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ORIGINAL PRE-CLINICAL SCIENCE

Electrical power to run ventricular assist devices using the Free-range Resonant Electrical Energy Delivery system

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LVAD;
FREE-D;
driveline;
TETS

BACKGROUND: Models of power delivery within an intact organism have been limited to ionizing radiation and, to some extent, sound and magnetic waves for diagnostic purposes. Traditional electrical power delivery within the intact human body relies on implanted batteries that limit the amount and duration of delivered power. The efficiency of current battery technology limits the substantial demands required, such as continuous operation of an implantable artificial heart pump within a human body.

METHODS: The fully implantable, miniaturized, Free-range Resonant Electrical Energy Delivery (FREE-D) system, compatible with any type of ventricular assist device (VAD), has been tested in a swine model (HVAD) for up to 3 hours. Key features of the system, the use of high-quality factor (Q) resonators together with an automatic tuning scheme, were tested over an extended operating range. Temperature changes of implanted components were measured to address safety and regulatory concerns of the FREE-D system in terms of specific absorption rate (SAR).

RESULTS: Dynamic power delivery using the adaptive tuning technique kept the system operating at maximum efficiency, dramatically increasing the wireless power transfer within a 1-meter diameter. Temperature rise in the FREE-D system never exceeded the maximum allowable temperature deviation of 2°C (but remained below body temperature) for an implanted device within the trunk of the body at 10 cm (25% efficiency) and 50 cm (20% efficiency), with no failure episodes.

CONCLUSIONS: The large operating range of FREE-D system extends the use of VAD for nearly all patients without being affected by the depth of the implanted pump. Our in-vivo results with the FREE-D system may offer a new perspective on quality of life for patients supported by implanted device.
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There are various biologic phenomena that can be altered or enhanced using electrical stimuli. Some of these are endogenous and others are exogenous, such as in the case of pacemakers that use batteries as a power source. Biologic organisms are constantly exposed to a variety of external electromagnetic forces, but delivery of such forces within the body for utilization is very limited. Exploiting the revolution in digital microelectronics for sensing and stimulating deep-seated human organs is hampered because the battery technology does not obey rules such as Moore's law governing processing power and has remained unchanged in its size constraints for the last few decades. Meanwhile, considerable progress has been made in understanding organ failure such as end-stage heart failure, which can be successfully addressed by implantation of artificial heart pumps (left ventricular assist devices or total artificial hearts), which essentially supplant the pumping action of the human heart. Such pumps require constant high electrical energy for safe and effectual functioning, with a need for a constant electrical supply that is unmet by existing battery technology. The only way these pumps can function uninterrupted is by connecting them to an external electrical power source across their pierced skin that carries the electrical wire. Violating the natural barrier of skin leads to infection and contamination. Another unintended consequence of powering in this manner is making the person who is supported by such a device lead their life tethered to an electrical power source, thus hampering quality of life and negating the benefit offered by the artificial heart pump, also known as a ventricular assist device (VAD).

The greatest challenge for VADs adopting wireless power, however, is that these devices require 5 to 25 W of power—a large amount for an implanted device. The transcutaneous energy transfer system (TETS), which has already been tried,[1,2] presented significant limitations in practical use despite its successful application in early-generation VADs and artificial hearts.[3] These limitations included: intolerance to misalignment between the external transmit coil and the implanted receive coil; and high dependence on the separation distance between the transmit coil and receive coil, at most 10 to 20 mm, which is not sufficient range for all patients, considering VAD patients vary drastically in size and body type. The inflexible range and misalignment between the coils diminish the practicality of the system. These systems, however, were remarkable at reducing the overall infection rate in this very ill group of patients.

