by 1–2 weeks due to patient and provider's schedules). Complete fusion was defined as bony trabeculation across the joint, clinical lack of motion across the joint, maintenance of hardware/fixation, and no radiographic signs of nonunion or pseudoarthrosis.

Other than yearly follow-up examinations, radiographs were not taken after fusion was achieved. During follow-up examinations, note was taken of any loss of fixation/hardware failure, arthrodesis breakdown, and the need for implant removal. Statistical significance was set at $P = .05$. The Stat-Sak package (Statools, Malden, MA) was used to conduct Student's *t* and Fisher exact tests on the study population.

Results

There were 19 women and 7 men, with 2 of the men having undergone bilateral surgery at different times. The mean age of the cohort was 55.5 years ± 11.7 years (range, 31–79). There were 19 right feet and 9 left feet. Of the 26 patients, 18 were diabetic. Radiographic consolidation across the intended fusion site was achieved in 24 of the 28 patients. This was achieved at an average time of 10.3 ± 4.0 weeks (range, 4–20). Follow-up averaged 27.2 months from the index surgery.

In the cohort, there were 3 patients who had prior failed first metatarsophalangeal (first MTPJ) implants and 4 who had prior failed arthrodeses. Sixteen patients had Charcot arthropathy. There were 11 patients identified as obese with a BMI exceeding 28. Other patients meeting our defining high-risk criteria included tobacco use (6 patients), alcohol abuse (4 patients), and immunosuppressive use (Table 1). With respect to surgical procedures, there were 16 tarsometatarsal fusions, 3 talonavicular fusions, 4 tibiocalcaneal fusions, 3 first MTPJ fusions, 1 ankle fusion, and 1 subtalar fusion. Five patients had postoperative infections: 2 required implant removal and went on to successful arthrodesis. Eight patients had the battery removed after the primary surgery.

Complications included 2 patients who sustained breakage of the cables to the bone stimulator. One patient fell 18 months postoperatively, with hardware failure of the first MTPJ fusion. She refused additional surgery because she was asymptomatic, though the arthrodesis had failed. Five patients needed additional surgery. In 1 Charcot foot, implant failure occurred with breakdown of the arthrodesis site. All of the patients who required additional surgery went on to subsequent arthrodesis. Statistical analysis using Fisher's exact test, comparing those who needed additional surgery and the presence of 2 or more risk factors, was significant ($P = .015$). The Student *t* test was performed to see whether 1 of the high-risk factors, diabetes, contributed to an increase time of consolidation. The difference between diabetic patients in consolidation (10.5 ± 3.7 weeks, N = 20) and nondiabetics (8.3 ± 3.2 weeks, N = 8) was not significant ($P = .15$). There was also no significant difference as to healing times of females versus males, 9.95 ± 4.06 and 11.11 ± 3.89 weeks, respectively ($P = .48$).

Discussion

Arthrodesis within the foot and ankle remains a valuable salvage procedure for a number of conditions including arthritis, Charcot neuroarthropathy, paralytic conditions, and failed surgical procedures. A subset of the population is at particular risk for delayed or nonunion. The high-risk designation was determined by the presence of 1 or more of the following criteria: diabetes, cigarette smoking, pharmaceutical immunosuppression, obesity, daily alcohol consumption, and previous nonunion. Our study showed that those with 2 or more of these risk factors were more likely to need additional surgery.

Nicotine use, or smoking, has been studied in regards to bone healing and nonunion. Smokers have a significantly

