CHAPTER **4**

THE EFFICACY OF IMPLANTABLE BONE STIMULATION IN ANKLE ARTHRODESIS

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Arthrodesis of the ankle has evolved as the preferred treatment for advanced ankle joint disease, which may be the end result of numerous conditions. The literature is replete with techniques for fusing the ankle, with at least thirty different techniques described since 1900.[1] Despite continuing advances and refinements in techniques involving rigid internal and external fixation,[2] a considerable risk for non-union still exists. Furthermore, there is a relatively "common" occurrence of pseudoarthrosis with ankle arthrodesis, with reported failure rates ranging from 0-41% throughout the literature.[3-7] Refinements in techniques continue to emerge with recent interest in biological and mechanical adjuncts to enhance success.

PREDISPOSING RISK FACTORS FOR NON-UNION

The predisposing risk factors for non-union in ankle arthrodesis have been described in the literature and are listed in Table 1.[3,5-9] In a study of posttraumatic ankle arthrodesis, Kenzora[6] found substantially dissimilar fusion rates for patients who experienced "high" and "low" energy injuries utilizing large half-pin external fixators. The energy level of the injury was defined by the degree of bony comminution, the presence of joint dislocation and the condition of the soft tissue envelope at the time of injury. High and low energy groups achieved 69% and 100% primary union respectively. They believed the increased incidence of non-union of the high-energy injuries of the distal tibia and talus were attributed to devascularized articular fragments resulting from periosteal degloving or from extensive violation of the periarticular soft tissue envelope during the initial surgical reconstruction.

Frey and associates[3] reported a failure rate of 41% in a review of 78 ankle fusions. They cited fracture type, avascular necrosis of the talus, prior infection, major medical problems, and open injuries as predisposing risk factors to failure. The highest incidence of non-union in their series was seen with combined plafond/talar fractures, followed by type II/III talar neck injuries. Eight of nine patients with avascular necrosis went on to develop non-unions. In addition they noted that the weber "C" ankle fracture had the highest rate of non-union. They found no statistical difference between internal and external fixation and the incidence of pseudoarthrosis.

In a series of 67 patients Perlman and Thordarson[5] demonstrated a non-union rate of 28% and delineated multiple factors associated with pseudoarthrosis, including a history of open trauma, tobacco use, alcohol use, illicit drugs use, and a history of psychiatric disorders or diabetes. Alcohol, drug use and psychiatric illness were related to issues of compliance rather than abnormalities in bone healing physiology. In this study, greater than half (53%) of the patients with posttraumatic arthritis secondary to open trauma developed a non-union.

The adverse effects of tobacco use on normal tissue metabolism and bone healing have been previously noted in the literature. Cobb[8] demonstrated that the relative risk of non-union in ankle arthrodesis was 3.75 times higher for smokers than nonsmokers. Recently, Ishikawa[10] reported a 2.7 times greater risk of pseudoarthrosis for smokers undergoing hindfoot fusions. Patients who stopped smoking prior to surgery had an "intermediate" non-union rate and they concluded that giving up smoking prior to surgery improved fusion rates but not to the level of that of nonsmokers.

Morgan et al[7] published results on 101 ankle arthrodeses in which they achieved a 95% success rate. All fusion sites united except in those patients with documented peripheral sensory neuropathy identified preoperatively.

Lance[9] found similar results in a series of 190 ankle fusions in which eight of the twelve neuropathic patients failed to fuse. They reported a 20% non-union rate and cited sensory neuropathy, technically deficient procedures, and the use of heterogenous bone graft as significant factors predisposing to non-union. They also reported a higher failure rate utilizing the transfibular approach. In addition, the authors noted an increased rate of pseudoarthrosis in

patients who underwent concomitant triple arthrodesis to be twice that of those who underwent ankle fusion alone (27% versus 13%).

These studies demonstrate the difficulties with achieving primary union in "high-risk" patients (i.e. post high energy trauma, smokers) and have prompted us to evaluate the efficacy of electrical bone stimulators on the success of ankle fusions at our institution. The purpose of this study was to evaluate the value of invasive bone stimulators utilized as an adjunct to enhance union in patients undergoing ankle arthrodesis.

