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# Study of the Pulse Waveform and the Design of the Portable, Non-invasive, Electromagnetic Stimulation for Enhancement of Fracture Healing

**Young-Hoo Kim,* Won-Ki Kim,** and Sung Jae Kim***

*Department of Orthopedic Surgery* and Department of Bioengineering,***
*Yonsei University College of Medicine, Seoul, Korea*

Since the concept of bioelectrical potentials in the bone was developed, various electrical systems have been utilized to heal non-united fractures.

The asymmetrical and time varied pulsed electromagnetic stimulator was designed and and utilized to treat eight fractures of the lower extremity and one congenital pseudoarthrosis of the tibia. Nonunited fractures, neglected old fractures, and a case of congenital pseudoarthrosis responded favorably to our designed pulse waveform. On the other hand, fresh fractures responded equivocally.

A newly designed electromagnetic stimulator which can deliver vascular and calcification pulses, will be developed on an industrial basis to provide various clinical and experimental applications.

**Key words:** Piezoelectricity, Streaming potential, Inductive coupling, Fracture.
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Numerous materials, methods and technologies have been employed to control sytemic factors which influence healing of the bone, cartilage, tendon and nerve tissues. None of which has shown any enhancement of the healing process of musculoskeletal tissue.

Recently, the concept of utilizing electricity to heal nonunited fractures has been developed. The initial report suggesting an intrinsic piezolectric quality of bone was made in 1953 by Fukada and Yasuda (1953). This finding was later substantiated by Bassett and Becker (1962), Shamos et al., (1979) and Friedenberg and Brighton (1966).

Yasuda (1953) demonstrated the appearance of new-bone formation in the vicinity of the cathode (negative electrode) when a current in the microampere range was supplied continuously for three weeks in the rabbit femur. He also described stress-generated potentials in bone in which the side of the bone under mechanical compression became electrongative and the side under tension became electropositive.

Although the piezoelectric theory may explain the origin of stress-generated potentials in dry bone, its ability to explain the origin

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of stress-generated potentials in fluid-saturated bone has been questioned. Anderson and Eriksson (1968, 1970) suggested that two independent mechanisms, piezoelectricity and streaming potential in fluid-saturated bone.

Due to the fact that alternating current has not been shown convincingly to be capable of inducing significant amounts of new-bone formation, the great majority of the studies investigating the effects of electricity on bone have dealt with direct current. To maintain a constant current source, adequate voltage and appropriate metallic electrodes should be employed. (Friedenberg et al., 1971 ab)

Electricity also can be induced in bone by means of an electrical field in which the electrical apparatus remains completely external to the animal or the patient's extremity. The electrical field can be inductively or capacitively coupled to the bone (Bassett et al., 1979; 1974; Black, 1984).

In capacitive coupling (Bassett and Pawluk, 1975; Brighton et al., 1976; Norton et al., 1977), an electrical field is induced in the bone by an external capacitor; that is, two charged metal plates are placed on either side of an animal's limb and are attached to an appropriate voltage source. The high voltage required to induce osteogenesis seems to preclude the clinical application of this method. In inductive coupling (Basett and Becker, 1962), a current varying with time produces a time-varying magnetic field which, in turn, induces a time-varying electrical field (Fig. I). Various pluses and patterns have been studied by Bassett et al., (1979, 1982, 1983). At present, they use a bipolar, quasirectangular base pulse pattern which is asymmetrical in timing and amplitude. The main polarity portion of each pulse is 200 microseconds in duration and the opposite polarity portion of each pulse is twenty microseconds. Each burst of pulses repeats at

