



Volume conduction energy transfer for implantable devices

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Abstract

A common model of power supply for implantable devices was established to study factors affecting volume conduction energy transfer. Electromagnetic and equivalent circuit models were constructed to study the effect of separation between the source electrode pairs on volume conduction energy transfer. In addition, the parameters of external signal including waveform, amplitude and frequency were analyzed. As the current amplitude did not lead to tissue injury and the current frequency did not cause nerve excitability, the recommended separation between the source electrodes was 3 cm, the proposed waveform of signal source was sinusoidal wave and the optimal frequency was 200 KHz. In agar experiment and swine skin experiment, the current transfer efficiencies were 28.13% and 20.65%, respectively, and the energy transfer efficiencies were 9.86% and 6.90%, respectively. In conclusion, we can achieve optimal efficiency of energy transfer by appropriately setting the separation between the source electrode parameters of the signal source.

Keywords: volume conduction, implantable device, simulation, energy transfer

INTRODUCTION

Implantable device is a micro-electronic device based on IC chips and can be implanted into the animal or human body for a long period of time. It can monitor physiological parameters or regulate physiological function in vivo. Two significant problems that prevent implantable devices from widespread utilization are a lack of an efficient energy source suitable for long-term operation, and a lack of a robust, low power consumption communication system that does not rely on wired connection. Reliable energy supply is a prerequisite for the stability of implantable devices, and also one of the main factors that affect the function, miniaturization and life of implantable

devices. Therefore, an efficient and stable energy supply system is very important for implantable devices.

So far, the energy supply approaches for implantable devices include implantable battery, nuclear energy, radio frequency coupling, pyroelectric technology, biofuel cell, photocell, micro-generator, and ultrasonic transducer^[1]. Although there are a variety of possible energy supply ways for implantable devices, only battery and magnetic induction technologies are widely used in clinical application. Limited battery life is the disadvantage of battery technology. When battery power runs out, it needs to be replaced during surgery. On the other hand, the physical size of a battery imposes restriction on the miniaturization of implantable devices. Magnetic induction technology can transfer

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energy from external to implantable devices inside the body, and some products have already been applied clinically^[2]. However, the energy transfer efficiency of this technology is very low (only 0.006% of non-core coupling coil is in use and operates at 418 MHz^[3]). In addition, magnetic induction technology with high frequency would generate radio frequency interference to other medical equipments nearby. Thus, a new transcutaneous energy supply technology needs to be developed.

In the study of data communication of implantable devices by using volume conduction, when ionic fluid in organisms (including the human body) is created in an electrical field, the directional movement of charged ions creates current which is called volume conduction^[4]. Taking advantage of this characteristic, investigators proved the feasibility of volume conduction energy transfer as a new power supply for implantable devices. Compared to radio frequency coupling, volume conduction has the following advantages: 1) it has a strong shielding effect on radio frequency coupling as the properties of volume conduction in organism lead to low energy transfer efficiency. On the other hand, volume conduction energy transfer takes advantage of volume conduction in organism to improve the efficiency of energy transfer. 2) Current frequency of volume conduction at 104 Hz level^[5,6] leads to low signal attenuation in tissues along with miniature radio frequency interference. 3) Energy transfer directly through the electrodes does not need coil or antenna structure, which reduces external interference effectively.

Investigators established electrode-skin equivalent circuit X model based on the characteristics of volume conduction energy transfer system^[7,8]. The model focuses on using methods of simulation to study the

material, shape and size of electrode, and skin impedance matching optimization is a key point in this model. The investigators obtained a scheme of improving energy transfer efficiency by optimizing the electrode size and shape in the model. An electrode-skin equivalent circuit X- Δ model was established that described the current transfer path more accurately^[9]. The model focuses on using methods of simulation to obtain the highest energy transfer efficiency by optimizing amplitude and impedance of the external signal source and impedance of implantable devices in a fixed electrode unit. It is believed that the separation between source electrodes is the most important factor in preventing short current which may improve energy transfer efficiency. To study the effect of separation between source electrodes, waveform, amplitude and frequency of external signal source in vitro, we constructed electromagnetic field and equivalent circuit model of volume conduction energy transfer system based on tissue characteristics.

MATERIALS AND METHODS

The electromagnetic field model of the volume conduction energy system

The electromagnetic field modeling method was described in detail previously^[10-12]. An electromagnetic field model was created by COMSOL Multiphysics V3.5 as shown in **Fig. 1**. The conductivity parameters of skin and electrode models were set at 0.21 S/m and 50,000 S/m, while size parameters of the rectangle electrode and agar slab were set at $1 \times 20 \times 10$ (mm) and $10 \times \Phi 200$ (mm), respectively. Electrode-skin contact impedance was set at 200 Ω , equivalent resistance of implantable devices was set at 1 K Ω ^[13-15], and signal source voltage in vitro was set at 5 V.

