CHAPTER 16

CLINICAL APPLICATION OF AN IMPLANTABLE DIRECT CURRENT BONE GROWTH STIMULATOR

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According to Wolff's law, living bone consistently adapts its internal architecture to meet mechanical stress in an optimal way. In 1953, Yasuda[1] hypothesized that the application of electrical current may be helpful in healing the non-united bone. Further, in 1957, Fukada and Yasuda[2] demonstrated that bone has piezoelectric properties in that it can generate electric potentials in response to mechanical stress. Since that time, combining Wolff's law with Fukada and Yasuda's research, the following clinical question has been raised: "Is it possible to accelerate or positively affect the process of bone healing by electrical stimulation?" Since the early 1960's, numerous investigators have explored this question. Today, the modulation of bone growth and repair by electrical and magnetic forces is generally accepted. Thus, the results of this research forces us to modify our concept of Wolff's law to include not only mechanical loading conditions, but also the response of bone to its electrical and magnetic environment.[3]

Today, electrically-induced osteogenesis may be observed with both invasive and noninvasive methods that involve various types of exogenous signals. In this paper, the author will review the clinical use of a surgically implanted, direct current bone growth stimulator.

BACKGROUND – DIRECT CURRENT STIMULATION

The majority of studies investigating the effects of electricity on bone have dealt with direct current. Therefore, today we have the greatest knowledge of this form of electricity. Simply stated, a direct current system consists of two electrodes, a positively-charged anode and a negatively-charged cathode, and a current source. Resistance builds up rapidly between the electrodes when they are inserted into body tissues. This leads to a concomitant decrease in current. With direct current, the current should remain constant, as pulsed direct current is not as effective in producing osteogenesis. For a constant current to be maintained, the power supply must contain a transistorized control circuit such that as the resistance increases, the voltage increases, and the current remains constant.

Using a constant current source, an osteogenic environment is created at the cathode. The reaction at the cathode results in oxygen consumption and the production of hydroxyl radicals: $4e^- + O_2 + 2H_2O = 4OH^-$. This reaction causes an increase in pH and lowers oxygen tension. An alkaline environment, or high pH, has been found to be favorable to calcification and may aid in the production of alkaline phosphatase, an enzyme important to new bone formation. Similarly, low oxygen tension has been shown to stimulate osteoblastic activity and to be favorable to bone formation as: (1) optimum bone growth in vitro occurs in low oxygen tension; (2) the PO_2 at the bone-cartilage junction in the physeal plate and in newly forming bone and cartilage in a fracture callus is low; and (3) physeal-plate cartilage cells, as well as bone cells, follow a predominantly anaerobic metabolic pathway.[4,5]

With direct current stimulation, cellular necrosis can occur at the anode. Varying amounts of cellular necrosis may occur in the vicinity of the anode, depending on the metallic composition of the anode, the surface area of the anode, and the current amplitude. Fortunately, cellular necrosis has not been reported to occur with a platinum anode at current levels that are osteogenic.[6]

Since direct current stimulation can produce hazardous effects, significant research has been undertaken to determine the optimal current, voltage, and design of an implantable system. It has been determined that a current between 10 and 20 microamperes and a voltage between 0.6 and 1.2 volts are optimal to promote an osteogenic environment and diminish cellular necrosis. Logically, the system's design should allow the cathode to be inserted into the area of desired osteogenesis and the anode should be made of platinum or another metal that minimizes the likelihood of cellular necrosis.

Initially, the marketed direct current systems were semi-invasive. The cathodes were inserted percutaneously or through open surgical incisions. The anode was a skin pad, and there was an external power source. More recently, totally implanted systems have been developed which must be surgically implanted, and the semi-invasive systems are now less popular.[7,8]

CLINICAL APPLICATION

Indications

The author's experience with a surgically implanted bone growth stimulator has been with the OsteoGen™ stimulator manufactured by EBI Medical Systems (Parsippany, N.J.). The OsteoGen™ is a useful adjunct for treating difficult areas of bone healing where surgery is already planned. Examples include repairs of nonunions and complex reconstructions, arthrodeses, or fractures which may be prone to nonunion or avascular necrosis. Further, if the use of a bone growth stimulator is planned and patient compliance is a concern, then a totally implanted unit may be advisable. There are no known definitive contraindications or adverse effects to the OsteoGen™, but due to limited clinical experience, the device is currently not recommended in the presence of active osteomyelitis, or for the treatment of pathologic fractures due to malignant tumors. Obviously, electrical bone growth stimulation will not be effective in fracture or nonunion sites with large gaps (i.e., gaps greater than 1 cm or more than one-half the diameter of the involved bone) or uncontrollable motion.

