DEVELOPMENT OF AN INTRA-ORAL BONE GROWTH STIMULATOR FOR TITANIUM DENTAL IMPLANTS

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ABSTRACT

A prototype intra-oral bone growth stimulator to promote bone growth for titanium dental implant is developed. The device is a self contained single-patient disposable unit that generates a pulsed electromagnetic field (PEMF) to the site of the implant. It is designed to be embedded into a mouth guard so that it can be conveniently and comfortably placed inside the oral cavity by the patient for two hours a day in an eight week treatment period. The device is designed to produce the PEMF, be small, hermetically sealed, and able to last for the entire duration of the treatment period.

BACKGROUND

A patient who received a dental implant has to wait for the bone to "knit" or integrate to it before a fixture can be secured onto the implant. In general, a patient has to wait up to 6 months before the fixture can be attached. In some patients, the progress of osteo-integration between the alveolar ridge and the implant is slower than normal. If this occurs, the implant will not have sufficient strength to support the attached fixture. A device that can stimulate and accelerate the process of osteo-integration will improve the success rate of this orthodontic procedure.

OBJECTIVES

This paper describes the development and verification of a "pre-clinical trial" prototype intra-oral device to promote bone growth in titanium dental implants. There were a number of engineering challenges in this project. The first was to identify the characteristics of the electromagnetic field to be produced by the device. A second engineering challenge was to develop a device which can generate the field inside the oral cavity to the target gum areas. A third challenge was to develop a prototype that could be worn by the patient in a comfortable and unobtrusive manner for the recommended period of time.

PEMF CHARACTERISTICS

Electric current and magnetic field have been shown to accelerate tissue growth in both in-vitro and in-vivo studies. Matsumoto et al [1] showed increase in bone formation around a rough-surfaced dental implant inserted into the femur of rabbits when a PEMF was applied. Ozen, J et al [2] reported significant increase in bone osteoblastic activity, new trabecular bone and fibrous tissue formation in the PEMF treated group after dental implants were inserted in rabbit mandibular model. Weintraub, in his 2004 critical review of electromagnetic stimulation [3], cited many studies on PEMF therapies.

The following PEMF parameters were chosen for the device in this project. They are similar to those quoted from studies that showed positive results. The PEMF waveform is shown in Figure 1.

- Pulse amplitude (magnetic field strength) > 2 Gauss (10 Gauss at center was used in design calculation)
- Pulse width = 250 μs at 50% duty cycle
- Number of pulses per burst = 20
- Burst repetition frequency = 10 Hz
- Treatment duration = 2 hrs per day
- Treatment period = 8 weeks

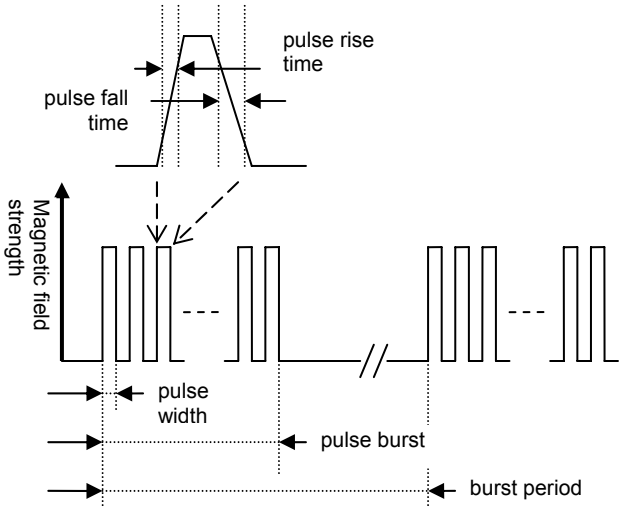


Figure 1. PEMF Characteristics

TRANSDUCER AND EXCITATION

Figure 2 is the first level architectural design of the device. It consists of a transducer to produce the PEMF, an excitation circuit to create the necessary current pulses to the transducer and a power source

