Development of an Implantable Biodegradable Electrical Stimulator for Bone Repair

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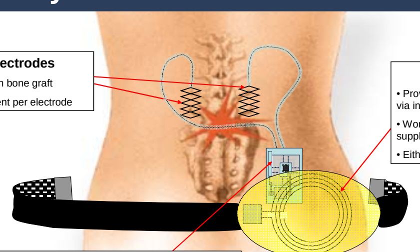
Abstract

The application of localized DC current stimulation to promote bone growth is an established technique for enhancing bone repair in difficult-to-heal cases, such as can be the case in many spinal fusion procedures. Since the power supply implanted at the time of surgery should be subsequently removed, widespread adoption of this technology has been limited. To overcome this we are developing an implantable biodegradable bone stimulator system. This device will obviate the need for an implanted power source, because the stimulator operates on wireless RF power transmission via inductive coupling to an external power source. The implanted coil is fabricated from a biodegradable magnesium alloy, while dielectric components and insulating packaging are made from 70:30 poly L: D/L-lactide (PDLA). Initial experimentation also demonstrates the feasibility of fabricating the stimulating electrodes from degradable magnesium alloys. While the RF rectifier and constant current source components have not yet been manufactured, we envision these active circuits being made either from biodegradable ZnO-based transistors or as an ultraminiature, non-degradable IC which would have minimal impact *in vivo*. The stimulator is being designed to provide a constant current of 60µA, while sustaining a serviceable life *in vivo* sufficient for the duration of spinal fusion (~24 weeks). Current efforts are focused on developing the passive RF inductor coil network and circuitry design for efficient power transfer. Preliminary data will be presented verifying wireless communication with this biodegradable RF circuit, as well as for magnesium electrodes in simulated body fluid.

Envisioned System



Mg Alloy Electrodes
- Cathodes implanted in bone graft
- Apply 30 µA DC current per electrode

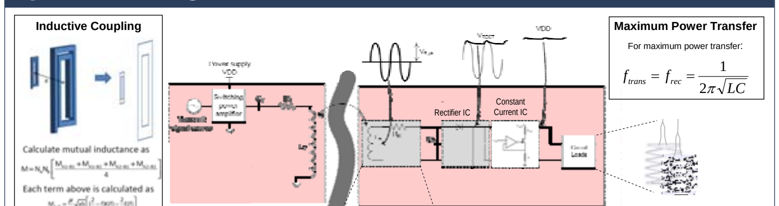
External RF Transmitter
- Provides power to the implanted circuitry via inductive coupling
- Worn by patient for prescribed intervals to supply current to healing site
- Either belt or vest worn implementation

Implanted Biodegradable Current Source
- Implanted approximately 1-2 cm below skin in abdomen
- Inductively coupled to external RF transmitter as a means of power transfer
- Provides signal rectification and regulation at 60 µA constant current
- Includes anode system ground
- Completely resorbable: conductors (Mg alloy), insulators & dielectrics (e.g., PDLA); active components (ZnO or ultraminiature non-degradable chip)

Advantages of Biodegradable System
- **Does not require second surgery to explant power supply**
- **No permanently implanted electrodes**

Disadvantage
- **Potential for lack of patient compliance**

System Design



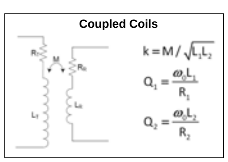
System Requirements
- **30 µA constant current supplied to each cathode**
- **Regulated supply voltage of ~3 V to operate IC's**
- **Minimum implant depth of 1 cm**
- **24 week functional service life of device**

