Electrical Stimulation of Bone: The Evolving Technology

This modality is a useful adjunct in the treatment of non-unions, delayed unions, fresh fractures, and Charcot osteoarthropathy.

Introduction

Bone stimulation is the use of energy transmitted through bone to accelerate bone growth. Although the concept of stimulating bone growth was discovered in the mid-twentieth century, technological advances recently allowed for the development of techniques capable of delivering the potentials necessary to modify bone. Bone stimulation is a useful adjunctive therapy for the treatment of non-unions, delayed unions, fresh fractures, and Charcot osteoarthropathy.

There are four distinct techniques for the delivery of electricity or mechanical pressure to bone.

Objectives

1) To understand the different technologies available for bone stimulation.

2) To understand the risk factors for the development of a non-union.

3) To understand some basic science concepts behind the development of bone stimulation.

By Linnie V. Rabjohn, DPM

Continued on page 168
Stimulation... ultrasound. Direct current stimulation utilizes electrodes implanted directly on the bone to deliver energy potentials to promote bone growth. Capacitive coupling uses either percutaneous skin electrodes or charged plates placed on the skin to deliver an electric current to the osseous area of interest. Inductive coupling uses electromagnetic fields to deliver the necessary bone stimulating potentials. Ultrasound uses acoustic radiation in the form of mechanical energy to stimulate healing. There are a variety of bone stimulators commercially available for adjunctive therapy which may be categorized according to the technique of stimulation (Table 1).

Origin of Bone Stimulation
The idea of bone stimulation through exogenous sources is a relatively new concept that has evolved over the last sixty years. In 1955, Yasuda was the first to report new bone formation at the site of electronegative potential. This discovery went largely unrecognized until it was confirmed some years later by Bassett and Becker. The first modern report of electric methods being used to heal a non-union was of a medial malleolus in 1971 by direct current technology. Since that time, there has been a large amount of research focused on the use of piezoelectric fields associated with bone and the application of bone stimulators based on this concept. Piezoelectricity is the ability of crystals to produce a voltage when subjected to stress. Bone contains calcium phosphate crystals, making it subject to modification by the introduction of voltage.

Wolff’s Law
Wolff’s law encompasses the idea that bone will adapt to introduced stress, that the form of bone will follow the function of the bone. Stress-generated potentials, small electric currents, in bone will change the activity of bone, allowing for this adaptation by modifying the activity of osteoblasts. Endogenous bioelectric potentials have been found in unstressed bone to have an electronegative reaction at the fracture site. Bone is most electronegative at areas of growth, such as fractures and epiphyseal plates. From this concept came the idea that electrical potentials sent through bone could accelerate the healing process of fresh fractures, delayed unions and non-unions.

The Science Behind Bone Stimulation
Bone is subject to electric stresses because it contains calcium phosphate crystals. The compression side produces a negative potential, while the tension side has a positive potential. The other form of electric potential associated with bone is transmembrane potential. These potentials are generated by the metabolism of a cell and are reliant on cell viability. The greater the cellular activity, the greater the negative potential generated. The potentials play an important role in early callus development and the remodeling stages of bone healing.

The application of these potentials by an external source can act to accelerate osseous healing by influencing the bone-healing cascade. The use of electrical stimulation leads to the production of more bone-forming cells by the osteoprogenitor cells. This in turn accelerates healing by augmenting the development of extracellular matrix.

The formation of a blood clot at the fracture site initiates the beginning phases of bone healing. The clot is composed of inflammatory cells and platelets.

Continued on page 169
Stimulation...

These cells are responsible for releasing factors that are required for bone healing. Primary fracture healing occurs when there is rigid internal fixation with minimal strain.4-9,10 This allows bone to be laid down across the gap directly. Secondary bone healing occurs due to strain, and results in intramembranous or endochondral ossification bone formation.

Intramembranous ossification occurs in the periosteum as the osteoblasts recruit the needed cells to that site. This allows for the formation of a granulation tissue that becomes cartilage. After this occurs, endochondral bone healing can occur. There are a variety of chondrocytes responsible for transforming the cartilage into bone. The chondrocytes initiate angiogenesis, which allows for the formation of vasculature channels that can bring osteoblasts to the site. This tissue must be calcified at this point before vascular invasion and trabeculation can occur.