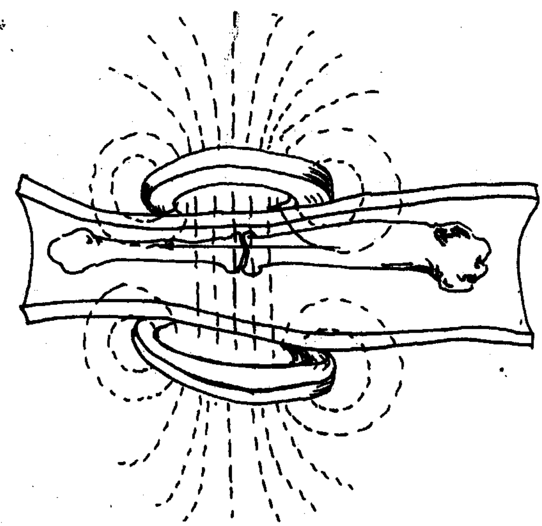

**Fig. 1.** Inductive coupling for electric field.

a rate of fifteen hertz. The peak amplitude of each individual pulse induces in the bone a peak current density of ten microampers per square centimeter.

Based on the cited laboratory findings, three of the electrical systems have been utilized for the treatment of ununited fracture: (1) the constant direct current/implanted electrodes and power-pack (invasive) developed by Dwyer and Wickham(1974) which is implanted into the non-union site under direct vision through an open procedure; (2) the constant direct current/percutaneous cathodes (semi-invasive) developed by Brighton et al., (1975), 1979); and (3) the inductive device developed by Bassett et al. (1974). Similarities of the three systems are as follows:

All three systems reportedly give the same over-all success rate of 80 to 85 percent. In order to be effective, all systems require that principles of good fracture management be followed rigorously; that is, the non-union must be adequately reduced and adequately immobilized during the entire treatment period. In order to be effective, all systems require that the electricity be concentrated or aimed exactly in the non-union site. All systems require about the same duration of time for healing-from three to six months. All systems are ineffective by and in themselves in the presence of a large gap at the non-union site. It appears that any gap that is larger than one-half the diameter of the bone at the level of the non-union does not contain enough responsive cells to form bone when stimulated by electricity. All systems are ineffective in the presence of a synovial pseudoarthrosis. The lining of the false joint must be removed first in order for the electricity to be effective. Finally, the early roentgenographic signs of healing are the same in the three systems; that is, sharp, distinct bone margins become fuzzy and indistinct, and the radiolucent line between the fragments takes on a smoky, cloudy appearance.

Difference between the three systems are as follows:

No surgery is required for the non-invasive system; percutaneous insertion of the cathodes is required for the semi-invasive systems; and two open operative procedures, one to implant the electrical apparatus and one to remove it after treatment, are required for the invasive system. The current costs of purchasing the semi-invasive and invasive systems are approximately equal; the rental cost of the non-invasive system is about three times higher. Both the semi-invasive and the invasive systems are completely portable, while the non-invasive system is not. Patient cooperation is not required for the invasive system, but definitely is required for both the semi-invasive system and the non-invasive system. Metal interference is not present with the semi-invasive and invasive systems, but may be present with the non-invasive system if highly magnetic metal is within the region of the non-union site. The presence of actively draining osteomyelitis is not a contraindication for the use of the non-invasive system, but is a contraindication for both the semi-invasive and the invasive system.

The purpose of this part of the project was to develop an adequate pulse waveform and to develop a portable, non-invasive, and inductive coupling electromagnetic stimulator. This stimulator could be utilized for fresh fracture, cartilage, ligament, and nerve injury treatment, as well as for growth plate stimulation in leg length discrepancy. It could also enhance the tissue ingrowth in cementless total joint replacement.

## DESIGN OF ELECTROMAGNETIC STIMULATOR (EMS) SYSTEM

In this study, we used a bipolar, quasi-rectangular base pulse pattern which was asymmetrical in timing and amplitude (Fig. 2). The main polarity portion of each pulse was 250 microseconds in duration, and the opposite polarity portion of each pulse was 30 microseconds. Each individual pulse in the bone was greater than 10 microampere per square centimeter. The inductive coupling electomagnetic stimulator was composed of a burst generator, current amplifier, magnetic coil and power supply as shown in Figure 3.

### 1) Burst generator

For inducing electrical current in the bone by an electromagnetic field, it would be provided by an appropriate burst waveform as in Figure 2.

