CHAPTER **3**

THE USE OF IMPLANTABLE BONE STIMULATORS FOR DIFFICULT MIDFOOT FUSIONS

Aimee A. Nichols, DPM
Craig A. Camasta, DPM
G. Clay Taylor, DPM

The risk for non-union is always a concern when attempting an arthrodesis procedure. The rate of non-union of midfoot arthrodesis has been reported to be between 3% to 7%.[1] Factors such as infection, avascular necrosis, previous nonunion, and major medical problems have all been cited as factors predisposing patients to nonunion of hindfoot fusions.[2,3] The rate of non-union in smokers can be up to three to four times higher than in non-smokers.[2,3] It is therefore imperative that these risk factors are identified pre-operatively and to aid in the creation of a surgical plan. Patients must be advised on the importance of smoking cessation, the increased need for nutritional support and limitation of consumption of drugs such as steroids or NSAIDS that may compromise bone or wound healing.

Implantable bone stimulators have proven to be very useful and effective in increasing the rate of union in difficult fusion patients. Revision arthrodesis may require the usage of an autograft in addition to an implantable bone stimulator to augment fusion in high risk patients.

MECHANISM OF ACTION

Bone has bioelectric properties like all other living tissues. Wolff's law suggests that there is a relationship between mechanical stimulus or strain and the biologic response of bone. This principle has led to the study of the effect of electrical stimulation on osseous cells and tissues and growth. Direct current stimulators are surgically implantable devices in which the battery is placed in soft tissue and the leads are placed within or adjacent to the fusion site. Currently, the only available invasive bone stimulator is the Osteogen (EBI) which has a titanium cathode wire which can be a single, double, or meshed lead. The cathode wire lead should be placed to have maximum contact with bone on each side of the fusion site but avoiding any metal implants. The leads can be placed directly into the fusion site or may be laced around the site utilizing drill holes. The battery should be implanted in an area with adequate subcutaneous tissue. The medial aspect of the leg is ideal for this, however, the lateral side can be used as well. If the battery is in a weight-bearing or prominent area, it has the potential to slough the soft tissue and become problematic. The battery will provide power from 6-12 months and may be removed surgically after union is achieved.

BACKGROUND AND LITERATURE REVIEW

The use of electrical stimulation for bone healing dates back to the early 1900's but it was not until the 1950's when Yasuda reported on the piezoelectric effects of bone.[4,5] These implantable bone stimulators were historically first used by surgeons attempting spinal fusions.[6] Paterson[7] in 1980 utilized bone stimulators for the treatment of delayed and non-unions in 84 ununited fractures. He found that 81 of 84 fractures healed at an average of 16 weeks. He also followed these patients at 10 years and found all fractures remained united and there were no adverse effects related to the implanted device or leads.[7] Kucharzyk in 1999 reported a clinical success rate of 95% in patients with posterior spinal fusion with an internal electrical bone stimulator compared to a 79% success rate without an electric stimulator.[8] A yet unpublished retrospective study by Fleming, Ruch and Weinstein[9] of 43 ankle fusions found an overall 86.4% success rate. Of these, 19 had implantable bone stimulators with 100% fusion rate and a 5.6 week faster radiographic time to union than the non stimulator group. The non-stimulator group exhibited only a 79.0% fusion rate.

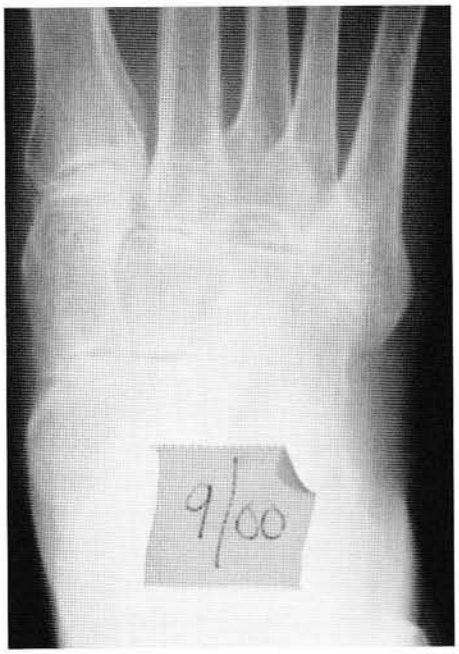


Figure 1A. Extensive degenerative arthritic changes at the talonavicular and naviculocuneiform joints.

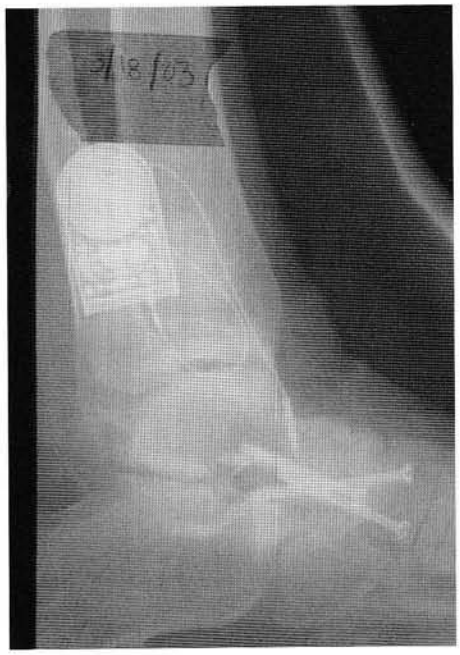


Figure 1B. Arthrodesis of the talonavicular and naviculocuneiform joints. Utilizing 4.0mm partially threaded cancellous screws. Note the placement of the cathode bone stimulator lead within the fusion site.