OsteoGen™ Unit

The OsteoGen™ unit is designed to produce a constant current of 20 (+/-2) microamperes (Fig. 1). The solid-state generator maintains this constant current between the anode and cathode despite wide variations of bone and tissue resistance. The generator is powered by a single lithium iodine battery which is contained within the generator's case. The generator case is hermetically sealed and is made of titanium. On one side of the case is a circular area which is platinized for anodic function. Thus, the generator serves as the anode. One end of the generator has a silicone elastomer hub. This hub has a small circular mark for suture attachment, if necessary. From this end of the generator, a 15-centimeter strand of stainless steel/silver wire protrudes which is insulated with a silicone elastomer. This wire terminates in a connector socket which links it to the cathode wire. The cathode is a 25-centimeter 3-strand titanium wire with a connector at its proximal end to allow linkage to the insulated strand. The stimulator comes gas sterilized, weighs roughly 10 grams, and should function for approximately 24 weeks.

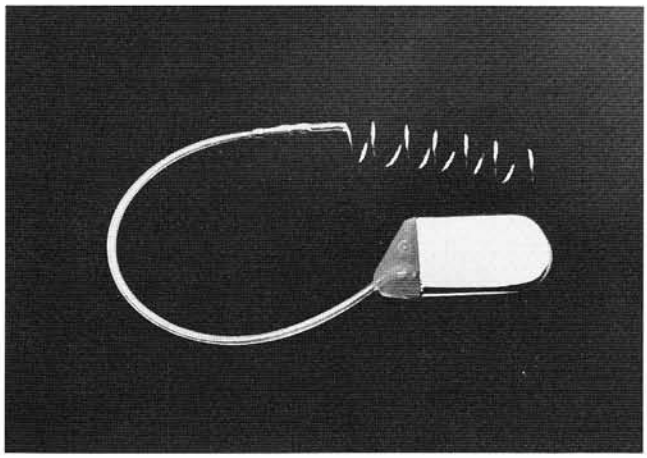

Figure 1. OsteoGenTM unit: a totally implantable direct current system.

Surgical Implantation

Intraoperatively, the OsteoGen™ should be tested prior to implantation. A telemetry circuit within the generator allows its function to be tested with an external implant tester (Fig. 2). The generator should be implanted within the subcutaneous tissues. Contact with soft tissue or muscle is acceptable, but contact with bone should be avoided. Obviously, the generator should be positioned to minimize patient discomfort and to protect it from external irritation or trauma. Further, the generator should not touch any metallic fixation devices as this may dissipate the current of the device. If potential generator migration is a concern, the generator may be sutured to soft tissue to maintain proper position. The suture can be placed through the circular mark on the silicone elastomer portion or hub of the generator. Ideally when inserted, the generator should be 8-10 centimeters away from the cathode. When used as an adjunct for rearfoot or ankle surgeries, the generator is best implanted in Kagar's triangle (i.e., the anatomical area anterior to the Achilles' tendon and posterior to the deep crural fascia). This area can also be used for forefoot applications if desired, as the

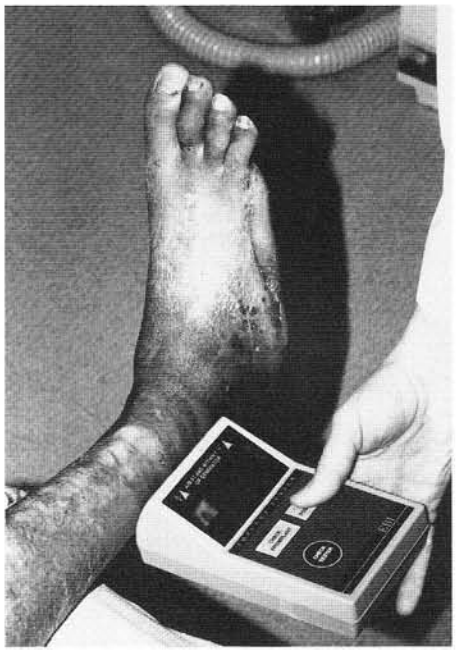

Figure 2. Implant Tester. The generator portion of the OsteoGen™ unit contains a telemetry circuit which allows its function to be checked. The Implant Tester is held against the skin directly over the implanted site of the generator. A button is pressed and a digital read-out describes the function as "OK" or "Inactive."

insulated strand can be tunneled subcutaneously from Kagar's triangle to the forefoot, and the titanium cathode utilized in the forefoot.