The osteoblasts are responsible for ultimately producing the woven bone that unites a fracture. Remodeling of the bone occurs in the final stages of bone healing. The bone produced must be remodeled to become structured like the original bone to allow for future integrity. Bone that does not progress from the bridging to the calcifying stage of the healing process will not unite.10

Non-unions

Indications for the use of bone stimulators include non-unions, delayed unions, failed arthrodesis, Charcot osteoarthropathy, and fresh fractures.11 This article will mainly focus on the use of bone stimulators for non-unions. The gold standard treatment for non-unions is the removal of necrotic bone tissue and stabilization by means of internal or external fixation.12 Treatment with a bone stimulator can be used as an alternative treatment or as an adjunctive treatment to the standard of care.

The most commonly fractured long bone of the lower extremity is the tibia, which is also associated with the highest incidence of delayed union and non-unions.13-15 This is the reason that many studies evaluating the efficacy of bone stimulation are involving non-unions of the tibia. Arthrodesis of the foot and ankle has a non-union rate of 5-10%, making bone stimulation a very useful and needed adjunct to therapy for foot and ankle surgeons.16 Risk factors for non-union include smoking, immunosuppressive drugs for inflammatory arthritides, diabetes mellitus, obesity, alcoholism, previous operation, hormones, use of illicit drugs, age, nutrition, fracture characteristics, location, comminution, vascular injury, soft tissue damage, infection, prior open trauma, psychiatric illness, and history of Charcot osteoarthropathy (Table 2).11,17-18

Having an understanding of the contribution of each factor of increasing the risk of non-union would assist in the decision process of utilizing adjunct electrical bone stimulation.11 The existence of such risks has made adjunctive procedures that promote bone healing desirable in an effort to decrease non-union rate. It is well-documented throughout literature that smoking can be detrimental to both soft tissue and bone healing.

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TABLE 2

<table>
<thead>
<tr>
<th>Risk Factors for Development of Non-Union</th>
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<tbody>
<tr>
<td>Smoking</td>
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<td>Inflammatory arthritides</td>
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<td>Obesity</td>
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<td>Previous surgery</td>
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<td>Fracture location</td>
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<td>Vascular injury</td>
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<td>Infection</td>
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<td>Psychiatric illness</td>
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Figure 1: The Orthopak® bone stimulation system by EBI medical products.
Success of bone stimulation on different forms of non-unions decreases in the following order: hypertrophic, oligotrophic, and atrophic non-unions. A hypertrophic non-union is a well-vascularized callus formation with no calcification between bone fragments. This form of non-union is the most capable of healing with inactivity and immobilization, and adjunct treatment of bone stimulation. No system will work for a true synovial pseudoarthrosis.

The incidence of pseudoarthrosis is at least four times greater in patients who smoke. There is also an increased risk of pseudoarthrosis in relation to grafts because nicotine inhibits the revascularization of grafts. There are a multitude of effects of nicotine, carbon monoxide, and hydrogen cyanide on tissue healing. These include tissue anoxia, cellular hypoxia, and an inhibition of the proliferation of cells, vasoconstriction, and a decrease in the oxygen-carrying capacity of blood.

To determine the presence of a pseudoarthrosis, a technetium 99 bone scan may be performed. If one is present, a “cold cleft,” or area of decreased activity surrounded by increased radioactivity, will be seen.

Direct Current Bone Stimulation

Direct current bone stimulation appears to work by a mechanism of stimulating the formation of bone by increasing the amount of intracellular free calcium and hydrogen peroxide generation at the cathode and the resulting increase in pH. The use of a direct current bone stimulation device may be either by an invasive technique of surgically implanting a battery and leads or through a semi-invasive technique which uses percutaneous electrodes connected to an external power device. The only commercially available direct current device is the Osteogen (EBI, Parsippany, NJ) which is invasive by technique.

There are currently no semi-invasive direct current devices available. The Osteogen utilizes a titanium cathode wire in the form of a single, double, or mesh wire that is implanted directly into the osseous site, allowing for maximal surface area of contact. It should have no contact with metal implants. The battery is an anode placed subcutaneously that is attached to the cathode. This battery will provide power from 6-12 months, making the device active for this time period. This device uses a constant current of 20 micro-amps and 1.0 volts per lead.