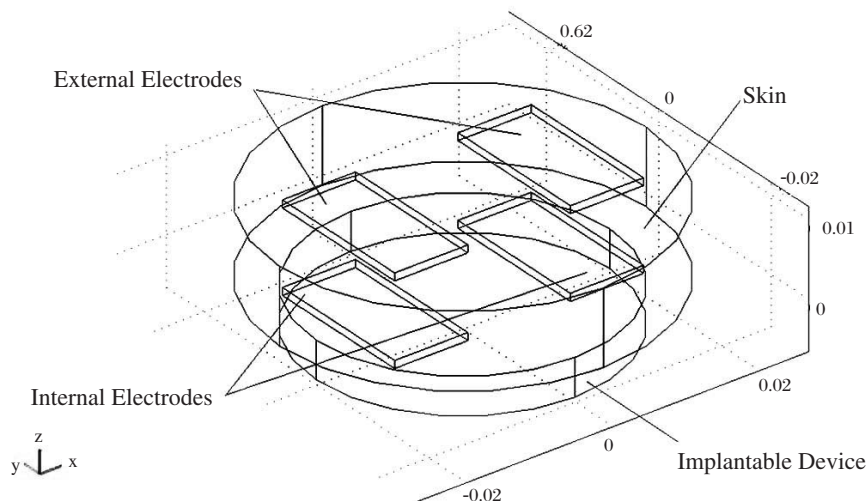


Fig. 1 The finite element model of energy transfer through volume conduction.

The circuit model of volume conduction energy system

The X model parameters Z_1, Z_2, Z_3, Z_4, Z_5 and X- Δ model parameters Z_s, Z_t, Z_d, Z_c were calculated from measured impedance data by agar and swine skin experiments (at 104Hz level). The current law is commonly used to measure the open-circuit impedance. We obtained the current value by sending a sinusoidal wave (5V Vpp, 50 KHz) between two terminals (12, 13, 14, 23 and 34), and then $Z_{12}, Z_{13}, Z_{14}, Z_{23}$ and Z_{34} were calculated according to Ohm's Law. Simulation models were established by Multisim 10 according to **Fig. 2**^[16].

Agar and swine skin assays

Agar was made with 0.63 gram NaCl per liter of water, aiming for a conductivity of 0.21 S/m, similar to that of the skin in the 104 Hz level. The size of agar slab was $10 \times \Phi 200$ (mm). Five agar slabs were used in each experiment. The electrodes were made of gold-plated copper, and were rectangular in shape and $1 \times 20 \times 10$ mm³ in size. The electrodes were placed as shown in **Fig. 3**. The separation between ipsilateral electrodes on the agar slab was defined as X (the separation between the external electrodes group), and the separation between contralateral electrodes on the agar slab was defined as Y (thickness of skin).

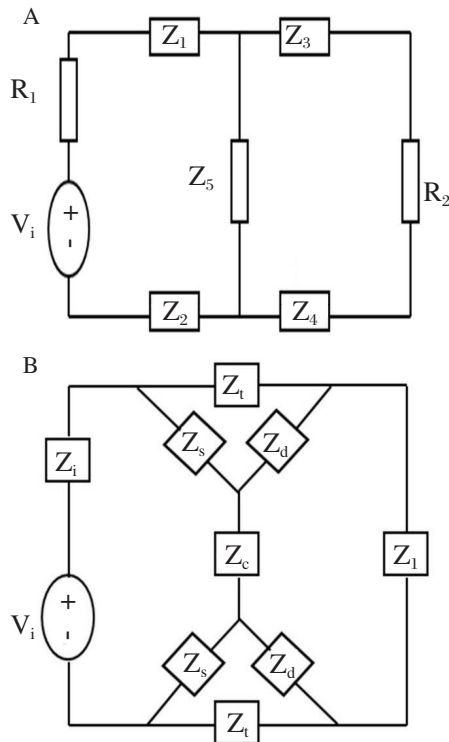


Fig. 2 Circuit model of volume conduction. A: X model; B: X- Δ model.

Swine skin assays were performed as described previously^[21]. All assays were undertaken within two hours after animals were sacrificed to minimize changes in the electrical properties of the skin samples. The size of swine skin was $5 \times \Phi 200$ mm² and five swine skin specimens were used in each experiment. The electrodes and their placement were the same as those for the agar assays. All animal care and use procedures were in accordance with guidelines of Nanjing Medical University Institutional Animal Care and Use Committee.

