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A Wireless Batteryless Implantable Radiofrequency Lesioning Device Powered by Intermediate-range Segmented Coil Transmitter

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Abstract

A batteryless implantable radiofrequency lesioning (RFL) device powered by magnetic coupling is presented. The implant is composed of bipolar RFL electrodes, an energy-receiving coil, and a resonant capacitor circuit for maximizing the received power and providing an appropriate voltage for the electrodes. A 40-cm transmitting coil designed to wrap around the patient's body is used to generate a uniform magnetic field in a large volume so precise coil alignment is not necessary. The transmitting coil is divided to 24 segments by resonant capacitors to significantly reduce the excitation voltage to a safe level. The system was tested using *ex-vivo* chicken muscle tissue. Experimental results show that with a transmitting coil excitation of 1.2 A_{rms}, the implant can lesion the muscle tissue by achieving a temperature of 55 °C. When the excitation increased to 1.6 A_{rms}, the tissue temperature was increased to 83 °C. FEA simulation results demonstrate that the human body SAR is lower than the safety limit of 2 W kg⁻¹ suggested by international guidelines when the excitation is 1.6 Arms.

I. Introduction

Radiofrequency lesioning (RFL) has been used to treat a variety of diseases by ablating tissue, such as cancer or pain signaling nerve tissue [1]-[2]. RF nerve lesioning is a common procedure used to treat several different pain syndromes afflicting millions of patients per year. In RF nerve lesioning treatments, a percutaneous electrode is inserted to the target

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nerve tissue and a grounding pad is placed on the patient's arm or leg. When an RF power source is applied, an electric current will flow between the electrode and the dispersive pad. The current concentrates around the electrode tip and generates heat, which causes protein denaturation and cell death, blocking the nerve from sending pain signals to the brain. However, the lesioned nerve regenerates and the pain returns, necessitating repeated procedures to maintain pain relief. Because a wired electrode is inserted through the skin to the target nerve during each procedure, patients experience significant pain, risk of complication, and cost as often as every several months using this technology.

In this paper, we propose a cost-effective, implantable RFL (IRFL) method to eliminate the need for repeated RFL procedures. With this system, the patient will undergo one initial procedure to implant the device near the target tissue, then for subsequent procedures, will simply place a portable transmitter around the body for a few minutes. There will be no electrode insertion through the skin, thus eliminating the risk of bleeding or infection, with all subsequent procedures. Unlike the conventional energy transmitting coil that required tens of kV [3], the transmitter uses a recently developed segmentation technique to significantly reduce the voltage over the coil to a safe level ($< 10 V_{\text{rms}}$) [4]-[6]. The energy receiver is tuned to the operating frequency to maximize the received power and minimize the implant size. The implanted device will automatically receive the energy wirelessly and lesion the target tissue. Bipolar RFL electrodes [7], instead of a monopolar electrode and a distant ground pad used in conventional RFL procedures, are used in the implant to minimize the device size. Since the voltage received by the receiving coil is already at radio frequency, there is no additional rectifier or RF generator needed for the electrodes. As a result, the power consumption, complexity, size, and manufacturing cost of the implant are significantly reduced. In addition, since the implant does not require an embedded battery, its manufacturing cost is further reduced and no replacement surgery is needed every several years because of the limited battery life.

II. Bipolar RFL Electrodes

A pair of bipolar RFL electrodes designed for peripheral nerve ablation is used to demonstrate the feasibility of the proposed wirelessly powered IRFL device. The electrodes are made of two AWG 20 wires and operate at 6.78 MHz. A finite-element analysis (FEA) simulation by Ansys Maxwell was performed to predict the current distribution and thus the shape of muscle tissue lesioned by the bipolar RFL electrodes. In the simulation model (Fig. 1), the electrodes were surrounded by a conductive medium that simulated the electrical properties of human muscle tissue. The simulated result (Fig. 2) indicates that the current density concentrates around and between the two electrodes. Since the power dissipation and tissue temperature are proportional to the current density, the simulated current density profiles can be used to predict the shape of the lesioned region. Experimental results with chicken breast tissue lesioned by the bipolar RFL electrodes will be presented in Section IV to compare with the simulated results. Unlike the monopolar counterpart, which usually generates spherically-shaped lesions, the bipolar electrode configuration can create lesions with different shapes for specific applications by changing the dimensions and orientations of the electrodes [7].

