CHAPTER 39

EFFICACY OF ELECTRICAL BONE STIMULATORS IN ANKLE ARTHRODESIS: Preliminary Data

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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, most commonly post-traumatic arthritis. 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. Historically there has been a relatively "common" occurrence of pseudoarthrosis with ankle arthrodesis, although fusion rates have varied from 0-41% throughout the literature.[3-7]

PREDISPOSING RISK FACTORS FOR NON-UNION

The predisposing risk factors for non-union in ankle arthrodesis have been well documented 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 with 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. They also reported, as other authors have concluded, that the weber "C" ankle fracture has the highest rate of nonunion. 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 nonunion 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. Greater than half (53%) of the patients with posttraumatic arthritis secondary to open trauma developed a nonunion.

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 nonunion in ankle arthrodesis was 3.75 times higher

Table 1

FACTORS ASSOCIATED WITH NONUNION

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

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" nonunion rate and they concluded that smoking cessation 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.

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% nonunion rate and cited sensory neuropathy, technically deficient procedures (specifically the transfibular approach), and the use of heterogenous bone graft as significant factors predisposing to nonunion. Interestingly, this group also found the non-union rate 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. 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.

ROLE OF ELECTRICAL STIMULATION IN ARTHRODESIS

Electrical stimulation has been utilized as early as 1816 for healing bone.[11] An interest in the electrical properties of bone and the application of electrical currents to stimulate bone began after the work of Yasuda[12] and Fukada and Yasuda[13] in 1955. Many authors have since published on the topic detailing the positive effects of electrical stimulation[14-17] as an adjunct to fusion and fracture healing in both laboratory and clinical models. This method has been used extensively in spinal surgery, and several authors have documented their positive experience in high-risk patient cohorts.[18-21] Both Rogozinski[20] and Kucharzyk[21] have showed dramatic reduction in nonunion rates in patients undergoing posterior spinal fusions with the use of an internal electrical stimulator. More recently, Donley and Ward[22] reported on 13 high-risk hindfoot fusions utilizing implantable bone stimulators. 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 negate the impact of certain risk factors, which may contribute to poor outcomes.

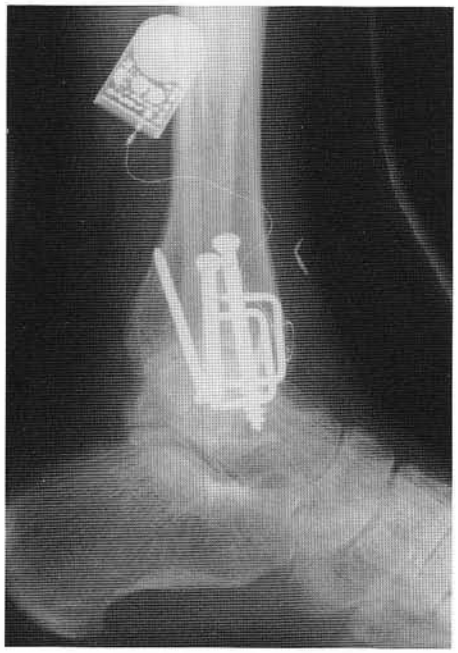

Figure 1. AP postoperative radiographs of an ankle arthrodesis performed with the traditional crossed screw method and supplemented staples to prevent sagittal plane rocking.