Unlike TETS, which uses inductive power transfer, our previously developed FREE-D system utilizes magnetic resonance power transfer, which can lead to improved efficiency across greater distances if proper tuning mechanisms are employed.[4] Performance and characteristics of the FREE-D system for both short and long range have been investigated and refined throughout extensive in-vitro studies using the HVAD (Medtronic, Minneapolis, MN) and HeartMate II, HeartMate 3 (Abbott, Chicago, IL), Jarvik 2000 (Jarvik Heart, Inc, New York, NY), and experimental total artificial heart (TAH) systems in terms of relations between pump flow, pump speed, pump power, and temperature.[4–7] Demo videos are available online from our previous in-vitro work showing the FREE-D system being able to rapidly adapt to various distances and misalignment between resonators and run the HeartMate II within a portable configuration.[6]

In this work, we present in-vivo results of the FREE-D system working across the short range of 10-cm and long range of 50-cm distances, which essentially signifies its effective 3-dimensional working space as 1-meter-diameter sphere with respect to the VAD patient at the center (Figure 1A), showing the step toward the vision of the FREE-D system for improving VAD patients' quality of life (Figure 1B and C). The

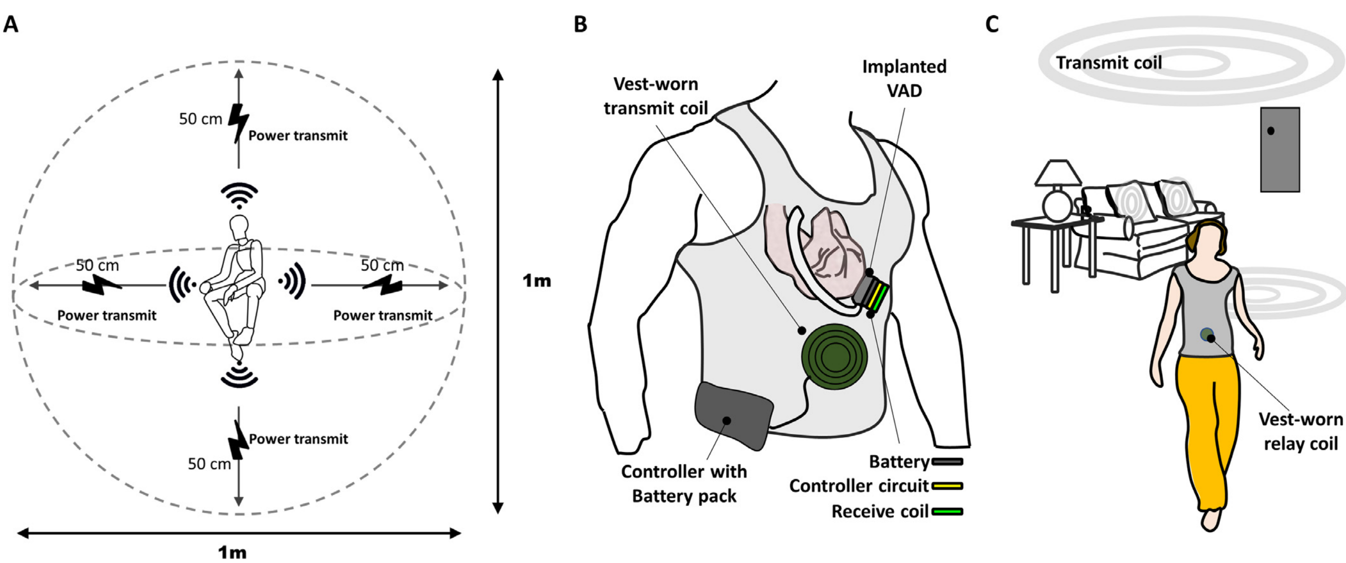

Figure 1 The FREE-D system for patients on LVAD support. (A) Conceptual schematic showing extendable range of wireless power transfer in 3-dimensional space within a long-range configuration. (B) The FREE-D system can transfer wireless power from the vest-worn transmit coil to the implanted receive coil for nearly any angular orientation. (C) Specific scenarios in which the long-range FREE-D system can significantly improve the VAD patient's quality of life with transmit coils installed throughout the patient's home and around the patient's household items.