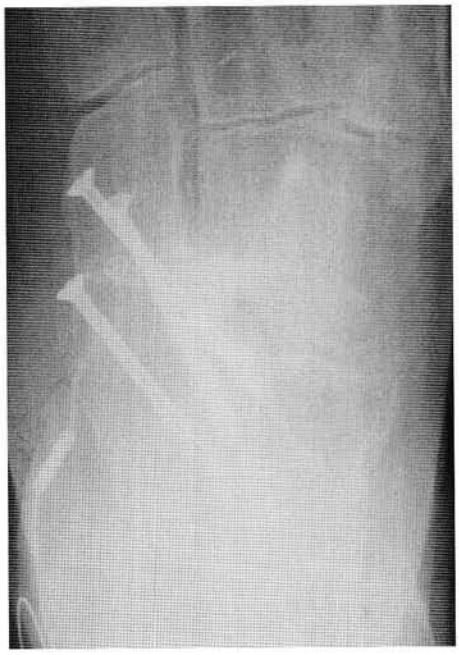


Figure 1C. Note the placement of the battery pack in the medial aspect of the leg above the sock line.

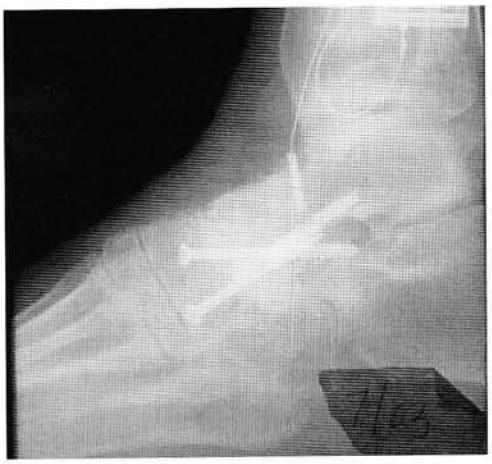


Figure 1D.

CASE 1: POST-TRAUMATIC ARTHRITIS IN A SMOKER WITH HISTORY OF NAVICULAR NON-UNION

A 33-year-old female presented two years after a automobile accident in where her right foot was "crushed" impacting the floorboard of the car. She sustained a fracture-dislocation of the talonavicular joint with communition of the navicular bone. Initial care included open reduction with internal fixation of the right foot and leg. The hardware had been removed prior to our treatment of her. She smoked one pack of cigarettes per week and reported occasional alcohol consumption. She was on hormone replacement therapy and was treated for chronic pain with oral and transdermal narcotics and muscle relaxants. She was painful at the site of injury and was walking with the assistance of an AFO brace and a cane. The patient ambulated with an antalgic gait and attempted to bear all of her weight on the lateral column of the right foot. Radiographs demonstrated extensive degenerative arthritis of the midfoot and non-union of the navicular fracture (Figure 1A).

The patient underwent a talonavicular and naviculocuneiform joint arthrodesis with implantation of a meshed Osteogen bone stimulator (Figure 1B). Autogenous tibial bone graft was also procured and implanted around the bone stimulator at the fusion site. The navicular non-union extended to the talonavicular as well as the naviculocuneiform joints. The meshed implantable bone stimulator cathode was placed along the medial aspect of the talonavicular joint and within the naviculocuneiform joint arthrodesis sites (Figure 1B). The battery pack was placed in a subcutaneous tunnel along the posteromedial aspect of the leg above the sock line (Figure 1C). The arthrodesis sites were fixated with 4.0 mm partially threaded cannulated cancellous bone screws. Standard soft tissue closure was performed and a below knee cast was applied. The patient was observed overnight and discharged non-weight bearing with crutches. The patient was poorly compliant regarding weight-bearing, and fell landing on the surgical foot four weeks postoperative. The patient's cast was dirty and broken down on the plantar aspect of the heel. However, radiographic evaluation demonstrated stable alignment of the fusion site. At four months postoperative, complete consolidation of both talonavicular and naviclo-cuneiform joints was evident. At nine months following surgery the patient was ambulating unassisted and with markedly reduced pain and edema (Figure 1D).