EBI OSTEOGEN™ IMPLANTABLE BONE GROWTH STIMULATOR

The EBI (EBI Medical System, Parsippany, NJ) OsteoGen implantable bone growth stimulator was used exclusively in this study. This device was originally designed as an adjunctive tool to improve union rates in long bone fractures[11] and has since been adopted for use in high-risk spinal fusions[12,13] and more recently employed in difficult hindfoot fusions.[14-15] It provides direct electrical current (DC) to the arthrodesis/fracture site via titanium leads in either mesh or straight configurations. The mesh and straight leads are 23 and 40 mm in length with each having approximately the same contact surface area. The stimulator unit is also available in both single and dual lead designs (Figure 1). The electrical field of influence around the cathode extends in a 5-8 mm radius with each lead generating approximately 20 microamperes. The cathode should avoid internal fixation in order to prevent lead breakage, current dissipation or subsequent corrosive changes. The manufacturer recommends placement of the generator casing 8-10 cm from the cathode.[11]

The stimulator is believed to exert its effect through a reduction reaction at the cathode, which establishes lower oxygen tension and an increase in local pH. These factors have been shown to provide an optimal osteogenic environment.

TECHNIQUE FOR STIMULATOR IMPLANTATION IN ANKLE ARTHRODESIS

The technique used for implantation of the device is dependent primarily on the form of fixation that is chosen. Traditionally, 2 – 3 large cancellous screws have been used to secure the arthrodesis site which leaves little room for lead placement between the fusion surfaces. Therefore the "fishscale" or "drillhole" method is employed following fixation placement (Figure 2). Multiple drill holes are created around the periphery of the joint extending into the fusion site. The straight lead is doubled upon itself and seated into the channels. Excess cathode can be placed anteriorly into the joint line and bone graft is then placed to secure it.

A second option allows for placement of the mesh lead directly into the joint when internal fixation is employed. Following insertion of the cannulated guide pins, the cannulated drill is used to overdrill the proximal screw hole to allow for minimal distraction necessary for lead placement around the corresponding areas of fixation. Although this technique optimizes cathode position, it carries a greater risk of lead failure and/or breakage.

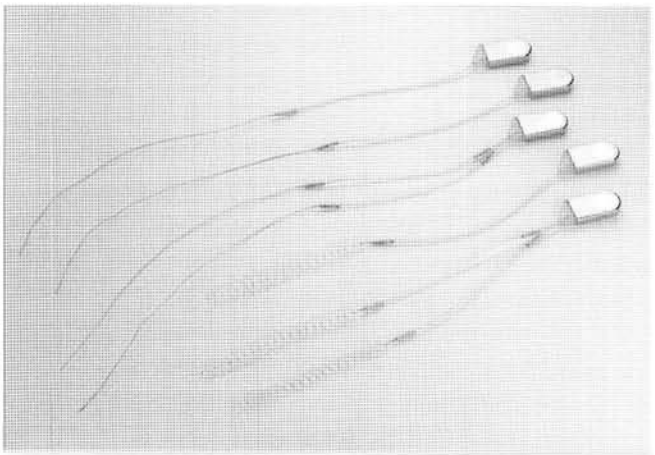

Figure 1. EBI OsteoGen Implantable Bone Stimulators. These devices provide direct electrical current (DC) to the arthrodesis/fracture site via titanium leads in either mesh or straight configurations. The stimulator unit is also available in both single and dual lead designs. The dual lead stimulator is particularly helpful in multilevel hindfoot fusions.

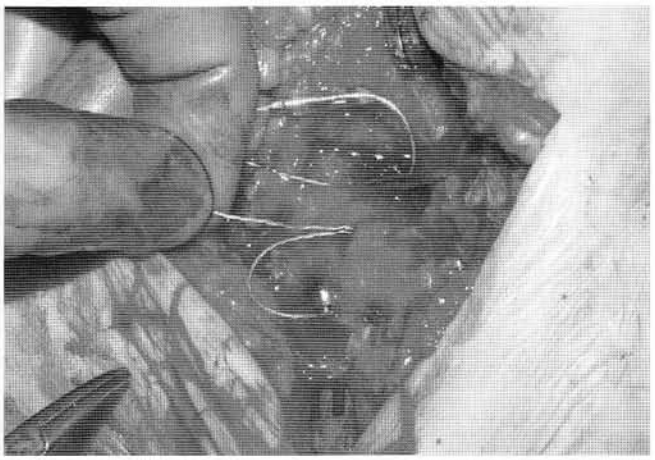

Figure 2. "Drill hole" method of lead insertion. Multiple drill holes are created around the periphery of the joint extending into the fusion site. The straight lead is doubled upon itself and seated into the channels. Excess cathode can be placed anteriorly into the joint line and bone graft is then placed to secure it.