Bone growth stimulation occurs around the titanium cathode wire. The cathode can be implanted in a variety of different ways. The three most common configurations are the helix, zigzag, and straight or "fishscale" patterns. Regardless of which configuration is utilized, the electrical current emanating from the cathode will traverse a cylindrical area approximately 5-8 mm in radius around the wire. Each configuration has advantages and disadvantages, and the optimal cathode configuration will ultimately be chosen based upon the surgical approach, fixation utilized, and the size of the area to be stimulated. Unlike the generator/anode, the cathode placement should be within bone as much as possible, and obviously within close proximity to the needed site of bone growth stimulation.

The helix configuration for the cathode wire is generally used for transverse, segmented, or comminuted patterns of injury or nonunion. The OsteoGen™ unit comes with a sterile, disposable plastic mandrel which can be used to help form a helix of the desired size for implantation. The helix-configured cathode can be implanted into a trough in bone, either alone or wrapped around a bone graft, directly implanted at the fracture site, or inserted into a drill hole.

The zigzag configuration is typically used for transverse or oblique areas where compression will be applied. The cathode is arranged in a flattened helix configuration in an appropriate zigzag or sinusoidal shape. It is then inserted between the bone surfaces to be compressed. If metallic fixation devices are also to be inserted across the bone surfaces to be compressed, care must be paid to avoid contact with the cathode.

The straight or "fishscale" configuration is the author's preferred cathode pattern for use in the foot and ankle. Most nonunions in the foot and ankle are too small to allow use of the helix or zigzag configurations. Further, the straight or "fishscale" patterns minimize the possibility that the cathode wire will contact internal or external metallic fixation devices. This configuration method involves the placement of drill holes across the nonunion, fracture, or arthrodesis site. The drill holes are placed carefully to avoid contact with metallic fixation devices. The cathode wire can then be fed into these holes in a single or straight fashion and woven back and forth. Alternatively, the wire may be bent or twisted upon itself and inserted in a "fishscale" fashion where the wire enters and exits the same end of the drill hole and jumps from hole to hole. As many drill holes can be used as will be accommodated by the cathode wire's length (which is typically 25 cm). For most applications in the foot and ankle, the author recommends using 3 or 4 drill holes separated by up to 1 cm.

Once the OsteoGen™ unit has been implanted, electrocautery or other electrosurgical instruments capable of producing radio-frequency voltages should not be utilized. Thus, hemostasis should be obtained prior to the insertion of the bone stimulation unit if electrocautery is to be used.

Postoperatively, the OsteoGen™ unit's function can be tested with the Implant Tester. Therapeutic diathermy should not be used in the area of the OsteoGen™ unit, as this equipment can produce voltages which may damage the bone stimulator's electronics.

Surgical Removal

The OsteoGen™ has an anticipated life span of 24 weeks, or roughly 5 to 6 months. This is usually more than sufficient to promote union at the desired location. Once union has been achieved, or when the stimulation unit becomes inactive, the generator and insulated wire may be removed. This is accomplished by surgically exposing the generator and proximal end of the insulated wire. The proximal end of the insulated wire is then firmly wrapped around a forceps or hemostat, and a sharp pull will decouple the connector allowing removal of the insulated wire. The titanium cathode and its portion of the connector remain permanently in their implanted site.

RESULTS

The OsteoGen™ implantable bone growth stimulator has been found to be effective in the management of nonunions. For the purposes of most studies, nonunion is defined as a fracture in which all healing processes have ceased, and yet bony continuity has not been restored. Nonunion is typically confirmed by roentgenography as evidenced by the complete absence of any sign of progressive healing visible on radiographs over at least a 3-month interval.

In 1980, Paterson et al.[9] reported on a controlled, multi-center clinical trial started in 1976 in Australia with an implanted bone growth stimulator. The early unit was called the Osteostim S12, and like the OsteoGen™, produced 20 microamperes of current. In 84 patients where the implanted bone growth stimulator was used to achieve healing of long bone nonunions and delayed unions, the overall success rate was 86%. In 1990, Cundy and Paterson[10] attempted to examine the initial group of patients to assess the long-term sequelae of patients in whom bone growth stimulation had been utilized. They were able to evaluate 37 of the original patients (38 cases) with an average follow-up of 10.25 years (range: 9.5 years to 11.9 years) after their initial treatment. They found that all of the united areas had remained healed, no refractures or injuries had occurred, and that normal bone remodeling had occurred. Further, they found no adverse effects of the generator or titanium cathode wire.