FREE-D system, proven to run continuously for 90 days in vitro without any interruptions or faults (Figure 2), was successfully operated within the maximum allowable temperature rise of 2°C in vivo, which complies with requirements established by the United States Food and Drug Administration (FDA) and the Federal Communications Commission (FCC).[8]

Methods

Theoretical basis of FREE-D operation

The FREE-D system consists of 2 magnetically coupled coils, transmit and receive coils, producing high-quality factor (Q) resonances (see Figures S1 and S2 in the Supplementary Material available online at www.jhltonline.org/). Each coil contains 2 elements, a single-turn drive loop and a multi-turn coil, which can be configured either combined or in a separated fashion. Alternating current (AC) signal delivered to the transmit coil induces oscillating magnetic field dispersed in all directions. The magnetic field that oscillates at a specific resonant frequency induces AC signal in the receive coil, which is then converted into a direct current (DC) voltage by a rectifier connected to it to power the implanted system controller. With varying distance or orientation between the transmit and receive coils, the specific resonant frequency at which 2 coils efficiently exchange energy by sharing magnetic field changes. The dynamic tuning scheme, one of the key features that distinguishes the FREE-D system from earlier inductive coupling technology, enables the system to rapidly adapt to these variations and select the ideal resonant frequency, achieving the maximum operating efficiency[5,9,10] (see Dynamic Power Delivery section in Supplementary Material online for further details). High efficiency is extremely important for regulatory compliance of wirelessly powered implanted medical devices. Higher efficiency implies lower transmit power levels for the same amount of power delivered to the VAD, which means lower field strengths and safer operating conditions for humans around the FREE-D system. The system-level block diagram of the FREE-D system shown in Figure S3 (see Supplementary Material online) outlines the design considerations for both the hardware and software associated with each element. An animation showing the theoretical concept of the FREE-D system is available online.[6]

Animal preparation

The institutional animal care and use committee at Yale University granted approval for all experimental protocols. Eight