TABLE 1 Patients with implantable bone stimulators

Pt #	Age	Sex	Diagnosis	R/L	DOS	OsteoGen Location	Prior Surg	Obese	Db	Smoker	ETOH	XR	Removal
1	31	F	Non-Union	LT	Apr-98	Naviculo-Cuneiform	Yes	Yes	No	No	No	4	Yes
2	56	F	DJD	RT	Jun-00	Ankle	Yes	Yes	No	No	No	6	No
3	70	F	Charcot	LT	Jul-00	Lis Franc's	No	Yes	Yes	No	No	6	No
4	52	F	DJD	RT	Jul-00	Subtalar	No	No	Yes	No	No	8	No
5	64	M	Charcot	RT	Dec-00	Lis Franc's	No	No	Yes	No	No	12	No
6	59	M	DJD	RT	Dec-00	Subtalar	No	Yes	No	No	No	12	No
7R	44	M	Charcot	RT	Feb-01	Lis Franc's	No	Yes	Yes	No	No	20	No
7L	44	M	Charcot	LT	Apr-01	Tibio-Calcaneal	No	Yes	Yes	No	No	6	No
8	79	F	DJD	RT	May-01	Lis Franc's 1–2	Yes	No	No	No	No	6	No
9	46	F	Charcot	RT	Jun-01	Tibio-Calcaneal	No	Yes	Yes	No	No	7	No
10	55	F	Charcot	LT	Jul-01	Tibio-Calcaneal	No	Yes	Yes	No	No	8	No
11	63	F	Non-Union	LT	Sep-01	Naviculo-Cuneiform	Yes	Yes	No	No	No	9	Yes
12L	50	M	Charcot	LT	Sep-01	Lis Franc's	No	No	Yes	Yes	Yes	10	No
13	47	F	Non-Union	RT	Nov-01	Lis Franc's 1	Yes	No	No	Yes	Yes	10	Yes
14	65	F	1st MPJ	LT	Dec-01	1st MP Implant	No	No	Yes	No	No	11	No
15	71	F	Charcot	LT	Jan-02	Lis Franc's	No	Yes	Yes	Yes	Yes	11	No
16	67	F	DJD	RT	Feb-02	Lis Franc's	No	No	No	Yes	No	12	No
17	52	F	Charcot	RT	Feb-02	Lis Franc's	No	Yes	Yes	No	No	14	Yes
18	27	M	Charcot	RT	Mar-02	Tibio-Calcaneal	No	Yes	Yes	Yes	No	17	No
12R	50	M	Charcot	RT	Apr-02	Lis Franc's	No	Yes	Yes	Yes	Yes	10	No
19	64	F	Charcot	RT	Apr-02	Lis Franc's	No	Yes	Yes	No	No	7	Yes
20	59	F	Charcot	RT	May-02	Lis Franc's 1–3	No	No	Yes	No	No	8	Yes
21	48	F	Charcot	RT	May-02	Chopart's	No	Yes	Yes	No	No	9	No
22	60	F	RA	RT	Jul-02	Lis Franc's 1–5, Chopart's	No	No	No	No	No	9	Yes
23	65	M	1st MPJ Implant	RT	Jul-02	1st MP	No	No	Yes	No	No	12	Yes
24	59	M	Charcot	RT	Jul-02	Lis Franc's 1–3, Chopart's	No	Yes	Yes	No	No	13	Yes
25	46	F	Charcot	RT	Jul-02	Lis Franc's	No	Yes	Yes	No	No	20	No
26	60	F	1st MPJ Implant	LT	Sep-02	1st MP	No	No	Yes	No	No	12	No

R/L, right/left; DOS, date of surgery; Db, diabetic; ETOH, alcohol abuse; XR, x-ray consolidation in weeks; Prior Surg, previous arthrodesis attempt; Removal, battery removal; patients in **BOLD**, patients needing additional surgery.

higher rate of nonunion than do nonsmokers (18.6% vs 7.1%). Ishikawa et al (14) reported the relative risk of developing a nonunion was 2.7 times higher for smokers than nonsmokers in hindfoot fusions (Fig 1).

The existence of such risks has made the use of adjunctive measures desirable in order to decrease the overall nonunion rate. The implantable bone stimulation device used in our study provides direct current to the healing bone mass. Bassett et al (15) reported that bone is most electronegative in areas of growth, such as fractures and epiphyseal plates. In 1981, Brighton et al (2) undertook the first multicenter study on the use of direct current in the treatment of nonunions. In their study of 178 nonunions, 149 (83%) achieved bony union with use of direct current electrical stimulation.

There is literature that supports the use of electrical stimulation in nonunion and delayed union cases (7, 16–18). These studies have demonstrated promise of this modality in spinal fusion. Kucharzyk (16) and Kane (7) demonstrated a statistically significant difference in union rates in a high-risk pool of patients who received electrical stimulation as compared to a similar pool who did not receive stimulation. Rogozinski et al (18) demonstrated a 96% versus 85% successful spinal fusion rate in those patients who underwent instrumentation with and without an internal bone stimulator, respectively.

Current literature lacks prospective or retrospective studies with electrical bone stimulation involving foot or ankle fusions in high-risk patients. Nonunion rates can be high with these procedures. Perlman and Thordarson (19) assessed nonunion risk factors in ankle fusions and reported 19 of 67 ankle fusions (28%) progressed to nonunion. The risk factors found to be associated with nonunion were diabetes, alcohol abuse, illegal drug use, smoking, psychiatric illness, and prior open trauma, the latter of which was statistically significant.

Two recently published studies investigated the effect of pulsed electromagnetic fields (PEMF or external electric bone stimulation) on rearfoot fusions. One prospective study by Dhawan et al (20) evaluated 64 consecutive rearfoot arthrodeses and found statistically faster healing with PEMF. However, a retrospective study by Saltzman et al (21) refutes these findings, showing PEMF application was only 26% successful in achieving arthrodesis.