In order to generate an arbitrary burst form and to change the waveform easily, we used an EPROM (2716) which has 1024 point sampling data which refreshed each digital data in a ratio of 200 KHZ and converted it to an analog signal by the D/A converter.

### 2) Current amplifier

Generated pulse energy from pulse generator

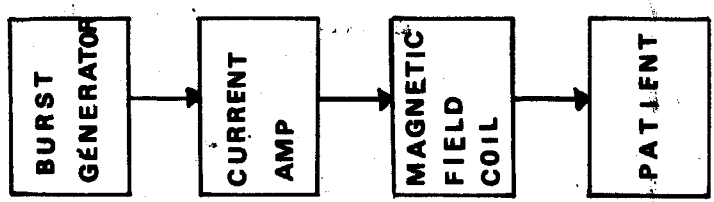


Fig. 2. System diagram.

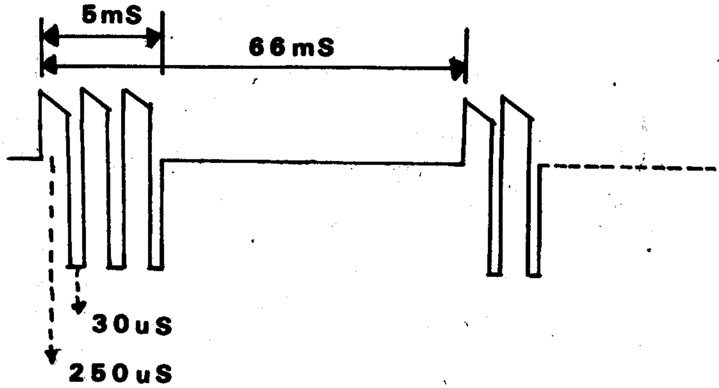


Fig. 3. Burst waveform.

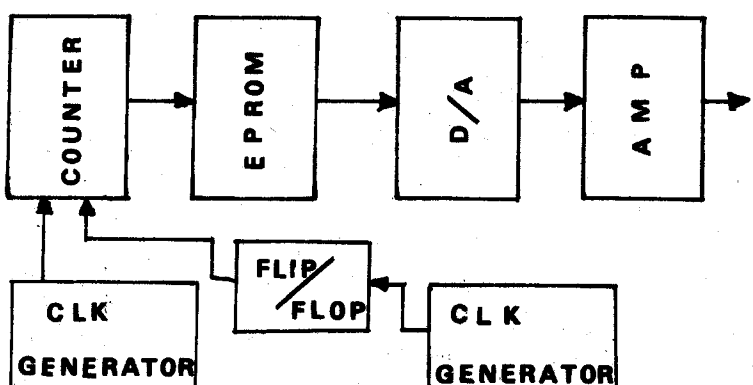


Fig. 4. Burst Generator.

was too weak to apply to a patient. This minute pulse energy was sufficient in the semi-invasive electrical stimulation system but required higher energy in the inductive coupling electromagnetic stimulation system. Therefore, the current amplifier as shown in Figure 5 should be needed to amplify the burst wave (Coughlin and Driscoll, 1982; Cromwell and Weibell, 1980). The output of the amplifier was calibrated through the detector coil which consisted of 50 turns of number 30 copper wire with an internal diameter of 5 millimenters. A positive waveform amplitude was 15mv per square centimeter in the bone.