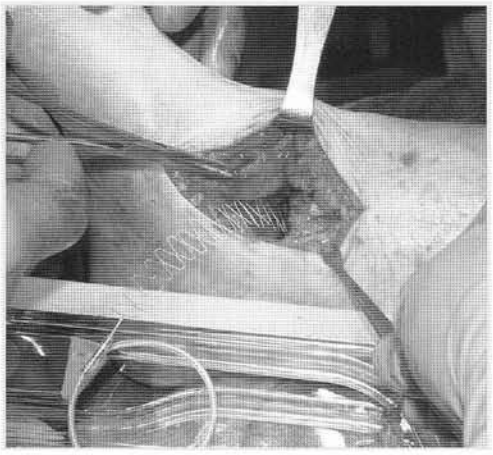

Figure 3. The mesh cathode is selected to increase the contact area between the lead and the adjacent fusion surfaces. The lead can be laid in an M or L configuration directly into the arthrodesis site.

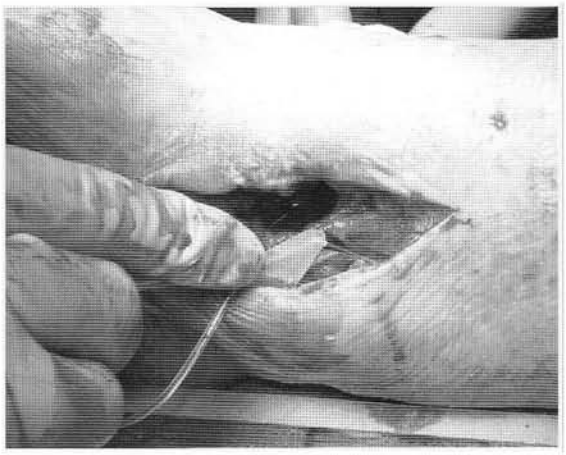

Figure 4. Placement of the battery pack in a subcutaneous channel 8 -10 cm from the arthrodesis site. This unit should be seated above the anticipated level of postoperative bracing or shoe gear to avoid irritation as swelling subsides.

When external fixation is the primary method of stabilization, the mesh cathode is selected to increase the contact area between the lead and the adjacent fusion surfaces (Figure 3). Since it is unlikely that the leads will come into contact with the small diameter transosseous wires, the mesh cathode can be laid in an M or L configuration directly into the arthrodesis site. Provisional Steinman pin fixation is then utilized and the wounds are closed in layers. The fixator may then be applied.

Once the cathode is in place, a subcutaneous tunnel is created posterolaterally or posteriomedially and the generator is passed 8-10 cm away from the surgical site (Figure 4). Generator placement is important because although a large percentage of the devices will become prominent and require removal after the edema subsides, there is generally less irritation if it is positioned above the boot top or the anticipated area of postoperative bracing.

MATERIALS AND METHODS

One hundred and two ankle fusions, performed at Northlake Medical Center between 1997 and 2003, were reviewed for this study. Complete charts and radiographs were available for evaluation of 41 patients undergoing 43 ankle fusions. Examination of preoperative and serial postoperative radiographs was performed. Intraoperative radiographs were evaluated if available. Medical records of each patient were reviewed and information collected included relevant demographic data (patient sex and age of the patient at the time of arthrodesis), underlying etiology of ankle pathology, previous operations, assessment of documented predisposing risk factors to non-union (as defined in Table 1), type of fixation used,

Table 1

FACTORS ASSOCIATED WITH NONUNION

Tobacco Use
Alcohol Use
Diabetes Mellitus
Psychiatric Disorder
Elicit Drug Use
Open Trauma
Post-traumatic Arthritis
High Energy
Low Energy
Prior Infection
Avascular Necrosis of the Talus
Prior Ankle Nonunion / Previous Ankle Fusion
Peripheral Neuropathy
Severe Obesity

additional surgical procedures, and the use of an internal bone stimulator. If the ankle arthritis was traumatic in origin, the trauma was classified as low energy or high energy according to Kenzora.[6]