CASE 2: PSEUDOMONAL SEPTIC ARTHRITIS OF THE GREAT TARSAL SYNOVIAL CAVITY

A 50-year-old male presented four weeks following incision and drainage of a spontaneous, non-traumatic, abscess of the midfoot. Extensive debridement of the tarsometatarsal and intercuneiform joints resulted in significant instability of the foot. He was under treatment with intravenous antibiotics for pseudomonal osteomyelitis and completed a six week course around the time of this surgery. Radiographic evaluation showed radiolucency of the bases of the second and third metatarsals and cuneiforms (Figure 2A). MRI examination was postitive for osteomyelitic bone changes to the bases of the second and third metatarsal as well as the medial, intermediate, and lateral cuneiforms (Figure 2B). Following serial debridements and wound care, it was deemed appropriate to perform definitive surgical treatment. Curettage debridement of the remaining joint surfaces, autogenous bone graft harvested from the distal tibia, implantation of a meshed bone stimulator, and placement of two external fixators was performed (Figures 2C, 2D, 2E). External fixation was chosen to span the fusion site and avoid placing additional hardware at the site of infection. Additional intraoperative bone cultures and and pathology confirmed the diagnosis of pseudomonal osteomyelitis. Corticocancellus bone chips were then used to pack the defect in the tibia at the donor site. A two centimeter incision was made on the posteromedial aspect of the leg and blunt subcutaneous dissection was used to create a channel to place the implantable bone stimulator, and a tendon passer was used to direct the lead distally into the midtarsal region. The patient was discharged on intravenous antibiotics and was instructed on pin care and dressing changes. At six weeks postoperative the patient exhibited radiographic evidence of bony consolidation, was changed to oral antibiotics, and allowed to bear weight on the foot in a surgical shoe. At eight weeks postoperative the patient was fully weight-bearing without pain or drainage from the pin sites. The bone stimulator battery with its wire lead and the external fixators were surgically removed. One year following surgery the patient was back to normal activities with no discomfort (Figure 2F) and the fusion sites remained well aligned and consolidated. The patient developed a stress fracture of the distal second metatarsal eighteen months postoperative, which was successfully treated with immobilization and gradually returned to normal activities and footwear.

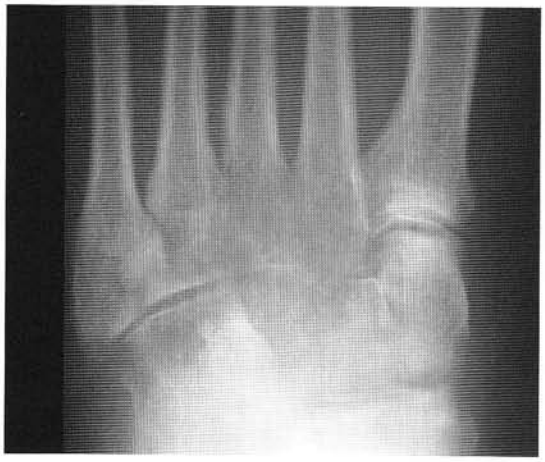


Figure 2A. Radiolucent appearance of the bases of the 2nd and 3rd metatarsals and the intermediate and lateral cuneiforms suggestive of osteomyelitis.

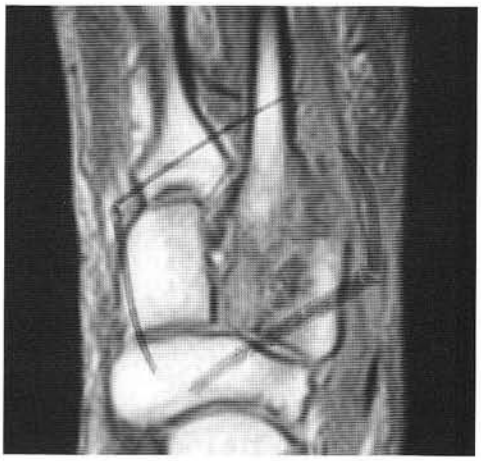
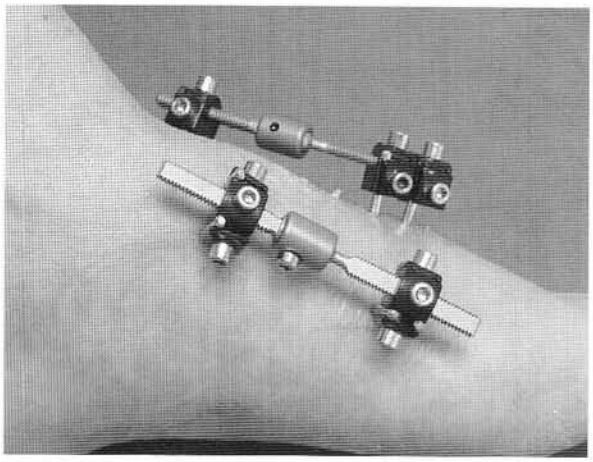


Figure 2B. A T1-weighted image showing fluid collection in the bases of the 2nd metatarsal and intermediate and lateral cuneiforms.



Figures 2C. Mini external fixators applied spanning the midfoot for stability.