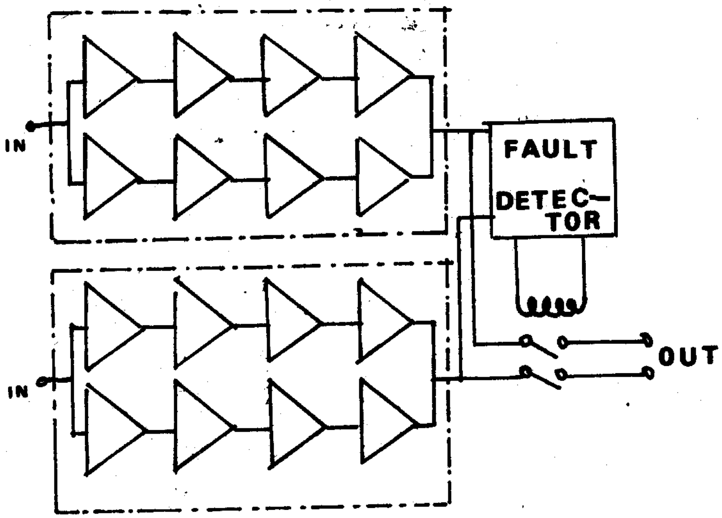


**Fig. 5.** Amplifier diagram.

## METHOD AND RESULT

The manaufactured coil based on the patient's x-rays were positioned on the cast facing each other at 180 degrees on the extremity. If they were wired so that one "pushed" the field and the other "pulled" it, the coils were aiding when the inter-coil distance was smaller than the diameter (Milsun, 1966; Pilla, 1979: Schilling, 1979).

The inter-coil distance was adjusted to equal or to be less than the radius of the pair of circular coils, and this was approved to produce uniform B fields (Webster, 1978). The electromagnetic stimulating system was applied over the patient's fracture site and was stimulated more than 12 hours per day. The results were evaluated by the patient's subjective symptoms and by periodical radiographic examination of the healing fracture. In an on-going prospective clinical study, nine patients were treated with electromagnetic stimulation. Two non-united fractures of the femoral shaft and one congenital pseudoarthrosis of the tibia appeared to be responding favorably to electromagnetic stimulation treatment; but the assessment of the final results needs to be observed a little longer. Five patients with acute fracture of the tibial shaft were stimulated for about 2 months and their results were equivocal. However, one patient with a neglected femoral neck fracture, who underwent closed reduction and internal fixation with hip nall 8 months following injury, achieved a perfect bone healing in a 2 month period of electrical magnetic stimulation.

## DISCUSSION

Bioelectrical potentials in bone have been characterized by an order of several millivolts in amplitude. The diaphysis is generally more positive than the proximal and distal metaphyses, and the surface of the cortex is everywhere electropositive relative to the medullary canal. The origin of these potentials has been investigated experimentally by many investigators, and the results of these investigations reveal that bioelectrical potentials are dependent upon cell viability so that amplitude is decreased with localized bone damage and after the death of the animal. But potentials are unaffected by denervation and arterial ligation. Furthermore, bioelectrical potentials become significantly eletronegative at the site of a fracture and increase electronegatively at the growth site as the growth rate increase (Black, 1984; Friedenberg et al., 1970).

Stress-generated potentials in fluid-filled bone are the result of electrokinetic effects. Typical values of electric fields generated by stress within the physiologic range are 2mv per centimeter for the average field and 200 to 500mv per centimeter for the maximum local field within an osteon. Electrical potentials are also observed in fluid-filled caritilage during deformation (Black, 1984).

The pulses can be designed to evoke specific biological responses. The pulse type in clinical use to treat ununited fracture (Bassett et al., 1979) is quite different from the type used to treated ostenonecrosis (Basett et al., 1981; 1983; Eftekhar et al., 1983). In a analysis of the frequency content of these two different pulses, the Fourier method demonstrates differences not only in primary frequencies but also in amplitude and harmonics. The osteonecrosis type (vascular pulse) lowers the content of cellular calcium (Bassett et al., 1979) and increases both transcription and translation, probably through stimulating, increased production of presumptive messenger RNA (m RNA) in the nucleus.

Pulses used to treat ununited fractures, on the other hand, do not affect m RNA synthesis, but they do appear to have a slight effect on the synthesis of presumptive ribosomal RNA (r RNA). Furthermore, rather than decreasing cellular calcium content, they increase it (Bassett et al., 1979). The latter effect appears to be involved as a primary mechanism of action in the healing of ununited fractures.