III. Wireless Power Transfer

A. Energy Receiver

The IRFL device is powered by a wireless power transfer system using near magnetic field coupling operating at 6.78 MHz. Since the received voltage is already at RF, no additional rectifier or RF generator is needed to power the RFL electrodes. The circuit schematic and structure of the IRFL device are shown in Fig. 3. The electrodes are directly powered by the receiving coil through a resonant capacitor network. The coil has two turns and is made of enameled copper wires. The receiver is tuned to the operating frequency with the capacitor network. Capacitors C_2 and C_3 form a low-loss potential divider to adjust the electrode voltage. All the components, including the electrodes, capacitors, and coil, are integrated together, so wire connection is not necessary during the implant surgery, promising reduced surgical time, complexity, and cost.

B. Segmented Coil Transmitter

A 40-cm Helmholtz coil transmitter (Fig. 4) was developed to generate a uniform magnetic field in the body. The transmitter was designed to wrap around the patient's body. Both the upper and lower coils have 3 turns. Each turn is made of twelve 18 AWG enameled copper wires connected in parallel. The magnetic field intensity generated by the transmitter was simulated using FEA. Fig. 5 shows the H_z field along the x - and z - axes. The simulated and measured results are consistent with a tolerance of 2.3%. All the plots reveal that the transmitter provides a uniform H_z field within a large volume in the body. The H_z field deviation is less than 4.5% within a range of ± 10 cm along the x -axis and 6.2% along the z -axis.

Although the transmitter can provide a uniform magnetic field in a large volume so that the receiver can be located deep in the body without precise alignment, the excitation voltage for the transmitter could be excessive [3]-[6]. Considering the 40-cm Helmholtz coil, the coil inductance is 17.6 μH . When the transmitter is excited by a current of $I_t = 1.5 \text{ A}_{\text{rms}}$, the transmitter voltage is $V_t = 1.1 \text{ kV}_{\text{rms}}$. Obviously, this high voltage requirement would cause safety issues and substantially increase the manufacturing cost. By applying a recently developed coil segmentation technique [4]-[6], the transmitting coil voltage can be significantly reduced to a safe level by dividing the coil with resonant capacitors. In the prototype under test, the coil was divided into 24 segments. The coil was tuned to 6.78 MHz with the segment capacitors inserted evenly over the coil. When the transmitter operates at the resonant frequency, the voltage across each segment is cancelled by the adjacent capacitor voltage. As a result, the required excitation voltage, which is proportional to the coil resistance (0.97 Ω), is very low. When the excitation current is 1.6 A_{rms} , the excitation voltage is 1.55 V_{rms} , which is much lower than the unsegmented counterpart (1.1 kV_{rms}). The segment voltage (46.9 V_{rms}) is equal to the unsegmented coil voltage divided by the number of segments.

C. Output Power and Energy Efficiency

The output power and energy efficiency of the energy coupling system were calculated [6] and verified by measurement. In the test setup, the receiving coil was positioned in the

middle of and parallel to the transmitter. The calculated and measured results are consistent with a tolerance of 5.5% as shown in Fig. 6. Since we found that the impedance of the RFL electrodes was between 55 and 80 Ω when the electrodes were inserted into a piece of chicken muscle tissue, we chose the capacitance values of C_2 and C_3 to achieve a maximum output power at $R_L \approx 60 \Omega$. From the result in Fig. 6, although maximum output occurred at $R_L = 62 \Omega$, high output power with 95% of the maximum value could be achieved in a wide load range between 41 Ω and 93 Ω . At $R_L = 60 \Omega$, the energy efficiency was 27.8%, which was 1.7% lower than the maximum efficiency at $R_L = 36 \Omega$.