The advantages to the use of direct current for bone stimulation are increased patient compliance because the device is implanted within the body, that the current is directly applied to the site with maximal intensity, and the constant stimulation of the osseous area. The disadvantages to the use of direct current in-
A different study also looked at high-risk patients undergoing foot and ankle arthrodesis procedures with implantation of a direct current bone stimulator.11 Patients were considered high risk based on the presence of one or more of the following: DM, obesity, habitual tobacco and/or alcohol use, immunosuppressive therapy, and previous history of non-union. The results demonstrated that arthrodesis of the foot and ankle may be enhanced by use of direct current bone stimulation. The high-risk of developing a non-union in foot and ankle arthrodesis leads to a considerable need for revision arthrodesis.

One study evaluated the use of direct current in ten consecutive revision arthrodeses performed on patients with aseptic non-unions.33 All obtained a solid union at an average of 12.8 weeks. The modified AOFAS scores 70% good to excellent results with use of direct current in revision arthrodesis. Donley and Ward, in the process of using direct current stimulation to achieve arthrodesis in a high risk population, also found an improvement in pain scores from a mean of 8.5 to 1.9 during the process.34 While it is highly apparent through numerous clinical trials that direct current bone stimulation aids in the achievement of osseous union, some authors believe that there is not sufficient evidence to use an invasive direct current device over the non-invasive PEMF device.38

Capacitive Coupling Bone Stimulation

Capacitance is defined as the ability of a device to store electric charge.1 The technique of capacitive coupling for bone stimulation has been described as either semi-invasive with the use of electrodes that are placed percutaneously over the area of osseous interest using a conductive gel applied to the skin, or through a noninvasive technique of using two charged plates to generate a flow of current.27,28 The non-invasive form of capacitive coupling is the only form commercially available as the Orthopak (EBI, Parsippany, NJ) (Figure 1).

The advantage of using an inductive coupling device is that it is the most non-invasive form of bone stimulation available.

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of 21 non-unions of the femoral and tibial shafts showed a significant difference in the union rates in patients receiving capacitive bone stimulation.39

In another study, 73% of established non-unions with at least a .5 cm. gap went on to solid union after the use of capacitive coupling.40 The results were better in the non-unions with metaphyseal gaps. The average time to healing of established non-unions in one study using capacitive coupling was 15 weeks. All the subjects with a plate distance of less than 80 mm. healed.41 This suggests that there is a relationship between the sufficient current and healing.

Inductive Coupling Bone Stimulation

Inductive coupling bone stimulators use a time-varied magnetic field using coils to deliver the flow of current to the site of osseous interest.27 There is an inverse relationship between the distance of the coils from the bone of interest and the strength of the current. Various configurations of coils have been developed to produce a more uniform current.42 Inductive coupling appears to stimulate osseous healing of a non-union by the differentiation of fibrocartilage cells by TGF-beta expression.43-44 The stimulation seems to occur through osteoblasts by an up-regulation of BMP-2 and BMP-4 expression and also by increasing the calcium uptake by nitric oxide synthase.45-47

There are two main categories of inductive coupling devices available commercially, combined magnetic field (CMF) and pulsed electromagnetic field (PEMF). The two categories differ based on signal type. PEMF uses a pulsed burst of power at 15 Hz.27 The two devices available that use the PEMF technique are EBI Bone Healing System (EBI, Parsippany, NJ) (Figure 2) and Physio-Stim Lite (Orthofix, McKinney, TX) (Figure 3).

The EBI Bone Healing System requires use of 10 hours a day while the Orthofix Physio-Stim requires three hours a day. CMF provides magnetic fields through a sinusoidal pattern at 76 Hz that is superimposed on a constant magnetic field. The current available model is the OL1000 (DJO, Vista, CA, which requires usage of 30 minutes a day.