RSEULTS

Effect of separation between source electrodes on energy transfer

Current and energy transfer efficiency of the electromagnetic model, X model, X- Δ model, agar experiments and swine skin experiments are shown in **Fig. 4**. Using a constant sinusoidal wave (5 V Vpp, 50 KHz), the energy transfer efficiency of the electromagnetic model, X model and X- Δ model, multiplied by 0.707 of the maximum energy transfer efficiency to achieve the effective value, was 9.42%, 14.02% and 9.85%, respectively, and the corresponding separation between source electrodes was 3 cm, 2.7 cm and 3 cm, respectively. Energy transfer efficiencies of the agar assays and swine skin assays with a separation distance 3 cm between source electrodes was 8.93% and 6.84%, which was equal to 64% and 66% of the maximum energy transfer efficiency, respectively. When the space of source electrodes was 3 cm, current and energy transfer efficiencies were 27.07% and 9.45% of the finite element model, 32.41% and 14.85% in X model, 27.22% and 9.69% in X- Δ model, 26.38% and 8.93% in the agar assays and 19.6% and 6.84% in the swine skin assays.

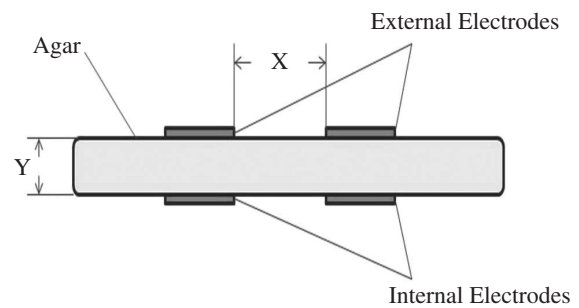


Fig. 3 Diagram of electrodes placement. The electrodes are made of gold-plated copper, and rectangular in shape and $1 \times 20 \times 10$ mm³ in size. The separation between ipsilateral electrodes on the agar slab is defined as X, and the separation between contralateral electrodes on the agar slab is defined as Y.

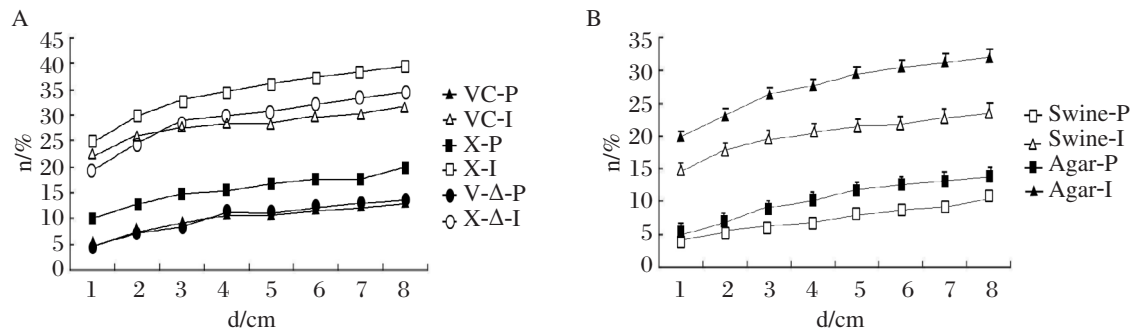


Fig. 4 Effects of separation between source electrodes during energy transfer in model simulation and agar and swine skin experiments. A: Effects of separation between source electrodes during energy transfer in model simulation. VC-I, X-I, X-Δ-I and VC-I, X-P, X-Δ-P represent current and energy transfer efficiency of the electromagnetic model, X model, and X-Δ model, respectively. The current and energy transfer efficiency of the electromagnetic model, model X, and model X-Δ increased with separation between source electrodes. B: Agar and swine skin experiments on effect of separation between electrodes on energy transfer. Agar-I, Swine-I and Agar-P, and Swine-P represent current and energy transfer efficiency of the agar experiments and swine skin experiments, respectively. Data shown are statistical results from five independent experiments (mean \pm SD). The current and energy transfer efficiency of the agar experiments and swine skin experiments increases with separation between source electrodes.

