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In Vivo Experimental Study of Thermal Problems for Rechargeable Neurostimulators

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Objectives: Eddy currents in the metal shell and copper losses in the coils generate heat in rechargeable neurostimulators, which increases the temperature of the adjacent tissue, potentially causing thermal damage of implant patients. Hence, there is an urgent need for a simple self-help method to measure the temperature of such subcutaneous devices.

Materials and Methods: A wireless rechargeable implant system was fabricated and tested with *in vivo* experiments in swine to measure the increasing temperatures of both the implant device and the adjacent skin. A total of three swine were used in the study with 13 wireless charging tests.

Results: It was found that the temperatures of both the implant and the skin rose consistently with an approximately linear relationship in most of the charging time, demonstrating that the neurosimulator temperature could be estimated from the skin temperature. The equilibrium temperature differences are all less than 2°C.

Conclusions: A convenient method was then given to monitor the adjacent skin temperature to evaluate the thermal hazards with a skin temperature threshold of 41°C. The proposed approach can be easily implemented by an implant patient at home to reduce the thermal risk, ease patient anxiety, and improve clinical outcomes.

Keywords: biological heating, *in vivo* experiment, neurostimulator, skin temperature, wireless charging

Conflict of interest: The authors reported no conflicts of interest.

INTRODUCTION

With the fast development of medical neuromodulation devices, rechargeable neurostimulators have been extended from rechargeable spinal cord stimulators (SCS) to rechargeable deep brain stimulators (DBS) having significant advantages of higher stimulation currents and longer useful lifetimes.

However, thermal problems caused by eddy currents in the metal shell and copper losses in the coils limit the charging rate of such implants. During wireless charging, the alternating electromagnetic field induces eddy currents in the metal shell encapsulating the stimulators that generate heat. In addition, losses in the copper windings of the energy receiving coils inside the implant increase the device heating and the temperature elevation. The heat generation is a function of the electromagnetic coupling conditions (distance, angle, alignment, etc.), resulting in uncertainty in the stimulator temperature. The excessive heat produced in the rechargeable neurostimulators then flows into the adjacent tissues, leading to higher tissue temperatures, which may cause thermal injury or even tissue necrosis. Recently, St. Jude Medical, one of the most famous medical device manufacturers, published safety information for its Eon and Eon Mini charging systems on its Web site (1). According to it, the company has received three reports of skin surface burns (one 2nd degree and two 1st degree burns) believed to be associated with heating during charging, and 325 patient complaints of warmth or heating at the device implant site during charging. What is more, some physicians or patients have requested explant surgery to address uncomfortable temperature elevations, resulting in total 72 explants for these stimulators. Some research has focused on this problem, but most studies have only used computer simulations and *in vitro* experiments (2–6), with often contradictory results (7).

Most implant patients who lack professional knowledge cannot accurately judge whether the device's coupling state and the internal temperature are suitable for charging. Hence, a convenient, effective method is needed to help them read the temperature of the subcutaneous device to reduce the potential thermal risk, ease their concerns, and improve clinical outcomes. The skin surface temperature immediately above the modulator may be the most promising indicator because it is not only close to the device temperature but also easily measured. If the relationship between the two temperatures is known, patients will be able to estimate the device temperature by measuring the skin temperature. To the best of our knowledge, there are no studies on wireless charging focused on the relationship between the adjacent skin temperature and the neurostimulator temperature. The research is related to one typical case of wireless charging with heat generation of subcutaneous

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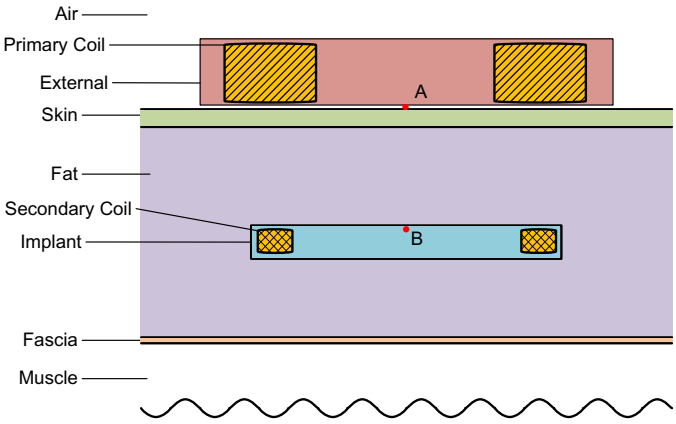

Figure 1. Schematic diagram of the rechargeable neuromodulation system. A, temperature measurement point on the skin; B, temperature measurement point in the implanted neurostimulator.