IV. Ex-vivo Tissue Ablation Experiment

The IRFL device wirelessly powered by the segmented coil transmitter was tested using *ex-vivo* chicken muscle tissue as depicted in Fig. 7. A temperature therapy pad heated by circulating hot water was operated under the chicken muscle to preheat and maintain the muscle at 37 $^{\circ}\text{C}$ to simulate human body temperature. The muscle temperature was recorded with a thermocouple sensor which was placed midway between the electrodes to ensure the temperature of the tissue in the whole target region was not less than the measured temperature. In conventional RFL operations, the electrode temperature is about 80 $^{\circ}\text{C}$ and the lesioned region boundary temperature is 55 $^{\circ}\text{C}$, at which biological tissue is considered lesioned [8]. We applied different transmitter excitation current levels (1.2, 1.4 and 1.6 A_{rms}) to determine the required excitation current and time to achieve tissue lesioning. The measured muscle temperatures versus time are shown in Fig. 8. After 500 s of 1.6- A_{rms} excitation, the tissue temperature increased to 83.3 $^{\circ}\text{C}$ which is more than sufficient for tissue lesioning. Even with a lower excitation of 1.2 A_{rms} for 73 s, the tissue temperature increased to 55 $^{\circ}\text{C}$, at which the tissue is considered lesioned. Despite this, to more accurately predict the required excitation level and duration, *in-vivo* large animal experiments should be performed.

Photos of the muscle tissue after 500 s of RFL are shown in Fig. 9. In each of the experiments, a piece of chicken muscle was placed on the top of the RFL electrodes so that the electrodes were entirely surround by muscle tissue. Since the shapes of the upper and lower muscle lesions were equivalent, only the lower muscle pieces are shown (Fig. 9(a)). The lesioned muscle tissue was cut vertically 4 mm from the electrode tips to show the cross sectional view of the lesioned tissues (Fig. 9(b)). The results show that as the excitation current increased, the lesioned area and depth increased.

V. Specific Energy Absorption Rate (SAR)

An FEA simulation for evaluating the SAR in the patient's body caused by the magnetic field generated by the transmitting coil was performed. The simulation model is similar to that used in [6]. In the treatment of chronic low back pain, the energy transmitter would wrap around the middle of the patient's torso, causing organs in the abdomen to be exposed to the magnetic field. Therefore, the FEA model was modified to include the abdomen as illustrated in Fig. 10. According to the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines, the localized SAR should be lower than 2 W kg^{-1} to avoid undesired tissue damage. From the simulated results (Fig. 11), the maximum SAR is 0.69 W

kg^{-1} when the transmitter current is 1 A_{rms} . Since SAR is proportional to the square of the excitation current, the maximum allowable transmitting current would be $1.70 \text{ A}_{\text{rms}}$. From the result of the *ex-vivo* chicken muscle lesioning experiment, the excitation current required to lesion muscle is lower than this current limit. Thus, the SAR caused by the energy transmitter is lower than the suggested maximum of 2 W kg^{-1} .

VI. Conclusions

A cost-effective IRFL device wirelessly powered by magnetic coupling is proposed and successfully demonstrated using *ex-vivo* chicken muscle tissue. With such a system, patients will no longer need to repeatedly endure the painful, risky, and costly procedures involved in conventional, wired RF nerve lesioning. The receiving coil has a diameter of 2.4 cm, which is smaller than many implantable devices currently used to treat similar pain syndromes, e.g. it is 80% smaller than a spinal cord stimulator generator [9]. We demonstrated that, with a transmitting coil excitation of $1.6 \text{ A}_{\text{rms}}$, the tissue temperature is 83.3°C . An FEA simulation was performed to evaluate the expected SAR in a human. The simulation results show that the SAR is lower than the safety limit of 2 W kg^{-1} suggested by the ICNIRP guidelines.

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Figure 1.
A 3-D FEA model for the bipolar RFL electrodes surrounded by a conductive medium simulating the electrical properties of human muscle.

Figure 2.

Simulated current density on the x - y plane with $z = 0$.

Figure 3.
(a) Circuit schematic and (b) structure of the IRFL device.

Figure 4.
A 3-D drawing of the segmented coil transmitter.

Figure 5. Simulated and measured H z along the (a) x -axis, and (b) z -axis of the 40-cm Helmholtz coil transmitter.

Figure 6. Calculated and measured output power and efficiency of the energy coupling system.

Figure 7.
Experimental setup for *ex-vivo* chicken muscle tissue ablation

Figure 8.
Temperatures of the chicken muscles during RFL with different excitation currents.

Figure 9.

(a) Top and (b) side views of the chicken muscle tissues 500 s after RFL with different excitation currents.

Figure 10.
Cross-sectional views of the FEA model for SAR evaluation.

Figure 11.
Simulated SAR of the FEA model on the x - z plane at $y = 0$.