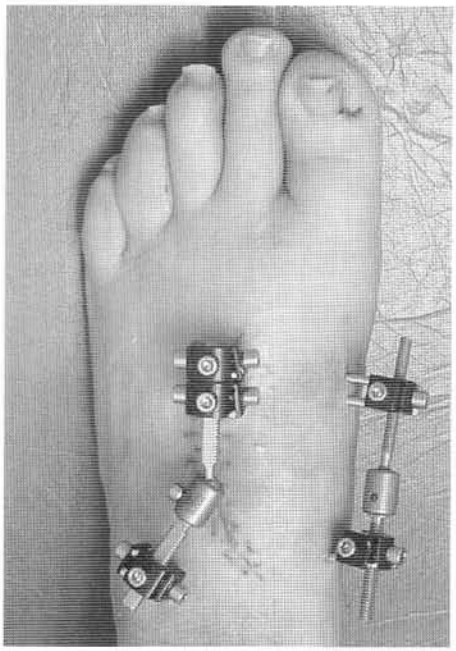


Figure 2D.

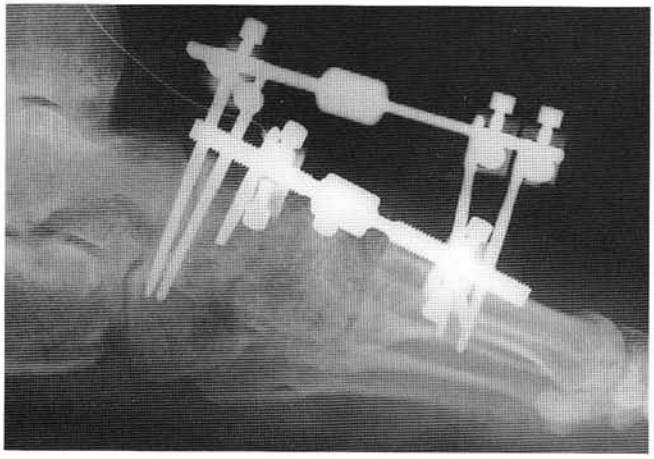


Figure 2E.

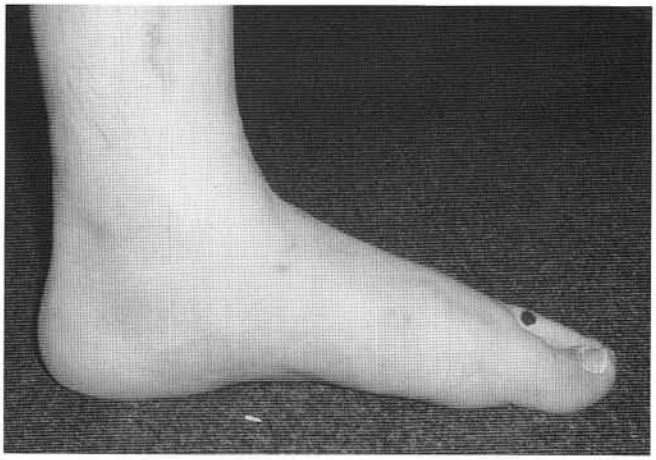


Figure 2F. Clinical appearance of the foot 1 year postoperative.

CASE 3: UNDIAGNOSED LISFRANC INJURY IN A CIGARETTE SMOKER

A 46-year-old female smoker presented with a one year history of pain and swelling on the dorsal aspect of her right foot following and inversion-type injury while at work. Initial treatment consisted of splintage, followed by a series of cortisone injections, with little relief. There was focal tenderness over the 3rd and 4th metatarsal-cuboid joints and intercuneiform joints between the second and third metatarsal bases (Figure 3A). Radiographic and CT examination revealed irregularity and arthrosis of the bases of the 3rd and 4th metatarsal-cuboid/cuneiform joints. She was a smoker at the time of initial evaluation and signed a contract to quit prior to surgery. The patient underwent a tarsometatarsal arthrodesis of the 3rd and 4th joints with compression staple fixation (Figure 3B). She was placed in a NWB cast following surgery utilizing a knee-walker for ambulation assistance. Throughout the post-operative course, there was increasing evidence of weight bearing due to the condition of the cast on the foot. She denied tobacco use in this time frame. At 10 weeks postoperative, there was bony resorption across the fusion site without evidence of bony consolidation (Figure 3C). At 3 months post-operative, the patient was dispensed an external bone stimulator and the importance of non-weight bearing was again stressed to the patient. At 4 month postoperative, there was no radiographic progression of union and the patient related symptoms similar to those she had prior to surgery. The patient underwent revisional arthrodesis of both fusion sites with autogenous calcaneal bone graft and platelet gel, plate fixation, and the implantation of an internal bone stimulator (Figure 3D and 3E). The bone stimulator's battery and lead were routed posterior to the fibula and seated in the posterior leg. Radiographic examination at week eight demonstrated good alignment and adequate bony trabeculation across the fusion sites (Figure 3F). The patient had pain at the site of the battery lead along the lateral heel consistent with sural nerve irritation/entrapment. Eight months following the revision surgery, the internal fixation and bone stimulator were removed, and the sural nerve was released via external neurolysis. Twenty months following surgery the patient was bearing weight and ambulating pain free in normal footwear.