Similarly in 1979, Brighton et al.[11] reported a success rate of 84% in 160 cases of nonunited fractures secondary to trauma. These authors did have an additional series of 11 early failures due to inadequate electricity, as they initially were using only a 10 microampere unit. The 84% success rate was for those cases where a 20 microampere unit, similar to the OsteoGen™, was used. These findings supported Brighton's later work where he found that a dose response curve is evident with bone stimulation current. With less than 5 microamperes, minimal to no osteogenesis is produced, whereas currents of 5 to 20 microamperes produce progressively increasing amounts of bone formation, and greater than 20 microamperes of current produces cellular necrosis.[12] Additionally in the 1979 study, 4 patients had chronic osteomyelitis at the nonunion site at the time of cathode insertion. In all four patients, electrical stimulation did not produce any new bone formation and the authors stated "it seemed to make the osteomyelitis worse."

In 1993, Cohen et al.[13] described a case report where the OsteoGen™ unit was utilized as an adjunct in the repair of a first metatarsocuneiform nonunion. Their patient was a 47-year old, insulin-dependent diabetic with Charcot changes at the tarsometatarsal joints. The initial surgery consisted of a Lisfranc's joint arthrodesis with internal screw fixation. Eight months later, the attempted first metatarsocuneiform joint arthrodesis had developed into a nonunion. Subsequent surgery involved removal of the old fixation, resection of the nonunion, insertion of an allogenic bone graft, insertion of an OsteoGen™ bone stimulation unit, and revisional fixation of the first metatarsocuneiform site with a plate and screws. Six months after the revisional surgery, complete radiographic and clinical union had occurred.

The author has been utilizing the OsteoGen™ unit for several years as an adjunct for treating difficult areas of bone healing where surgery is already planned. Repairs of complex nonunions, complex arthrodeses including Charcot foot or ankle reconstructions, fractures or fusions "at risk" (i.e., a fracture or arthrodesis where the potential for healing has been compromised), and areas with comparatively dysvascular bone or areas prone to avascular necrosis are enhanced by postoperative bone stimulation (Figs. 3A-3F).

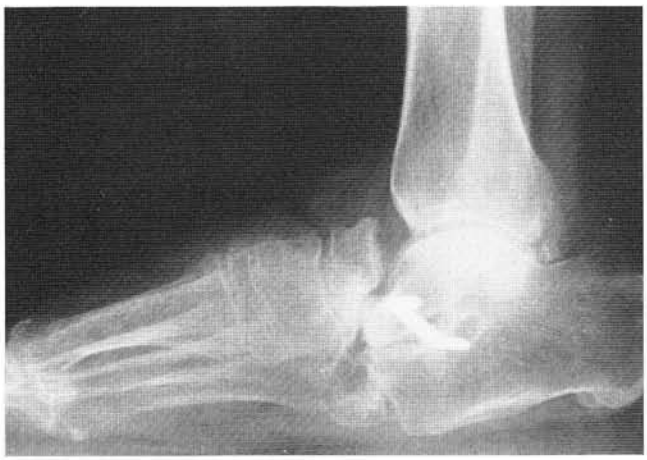

Figure 3A. A 71-year-old patient with nonunion of the midtarsal joints, 1 year and 2 months following attempted triple arthrodesis. Lateral radiographic view of preoperative position.

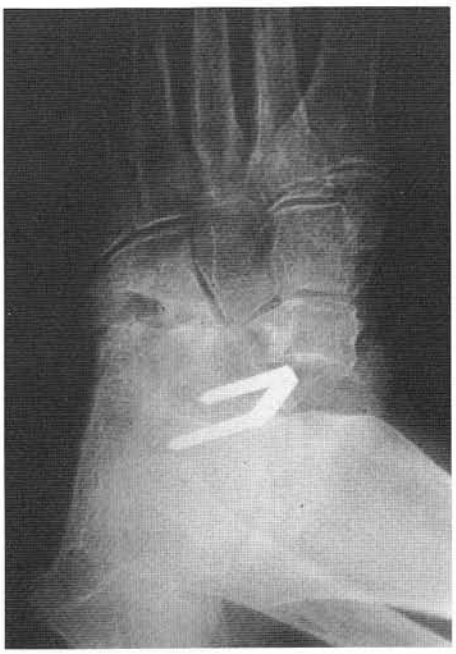

Figure 3B. Oblique preoperative view.