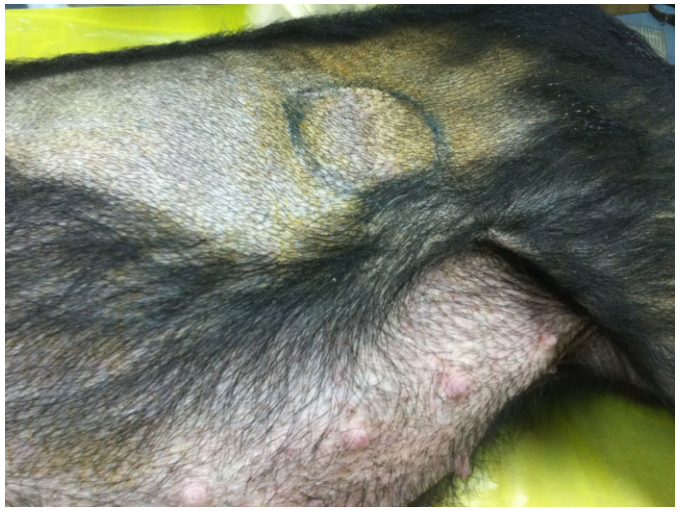

Figure 2. The wound on one swine one week after surgery. The circle marks the location for external coils to ensure consistent positioning in different tests.

metallic implants exposed to electromagnetic fields and other possible heating sources (8–13). Both the experiment methods and the basic conclusions can be related to other similar circumstances. About 25 million Americans rely on implant medical devices for life-critical functions (14) with 5 million patients living with implanted devices (pacemakers and implantable cardioverter-defibrillators) worldwide (15).

This report describes *in vivo* experiments using rechargeable neurostimulators with heating. The rechargeable system was fabricated and tested in swine. The *in vivo* data describes the relationship between the adjacent skin temperature and the device temperature. The results can be used to prevent thermal damage during wireless charging by monitoring the skin temperature instead of the inside temperature.

IN VIVO EXPERIMENTS

Device and Model

As with common rechargeable neuromodulation devices, the implantable wireless charging system in this work included an implant and an external device as shown in Figure 1. The implant had wireless energy receiving circuits, wireless communication circuits and temperature measurement circuits encapsulated in a titanium shell due to titanium's excellent biocompatibility. The external device consisted of a control unit, wireless communication circuits and wireless energy transmission circuits. Just add corresponding stimulation circuits to the implant device and it can be used as a rechargeable DBS, a rechargeable vagus nerve stimulator, a rechargeable SCS, etc. As shown in Figure 1, the implant device was placed in the subcutaneous fat layer, while the external device was close to the skin. During wireless charging, the axes of the two devices were aligned as well as possible.

The titanium shell plays a critical role in rechargeable neurostimulator heating since the heat produced by eddy currents in the shell is the main source of the heating and because it is the contact interface between the tissue and the device. Hence, the stimulator temperature in this study was measured on the inside surface of the titanium shell at point B in Figure 1 with a sensor having a negative temperature coefficient of resistance (NTC, 001T1002FF, provided by Vishay, accuracy $\pm$ 0.2°C). After sampling and the analog-to-digital conversion, the temperature is sent via the wireless communication to the external device, which improves the long-term reliability of the implant *in vivo* because of the reduced infection risk without the transcutaneous transmission line.

The skin temperature was measured by a flexible fiber optic temperature sensor (Model m3300, Luxtron Corporation, Santa Clara, CA, USA; accuracy $\pm$ 0.2°C) at Point A as shown in Figure 1. The fiber optic sensor is regarded as the ideal thermometer for medical radio frequency research for its electromagnetic interference immunity and inherent stability.

Preexperiment used the fiber optic sensor to evaluate the NTC sensor due to the potential interference between the wireless charging electromagnetic field and the NTC sensor. The results showed no significant influence of the electromagnetic field in this research on the NTC sensor's accuracy.

Animal Preparation and Experimental Setup

In vivo animal experiments were conducted in Beijing Tiantan Hospital affiliated to Capital Medical University, and swine were chosen for their skin thickness is close to that of humans. A total of three swine were used in the study (weighing 18–22 kg) with each implanted with a separate rechargeable device. All experimental procedures and protocols were approved by the University Committee on Research Practice at Capital Medical University, and the National Institutes of Health guide for the care and use of laboratory animals (16) was strictly followed during the experiments.