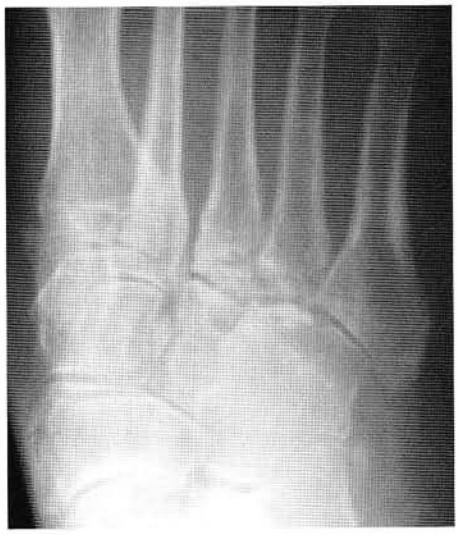


Figure 3A. Arthrosis and irregularity of the 4th and 5th metatarsal-cuboid articulations.

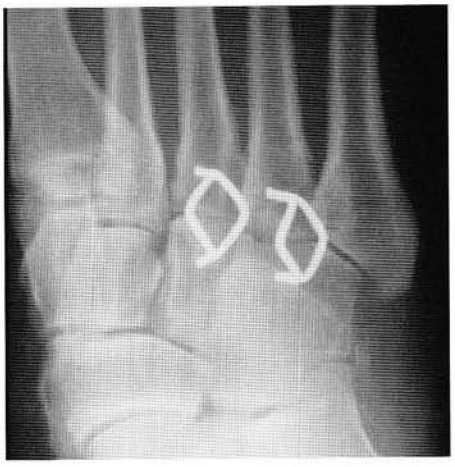


Figure 3B. Tarsometatarsal arthrodesis of the 3rd and 4th metatarsocuneiform joints with compression staple fixation.

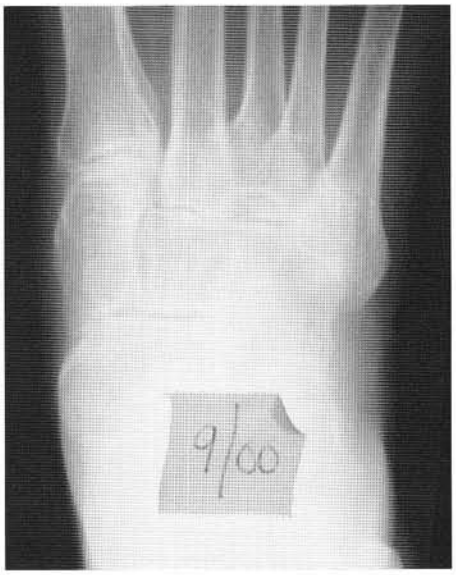


Figure 4A. Note early arthritic changes at the 1st metatarsocuneiform and naviculocuneiform joints.

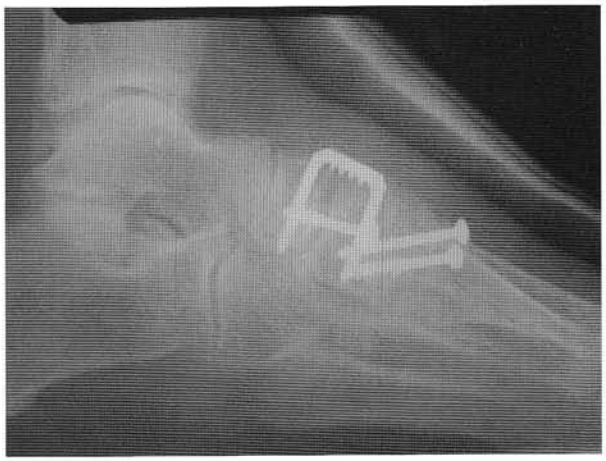


Figure 4B. First metatarsocuneiform and naviculocuneiform fusions with screw and staple fixation.

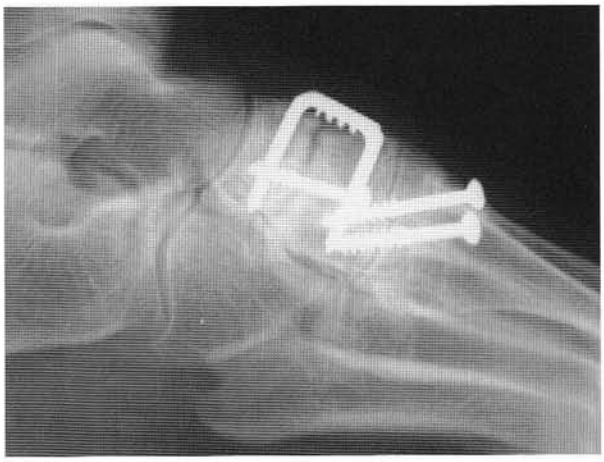


Figure 4C. Lack of trabeculation across the 1st metatarsocuneiform joint fusion site.