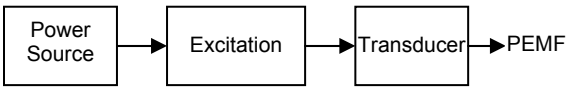


Figure 2. Block Diagram of Device

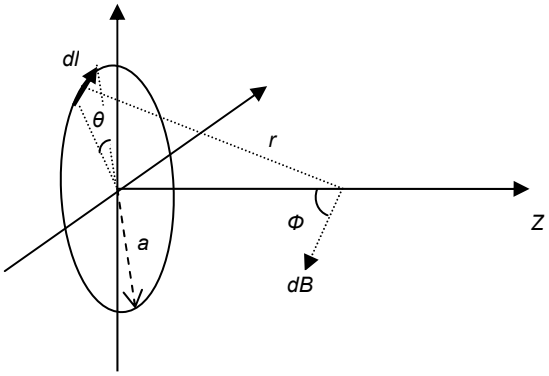


Figure 3. Magnetic Field Produced by a Circular Coil

Consider a single-turn circular coil with a radius *a* (Figure 3). If the current flowing through the coil is *I*, at a distance *z* away from the centre of the coil, a magnetic field *dB* is induced by the current element in a small segment *dl* of the loop. *dB* is given by:

$$dB = \frac{\mu_0}{4\pi}\frac{I.dl}{r^2} = \frac{\mu_0}{4\pi}\frac{Iad\theta}{r^2}$$

From the above expression, it can be shown that the magnetic field B_z along the Z axis of a coil with N turns is:

$$B_z = -\frac{\mu_0 NIa^2}{2r^3} \quad \text{.....(1)}$$

As the transducer must be placed near the dental implant inside the oral cavity, very thin insulated copper wire is chosen to form circular coils to produce the magnetic field. Figure 4 shows two such coils placed at a distance b mm away from the center on each side of the dental implant. Note that a typical titanium dental implant (rectangular shaded area in the diagram) is 4 mm in diameter and 8 to 15mm long. If the current in both coils are equal (*I*) and flowing in the same direction, from equation (1), the magnetic field *B* strength at the centre of the two coils is equal to:

$$B = B_1 + B_2 = 2B_z = 2\frac{\mu_0 NIa^2}{2\left(a^2+b^2\right)^{3/2}} = \frac{\mu_0 NIa^2}{\left(a^2+b^2\right)^{3/2}} \quad \text{....(2)}$$

where B_1 and B_2 are the magnetic fields due to coil 1 and coil 2 respectively

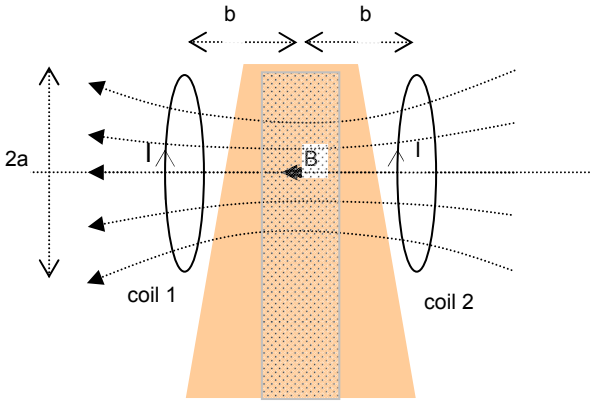
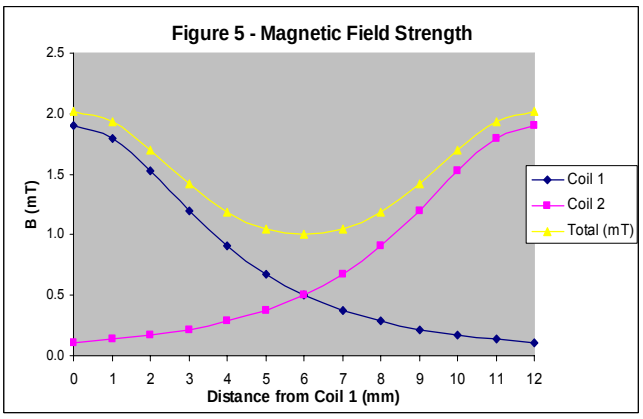


Figure 4. Magnetic Field B at the centre of 2 coils

To produce a magnetic field of 10 Gauss (B = 1 mT), two 200 turn (N = 200), 10 mm (a = 5 mm) diameter coils separated by 12 mm (b = 6 mm) were selected as the transducer. The permeability between the coils is approximately equal to that in free space as both tissues and titanium are non-ferromagnetic, i.e., $\mu_0 = 4\pi \times 10^{-7}$ T.m/A. With these parameters, the excitation current *I* calculated from equation (2) is:

$$I = \frac{\left(a^2+b^2\right)^{3/2}}{\mu_0 Na^2}B = 0.076A = 76mA \quad \text{.....(3)}$$

Figure 5 shows the plot of the calculated magnetic fields along the center axis of the coils at different locations from coil 1 using this excitation current.