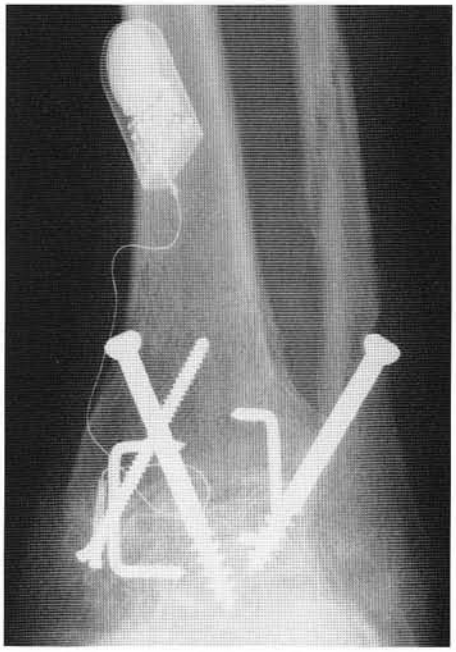

Figure 2. Lateral postoperative radiographs of an ankle arthrodesis performed with the traditional crossed screw method and supplemented staples to prevent sagittal plane rocking.

Electrical implantable stimulators, such as the EBI OsteoGen™ unit, work mainly through direct current stimulation. This device was developed primarily as an adjunct for high-risk spinal fusions and works through a reduction reaction at the cathode, which establishes lower oxygen tension and an increase in pH. These factors have been shown to provide an optimal osteogenic environment to maximize surgical success.

MATERIALS AND METHODS

A total of 102 ankle fusions, performed at Emory Northlake Regional Medical Center between 1997-2002, were reviewed for this study. Complete charts and radiographs were available for evaluation of 49 patients. At the current time 41 complete records have been reviewed. There were 22 females and 19 males with a mean age of 56 years. Examination of preoperative, intraoperative and all postoperative plain radiographs was performed. Medical records of each patient were reviewed and information collected included demographic data, 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 (i.e. smoking history, open or high energy trauma, etc.), type of fixation used, additional surgical procedures, and the use of an internal or external bone stimulator. If the ankle arthritis was traumatic in origin, the trauma was classified as low energy, high energy or open fracture according to Kenzora.[6]

The surgical technique involved a lateral and ancillary medial incisonal approaches which were carried out under pneumatic thigh tourniquet. A combination of transfibular and malleolar sparing techniques were utilized depending on surgeon preference. Fusion surfaces were decorticated to a healthy cancellous substrate utilizing either an osteotome or a power saw. Primary fixation was accomplished with two to three screws and supplemented with large Blount staples when necessary (Figures, 1, 2). When indicated, a circular wire fixator or half-pin monorail device was utilized to optimize fixation constructs (Figure 3). The decision to augment fusion with implantable bone stimulation was based on the surgeons' experience.

In all patients with implantable devices, the EBI (Parsippany, NJ) OsteoGen™[23] (Figure 4) electrical internal bone stimulator was utilized. The straight or fish scale (Figure 5A) method of cathode placement was primarily chosen in instances of internal fixation to avoid contact of the titanium lead with the stainless steel screws. The mesh (Figure 5B) cathode was placed directly between the contact surfaces for arthrodesis with external fixation techniques.

Delayed union was defined by the absence of radiographic evidence of osseous union at 6 months. A nonunion was similarly defined, except that the time frame was 12 months (Figure 6). Bony union was defined by radiographic evidence of osseous trabeculae crossing the arthrodesis site (Figure 7). Further investigation was performed on patients with nonunions to identify possible reasons for failure including predisposing risk factors, technical errors and if in fact electrical stimulation was utilized.

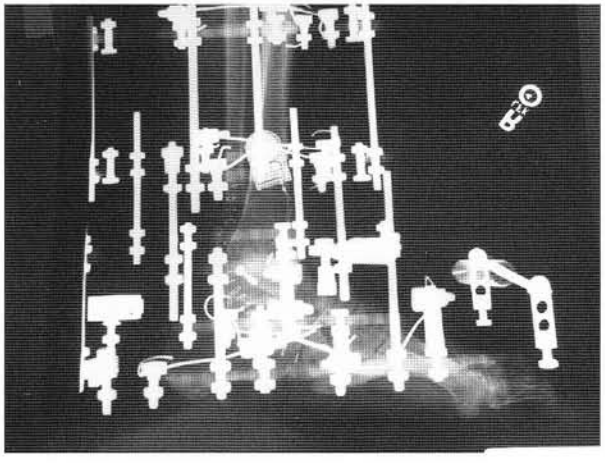

Figure 3. Lateral postoperative radiographic of an Ilizarov wire fixator used for posttraumatic arthritis resulting from a high-energy ankle fracture with adjunctive internal bone stimulation.