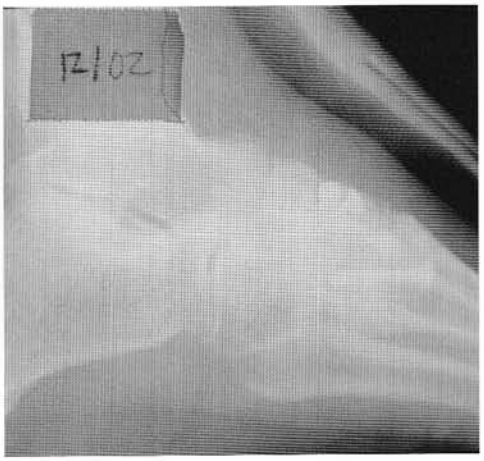


Figure 4D. Revisional arthrodesis utilizing screws.

the following months that there was again failure of trabeculation across the arthrodesis sites and further arthritic changes were occurring especially at the 1st metatarsocuneiform joint (Figure 4E). At this time a second revisional arthrodesis was performed utilizing a 5-hole plate, screws, autogenous tibal bone graft, and internal bone stimulation. Nine months after the second revision, the patient was pain free, back to normal activities, and demonstrated radiographic union at both arthrodesis sites (Figure 4F).

CONCLUSION

Multiple or adjacent midfoot fusions increases the risk of delayed union or failure of bone to unite. Poor compliance with non-weight bearing and cigarette smoking further increases the risk of poor bone healing in the foot. The use of supplemental bone healing aids such as an internal bone stimulator, autogenous bone graft, and stable internal fixation, has a role in revisional midfoot surgery.

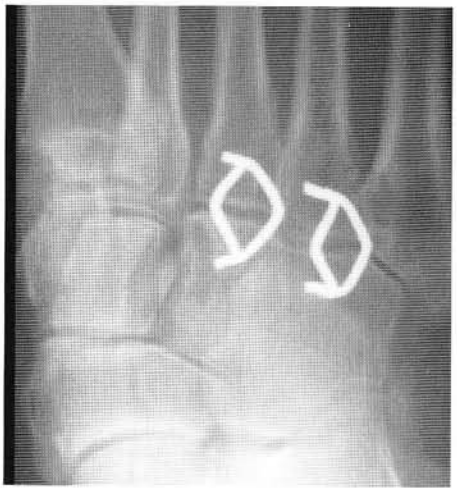


Figure 3C. Note good alignment but with gapping across the intended fusion site without bony consolidation.

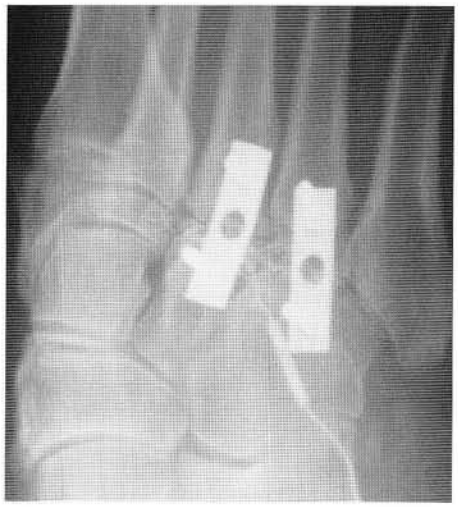


Figure 3D. Revisional arthrodesis of the 3rd and 4th metarsocuneiform and metatarsocuboid joints. Fixation with 2 two-hole plates and internal bone stimulator.

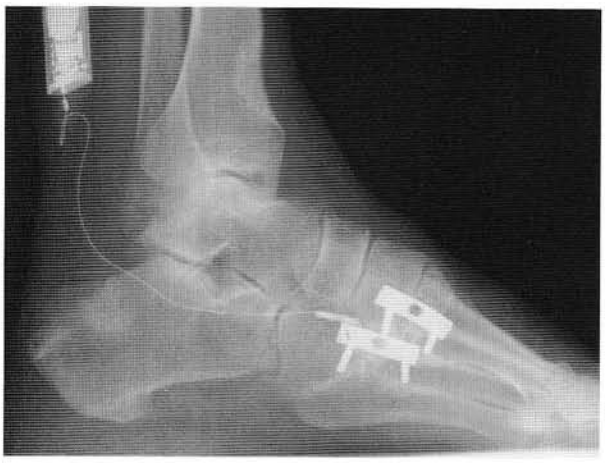


Figure 3E.

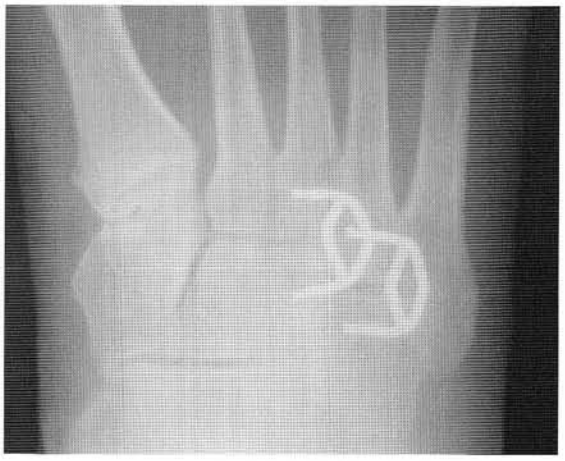


Figure 3F. At 8-week follow-up showing bony trabeculation across fusion sites with excellent alignment of arthrodesis sites.

