醫工學會誌：第5卷，第2號，1984
J. of KOSOMBE: Vol. 5, No. 2

研究論文
84—2—02

The Study on Electromagnetic Stimulator for Healing of Ununited Fracture

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1. Introduction

As early as 1841, man has attempted to treat nonunions with electrical current. The first studies to be performed on the electrical properties of bone were conducted by Yasuda and Fukada in Japan in the mid-1950's. They found that mechanically stressed bone generated an electrical potential, areas of compression were electronegative and areas of tension were electropositive. Bassett and Becker in the late 1950's, and Shames and Lavine in the early 1960's began similiar experiments in the United States. Fridenberg and Brighton began studies on viable nonstressed bone in 1961. They found that areas of active bone growth and repair were electronegative when compared to less active areas. It is fascinating to note that none of the four research groups mentioned above knew of one another's work during the early phases of their individual studies. During the 1960's many investigators demonstrated that the application of a small amount of electric current, be it constant current or pulsed current, stimulated osteogenesis at the negative electrode or cathode. Much of the literature appearing during these years was confusing and even contradictory due primarily to the lack of quantitation in many of the studies reported. However, one dominant theme slowly evolved: electricity could indeed induce osteogenesis, given proper voltage and current parameters and the proper tissue environment.

Clinical trials using electricity in various forms in the treatment of delayed union, nonunion, and congenital pseudoartrosis began in the early 1970's. Again, as occured during the previous decade in the laboratory studies, confusion arose in many areas. Much of this confusion still remains today. Constant direct current, pulsed current, and electromagnetically to heal bone defects with varying degrees of success. To this date it is not known which form of electricity is most efficient in stimulating osteogenesis.

Also, electricity can be applied to bone

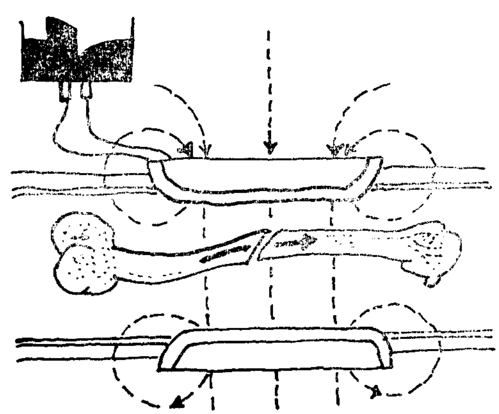

Fig. 1. Inductive coupling method : noninvasive

<1984. 10. 15 접수>

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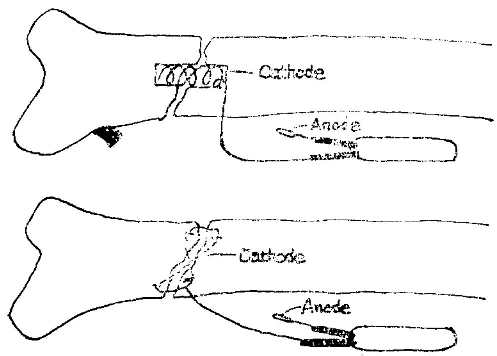

Fig. 2. Semi-invasive method

using an invasive technique, wherein electrodes, leads, and power pack are all implanted in the nonounion extremities; a noninvasive technique, wherein current is induced in the nonunion but all of the electrical apparatus remains exterior to the skin (Fig. 1); and a semi-invasive technique, wherein only the cathode is inserted into the nonunion site (Fig. 2).

At present the clinical indications for favoring one technique over another have not been defined. These system reportedly give the over all success rate of 80 to 85%.

The purpose of this study is to design and manufacture noninvasive and inductive coupling method, which can be utilized for fresh fracture, cartilage, ligament, and nerve injury treatment as well as growth plate stimulation and in leg length in cementless total joint replacement.

2. Physiology of Bone Formation

The detailed chemical composition of bone is given in Table 1 and bone consists of two quite different materials plus water; collagen, the major organic function, which is about 40% of the weight of solid bone and 60% of its volume, and bone mineral, so called "inorganic" component of bone, which is about 60 % of the weight and 40% of its volume.