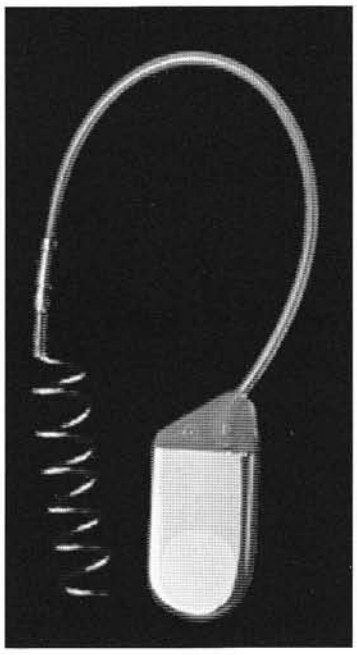

Figure 4. EBI (Parsippany, NJ) OsteoGen™ single lead implantable spinal stimulator.

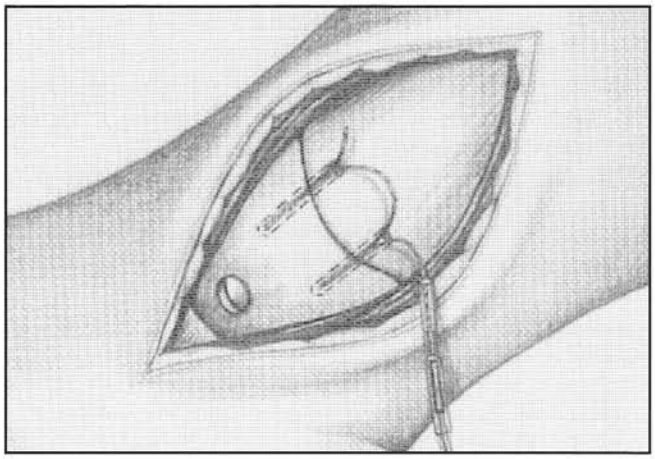

Figure 5A. The straight or fish scale method of cathode placement internal fixation to avoid contact of the titanium lead with the stainless steel screws. (Adapted from EBI OsteoGen™ product brochure.)

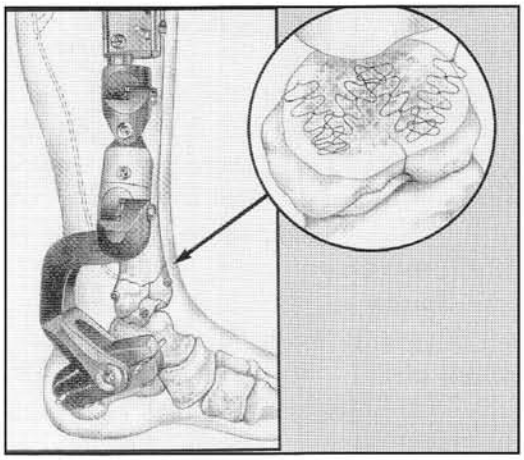

Figure 5B. "Mesh" configuration for ankle arthrodesis with external fixation constructs. (Adapted from EBI OsteoGen™ product brochure.)