CASE 4: LISFRANC ARTHRODESIS WITH DEVELOPMENT OF NON-UNION

A 57-year-old female was seen in the emergency room after stepping out of bed and twisting her foot. She was diagnosed with "two foot fractures and calcium deposits" and placed in a splint. She continued to have pain for the next two weeks and was referred by her primary care physician to a podiatrist for treatment. She had pain localized to the 1st metatarsocuneiform and naviculocuneiform joints, aggravated by ambulation. She had a past medical history significant for coronary artery disease, multiple DVTs and a pulmonary embolism, depression, migraine headaches, and extensive gastric surgery. She was taking Vioxx, Premarin, Zantac, Depakote, Prozac, trazadone and Zomig. She denied the use of tobacco or alcohol. More than one year after her injury she had progressive arthritic changes at the naviculocuneiform and 1st metatarsocuneiform joints (Figure 4A). She subsequently underwent a 1st metatarsocuneiform and naviculocuneiform arthrodesis utilizing screw and staple fixation (Figure 4B). She was placed in a NWB cast following surgery for 8 weeks. It was noted on radiographic evaluation that trabeculation was not progressing across the arthrodesis sites (Figure 4C). She declined further surgical intervention and was managed by pain control measures and protected weight-bearing. Seven months following her initial surgery she underwent a revisional arthrodesis of the same joints, fixated with compression screws (Figure 4D). It was noted over

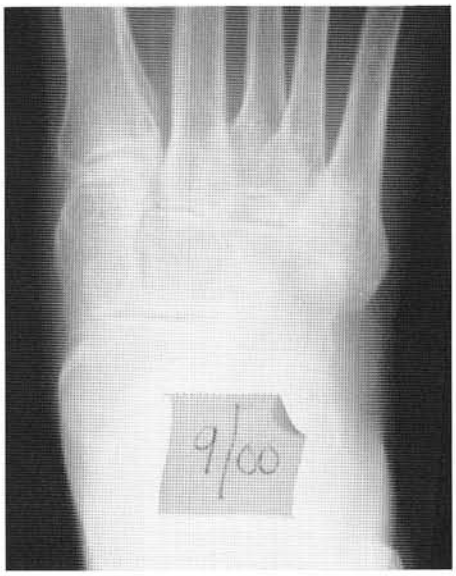


Figure 4A. Note early arthritic changes at the 1st metatarsocuneiform and naviculocuneiform joints.

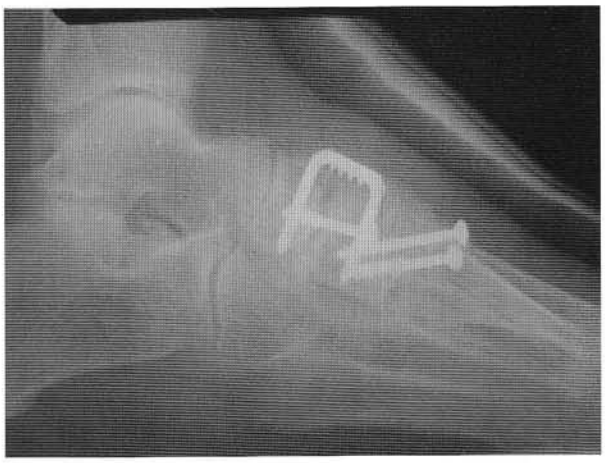


Figure 4B. First metatarsocuneiform and naviculocuneiform fusions with screw and staple fixation.

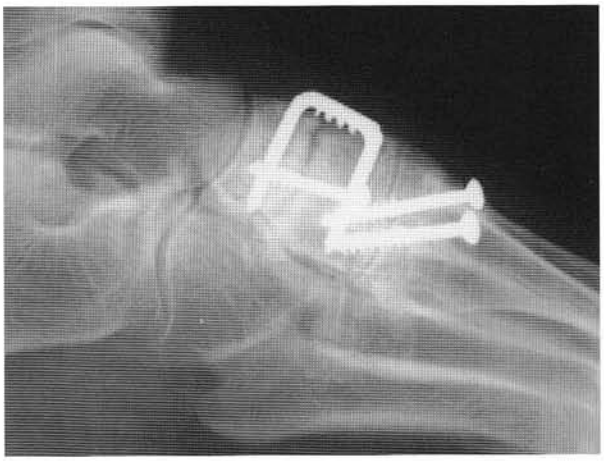


Figure 4C. Lack of trabeculation across the 1st metatarsocuneiform joint fusion site.