Operative reports were compiled for data analysis. All operations were carried out under pneumatic thigh tourniquet and general inhalation anesthesia. The surgical techniques involved lateral and ancillary medial incisonal approaches. A trans-fibular or malleolar-sparing technique was utilized depending on surgeon preference. Fusion surfaces were decorticated to a healthy cancellous substrate utilizing either an osteotome and rotary burr or a power

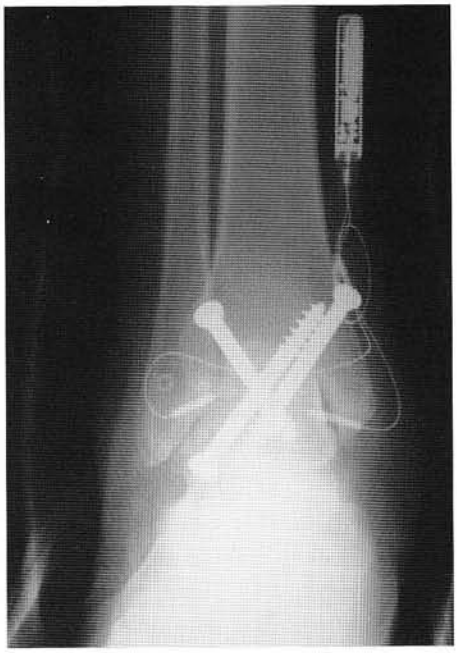

Figure 5A. AP radiograph of an ankle fusion secured with three 6.5mm cancellous screws. The "drill hole" method of lead placement was used to avoid contact with the internal fixation. Note the posteromedial placement of the battery pack.

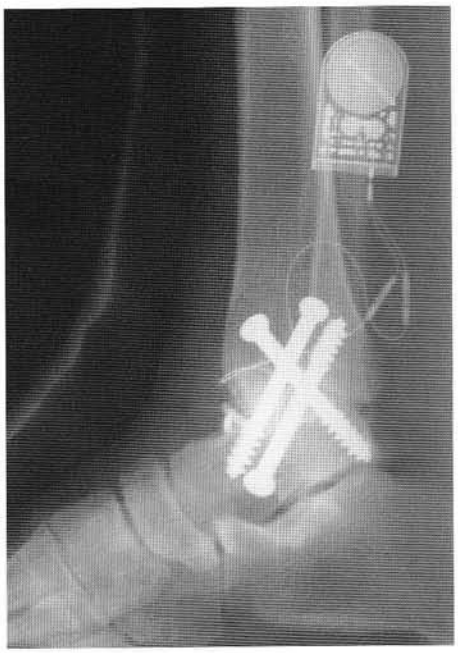

Figure 5B. Lateral radiograph.

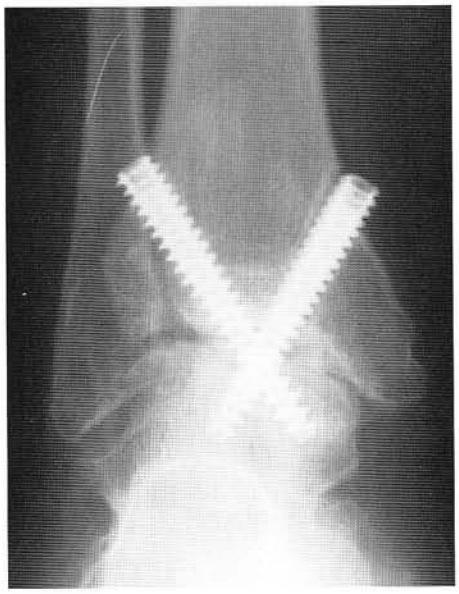

Figure 6A. Nonunion following an arthroscopically assisted ankle arthrodesis. Revisional ankle fusions are a primary indication for the use of implantable bone stimulation.

