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Short Communication

In vivo demonstration of ultrasound power delivery to charge implanted medical devices via acute and survival porcine studies

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ABSTRACT

Animal studies are an important step in proving the utility and safety of an ultrasound based implanted battery recharging system. To this end an Ultrasound Electrical Recharging System (USER™) was developed and tested. Experiments *in vitro* demonstrated power deliveries at the battery of up to 600 mW through 10–15 mm of tissue, 50 mW of power available at tissue depths of up to 50 mm, and the feasibility of using transducers bonded to titanium as used in medical implants. Acute *in vivo* studies in a porcine model were used to test reliability of power delivery, temperature excursions, and cooling techniques. The culminating five-week survival study involved repeated battery charging, a total of 10.5 h of ultrasound exposure of the intervening living tissue, with an average RF input to electrical charging efficiency of 20%. This study was potentially the first long term cumulative living-tissue exposure using transcutaneous ultrasound power transmission to an implanted receiver *in situ*. Histology of the exposed tissue showed changes attributable primarily due to surgical implantation of the prototype device, and no damage due to the ultrasound exposure. The *in vivo* results are indicative of the potential safe delivery of ultrasound energy for a defined set of source conditions for charging batteries within implants.

1. Introduction

Increasing power needs for implanted devices that support new therapies, combined with advanced rechargeable lithium ion chemistries, drive the interest in rechargeable (secondary) batteries in implanted medical devices [1–3]. Commercially, the development of recharging systems is being driven by an expanding market for neurostimulators for pain management, about 40% of which contain a rechargeable secondary battery. While battery development research continues, Li-ion is currently the rechargeable battery of choice because of its high specific energy density, cell voltage (3.6–4.2 V), significant number of discharge–recharge cycles, and lack of the need for periodic complete discharge. For the current project, only Li-ion batteries were available as the only option through one of the major suppliers of implantable batteries, (Greatbatch, Clarence, NY).

The electromagnetic inductive coupling method for recharging of batteries has been under investigation and development for over 60 years [4,5]. While the inductive coupling technique remains useful, its limitations have been pointed out in [6,7]. Hence there has been a continuous search for other methods of power delivery to implanted devices, including optical [8], energy harvesting [9,10], and ultrasound [6,11]. This is also the emphasis of the ultrasound-based Ultrasponder Project taking place in the European Community [7,12]. That effort is focused on 10–20 cm deep, mW level power transfer. In contrast, the present effort is to find more general applications where ultrasound power transmission over 1–2 cm at 100–500 mW levels can be of benefit. Wireless inductive charging is used in some spinal cord stimulators.

The objective of the present project is to report on bio-acoustic aspects of power delivery using ultrasound energy, rather than present a competing argument to the use of inductive power charging systems. In addition to some comparison of physical basis of ultrasound versus inductive charging methods described in the literature such as delivery of energy at depth, heating as well as interference with other electromagnetic fields [6,7,16], the rationale for development of alternative transcutaneous methods to inductive methods is to provide options to potentially reduce long-term exposure to electromagnetic radiation.

Few published papers appeared on the subject through 2002 [13,14] although an early patent was granted [15]. Kawanabe et al. [13] and Suzuki et al. [14] refer to an ultrasound power

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delivery in a live goat, and present results on choice of frequency, efficiency, and temperature which we have generally validated. But their description is brief and lacking in experimental detail and presented data. Ozeri et al. [6,11] presented thorough designs and analyses of an ultrasound charging system and performed *in vitro* tests, but did not report *in vivo* tests. Papers from the Ultrasponder project focused on progress in deep delivery of power [7,12] but have not published detailed animal studies. Denisov and Yeatman [16] used modeling and simulations to predict and compare the optimum propagation distances and sizes of ultrasound versus inductive coupling devices. As an extension of the previously mentioned work, it is useful to study and experimentally validate our parameters for application, as well as characterize factors not considered by previous investigators, which may play a role in concept implementation. Based on the relative paucity of *in vivo* results using ultrasound, our project has focused its effort in describing the unique aspects of implementing ultrasound based charging of batteries within implants via several porcine acute studies as well as a survival study, whereby the safety and practical parameters for the ultrasound approach could be better defined.

Given the practical problems and safety issues associated with using this ultrasound technique over several weeks in a living, ambulatory animal and eventually a human, *in vivo* acute and survival studies are essential. To our knowledge the present paper describes the most extensive *in vivo* results of wirelessly transmitting 300 mW of power transcutaneously to an implant, using ultrasound. Transmitter and receiver platforms, and charging electronics were developed, that were different in detail from previous efforts.