Table 1. Composition of compact bone

Element	Femur Bone	Element	Femur Bone
H	3.4%	C	15.5%
N	4.0%	O	44.0%
Mg	0.2%	P	10.2%
S	0.3%	Ca	22.2%

The mechanism by which electricity induces osteogenesis as follows ; 1) When electrical current is induced in osteogenesis, oxygen is consumed and decreasing local tissue oxygen tension and increasing alkalinity. 2) Low tissue oxygen tension has been shown to be favorable to bone formation. 3) Bone formation follows a predominantly anaeorbic metabolic pathway. 4) Studies of bone forming junctions have demonstrated that an alkaline pH is present in the zone of hypertrophic cells of the growth plate when calcification begins. Obviously, additional mechanism must exist in electricity induced bone. While they are yet to be defined, clinical experience to date supports the efficacy of the electrical current stimulation technique. Research is continuing in attempt to isolate the physiological chain of events leading to osteogenesis in bone and cartilage cells.

3. Pulsed Electromagnetic Stimulation System (PEMS)

The pulsed electromagnetic stimulation system is based on Faraday's law, that is, current is induced at conductor in time varying electromagnetic field. Advantages of this system compared to other methods are as follows ; 1) Sugically noninvasive treatment assembly and position block are centered over

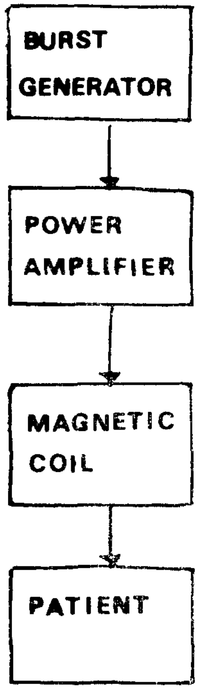

Fig. 3. The system diagram of PEMS

fracture external skin, plastic orthosis or plaster cast surface. 2) Compatible with previously infected and activity draining nonunions. 3) Proven safe because electromagnetic fields no harmful to human body. 4) Eliminates the risk of in fection associated with the use of other electrical and surgical procedures.

This system is composed of burst generator, power amplifier, magnetic coil (Fig. 3).

(1) Burst Generator

In this study, we used bipolar quasirectangular pulse pattern which has asymmetrical in timing and amplitude. The main polarity portion of pulse is 240 microseconds which increase blood flow in fracture site and opposite of polarity portion is 30 microseconds which effect calcification. Fig. 4 shows burst waveform and Fig. 5 shows the frequency spectrum of burst wave.

In order to generate and modify easily, we used 2 Kbyte EPROM (2716). 1024 sampled data of designed burst waveform are written by EPROM writer and are refreshed in the clock rate of 200 KHz and converted to anlog signal by 8 bit D/A converter (MC 1408). The burst repetition rate is 16 Hz controlled by flip flop (Fig. 6).

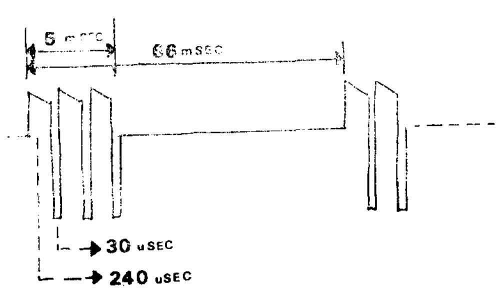

Fig. 4. The burst waveform

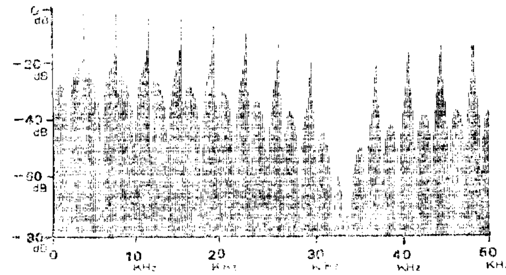

Fig. 5. Frequency spectrum of the burst wave

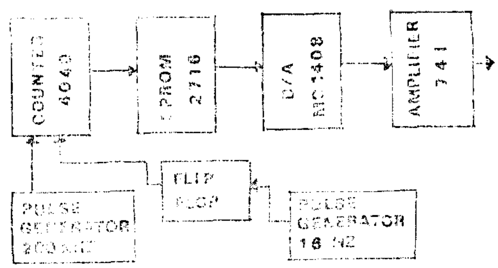

Fig. 6. Burst generater

(2) Power Amplifier

Generated pulse energy of the burst generator is sufficient in case of invasive or semi-invasive methods but in case of pulsed