The use of CMF is based on calculations that predicted coupling to calcium-dependent cellular signaling processes in tissues.40-41 The two different methods of making available electromagnetic waves at the different Hz frequencies bring into question which method is more successful in stimulating bone. A study evaluated the efficacy of low-frequency electrical fields on osteogenesis and found that some methods provide a magnitude of power in tissue that may not be needed to stimulate the desired...
bone stimulation available. Prior to FDA approval of PEMF, it had been shown to have an efficacy rate in one study of 77% fracture non-unions and 82% non-unions stemming from failed arthrodesis. Bassett and colleagues in the same year also showed an overall union rate of 125 tibial delayed unions or non-unions of 87%. A review of 44 articles focused on the effectiveness of PEMF. For non-unions of the tibia fractures, 81% healed with PEMF and 82% with surgery. After multiple failed surgeries, the success rate of PEMF is reported to be greater than with surgery; this discrepancy increases with additional numbers of prior surgeries.

In infected non-unions, the results of surgical treatment decreased by 21% and were less than the results utilizing PEMF. In open fractures, surgical healing exceeded PEMF whereas in closed injuries, PEMF cases healed more frequently. In general, the review found that PEMF treatment of un-united fractures has proved to be more successful than noninvasive traditional management, and at least as effective as surgical therapies. PEMF treated osteotomies demonstrated a faster recovery of dynamic load-bearing with increased load bearing capacity compared with the untreated group. The biomechanical properties of the healing osteotomy were significantly better in the PEMF treated group, suggesting that not only does it stimulate bone growth, but that the resulting bone is of high quality and strength.

In a prospective, randomized clinical trial evaluating PEMF, 64 patients underwent a triple arthrodesis or isolated hindfoot arthrodesis. There was a significant reduction in the time required for a union in the talonavicular and calcaneocuboid arthrodesis in the PEMF-treated group, and a trend towards a faster union rate in the STJ arthrodesis group. This study excluded patients at high-risk, specifically those who had rheumatoid arthritis, diabetes mellitus, or use of corticosteroids, which decreases the strength of the study. In a retrospective case series looking at non-unions after foot and ankle arthrodesis, the authors do not recommend the use of PEMF and immobilization as a protocol for treating delayed union in foot and ankle arthrodesis. They hypothesized that the mechanical difficulties in orienting the coils around the foot and ankle may partially explain the lower success compared with long bones. The rate of success was substantially lower than that of use in long bone delayed unions.

A study looking at time usage and efficacy of PEMF for fracture non-unions showed that patients who used the device less than an average of three hours a day had a success rate of 35.7%. Patients who used it more than three hours daily had an 80% success rate.

A fairly consistent radiographic progression to union from non-unions treated with PEMF has been described. The non-union gap is predicted to widen during the first six to eight weeks of treatment. The theory behind the widening is that an increase in vascular activity occurs along the gap. There were no statistical significance beyond three hours.

Figure 5: The Exogen® bone stimulator from Smith & Nephew products.

In a prospective, randomized clinical trial evaluating PEMF, 64 patients underwent a triple arthrodesis or isolated hindfoot arthrodesis.
with a debridement of the non-union gap. During the second and third months, “gap clouding”, which is the stippled calcification in the central portion of the non-union fibrocartilage, occurs. Sclerosis appears in the third and fourth months as the sharp sclerotic margins of the non-union become more diffuse in appearance due to the vascular invasion and process of creeping substitution. Between the fourth and sixth month, trabecular bridging should be present. The final radiographic healing stage is the restitution of the intramedullary canal.

PEMF will not work if a synovial pseudoarthrosis is present, if the fracture exceeds 5 mm., or when the fracture is not adequately immobilized. Presence of fibrocartilage is correlated with responsiveness to PEMF leading to bony union. Presence of a fracture gap of dense fibrous tissue lacking these osteogenic biochemical markers is correlated with unresponsiveness to PEMF.

**PEMF and Articular Cartilage**

The physiology of articular cartilage is relatively unknown, but it is generally accepted that the cartilage has little to no regenerative potential and degrades over time. Development of technology to slow the degradation of cartilage overtime is lacking because of the lack of information. Articular cartilage is composed of hypocellular, avascular, and alymphatic tissue. The cartilage contains a dense collagen and proteoglycan matrix which provides a low-friction surface that is resistant from wear for both shear and compressive forces. PEMF has been considered for adjunctive therapy to treat the inflammation associated with degenerative joint disease.