Operational Frequency

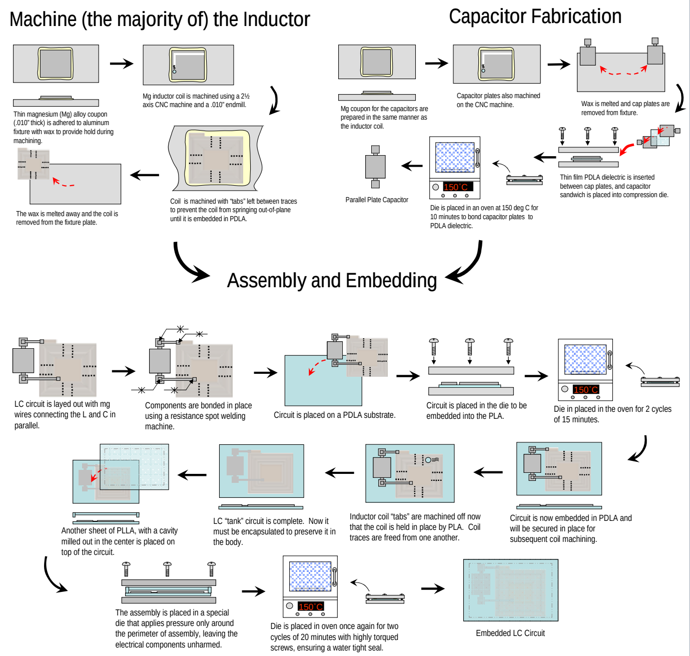
Our current prototype is designed to resonate at 13 MHz.

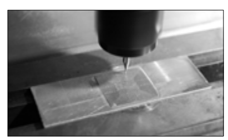
f_{res}= 13 MHz

L = 2.2 µH C = 90 pF

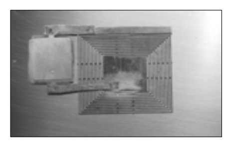


Prototype RLC Circuit Fabrication

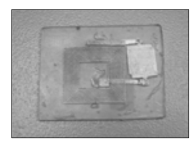




Micromilling of coil



Assembled coil/capacitor



RF circuit embedded in PDLA

Future Work

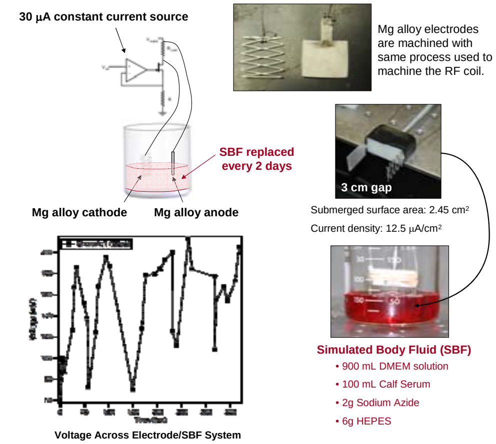
- Conduct a long-term study of the device performance over 24 weeks *in vitro* (note: this is worse-case since *in vitro* degradation in SBF is much faster than *in vivo*)
- Optimize design of the Tx/Rx circuitry for maximum power transfer efficiency
- Refine the prototype fabrication process
- Integrate microminiature constant current source integrated circuit into the prototype
- *In vivo* studies

Methods and Results

Feasibility of Using Magnesium Alloy Electrodes

Objective and Experimental Set-up

- Monitor applied voltage needed to drive 30 µA through Mg electrodes/SBF system as the electrodes degrade over time in simulated body fluid (SBF)
- Verify that the system resistance remains low enough to drive 30 uA with no more than a few hundred millivolts



Voltage Across Electrode/SBF System

Feasibility of a Mg/PLA RLC Circuit

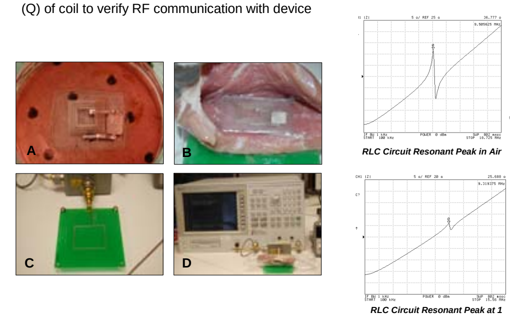
Objective and Experimental Set-up

A. Submerge embedded coil in SBF to allow device to degrade over time *(at the time of this poster presentation, the circuit was in SBF for 2 days)*

B. Periodically transmit to device embedded at 1 cm depth in pork belly using a PCB transmitter coil

C. Transmitter PCB coil

D. Use Agilent 4395A Network Analyzer to monitor resonant frequency and quality factor (Q) of coil to verify RF communication with device



RLC Circuit Resonant Peak in Air

RLC Circuit Resonant Peak at 1 cm Depth in Pork Belly

Acknowledgements

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