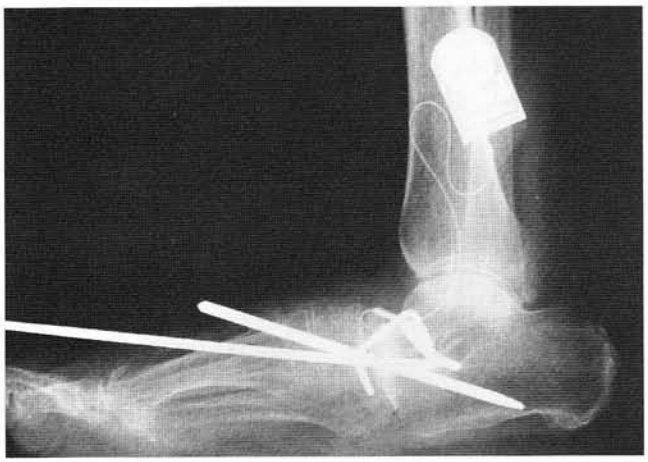

Figure 3C. Immediate postoperative radiograph. Procedures included revisional midtarsal joint arthrodesis and naviculocuneiform arthrodesis with Steinmann pin fixation. A tendo Achillis lengthening was also performed. The bone stimulator's cathode wire can be noted at the midtarsal joint fusion site. The generator with its anode are implanted in Kagar's triangle.

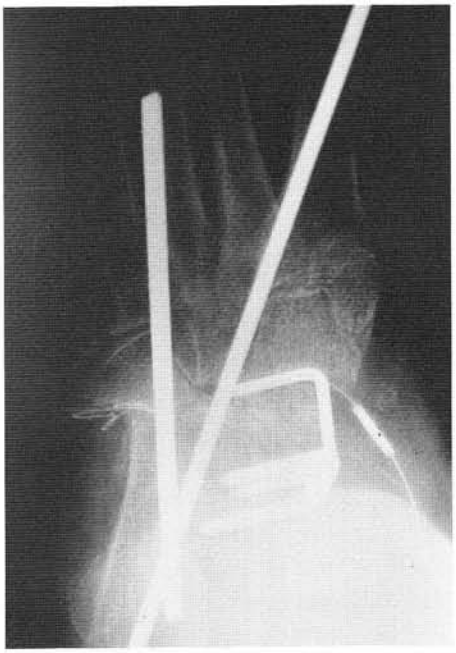

Figure 3D. Postoperative oblique view.

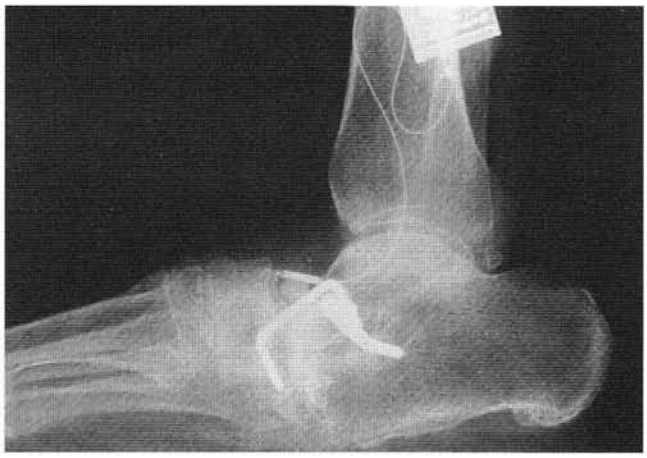

Figure 3E. One year postoperative lateral radiograph. Note that the patient elected not to have the generator removed.

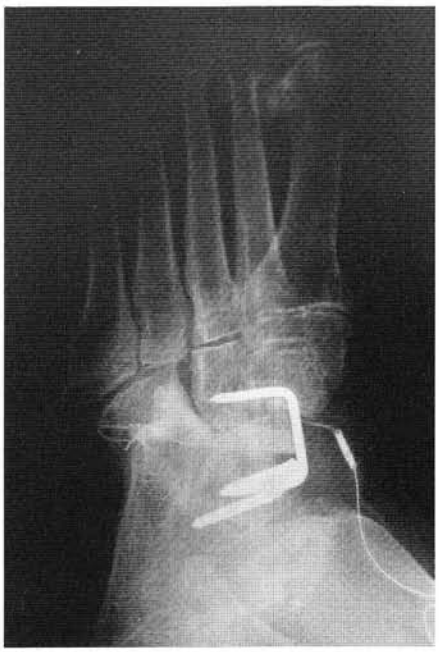

Figure 3F. One year postoperative oblique radiograph. The patient is pain-free and ambulating well in an orthopedic shoe.

SUMMARY

Electrical bone growth stimulation should rarely be used alone for the management of a difficult fracture or an established nonunion. Non-weight bearing and immobilization of the involved site are usually mandatory for bone growth stimulation to be optimally effective. In many instances, surgical resection and repair of the nonunion must be done before bone growth stimulation can be beneficial. However, when indicated, a totally implanted direct current bone growth stimulation unit can be a useful adjunct in the area of difficult bone healing and can aid in new bone formation and bone healing.

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