In a study evaluating the effectiveness of PEMF in such a situation, the authors concluded that PEMF can be used following minimally-invasive surgery, such as arthroscopy, to control inflammation and enhance functional recovery, and to protect articular cartilage. PEMF has the ability to permeate the articular cartilage and the underlying subchondral bone. The use of PEMF can be aimed at controlling inflammation, stimulating the anabolic activity of the chondrocytes, and preventing cartilage degeneration resulting in a chondroprotective effect. The authors do not advocate the use of PEMF on joint inflammation associated with systemic disease like rheumatoid arthritis. In a different study, patients who were status post-arthroscopic chondroabrasion or microfracture treatment of chondral lesions were instructed to use PEMF for six hours a day. The results showed a lower use of non-steroidal anti-inflammatories and a faster functional recovery.

**Ultrasound Bone Stimulation**

Ultrasound is the use of acoustic radiation above the limit of human hearing. It is a form of mechanical energy that can be transmitted into the body through pressure waves. This causes a biochemical event at the cellular level. Ultrasound for bone stimulation uses low-intensity, high frequency waves to stimulate growth. The ultrasound model available for bone stimulation is the Exogen (Smith & Nephew, Memphis, TN) (Figure 5).

The recommended daily use of Exogen is 20 minutes. The presence of metallic implants seems to have no effect on the efficacy of electromagnetic stimulators. With ultrasound, however, only one study has shown that tibia fractures fixated with an intramedullary nail showed no acceleration of bone healing both clinically and radiographically.

The mechanism of action for bone growth using ultrasound is not based on thermal effects. On a micro-level, ultrasound appears to stimulate the production of prostaglandin E2. Also, in a study evaluating rat models, ultrasound increased the mechanical properties of the callus and stimulated the production of aggregan mRNA and procollagen mRNA. A calcium flux also occurs within seconds of starting the ultrasound treatment.

The effect of ultrasound on bone at a larger level appears to be on the hypertrophic cartilage cells that produce calcified matrix as well as the osteoblasts that produce the bony collar. Ultrasound used in this way has been found to not only increase the chondrocyte population and the soft-collus formation, but also shows acceleration of the endochondral ossification, and increases the strength of the fracture site.

In animal studies, the stimulation of callus tissue and bone healing has been apparent with the use of ultrasound. Duarte’s study showed both radiographic and histologic acceleration of healing in rabbit fibular osteotomies made by drill hole. In vitro mouse metatarsals, low-intensity ultrasound applied for 20 minutes daily stimulated the growth lengthwise of the calcified diaphysis within days. Both the bony collar and the calcified hypertrophic cartilage were increased with treatment. This is either due to an increased number of osteoblasts or increased activity of the osteoblasts present. Sciographic control of the healing process was faster in ultrasound-treated animals when compared to untreated control animals.

In humans, ultrasound has been shown to accelerate the consolidation of acute tibia diaphyseal fractures by 40% both radiographically and clinically. Not only does ultrasound appear to stimulate cortical bone growth,
Stimulation...

but it has been shown to stimulate cancellous fractures as well.\(^{73}\)

It has also been studied using osteotomies of the human lower extremity and been found to accelerate the bone healing process.\(^{74}\)

In a study evaluating fresh distal radial fractures, ultrasound resulted in a significantly shorter time to union.\(^{44}\)

For non-unions, ultrasound showed an overall healing rate of 86%.\(^{65}\)

The negative effects of smoking and subsequently nicotine on healing of bone was minimized by the use of ultrasound in one study.\(^{75}\)

Recognition

I would like to extend my appreciation to Daniel Yarmel, DPM, a third-year resident at Pennsylvania Presbyterian Medical Center. He gathered many of the journal articles used for citation for this review article.

References


In a study evaluating fresh distal radial fractures, ultrasound resulted in a significantly shorter time to union.


Continued on page 176
Stimulation...