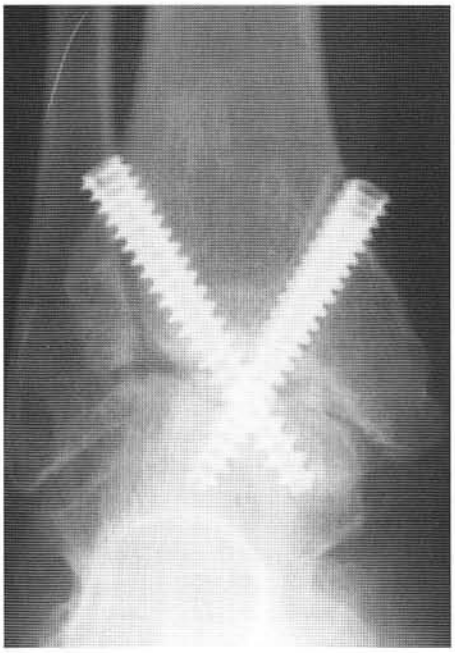

Figure 6. Ankle arthrodesis nonunion.

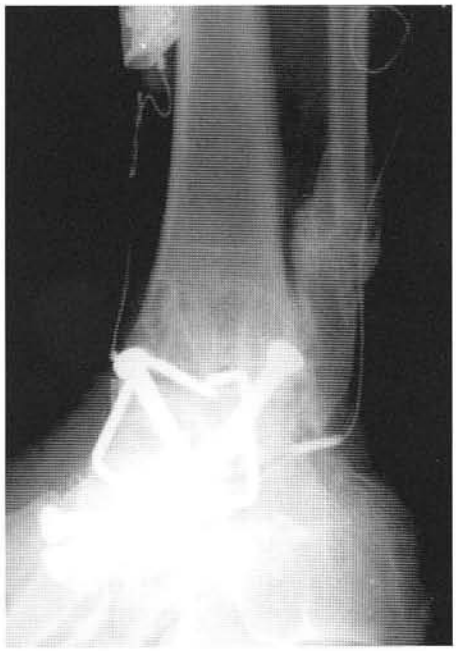

Figure 7. Osseous consolidation 9 weeks status post ankle fusion.

PRELIMINARY RESULTS

The overall nonunion rate in the study was 12.3%. Two nonunions occurred with internal fixation and three occurred with external fixation. The average overall time to radiographic union was 11.5 weeks. Approximately 90% of patients had at least one documented risk factor for nonunion. The most common risk factors were posttraumatic arthritis and peripheral neuropathy.

Thirty eight percent of patients undergoing ankle arthrodesis received implantable stimulators as an adjunctive measure. No delayed or nonunions occurred in the presence of the EBI implantable electrical stimulators regardless of the number of risk factors. The average time to nonunion with internal bone stimulation was 12.4 weeks. All but one of the patients with internal stimulators had a least two documented risk factors for nonunion. The average number of risk factors per patient receiving internal stimulation was 2.3. Only five of the implantable battery units had to be surgically removed because of subsequent irritation.

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 using advanced internal and external compression techniques possible, there is still an elevated nonunion rate reported in the literature among certain high-risk patients. The documented risk factors should be identified in the preoperative period and patients with one or more of these risk factors should be counseled regarding their increased risk of nonunion.

The overwhelming majority of clinical studies concerning electrical implantable stimulators have been associated with spinal fusions. With the exception of Donley and Ward who evaluated 13 hindfoot fusions, of which only three were ankle fusions, the authors' are unaware of any literature, which evaluates the efficacy of spinal stimulators specifically to ankle arthrodesis. Our initial experience with internal stimulators was with revisional ankle fusions and early success has lead to a broader, more aggressive application in order to maximize surgical outcomes. Our preliminary data indicates that implantable bone stimulators have a significant role in ankle arthrodesis and perhaps negates or minimizes the biological predisposition to failure. In our initial survey there were no nonunions in patients when internal electrical stimulators were utilized despite the number of risk factors present preoperatively. Patients receiving stimulators had a prolonged time to union when compared to the overall time or those without stimulators. One possible explanation for this finding is that the patient population receiving adjunctive electrical stimulation demonstrated the greatest risk for failure and therefore had longer healing times. 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. With further evaluation of our data we hope to create clinical guidelines for use of these devices.

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