Based on these specifications, a circuit consisting of a PIC10F200 series microcontroller, a coil driver transistor, a micro sized pushbutton switch and an on/off indicating light emitting diode (LED) was designed. A microcontroller offers the flexibility that almost any pulse shape and timing configurations can be programmed. This approach also provides a minimum number of components with very small dimensions.

POWER SOURCE

The power requirements created the following challenges. It must be able to deliver a peak pulse current of 76 mA, it must last for the entire treatment duration of 8 weeks and it must be small in size and able to be totally sealed. 200 turns of 39 AWG (0.0035 inch diameter) insulated copper wire was used to form the coils. This wire is rated at 890 Ω per 1000 ft.; so 2 circular coils (diameter 10 mm, 200 turns each) result in an estimated total resistance of 36.6 Ω. Applying 3.0 V across the coils and taking into account a voltage drop in the coil driver transistor of 0.13 V result in a peak current through the coils of approximately 78 mA. The circuit draws an average current of 3.8 mA when the duty cycle of the pulses is taken into account. A total operating time of 2 hours per day for eight weeks (112 hours) requires 426 mAhr from the power source. The microcontroller consumes less than 350 μA when it is fully on and only 0.10 μA when it is in sleep mode; therefore it needs less than 40 mAhr for the entire treatment period.

In order to supply a minimum of 466 mAhr, a battery configuration consisting of two AAAA alkaline cells connected in series supplying 3 volts at 625 mAhr was chosen. This produced the smallest off-the-shelf battery configuration with an excess of about 159 mAhr for powering the on/off indicator LED. Programming the LED to turn on for 2 seconds at startup and then blinking at 100 mSec ON and 1 second OFF thereafter requires only 40 mAhr total. Based on these calculations, the batteries should have enough capacity to last for the entire treatment period.

PROTOTYPE

Two prototypes were produced for design verification. The coils were wound on a Delrin bobbin, removed and encapsulated in medical grade silicon to facilitate handling. The electronic circuit was surface mounted onto an extra thin printed circuit board and placed on top of the 2 batteries. The batteries and electronic circuit was shrink-wrapped and sealed. Figure 6 is a picture of the prototype device.

Figure 6. Prototype Stimulator

The entire unit was designed to be encapsulated into a month guard with the coils located on each side of the gum and alveolar ridge containing the dental implant. The battery/electronic module was designed to be placed horizontally between the molars and the cheek inside the month. Similar to ordinary mouth guards, the device could be placed and removed by the patient without the need of any tools.

DESIGN VERIFICATION

The prototype was laboratory tested and found to conform to all designed specifications. Below are descriptions of some of the tests:

The pulsed magnetic field characteristics were measured using a Hall Effect sensor (Allegro A1323EUA) with a sensitivity of 2.5mV/G±5%. The sensor was placed between the 2 coils which were positioned 12 mm apart (Figure 7). A 2-dimensional linear translation stage with 1 mm resolution was used to move the sensor along and vertical to the axis of the coils. The output of the sensor was observed with an oscilloscope. The measured PEMF waveform agreed with the designed specifications (within ±10%).