Nonunions and delayed unions can be characterized as an arrest of fracture healing at an intermediary stage of repair, at which time the fracture gap is bridged by fibrocartilage (Basett, 1982; 1983). Normally, calcification of this tissue ensures, setting the stage for vascular penetration, chondroclasis, and replacement by fiber and lamellar bone. The process is similar in many respects to endochondral ossification. In the ununited fracture, the fibrocartilage persists for months or years in the gap area and blocks vascular invasion until calcification has occurred. The 15HZ pulse burst PEMF, in use for treatment of this condition, not only increases the calcium content of chondrocytes but also appears to trigger calcification of the blocking fibrocartilage so that the normal final phases of fracture healing can follow.

Black (1984) divided the fracture healing into four stages: inflammation, soft callus, hard callus and remodeling. He theorized that different types of electrical pulse might be required in each stage of the fracture healing. Biopotentials might be expected to dominate in the inflammation and soft calluse stages, when these potentials are relatively abnormal in distribution and when mechanical integrity is relatively low. Strain-related potentials might be expected to dominate in the hard callus and remodeling stages, when biopotentials are relatively normal and structural integrity is relatively high, thus producing large strain-related potentials for small deformations. Similarly, exogenously generated constant electrical signals might be expected to act as healing stimuli in the early stages of fracture healing; whereas exogenously generated time-varying electrical signals might be expected to have a greater effect on the later stages.

The over-all success rate of electrical systems in ununited fracture treatment has been reported to vary between 80 and 90 percent. But there is not enough information about the pulsewave form and its clinical data in the treatment of the acute fracture. Miller et al., (1984) evaluated the use of pulsed electromagnetic field stimulation to affect th rate of healing of segmental autogenous cortical bone grafts in 20 adult mongrel dogs. The results of their investigation indicated that there was no significant effect on the biomechanical strength, histological presentation, or time of union.

Other studies evaluated the effectiveness of pulsating electromagnetic fields in the treatment of nonunions in adult dogs. The results of their experiments demonstrated that the stimulated bones were neither radiologically nor mechanically superior to the controls. All of these dissimilar results of pulsed electromagnetic field stimulation in clinical and animal expreiments, particularly, in the fresh fracture treatment, have implied particular pulse configuration might be required for different stages of fracture healing.

Our clinical results, at this moment, are promising; however, further observation and more clinical volume should be required to adequately assess its effectiveness.

We are in the process of manufacturing special, current amplifiers to provide the combined vascular and calcification pulses alternatively to acute or non-united fractures. The second part of this project will be done on animal models.

Current inductive coupling devices (Electro-Biology, Inc) are available on the market. Since the pulse-shaping circuits and coils are provided by the manufacturer by prescription for each patient, an accurate measurement of the final intercoil distance [within + 0.25 inch (0.6 centimeter)] is necessary. This step determines the size (diameter) of the coils and the voltage applied to the coils. Cast thickness (diameter, not circumference) is measured with calipers at the level of the fracture. After calibration by the manufacturer, the equipment is delivered to the orthopedic surgeon and then to the patient. This procedure takes an unnecessarily long period of time, and the device is expensive. Moreover, it is almost impossible to maintain the exact intercoil distance in case the cast is changed during the waiting period.

Because our device will supply optimum energy control to each patient, intercoil distance will not be a critical problem in the maintenance of the osteogenetic electrical field. Thus, this device can be supplied rapidly to each patient on a custom made basis. Furthermore, it will be very helpful in reducing medical costs because importation of expensive foreign products will no longer be necessary.

Clearly, a newly designed electromagnetic stimulator, capable of providing combined vascular and calcification pulses, will be applied to patients who have sustained bone fractures, injury to cartilage, ligaments and nerves, and avascular necrosis of bones.

## SUMMARY

Our own non-invasive and inductive coupling electromagnetic stimulator design has been utilized to treat 2 non-united fractures of the femur, 1 congenital pseudoarthrosis of the tibia, and 1 neglected femoral neck fracture, which had undergone closed reduction and internal fixation with hip nail 8 months following injury, obtained a solid union in 2 months of stimulation. Two non-united fractures are responding favorably. However, acute fractures appear to be responding equivocally to current pulse waveform.

We are developing a portable electromagnetic stimulator which is capable of treating all bone fractures, injury to cartilage, ligaments, and nerves, and avascular necrosis of bone.

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