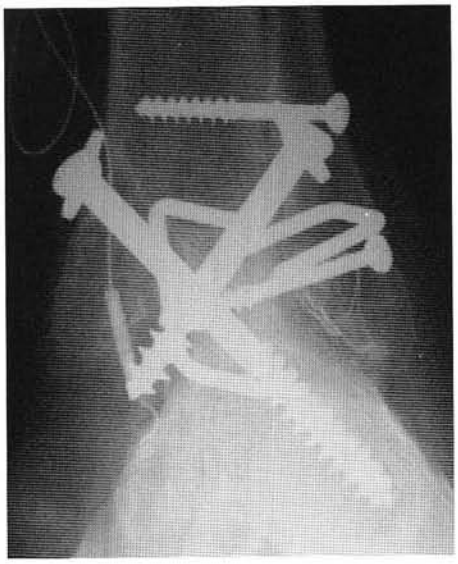

Figure 6B. Same patient showing radiographic consolidation at 10 weeks following revisional fusion with implantable stimulator.

saw with adequate cold saline irrigant. Steinmann pins or cannulated guide pins were used for provisional fixation and intraoperative fluoroscopy or plain film radiographs were obtained to assess fixation and arthrodesis position. Primary fixation was accomplished with two or three screws and supplemented with large Blount staples when necessary (Figures 5). In cases where external fixation was used for static compression arthrodesis, either a circular wire fixator or half-pin monorail device was applied after joint preparation. The decision to augment fusion with implantable bone stimulation was based on the surgeons' experience. EBI's OsteoGen™ implantable device was used exclusively when bone stimulation was employed. Postoperative management consisted of strict non-weight-bearing in a short leg cast until clinical/radiographic union was achieved. Circular ring fixators were weightbearing as tolerated 1 week postoperatively.

Serial post-operative radiographs were analyzed to establish the approximate time of osseous union. Fusion success was determined by radiographic evidence of osseous trabeculae crossing the arthrodesis site. Delayed union was defined by the absence of radiographic union at 6 months postoperatively but radiographic consolidation before 12 months. A non-union was defined as the absence of clinical or radiographic signs of union at 12 months[3] (Figure 6).

Analysis was performed on divided groups, those who received implantable bone stimulators and those who did not, for several outcomes: rate of union, average time to union in weeks, and specific risk factor assessment.

Analysis was also performed on the non-union group alone as a subset of the entire study population. The occurrence of each particular risk factor was identified in this cohort. As a result of the high union rate in the stimulated group, the non-stimulated group was used to assess technique modifications including fixation types and variations in the surgical approaches utilized. Revisional ankle fusions were also evaluated with respect to rates of union and overall time to union.

There were three different statistical tests performed depending on the type of variables involved (continuous such as time or categorical such as gender) and number of observations with characteristics. For statistical comparison of continuous variables (time to union), a two-sample t-test was performed with the hypothesis being that the variable (time to union) has the same mean within the two defined groups (no electrical stimulation vs. electrical stimulation).

To statistically evaluate relationships between two categorical variables (for example, Gender and Electrical/No electrical Stimulation), Pearson's Chi-Square was used. However, when the number of expected frequencies was low due to the small sample size, Fisher's Exact test was used to determine if there is any association between two categorical variables.

RESULTS

Forty-one patients underwent 43 ankle arthrodeses. Of the 41 patients, there were 18 males and 23 females. The average age at the time of fusion was 54, with ages ranging from 31-80 years. The combined overall success rate was 86.4% with an average time to union of 12 weeks.

Etiology of Ankle Pathology

Fifty one percent (n = 22) of the patients required arthrodesis as a result of traumatic arthritis primarily stemming from a combination of high and low energy ankle fractures. (Table 2) Of the 22 patients, nine of them suffered high energy ankle fractures (41%), while 8 had low energy (36%) ankle injuries. There were also 4 pilon (18%) fractures and one osteochondral lesion (5%). Open injuries were reported in two patients.

Arthrodesis was performed for nontraumatic arthritis in 21 patients (49%) (Table 2). These conditions included primary osteoarthritis, neuromuscular disease, charcot arthropathy and talar osteonecrosis.

Performance of the Implantable Stimulator

There were 19 patients in the stimulated group and 24 patients in the non-stimulated group. The average age in the two groups 53.8 and 54 respectively. Each group had an average of 2 risk factors for non-union.