Based on previously reported work [6,11,23], tests such as determining the most efficient transducer frequency, transducer dimensions, and propagation through different media, were repeated for our particular designs and objectives. These water tank and *in vitro* results are reported here to facilitate the understanding, capabilities, and limitations of the system whose data we are reporting. However the focus is always on the novel *in vivo* tests. In addition, cooling methods were developed that would allow delivery to larger batteries with transmitted power over 1 W without increasing tissue temperatures beyond current implant device recommendations of 2–4 °C [17]. This anticipates the possible use of transcutaneous ultrasound energy delivery for ventricular assist devices [18].

This paper begins by describing the design and *in vitro* performance characterization of two generations of ultrasound based recharging systems, one where the receiver is tethered to a controller box, and the second, which is linked wirelessly to a base station. Charging of a secondary battery in the receiver module is then described for a series of acute *in vivo* experiments using a porcine model. An envelope of ultrasound source conditions was obtained, whereby the goal was to deliver charging power *in vivo* without any histologically apparent thermal tissue effects. During the final phase of the project a 25-day survival study was conducted. Results in terms of repeated battery recharging capability, system efficiency, temperature changes as well as tissue effects are presented.

2. The elements of the Ultrasound Electrical Recharging (USER™) System

A USER system consists of an ultrasound transmitter, its power driving electronics and an implanted receiver transducer which converts acoustic to electrical energy. From that point the energy can be stored in a battery or used directly to power a therapeutic application. In order to test the energy transfer concept through 10–20 mm of tissue, two versions of implantable prototypes were developed, a tethered "Gen 1" and a wireless "Gen 2." For simplicity, the Transmitter and Receiver transducers were planar circular discs, usually 25 mm in diameter. The transmitter was powered with a waveform generator-power amplifier combination (BK Precision 4070A, ENI 240L). The Gen 2 receiver prototype was a sealed wireless system intended as a long-term *in vivo* implant, hence had a biocompatible poly-ether-ether-ketone (PEEK) top shell with a stainless steel bottom plate. Transmit–receive experiments to test the efficacy of the prototypes were performed either in a tank filled with distilled water, or on a benchtop whereby excised porcine skin tissue was interleaved between the transmitter and receiver ("sandwich model"). The transmitter is placed at the top of the tissue surface using a manual tripod mechanism, so that the transmitter and receiver faces are aligned to generate optimal charge current for the battery. Schematics of the arrangement for experiments in a water tank as well as the benchtop tissue experiments are shown in Fig. 1.

Both implants were connected to a computer for bi-directional signal control. This system was coded using C++ and Signal Express (National Instruments). At the receiver, as the charging sequence is initiated, the RF signal from the piezo-transducer passes through a bridge rectifier built with discrete low forward voltage Schottky diodes. The DC is filtered, passed through a current-sense resistor, its drive voltage limited by a Zener diode. Then the DC is passed through a MOSFET device that acts as a variable current-sense resistor for the charging chip, regulating the battery charging current via varying its gate voltage. The charging chip receives its operating voltage from the rectified RF voltage.

The wireless Gen 2 prototype communicated with the controlling base station on the 405 MHz medical device wireless-band. The biocompatible PEEK-stainless steel implant was 70 mm in diameter, and contained the medical grade Li-ion 200 mA h battery (4.1 V maximum voltage), the charging, wireless, and microcontroller drive circuitry. The receiver RF antenna for the implant was built along the circumference inside the implant. The 1 MHz, 25 mm diameter active face ultrasound-receiver transducer was placed flush with the face of the implant. To ensure biocompatibility during survival animal studies the whole implant assembly was coated with Parylene. The transmitter transducer was matched in frequency and size to the 25 mm diameter receiver transducer. For most of the studies drive times and input RF power were in the range of 1–150 min and 0.5–4 W, respectively. A photograph of the designed wireless implant prototype, the medical band RF communicating base station, as well a transmitter transducer are shown in Fig. 2. This system is not limited to a specific rechargeable battery, rather the charging current available from the ultrasound receiver can be used for any battery type or to drive an application directly.

3. Transducer selection and optimum operating frequency range

Implementation of the USER concept for transcutaneous ultrasound-based energy transfer system involved several acoustic source-target considerations. Notable aspects were focused or non-focused systems, transducer material, operating frequency, source output power, and dimensions of the transmitter and receiver. Single-element, PZT 4 and PZT 8 planar circular disc transducers in aluminum housings were constructed by American Piezo Ceramics International (APCI, Mackeyville, PA). The air backed PZT 4 and PZT 8 material discs were appropriate for high power continuous operation, due to their low loss factor. The elements were bonded with low viscosity epoxy (Hysol E120HP), to the aluminum faces to ensure good electrical and thermal contact, the Al layer thickness being impedance matched with tissue. Resonance frequencies were obtained by considering material