The rechargeable devices were implanted surgically. Food was withdrawn 24 hours before surgery, and general anesthesia was induced by intramuscular injection of xylazine hydrochloride. After shaving and additional local anesthesia using 10% lidocaine, an incision was made on the side of the swine waist. A subcutaneous pocket approximately 1 cm deep was made to mimic a human implant depth with the implantable device fixed inside. Finally, the wound was sutured and sterilized with iodine and 75% alcohol. The swine were injected postoperatively with penicillin to prevent infection.

A few dozen wireless charging tests were then carried out. A week after the implant surgeries, the wounds had healed well as shown in Figure 2 and general anesthesia was induced again by xylazine hydrochloride. The depths of the rechargeable devices implanted in the bodies were accurately measured using a B ultrasonic system

Table 1. Experimental Results.

Trial no.	Swine no.	Implant depth/mm	Implant temperature rise/°C	Implant temperature max/°C	Skin temperature rise/°C	Skin temperature max/°C	Temperature difference*/°C
1	α	10.3	3.5	37.3	5.8	35.7	1.6
2			4.2	37.2	4.4	35.4	1.8
3			4.6	38.7	4.9	37.5	1.2
4			4.9	40.4	5.3	39.2	1.2
5			5	39.1	4.5	35.8	3.3†
6	β	8.0	3	36.6	4.2	35.2	1.4
7			2.9	36.3	4.3	35.2	1.1
8			2	36	2.6	35.2	0.8
9			5.6	39	7.1	38	1
10			5.5	39.1	6.6	37.6	1.5
11			3.6	37.5	3.5	36.9	0.6
12	γ	7.2	2.7	37.1	4.6	35.9	1.2
13			3.7	37.8	4.2	36.1	1.7†

*The temperature difference at thermal equilibrium.
†The experiment was ended before the temperatures reached equilibrium with the temperature difference for the highest temperatures shown here.

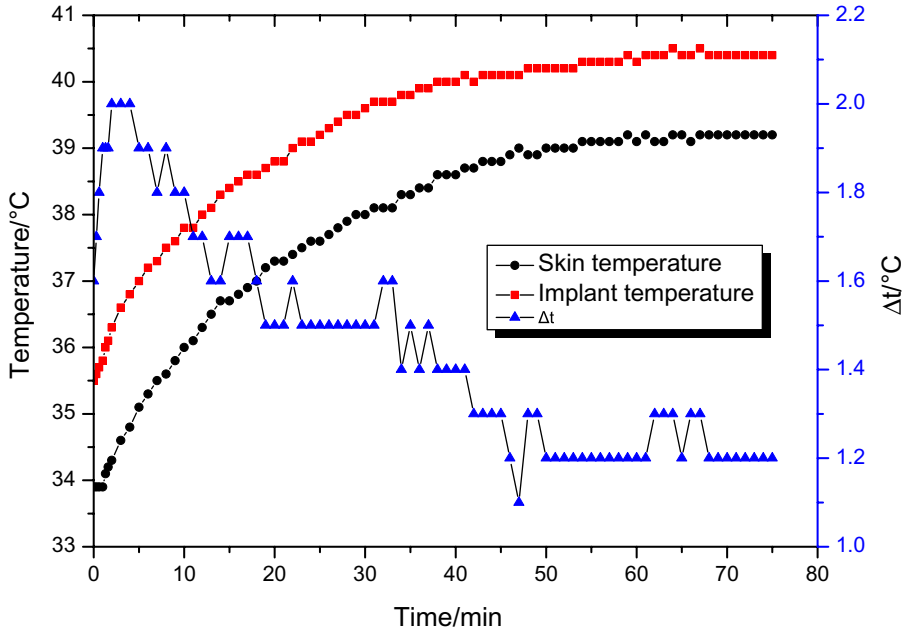

Figure 3. Temperature–time profile during wireless charging: the rechargeable implant device temperature (squares), the skin temperature (circles), the difference between the two temperatures (triangles).