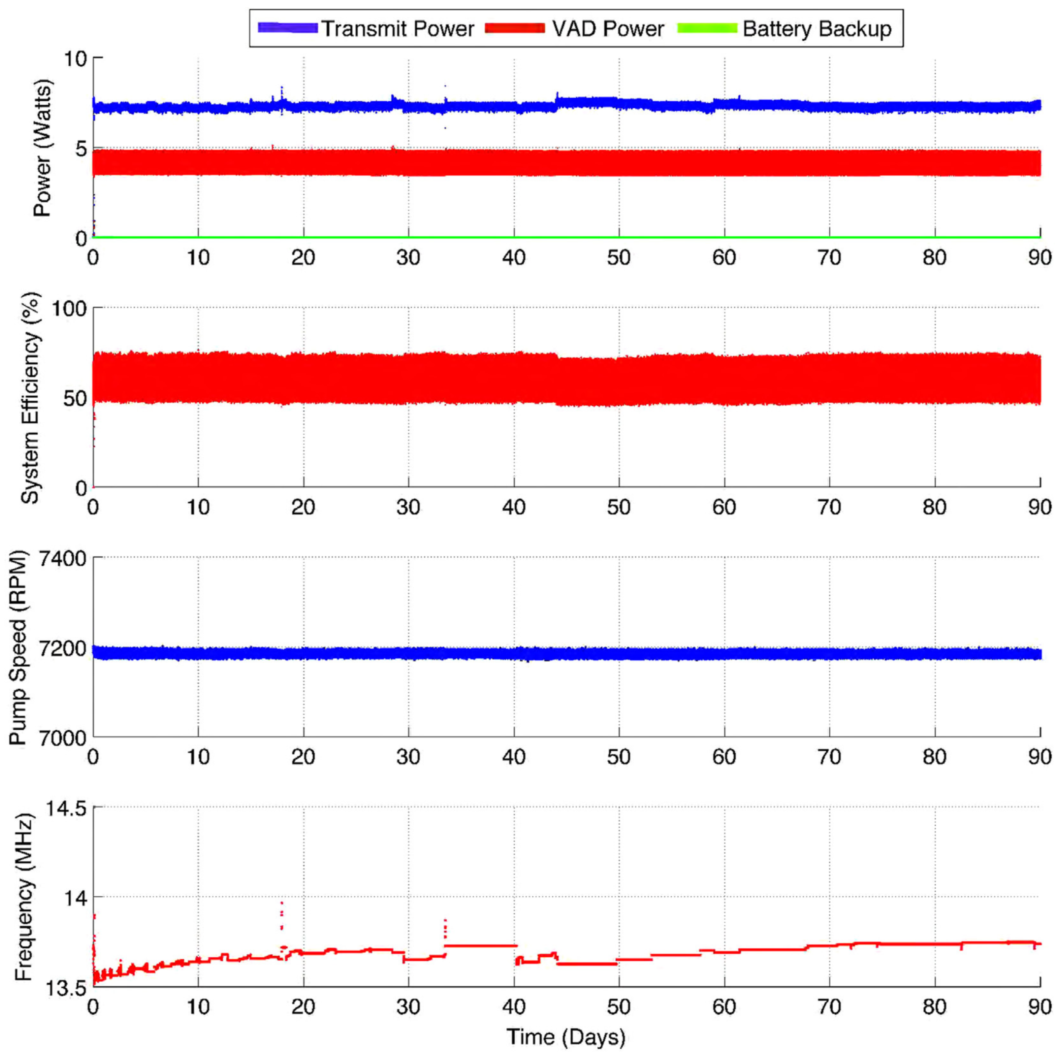

Figure 2 Long-term continuous operation of the FREE-D system. The system was continuously run in bench-top preparation for 90 days without any interruptions or faults. Power consumption, system efficiency, and pump speed were all stably maintained.

Yorkshire pigs (both male and female, 41 to 50 kg) were anesthetized based on a refined protocol that significantly improved outcomes compared with the standard swine anesthetic regimen by properly maintaining cardiac function without ventricular fibrillation during entire period of in-vivo experiments.[11]

Surgery and instrumentation

The HeartWare HVAD was used for all 8 in-vivo experiments. A median sternotomy was used for the surgical approach, which was performed without the use of cardiopulmonary bypass. Teflon pledgeted sutures were placed radially around the left ventricular apex and the inflow cannula tip was inserted and seated at the apex. The outflow graft was connected to the ascending aorta in standard fashion. The FREE-D receiver, which contains the controller circuit and backup battery, was mounted directly beneath the HVAD for optimal heat dissipation. We have previously described an implantable controller with an extremely small footprint that is capable of producing an artificial pulse timed with the patient's electrocardiogram (ECG).[12,13] The size of the footprint was 40 to 50 mm in diameter.[14] Further details for transmitter and receiver design, pressure, flow, and ECG measurement are described in the Supplementary Material online.

After implantation, an external power supply was used to start up the VAD due to the high initial power consumption required by the magnetically levitated motor. After initial power-up, the receive coil was placed beneath the skin, as shown in Figure 3A. The external transmit coil directly connected to the transmitter was held 10 cm away from the surface of the skin for short-range configuration and 50 cm for long-range configuration within an additional external coil as a relay coil placed 10 cm away from the skin (Figure 3). Temperature, pressure, and flow sensors were installed around the receive coil and around the animal's heart to analyze any impact that the wireless power may potentially have on the cardiac function of the animal. A thermal camera (FLIR E4; FLIR Systems AB, Sweden) was also placed to monitor the temperature of the animal and the coils.

The average pump speed was measured by back electromagnetic field (EMF) from the motor controller, and the average pump power was measured by voltage and current sense amplifiers on the receiver circuit. Thermocouples were placed inside the skin above the receive coil, directly above the receive coil, directly below the receive coil, and in rectum to measure core temperature. The maximum temperature rise during wireless power operation was measured at each position.

Statistics

Power efficiency was measured in real-time for all 8 experiments throughout the duration of each experiment. Averaging power efficiency variations measured from each experiment, 4 data sets for short-range and 4 data sets for long-range configurations were considered in the analysis. A 2-sample *t*-test was used with $p < 0.01$ considered significant.