Effects of waveform, amplitude, frequency of external signal source on energy transfer

The influences of waveform on energy transfer efficiency are shown in **Fig. 5** with the amplitude, frequency of external signal source and separation between electrodes fixed (5 V, 50 KHz, 3 cm). In swine skin assays using the X-Δ model, the current amplitudes in vitro were 9.11 mA and 3.84 mA of square wave, 6.43 mA and 3.69 mA of sinusoidal wave, 5.27 mA and 3.52 mA of triangular wave, respectively. The current transfer efficiencies were 28.32% and 21.45% of square wave, 27.21% and 20.62% of sinusoidal wave, 25.99% and 19.34% of triangular wave, respectively. In addition, the energy transfer efficiencies were 14.20% and 10.11% of square wave, 9.69% and 6.90% of sinusoidal wave, 7.81% and 5.59% of triangular wave, respectively.

Energy transfer efficiency of simulation and experiment are shown in **Fig. 6** with the waveform,

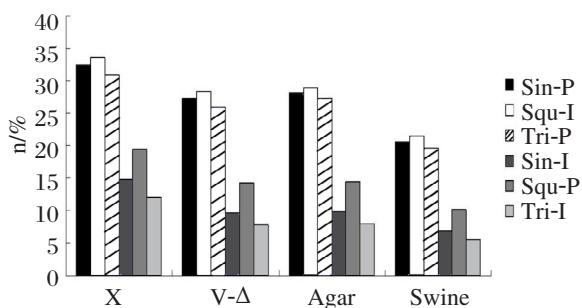


Fig. 5 Model simulation and experiments of effect of waveform of signal source on energy transfer. X, X-Δ, Agar, and Swine represent X model simulation, X-Δ model simulation, agar experiments, and swine experiments, respectively. Sin-I, Squ-I, Tri-I, Sin-P, Squ-P, and Tri-P represent the sine wave, square wave, triangle wave current and energy transfer efficiency.

frequency of external signal source and separation between electrodes fixed (sinusoidal wave, 50 KHz, 3 cm). In swine skin assays using the X-Δ model, the amplitude range was 2-10 V, energy transfer efficiency was stable at 9.6% and 6.9%, with no more than 0.5% fluctuation. The current amplitude in vitro was 18.4 mA and 7.47 mA and the charging current was 5.30 mA and 1.96 mA, when the signal source amplitude was 10 V.

Energy transfer efficiency of the swine skin assays are shown in **Fig. 7** with the waveform, amplitude of external signal source and separation between electrodes fixed (sinusoidal wave, 5 V, 3 cm). When the signal source frequency was increased from 50 KHz to 200 KHz, current transfer and energy efficiency slowly increased from 17.0% and 7.0% to 22.8% and 15.3%, respectively. Current and energy transfer efficiency remained at 23% and 15.8%, with no more than 0.5% of fluctuation when frequency ranged from 200 KHz to 300 KHz.

DISCUSSION

Current and energy transfer efficiency increased with separation between source electrodes at the cost of implanting and fixation difficulty. Considering both energy transfer efficiency and implanting convenience, in clinical application, we generally set 0.707 multiplied by the maximum energy transfer efficiency as the optimum value. According to the simulation results, the proposed separation between electrodes was 3 cm. In the agar and swine skin experiments, when the space was 3 cm, energy transfer efficiencies were 0.64 and 0.66 of the maximum energy transfer efficiency and close to 0.707. Therefore, we suggest that the separation between source electrodes is about 3 cm.

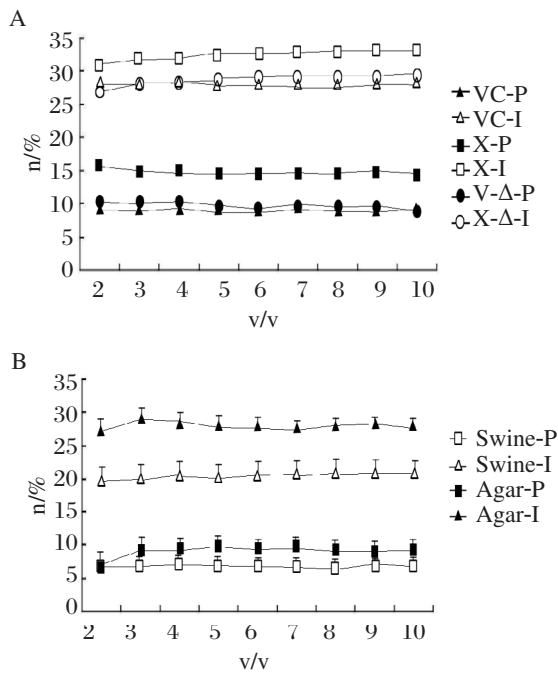


Fig. 6 Model simulation and agar and swine skin experiments of effect of amplitude of signal source on energy transfer. A: Model simulation of effect of amplitude of signal source on energy transfer. The current and energy transfer efficiency of the electromagnetic model, X model and X-Δ model remains unchanged. B: Agar and swine skin experiments of effect of amplitude of signal source on the energy transfer. The current and energy transfer efficiency of the agar experiments and swine skin experiments remains unchanged.