Dr. Rabjohn is an associate at the Arlington/Mansfield Foot and Ankle Center in Arlington, Texas. She completed her residency at The Graduate Hospital of Philadelphia, Pennsylvania.
1) Which form of bone stimulation uses electromagnetic fields to deliver electricity to bone?
   A) Capacitive coupling
   B) Inductive coupling
   C) Direct current
   D) Ultrasound

2) Which form of bone stimulation uses electrodes that are directly implanted on bone?
   A) Inductive coupling
   B) Capacitive coupling
   C) Direct current
   D) Ultrasound

3) Which form of bone stimulation uses acoustic radiation to transmit mechanical energy in the form of pressure waves to bone?
   A) Inductive coupling
   B) Capacitive coupling
   C) Direct current
   D) Ultrasound

4) Which form of bone stimulation uses charged plates to conduct electricity across bone?
   A) Inductive coupling
   B) Capacitive coupling
   C) Direct current
   D) Ultrasound

5) Which portion of the direct current technology is placed in direct contact with the bone?
   A) the titanium cathode
   B) the anode battery
   C) both
   D) neither

6) In which of the following conditions would one expect not to find electronegative charges on bone?
   A) Fractures

7) Which type of non-union is most likely to obtain a beneficial result with the use of a bone stimulator?
   A) Oligotrophic
   B) Pseudoarthrosis
   C) Atrophic
   D) Hypertrophic

8) Which type of non-union can be defined as having a well-vascularized callus with no calcification between bone fragments?
   A) Hypertrophic
   B) Oligotrophic
   C) Atrophic
   D) Pseudoarthrosis

9) Smoking causes which of the following effects on tissue healing?
   A) Tissue anoxia
   B) Vasodilation
   C) Both a and b
   D) Neither a or b

10) Which form of bone stimulation will be successful in a true synovial pseudoarthrosis?
    A) Direct current
    B) Inductive coupling
    C) Ultrasound
    D) None of the above

11) A technetium 99 bone scan can be used to detect a “cold cleft” which is indicative of the presence of a pseudoarthrosis. Which of the following best describes the “cold cleft?”
    A) Increased activity at the site of non-union surrounded by increased radioactivity
    B) Decreased activity at the site of non-union surrounded by increased radioactivity

12) Which form of bone stimulation requires not only a primary surgical implantation but also a possible secondary surgery for removal?
    A) Direct current
    B) Inductive coupling
    C) Capacitive coupling
    D) Ultrasound

13) Which type of inductive coupling uses a sinusoidal pattern of magnetic energy superimposed on a constant magnetic field?
    A) Direct current
    B) PEMF (pulsed electromagnetic fields)
    C) CMF (constant magnetic fields)
    D) Both b and c

14) Which form of bone stimulation, by the instructions given by the manufacturer, has a recommended usage of less than one hour?
    A) Ultrasound
    B) PEMF
    C) CMF
    D) Both a and c

15) Which bone is the most commonly fractured long bone of the lower extremity and also has a high risk of non-union?
    A) Femur
    B) Fibula
    C) Tibia
    D) Metatarsal

See answer sheet on page 179.
16) Which of the following bone stimulators needs direct contact with skin to be effective?
   A) PEMF
   B) CMF
   C) Ultrasound
   D) All of the above

17) Which of the following is the best description of Wolff’s Law?
   A) When possible, primary bone healing should be attempted on fractures
   B) Form follows function and bone will adapt to stresses placed on it
   C) All fractures should be immobilized
   D) Both a and c

18) Which of the following is the definition of primary fracture healing?
   A) Providing minimal to moderate strains to accelerate the rate of healing
   B) The bone healing process that includes intramembranous and endochondral ossification
   C) Providing minimal strain and rigid internal fixation across fracture sites
   D) All of the above

19) The “gold standard” of treatment for a non-union includes all the following except:
   A) Removal of all necrotic bone
   B) Immediate placement of a direct current bone stimulator
   C) Stabilization of the fracture with internal or external fixation
   D) All of the above are part of the “gold standard” treatment.

20) The risk factors for the development of a non-union include all of the following except:
   A) Soft tissue damage
   B) Infection
   C) Psychiatric illness
   D) Rigid fixation

See answer sheet on page 179.
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Note: If you are mailing your answer sheet, you must complete all information on the front and back of this page and mail with your credit card information to: Podiatry Management, P.O. Box 490, East Islip, NY 11730.

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179
EXAM #1/08
Electrical Stimulation of Bone: The Evolving Technology (Rabjohn)

Circle:
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Please indicate the date you completed this exam
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How much time did it take you to complete the lesson?
______ hours _____ minutes

How well did this lesson achieve its educational objectives?
______ Very well  ________ Well
______ Somewhat  ________ Not at all

What overall grade would you assign this lesson?
A   B   C   D

Degree_____________________________________

Additional comments and suggestions for future exams:
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