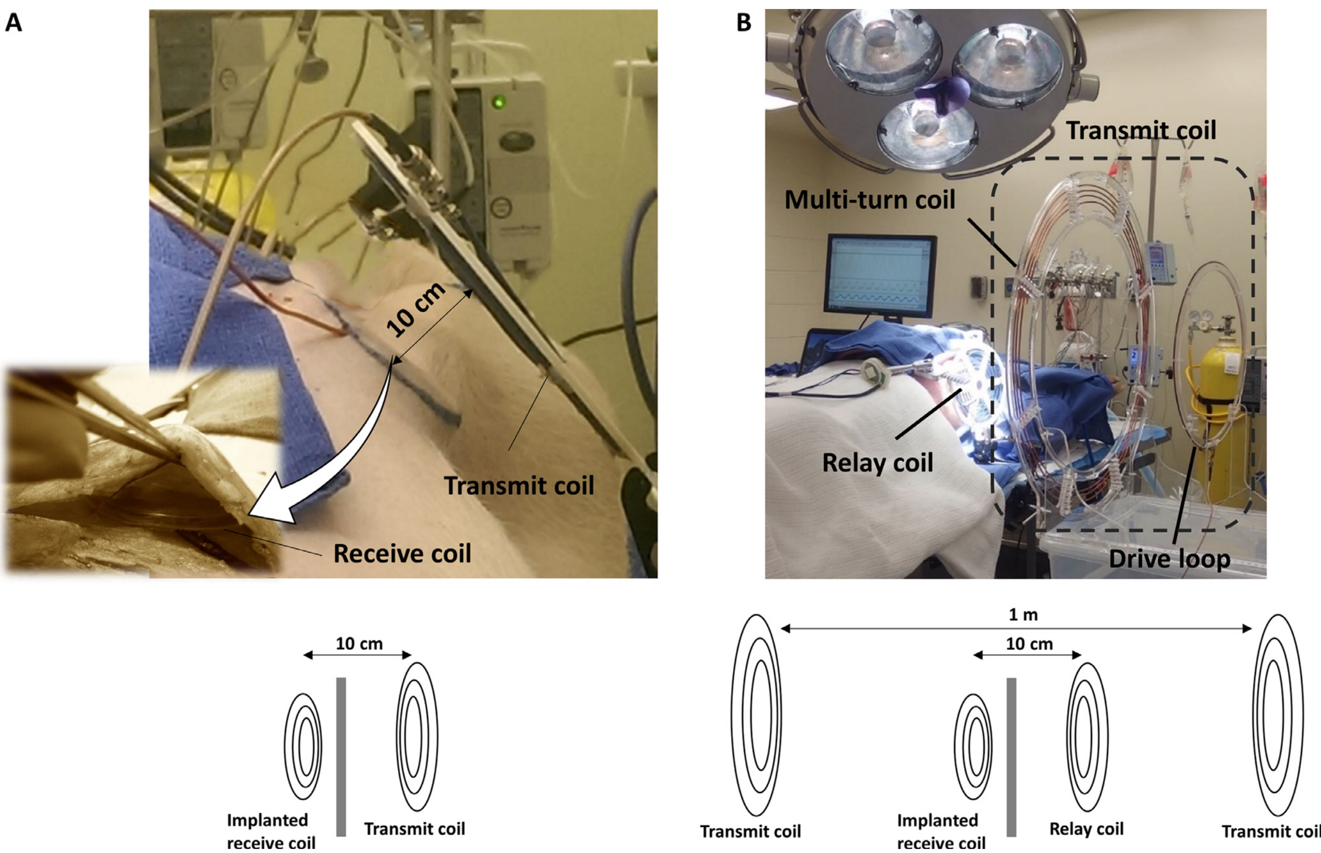

Figure 3 In-vivo FREE-D system configurations. (A) Short-range configuration with the external transmit coil directly connected to the FREE-D transmitter stand 10 cm away from the implanted receive coil beneath the animal's skin. (B) Long-range configuration where the large external transmit coil is directly connected to the FREE-D transmitter stand 50 cm away from the implanted receive coil with an additional external coil placed between them as a relay coil, which is 10 cm away from the skin.

Results

Pre-clinical applications in vivo

For every experiment, HVAD was successfully implanted, and the pigs remained in stable condition on wirelessly powered HVAD support for the full procedure duration. Pump speed was between 1,700 and 2,500 rpm in the in-vivo experiments, which produced a pump flow between 2 and 4 liters/min. Experiments were performed with anesthetized swine with the heart continuing to beat during the entire procedure.