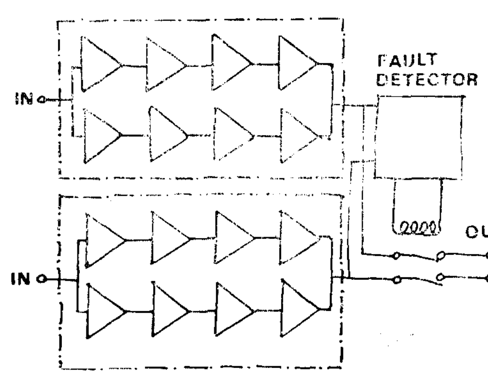

Fig. 7. Power Amplifier

electromagnetic field method is too weak to induce proper level of current. Therefore power amplifier should be needed to amplify this minute energy. We used MOS FET DC/push pull amplifier (MD 2200) and in fault condition, fault detector open relay to cut off input of magnetic coil (Fig. 7).

(3) Magnetic Coil

The design of magnetic coil is based on the patient's radiography and distance of fracture site. Since magnetic coil is designed so that one "pushes" the field and the other "pulls" it, the coils are aiding when inter-coil distance is smaller than the coil diameter. From a practical point in the clinic, intercoil distances equal to or less than the coil diameter produce uniform magnetic field. The driving voltage to magnetic coil is calibrated through the detector coil which is consisted of #30 copper wire with an internal diameter of 5mm.

4. Discussion

The manufactured coil are positioned facing each other at 180 degrees on the fracture site (Fig. 8) and checked by radiography. Patients are applied to PEMS more than 12 hours per day and states of healing in the fracture site are evaluated periodically by radiography.
In present, 10 patients apply this system and summary of results are showed in Table 2. According to Table 2, most case of the patients except one show good results or progressive. In case of patient 5, we guessed that burst waveform is not adequate to this type of patient and since inter-coil distance is larger than the other, power may be insufficient level.

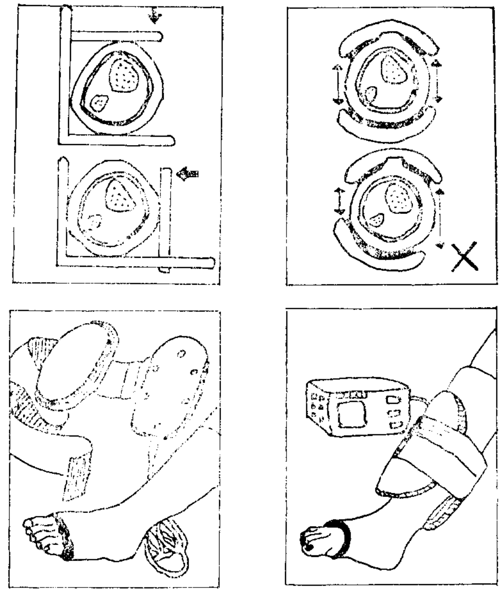

Fig. 8. Installation of PEMS

Table 2. Summary of results

Patient	Fracture site	Period	Result
No. 1	tibia	2 month	good
No. 2	tibia	2 month	good
No. 3	tibia	2 month	good
No. 4	knee	3 month	good
No. 5	hip joint	2 month	no active
No. 6	femur	3 month	progress
No. 7	tibia	1 month	progress
No. 8	femur	1 month	progress
No. 9	tibia	1 month	progress
No. 10	tibia	1 month	progress

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= 국문초록 =

비접합성 골절의 치료를 위한 전기자기 자극기에 관한 연구

연세대학교 의과대학
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비접합성 골절의 치료를 위한 전기적인 방법으로는 관혈적인 방법, 부분적으로 관혈적인 방법, 비관혈적인 방법 등이 있는데, 비관혈적인 방식은 다른 방법들과는 달리 수술 등 외과적 처치 등이 필요하지 않을뿐더러 환자에게도 가장 안전한 방식이다. 본 논문에서는 유도 결합 현상을 이용한 비관혈적인 전기 자기 자극기를 설계, 제작하였으며, 임상 실험 결과 좋은 결과를 보이고 있다.