Fusion success was determined radiographically and compared between the two groups. In the non-stimulated

Table 2

ETIOLOGY OF ANKLE PATHOLOGY

Post –Traumatic (N = 22)	
Ankle Fractures	17/43
a. Low Energy	8/43
b. High Energy	9/43
Pilon Fractures	4/43
Osteochondral Lesions	1/43
Non-Traumatic (N = 21)	
Neuromuscular Disease	8/43
Charcot Arthropathy	1/43
Talar Osteonecrosis	1/43
Primary Osteoarthritis	11/43

group, the fusion success rate was 79% and the non-union rate was 21%, compared with a fusion success rate of 100% and a non-union rate of 0% in the stimulated group. Statistical significance was evident via Pearson's chi-square test (P = 0.05). There were three delayed unions in the non-stimulated group and no delayed unions in the stimulated group.

The two groups were also evaluated with regards to the overall time to radiographic union. The stimulated group consolidated on average 5.6 weeks faster than the non-stimulated group with an average to time to union of 9.6 weeks and a range of 6-16 weeks. The average time to union in the non-stimulated group was 15.2 weeks with a range of 7–36 weeks. The rate of union between the two groups was statistically significant via Pearson's chi-square test with a P = 0.005.

Risk Factor Analysis

The number of risk factors as a percentage was evaluated in both the stimulated and non-stimulated groups and is presented in Table 3.

Additionally risk factor analysis was performed to evaluate the incidence and number of risk factors among those patients who resulted in non-union. As a result of the small number of patients in the category, no statistical relationship could be established; however the data suggests that those patients who sustained high energy injuries were more likely to develop a non-union (60%).

Table 3

NUMBER OF RISK FACTORS PER GROUP

Stimulated Group	
No. of Risk Factors	**Percentage**
Zero	5%
One	21%
Two	37%
Three	37%
Four	0%
Non-stimulated Group	
No. of Risk Factors	**Percentage**
Zero	5%
One	21%
Two	37%
Three	37%
Four	0%

There was a significant correlation between the incidence of non-union and the age at the time of fusion (P = 0.043). Those patients over the age of 55 years old had a greater risk of developing a non-union versus younger patients. The average age of the patients who went onto non-union and went onto successful union was 66 and 52 years of age respectively.

Technique Modifications

As a result of the 100% union rate in the stimulated group, the non-stimulated group was used to evaluate technique modifications including fixation types and variations in the surgical approaches utilized. Overall, the percentage of union in the internal and external fixation groups was very similar (73% versus 79%). However, the internal fixation group consolidated significantly quicker than the external fixation group with healing times of 10 and 18 weeks respectively (P = 0.039). There were 3 non-unions in the external fixation group compared with 2 non-unions in the internal fixation group.

Additionally, the rate and percentage of union were also analyzed with respect to the surgical approach. Malleolar sparing and transfibular techniques were compared and yielded little difference with regards to overall success. Those patients where the fibula was left intact had an 80% union rate versus those patients who were fused via the transfibular approach with a 73% success rate. Although these values were not statistically significant, the time to union between these groups demonstrated a statistically significant correlation. The average time to union in the malleolar sparing group was 11 weeks while the transfibular group demonstrated a prolonged healing time of 18 weeks. Statistical comparison of these groups yielded a P value of 0.030.

Revisional Ankle Arthrodesis

There were 5 revisional ankle arthrodeses which all went on to uneventful union (100%) in an average of 13.8 weeks. Four of the five (80%) ankles received implantable bone stimulators at the time of revision.

DISCUSSION

Ankle arthrodesis is the definitive treatment for end stage ankle arthrosis and failure to obtain bony consolidation can lead to increased patient convalescence and a need for revisional surgery. Despite a greater understanding of the importance of soft tissue preservation and the advent of advanced internal and external fixation techniques, there is still an elevated non-union rate reported in the literature

among certain high-risk patients.

Electrical stimulation has been utilized as early as 1816 for bone healing.[16] Renewed interest in the electrical properties of bone and the application of electrical currents began after the work of Yasuda[17] and Fukada and Yasuda[18] in 1955. Many authors have since published on the topic detailing the positive effects of electrical stimulation as an adjunct to fusion and fracture healing in both laboratory and clinical models.[12-15,19-23] This method has been used extensively in spinal surgery, and several authors have documented their positive experience in high-risk patient cohorts.[12, 13] Both Rogozinski[12] and Kucharzyk[13] have showed dramatic reduction in non-union rates in patients undergoing posterior spinal fusions with the use of an internal electrical stimulator. Improved clinical success rates among those patients who received implantable stimulation.[13]