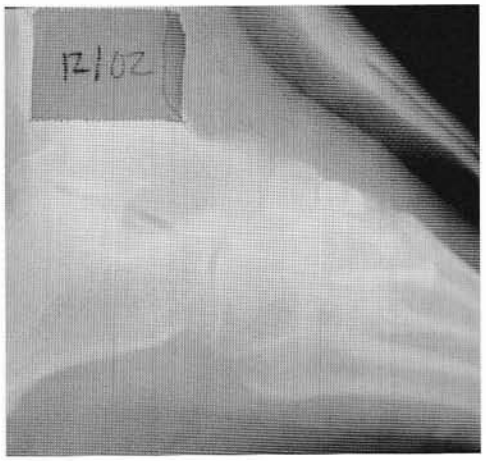


Figure 4D. Revisional arthrodesis utilizing screws.

the following months that there was again failure of trabeculation across the arthrodesis sites and further arthritic changes were occurring especially at the 1st metatarsocuneiform joint (Figure 4E). At this time a second revisional arthrodesis was performed utilizing a 5-hole plate, screws, autogenous tibal bone graft, and internal bone stimulation. Nine months after the second revision, the patient was pain free, back to normal activities, and demonstrated radiographic union at both arthrodesis sites (Figure 4F).

CONCLUSION

Multiple or adjacent midfoot fusions increases the risk of delayed union or failure of bone to unite. Poor compliance with non-weight bearing and cigarette smoking further increases the risk of poor bone healing in the foot. The use of supplemental bone healing aids such as an internal bone stimulator, autogenous bone graft, and stable internal fixation, has a role in revisional midfoot surgery.

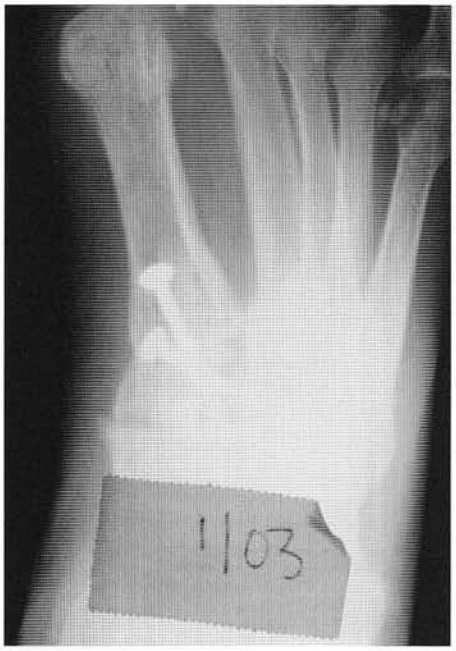


Figure 4E. Second revisional arthrodesis utilizing a plate, screws, autogenous bone graft and internal bone stimulation.

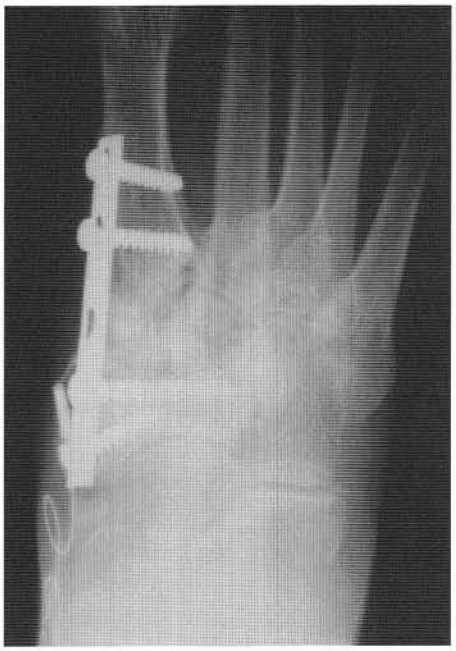


Figure 4F. Complete union of both arthrodesis sites with excellent alignment.

REFERENCES

1. Bibbo C, et al. Complications of midfoot and hindfoot arthrodesis. *Clin Orthop Rel Res* 2001;391:45-58.
2. Cobb TK, et al. Cigarette smoking and nonunion after ankle arthrodesis. *Foot Ankle* 1994;15:64-7.
3. Frey C, et al. A review of ankle arthrodesis; predisposing factors to nonunion. *Foot Ankle* 1994;15:581-4.
4. Yasuda, I, Fakada E. On the piezoelectric effect of bone. *J Physiol Soc Jpn* 1957;12:1158.
5. Yasuda I, Noguchi K, Sata T. Dyamic callus and electric callus. *J Bone Joint Surg* 37: 1292, 1955.
6. Dwyer AF. The use of electrical current stimulation in spinal fusion. *Orthop Clin North Am* 1975;6:265-79.
7. Paterson DC, Lewis GN, Cass CA. Treatment of delayed union and nonunion with an implanted direct current stimulator. *Clin Orthop* 1980;48:117-28.
8. Kucharzyk DW. A controlled prospective outcome study of implantable electrical stimulation with spinal instrumentation in a high risk spinal fusion population. *Spine* 1999;24:465-9.
9. Fleming J, Weinstein RB, Ruch JA. (Unpublished observations)

ADDITIONAL REFERENCES

Cundy PJ, Paterson DC. A ten-year review of treatment of delayed union and nonunion with an implanted bone growth simulator. *Clin Orthop* 1990;259:216-22.

Komeda GA, Myerson MS, Biddinger KR. Results of arthrodesis of the tarsometatarsal joints after traumatic injury. *J Bone Joint Surg Am* 1996;78:1665-76.