(TH-100,TEKNOVA, Beijing, China) with depths between 7 and 10 mm with different swine, which is similar to the actual depths in human clinical treatments, as shown in Table 1. Prior to charging, the external wireless energy transmission coils were fixed in place with medical tape over the implant device, with enough time allowed for initial thermal equilibrium. During charging, energy was transferred into the implant device with a constant wattage, which increased the stimulator battery power, device temperature, and skin temperature. Both temperatures were measured and recorded. In addition, the swine rectal temperature and the ambient temperature also were monitored throughout the experiment. The rectal temperature decreased due to the anesthesia, while the ambient temperature remained at 22°C. The wireless charging was continued until a new thermal equilibrium was reached as represented by a stable device temperature and skin temperature, with the time to not exceed 3 hours to avoid hurting the swine by the anesthesia. Repeated experiments were conducted once a week.

RESULTS

Temperature Changes

A total of 13 wireless charging tests were conducted with the results listed in Table 1. Figure 3 shows the temperature changes during one test no. 4. During charging, which started at 0 min and lasted 75 min, obvious changes were observed in both the implant temperature and the skin temperature. The implant temperature increased from 35.5°C to 40.4°C, an increase of 4.9°C, while the outside temperature rose from 33.9°C to 39.2°C, an increase of 5.3°C.

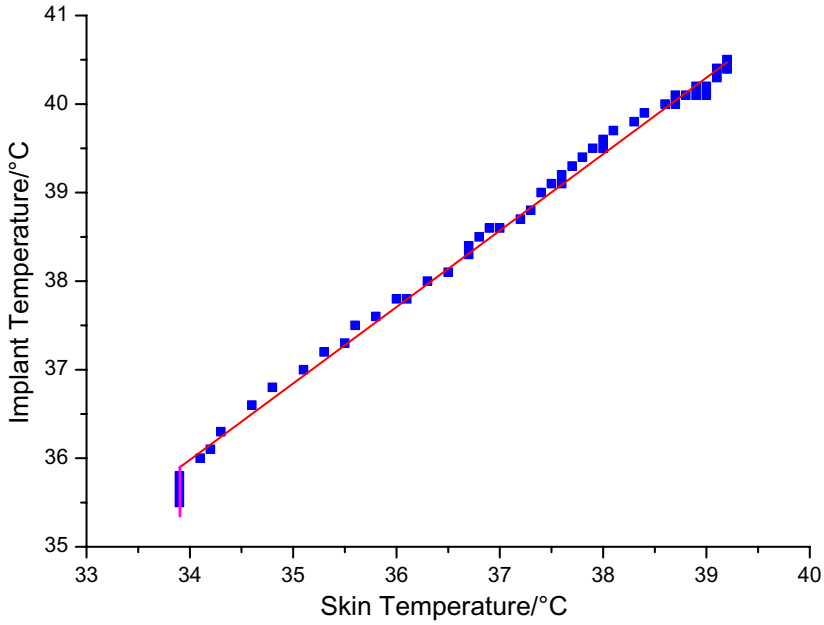

Figure 4. Relationship between the implant temperature and the skin temperature for test 4.

Both temperatures increased faster during the first 40 min, then remained stable after 60 min as the new thermal equilibrium was reached.

Thus, the tests showed that the skin temperature increased with the device temperature, with temperature differences between 1.1 and 2.0°C. Therefore the device temperature can be estimated from the skin temperature. Prior to charging, the initial neurostimulator temperature was 1.6°C higher than the skin temperature, representing the normal physiological phenomenon that heat produced by metabolism flows out into the surrounding environment. During the initial wireless charging, the neurostimulator heating lead to a rapid rise of the implant temperature, with the heat transmission having a lag time, resulting in maximum temperature difference of 2°C. The tissue thermal conductivity then increased due to the higher heat dissipation by the blood flow at higher temperature, which reduced the temperature difference to 1.2°C after reaching the new stable temperature.

Relationship Between the Two Temperatures

The relationship between the neurostimulator temperature and the skin temperature is shown in Figure 4 for test 4, where horizontal axis presents the skin temperature and the vertical axis represents the corresponding neurostimulator temperature. The curve can be divided into two parts: 1) At the beginning of the charging, the implant temperature increased rapidly, while the skin temperature changed little, expressed by a short vertical line in Figure 4. This phase is short and has low temperatures, so should rarely result in thermal damage, so it is not important in this paper. 2) As the charging continued, both temperatures rose consistently with an approximately linear relationship, shown by the sloping line in Figure 4. Similar patterns were found in the other 12 charging trials, demonstrating that the neurostimulator temperature could be estimated from the skin temperature.