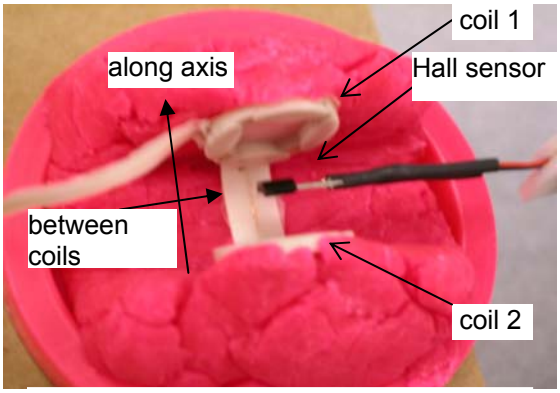
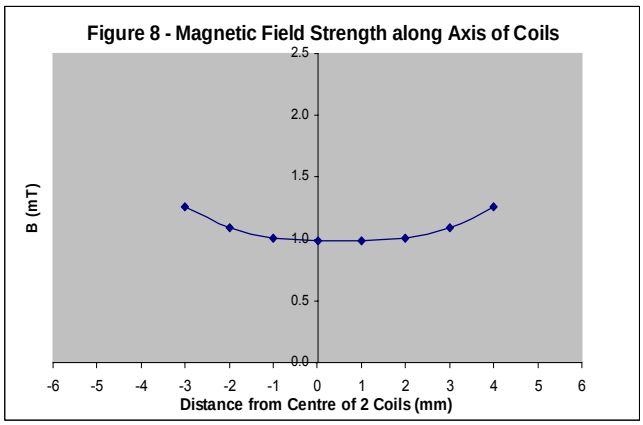
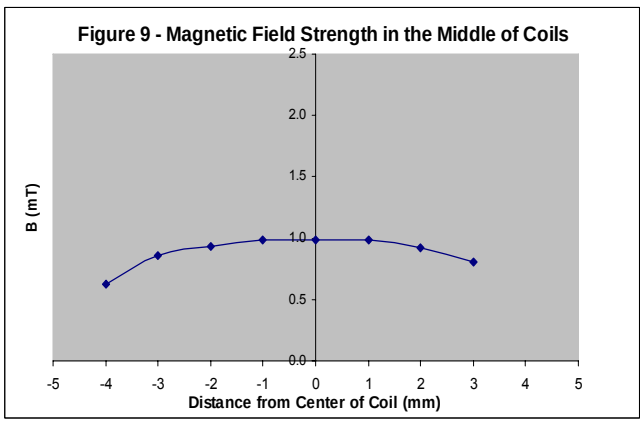


Figure 7.Hall Effect Sensor

The magnitude of the pulsed magnetic field strength at different locations along the central axis of the coils were measured and plotted in Figure 8. The minimum field strength of 0.98 mT (9.8 gauss) was obtained at the middle of the coils. Figure 9 shows the magnetic field strength measured perpendicular to the axis of the coils at equal distance from each coil. It showed that the field strength was the highest at the coil axis and decreased as the sensor was moved toward the edge of the coils. These measurements confirmed the magnetic field strength was above 2 gauss (the minimum design field strength) at any location within the cylindrical volume bound by the 2 coils.





The temperature rise of the battery/electronic module was measured using a temperature monitor and a pair of temperature sensors (YSI400 thermistors, $\pm 0.2^{0}$C). One sensor was attached to the module and the other was used as a control to monitor the ambient temperature. The device was thermally insulated by placing it inside a tight fit Styrofoam enclosure. Note that this would be the worst case scenario as the module, under the intended operational condition, would be embedded into a mouth guard type of enclosure with little thermal insulation. The stimulator was activated and the temperatures were measured continuously over a 2 hours time period. The maximum temperature rise was 3.1 ^{0}C. Based on this result, when the device is placed inside the oral cavity (37 ^{0}C), the maximum temperature of the device should remain below 41 ^{0}C which is a safe temperature for continuous tissue contact.

An accelerated battery life test was performed with the timer altered to run for 18 hours per activation. The circuit was run for 18 hours per day for 6 days (roughly equal to the ON time of the designed treatment period). At the end of the test, the battery voltage level was measured to be 2.6 V which is still sufficient to power the electronic circuit (> 2.0 V) and provide at least 85% of the initial field strength.

To test for gas emission and waterproofing requirements, the unit was turned on and submerged into a bath of degassed water for 2 days. There were no observable water leakage into the module and no gas emission from the module. The device was functioning properly after removed from water.

FUTURE WORK

A small batch of prototypes is being fabricated for clinical trial. The device can be further miniaturized by using custom-made batteries instead of off-the-shelf AAAA cells. The device can be adapted for non-invasive bone or tissue stimulation on other parts of the body.

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