Recently, two smaller studies have documented the beneficial use of electrical bone stimulation in ankle fusions. Donley and Ward[14] reported on 13 high-risk hindfoot fusions utilizing implantable bone stimulators. Nine of these fusions involved the tibiotalar joint in which no non-unions occurred. Overall, they achieved a 92% union rate despite multiple risk factors including smoking, high-energy trauma, neuropathy and talar osteonecrosis. They concluded that implantable devices are beneficial in high-risk populations and may offset the impact of certain risk factors, which contribute to poor outcomes. Davis and Cohen[15] reviewed the results of 13 ankle fusions and also reported a 92% success rate utilizing the implantable EBI device. The indications in their patient population included 7 non-unions, 4 cases of talar osteonecrosis, 1 failed total ankle arthroplasty and 1 patient who had a strong smoking history. Four battery packs required removal postoperatively.

Our data in this series of 43 ankle fusions suggests that electrical implantable bone stimulators have a significant role in success of ankle arthrodesis. Although our study was retrospective in nature, the two patient subsets (stimulated/non-stimulated) were matched with regards to the number of risk factors and the overall age of the patients at the time of surgery. This allowed for an easier determination of the influence of the stimulator in the overall outcome of the procedure. Radiographic union occurred in the stimulated group at an average of 9.6 weeks which was statistically significant when compared to the non-stimulated group. We acknowledge the fact that clinical union likely occurred prior to radiographic union because of the typical lag period experienced with plain film radiographs and our results would therefore reveal a greater impact of the stimulator in healing. The stimulated group also exhibited a 100% union rate which was statistically significant. We attribute this high success rate to the performance of the stimulator in these 19 ankles. In addition all revisional ankle fusions also consolidated 100% of the time in which 80% had implantable stimulation.

Risk factor analysis demonstrated patients who were over the age of 55 had a significantly increased risk of non-union. Frey et al.[3] also reported increased risk of non-unions in patients over 40 years old. Although the numbers were too small for statistical analysis, a trend toward significance was noted in those patients who developed non-unions and had high energy arthritis. Several other authors have noted similar findings.[3,5-6]

In addition, the current investigation examined secondary technical factors we believe exert a role in the success of ankle arthrodesis. These included the type of fixation and the surgical approach with special regards to the sparing or removal of the fibular malleolus. As a result of the 100% union success, the stimulated group could only serve as a control group for this part of the study and therefore the non-stimulated group was observed. Overall there was no statistical significance between the internal and external fixation groups; however the time to union of the internal fixation was significantly greater than that of the external fixation group. Furthermore, the patients who underwent the transfibular approach had statistically slower healing times than those who had malleolar sparing procedures despite having similar union rates. We attribute faster healing times in this group of patients because of the ability to minimize damage to the periarticular vasculature and the peroneal artery. This was well demonstrated by Miller's in cadaveric study examining the two approaches.[24]

In addition to the large cost, there are several drawbacks to the use of this device. Since it was originally designed for the treatment of long bone fractures, its sizeable generator is, in many instances, too large for the subcutaneous pockets about the foot and ankle which frequently requires removal when the postoperative swelling has subsided. Approximately 40% of our patients required a second procedure for removal of the generator casing. Placement of the generator in the subcutaneous tissues posteriomedially above any area of anticipated bracing seems to avoid irritation and the need for subsequent removal. Secondly, although there has been no known failure of the device resulting from lead breakage in our hands, this scenario continues to remain a possible source of problems with the usage of internal fixation. "Blind" lead placement with the possibility of contacting internal fixation poses a significant threat during surgery. Further product development is needed to enhance the technique of lead placement to ensure maximum potential.

CONCLUSION

The results of the current study compare favorably to the prior investigations in the literature and demonstrate that implantable electrical stimulators in ankle arthrodesis combined with rigid fixation and soft tissue preservation can increase surgical success. Although these devices raise cost issues, they guarantee patient compliance and have been proven to improve fusion rates especially in those patients with significant or multiple risk factors. Our initial experience with implantable stimulation involved application with revisional ankle fusions and early success has evolved into a broader, more aggressive usage in order to maximize surgical outcomes. We believe, based on our data, that these devices negate or minimize the biological predisposition to failure in the high-risk patient population. Larger studies are needed to contribute to the establishment of clinical guidelines for usage of these devices.

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