Temperature Difference at Equilibrium

The wireless charging heating increases both the skin temperature and the neurostimulator temperature to the highest values at the new temperature equilibrium, which is also most likely to cause thermal damage. The experimental data from Table 1 shown in Figure 5 show the temperature differences plotted against the highest implant temperatures. Within the scope of the implant depths and charging powers involved in this research, the equilibrium temperature differences are all less than 2°C with no significant correlation with the equilibrium neurostimulator temperature.

The Henriques–Moritz cell injury criterion (17) is commonly used to assess thermal tissue damage as follows:

$$\Omega(t) = A\int_0^t e^{-E_a/(R_b T(\tau))} d\tau$$

In this expression, A is a pre-exponential factor, t is time, T(τ) is the tissue temperature at time τ, Ea is the activation energy corresponding to temperature T(τ), and Rb is the universal gas constant. Ω, the thermal damage index is a function of the temperature combined with the time, with the commonly accepted threshold for observable thermal damage being $\Omega \approx 1$. However, this complex formula cannot be easily used by the implant patient to rapidly assess the thermal damage. Therefore, an isoeffect thermal dose was proposed as a determinant of tissue thermal damage by converting the time–temperature combination to an equivalent number of minutes at 43°C, which is called CEM43 (18). However, the precise minutes at CEM43 for thermal damage varied greatly among tissues and even among different studies (18,19). In order to ensure the implant patients of absolute safety, a simple and conservative lower thermal doses boundary was selected in this job for the equivalent temperature of 43°C lasting for 1 min (20). Since sampling times for temperature monitoring devices vary, 1 min is a typical selected value because it satisfies most thermometers' sampling frequencies. Thus, rechargeable neurostimulator temperatures should be kept below 43°C, which can be realized by limiting the adjacent skin temperature to less than 41°C assuming a maximum equilibrium temperature difference of 2°C. This convenient method that monitors the skin temperature, which can be easily implemented by the implant patient at home, will significantly improve thermal safety.

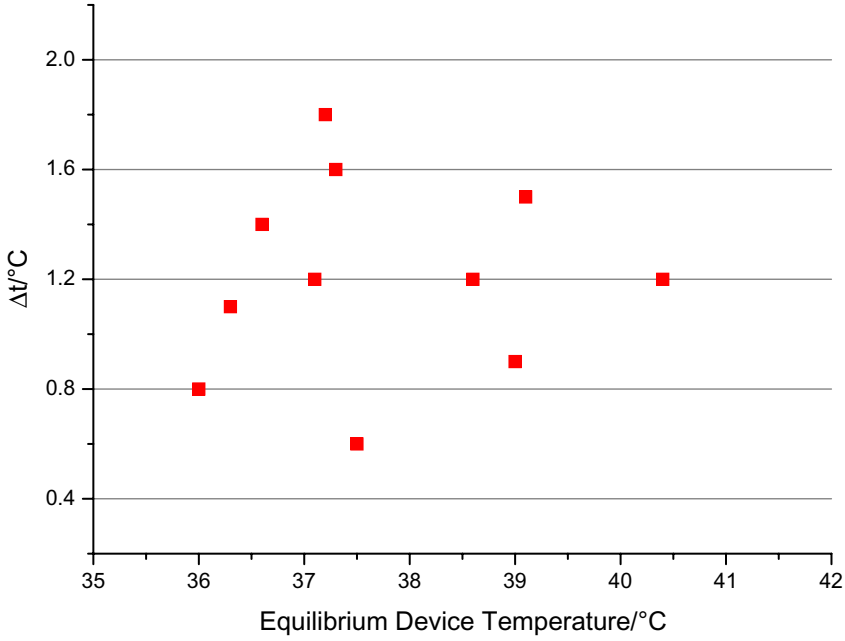

Figure 5. Equilibrium temperature differences between the equilibrium neurostimulator temperature and the equilibrium skin temperature.

DISCUSSION

Elevated temperatures in rechargeable neurostimulators were measured in swine *in vivo* because swine skin tissues and human skin tissues have similar electromagnetic and thermal properties, including the density, thermal conductivity, and specific heat (21,22). This work's contributions are that *in vivo* experiments are better than *in vitro* experiments for representing the tissue heat dissipation and temperature increased since they more accurately represent the blood flow and the organism's thermoregulation. In addition, *in vivo* experiments better reproduce the thermal contact resistance between the energy transmission coils and the skin than computer simulations with ideal interfaces between regions. Hence, the *in vivo* experiments described here more accurately simulate real rechargeable neurostimulator heating in humans.