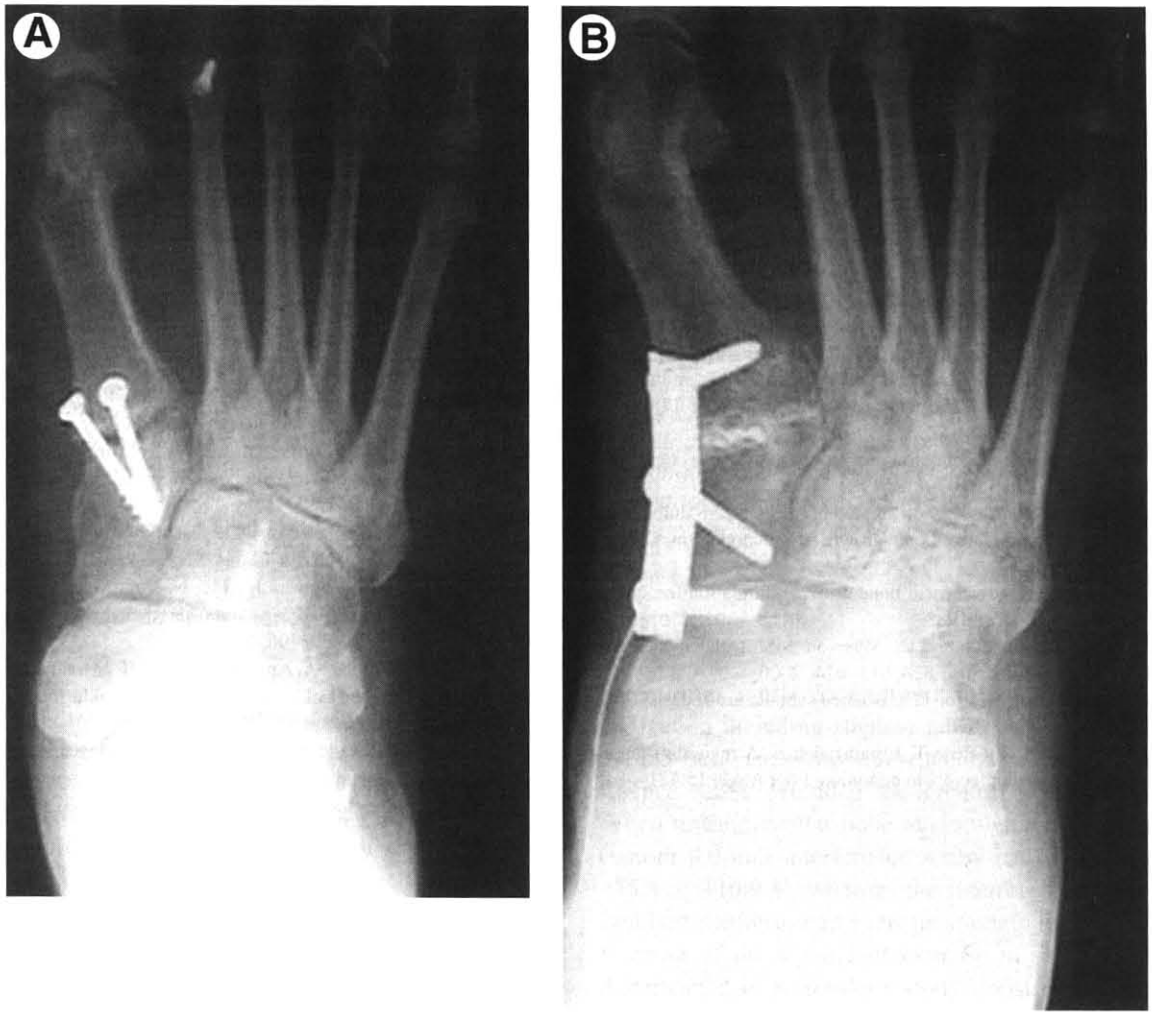

FIGURE 1 *(A)* Preoperative AP view of the foot with a nonunion of a Lapidus procedure in a smoker. *(B)* Postoperative AP view showing revision arthrodesis with dorsal plate and internal stimulator.

In another study involving implantable electrical bone stimulation, Donley and Ward (12) used internal electrical bone stimulation units identical to those in the current study and achieved arthrodesis at a mean 24.6 months in 12 of their 13 patients. They also showed an improvement in pain scores from a mean of 8.5 to 1.9 in a high-risk hindfoot fusion population (12). Although neither that study nor the current study provided a comparison group, the positive results of both studies suggest that internal electrical bone stimulation may assist in fusions of the foot and ankle in high-risk patients. The current study is also limited by potential investigator bias, as the evaluators were not blinded. The relatively short followup of both studies also needs to be taken into account.

Another weakness of this study was the lack of a rating instrument. A uniform rating scale was not used for 2 reasons: this was a multicenter study, and the same nonbiased evaluator could not assess all the patients. Second, numerical scoring systems such as the American Orthopedic Foot and Ankle Surgeons' (AOFAS) rating scale (22) deduct points for lack on motion, which is not consistent given the desired result of an arthrodesis.

Future research could compare the risks for complications between an implantable bone stimulation groups versus a nonimplantable group in high-risk patients. Larger sample sizes would allow for better evaluation of the various risk factors, including those factors that have not been studied thoroughly, such as obesity. Double-blinded, placebo- controlled studies would be ideal, but may not be reasonable in a private-practice setting.

Conclusion

Arthrodesis of the foot and ankle can be enhanced by the use of implantable bone stimulation in a high-risk popula-

tion. However, as noted by previous literature and our study, this patient population is still susceptible to complications such as nonunion and arthrodesis breakdown.

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