We found that the current transfer efficiencies of square wave, sinusoidal wave and triangular wave were very close to one another, and energy transfer efficiency followed the order of square wave > sinusoidal wave > triangular wave. Although the energy transfer efficiency of square wave was slightly larger than that of sinusoidal wave, there were still some disadvantages for square wave as its frequency components were more complex. There were numerous high-order harmonics which may cause high frequency interference. Therefore, sine wave was the proposed waveform.

As the amplitude of external source increased, the internal charging current also increased while the current and energy transfer efficiency remained unchanged. Thus, properly increasing the amplitude of external signal source to obtain larger charging current and shorter charging time may be a good choice in clinical application. According to the national standards for electricity safety^[22], the skin perception threshold increases from 10 mA to 100 mA (rms) as the frequency ranged from 10 KHz to 100 KHz. Furthermore, the skin perception threshold is up to hundreds of milliamperes when the frequency is larger

than 100 KHz. In this case, when the amplitude of the signal source was up to 10 V, the current was 18.4 mA in vivo and 7.47 mA in vitro, which do not cause any damage to the skin tissue. Therefore, the amplitude of the external signal source could be further increased.

In this study, the frequency of the external signal source was in the range of 50 KHz to 300 KHz. There is hardly any radio frequency interference on medical equipments nearby when the frequency is below 300 KHz^[23]. Previous studies on biological reactions focused on charging rechargeable battery of implantable devices without tissue injury. Those considerations did not take into account the effect of frequency and amplitude of external signal source on the nervous system. Thus, it is very important to protect patients from tingling, burning or other uncomfortable feelings. The neuromuscular reaction to stimulus depends on its frequency and amplitude. When the amplitude of stimulus reaches a certain value, the reaction mainly depends on frequency. Neuromuscular tissues show excitation when the stimulus ranges from 1 Hz to 1 KHz, whereas it may be either excitatory or inhibitory at 1 KHz to 50 KHz. When the frequency of stimulus exceeds 50 KHz, neuromuscular tissues do not respond^[24]. Taking into consideration all of the above mentioned aspects, the frequency of the external signal source should be set above 50 KHz. Current and energy transfer efficiency slowly increased with the frequency of the external signal source in the swine skin experiment. As 200 KHz was the stationary point of current transfer efficiency curve (Fig. 7) and power consumption may increase with the frequency, the frequency of external signal source was proposed to be 200 KHz.

Compared with the measured value of current and energy transfer efficiency which was obtained from the agar experiment, the value from X model simulation was significantly larger, while the values from electromagnetic model and X-Δ model simulation are consistent with that from the agar experiment. There-

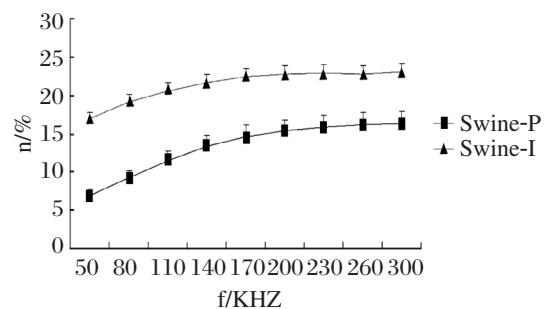


Fig. 7 Swine skin experiments on effect of frequency of signal source on the energy transfer. Swine-I and Swine-P represent the efficiency of current and energy transfer, respectively.

fore, the electromagnetic model and X- Δ model will be used as key models to study volume conduction in the future. Compared with the measured values of current and energy transfer efficiency, which was obtained from electromagnetic field model and circuit model stimulation and the agar experiment, the values from the swine skin experiment were significantly lower. There were three reasons: 1) Test environment was not ideal, and it could not simulate skin environment very well; 2) Contact resistance between electrodes and swine skin was relatively large; 3) Swine skin was not fresh enough, and it did not have enough biological activity.

In conclusion, electrical energy in vitro can be transformed efficiently into implantable devices in vivo through volume conduction. In our model of volume conduction energy transfer, optimal energy transfer efficiency is achieved by setting the electrodes 3 cm apart with wave and frequency of the signal source as sinusoidal wave and 200 KHz. In future studies, physiological details could be included in the model, adding representation of non-linear behavior due to chemical or biological processes inherent in the system, to make the model applicable.

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