There are still several limitations in the *in vivo* experiments used in this study. First, there is a consensus that the temperature regulation ability of swine is weaker than that of humans, so the elevated device temperature measured in swine can be considered as a conservative estimate of that in humans. Second, the wireless charging *in vivo* experiments were carried out under anesthesia. The anesthesia slows the body blood flow and reduces the heat dissipation. Therefore, the device temperatures under anesthesia may be higher than for normal conditions, so the experimental data can be considered to be conservative. However, sustained anesthesia will also reduce the basal body temperature that will affect the tissue temperature increase. For example, the swine rectal temperature dropped 1–2°C during the 3 hours of anesthesia in these experiments. Further experiments are needed to obtain *in vivo* data for normal conditions.

Last but not least, there is still a possibility that the approach proposed in this paper to prevent heat damage may yield false positive alarms when skins are burned by greater heat caused from external charging coils for some other chargeable stimulators if it is designed poorly or used in poor coupling states (such as great misalignment). In this situation, greater heating flows from external power coils to the skin, leading to a decrease in the temperature difference between the implant and the skin and an increase in the possibility of false positive alarms given the preset skin temperature threshold. However, from the perspective of safety, our method can be recognized as a more conservative approach and still works on under this circumstance. Ensuring 100% safety of patients has the highest priority. It is worth increasing the errors of alarm while reducing the potential risk taken by patient. On the other hand, various measures can be taken to effectively reduce the heat generation *in vitro* and the heat transmission into the skin, while controlling thermal state of the implant devices is much more difficult. Therefore, minimizing and controlling the implant device heating is perhaps the biggest challenge for transcutaneous energy transfer, making our approach more valuable in use.

CONCLUSIONS

The heating and temperature increases in metallic implants in time-varying electromagnetic fields are of great interest, with a typical example being rechargeable neurostimulator heating during wireless charging. Most current research has used *in vitro* tests and bio-heat simulations. This study used a wireless chargeable implant system with swine *in vivo* experiments measuring the temperatures of both the device and the adjacent skin. The equilibrium temperature differences were found to be less than 2°C. A convenient method was then given to monitor the adjacent skin temperature to evaluate the thermal hazards with a skin temperature threshold of 41°C. The proposed approach can be easily implemented by implant patient at home to reduce the thermal risk, ease patient anxiety, and improve clinical outcomes.

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Authorship Statement

All authors contributed to the development of the rechargeable implant system and the implementation of the *in vivo* experiments. All authors contributed to the manuscript writing and approved the final version.

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COMMENTS

More and more rechargeable neurostimulators are being used in the field of neuromodulation. Precisely because of having longer life and better economy, it will be the direction of future development. But at the same time some problems cannot be avoided, such as the thermal problem discussed by the authors. How to control and detect heating problems caused by the stimulation itself has become very important; this study has noted it and drawn some meaningful conclusions.

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The utilization of rechargeable implants is a rapidly growing market of medical devices. They are prominently employed for non-critical therapies, such as pain management. The recharging capability allows the user to extend lifetime of battery-operated devices that require electrical power.

During the recharging operation, an external device is placed in close proximity to the implant and electromagnetic coupling occurs between the two components. The coupling, and induced electrical current, results in battery recharge.

Despite the positive aspects of these rechargeable devices, a concern has grown in recent years. That concern is with respect to tissue heating and potential burn injuries. As tissue temperatures increase, and as exposures are lengthened, the likelihood of injury increases.

It would be useful if a non-invasive methodology were available to allow tissue temperatures to be known. Heretofore, temperatures within the tissue were unknown and could only be determined in carefully controlled animal models.

The present paper provides a simple yet effective methodology for estimating deep tissue temperatures. That method relates a measured skin temperature to temperatures beneath the skin. The remarkable congruence justifies its use in practice. The method employed here takes advantage of technologies that use skin temperature, for instance, to infer body core temperatures. It is hoped that similar applications of this technique can be put into practice for other implantable devices.

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To a large extent, the success of neuromodulation depends on the use of fully implanted pulse generators to drive the stimulating electrodes. In the accompanying paper, Chen and colleagues address what is at least a minor potential hazard of such devices, feeling of thermal discomfort and (potentially) thermal injury when the devices heat during recharging of their batteries.

The basic parameters of the problem have been studied, for example by Lovik and colleagues (1). The devices, which are implanted just beneath the skin, are recharged when the patient places an antenna containing a magnetic coil over the device. The coil is excited by a current at, typically, 40 kHz and the resulting magnetic field is picked up by the implant, producing a current that is used to recharge its batteries. This technology is well established, and has been used for much higher power implanted devices than neurostimulators, including an artificial heart.

The problem, it seems, is that the case of the device is heated by eddy currents that are induced in it by the field. The amount of heat transferred to the tissue surrounding the implant is small (equivalent to less than 0.5 watts) but in time heat will build up. The patient can

perceive a sensation of heat or thermal pain, depending on the temperature increase. Conceivably, thermal injury can occur at the site of the implant, although presumably most patients would have stopped charging the implant long before that point had been reached.

The devices that seem to be most at risk of this problem are the St. Jude Eon and Eon Mini (St. Jude Medical, Neuromodulation Division, Plano, TX, USA), and the problem seems to be exacerbated when the antenna and implant are misaligned. The dimensions of the problem are indicated in a "Dear Doctor" letter issued by St. Jude on July 26, 2012, which stated St. Jude Medical has received 325 total patient complaints of warmth or heating at the device implant site during charging for the Eon and Eon Mini spinal cord stimulation systems, which equates to 0.46% of total implants as of June 30, 2012. Some physicians or patients have requested explant surgery to address uncomfortable temperature elevations. These reports resulted in a total of 72 explants for the Eon and Eon Mini spinal cord stimulators, or a rate of 0.10% of total implants.

A search of the FDA Maude database for reports of injury from the St. Jude EON implantable pulse generator resulted in 767 hits, many referring to "burning" sensations associated in some way with the neuromodulation device or its leads. From the rough descriptions of the problems in the database, it seems that a fraction of these are likely to be a direct consequence of heating of the device during charging, but I could locate no reports of serious tissue injury. In short, overheating of the implanted pulse generator during charging is evidently an uncommon problem that can cause discomfort or pain to the patient but appears unlikely to cause serious damage. As St. Jude pointed out in its "Dear Doctor" letter, removing the implants has its own risks, apart from depriving the patient of the benefits of therapy.

In the accompanying paper, Chen and colleagues develop a simple thermal model that predicts the tissue temperature increase during charging, in particular the increase in skin temperature directly over the pulse generator, which they find to be within 2 C of the implant temperature. They propose to "monitor the adjacent skin temperature to evaluate the thermal hazards", setting off an alarm (or possibly shutting down the charging process) when skin temperature reaches 41 C. While they acknowledge that false-positive alarms are possible, "ensuring 100% safety of patients has the highest priority", they say, and "it is worth increasing the errors of alarm while reducing the potential risk taken by patient."

This suggestion, as a practical matter, has two problems. First, due to biological variability and other variables, the actual temperature differences between the skin and implant may be more or less than the 2 C assumed by Chen et al. The kinetics of thermal damage are such that most tissues can be held at temperatures below 43 C for extended times without damage, but above 43 C thermal damage will quickly occur. Setting the threshold skin temperature for the alarm at 41 C as suggested by Chen et al will result in an unknown safety margin that will vary considerably among patients and may be inadequate for some. There is no such thing as "100% safety". In any event, most patients (although perhaps not those with neuropathy) would be acutely uncomfortable before frank thermal damage sets in, and would discontinue charging their device. A more effective intervention would seem to be careful education of the patient about how to safely recharge the device.

The second problem is related to the statistics of testing. Taking at face value, St. Jude's statement that 0.1% of devices require explantation due to excessive heating, it is clear that episodes of heating that are sufficiently painful to cause the patient to have the implant removed are very uncommon. It seems that the incidence of frank thermal injury (of the sort that Chen et al want to protect against) is even lower. The false positive rate of the alarm would have to be *very small* or the system will be swamped with false positive alarms. It seems unlikely that this level of performance would be possible with an indirect method based on monitoring skin temperature. Too many false positives might scare the patient into having the device explanted or, more likely, cause the doctors to disconnect the alarm.

St. Jude should simply fix the problem. It is not that difficult, and at least two other companies make similar devices that are much less prone to overheating. The transcutaneous charging technology, the battery technology, the programmed charging protocols built into the system, and the instructions to patients should all be such that the patients do not experience discomfort in the first place.

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