In the short-range configuration, the external transmit coil and the implanted receive coil beneath the animal skin were 10 cm apart with the FREE-D transmitter directly connected to the external transmit coil (Figure 3A). In the long-range configuration, the external transmit coil connected to the FREE-D transmitter is 50 cm apart from the implanted receive coil within an additional external coil placed 10 cm away from the skin of the animal, just like the short-range configuration, acting as a relay coil (Figure 3B).

After all FREE-D system components and measurement probes were in place, the wireless power was enabled using a combination of frequency tracking, adaptive impedance matching, and power tracking. In every experiment, the wireless power successfully powered the HVAD without any contribution from the backup battery power.

The mean and standard deviation for time duration, animal weight, pump speed, and pump power for all 8 experiments were 125.5 ± 33.1 minutes, 46.9 ± 3.1 kg, 2,210 ± 230.0 rpm, and 2 ± 0.3 W, respectively. The time duration refers to the length of time that the HVAD was powered by wireless power.

The system efficiency, which represents power delivered to the VAD divided by power input to the transmitter, was significantly higher in the short-range configurations, indicating better efficiency (Figures 4 and 5). However, the long-range configuration achieved a 10-fold improvement in range with only 7.5% efficiency reduction. Also, the efficiency can be correlated with the pump speed and power level, which varied between each experiment. For lower power levels, the efficiency was lower because the static power consumption to perform adaptive tuning consumes approximately 0.7 W. Compared with humans, pigs do not require a similarly high blood flow rate and, consequently, the power level was much lower in the animal experiments.

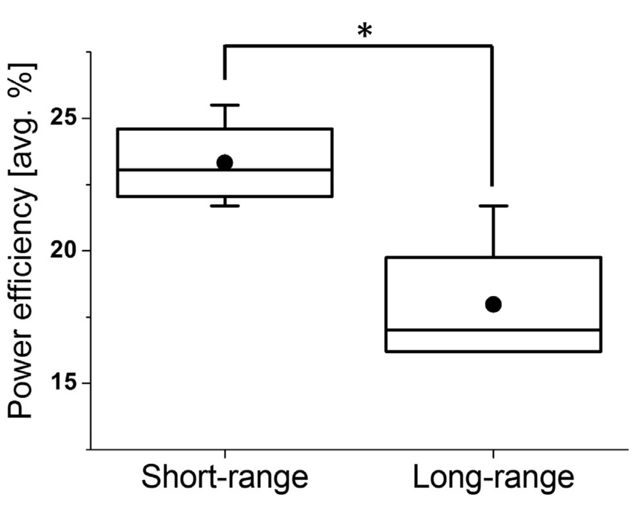

Figure 4 Comparison of power efficiency between short- and long-range configurations. The average system efficiency was significantly higher for the short-range configuration compared with the long-range configuration ($p < 0.01$). Dot and horizontal bar inside the box indicate mean and median value, respectively.

Effect on local and body temperature

The temperature measurements show that the heat generated by the FREE-D system never exceeded the maximum allowable temperature deviation of 2°C for an implanted device inside the trunk of the body (Figures 5 and 6). The greatest temperature rise occurred above the receive coil. This result can be understood by considering that, closer to the surface of the skin, the natural air flow helps regulate temperature. Similarly, closer to the inside of the body, blood flow and thermoregulation will help maintain a more constant temperature as blood carries heat away from the coil. Directly above the receive coil, both of these thermoregulating mechanisms would be minimal, resulting in the greatest temperature rise. For example, the temperature below the coil was 33.45°C before wireless power was enabled. Over the next 45 minutes, the temperature below the coil rose to a maximum of 34.46°C and maintained a relatively stable temperature for the duration of the experiment until wireless power was disabled and the coil temperature returned to its initial value. The temperature probe above the receive coil (closer to the surface of the skin) started at 31.18°C and rose to a maximum temperature of 32.94°C. The oscillations of this temperature measurement were attributed to the temperature control of the room itself. At the end of the experiment, the HVAD was turned off and the experiment concluded.

Temperature rise in the FREE-D system could be predominantly caused by thermal conduction and thermal radiation. Current flowing through the receive coil dissipated as heat across the small resistance presented by the turns in the coil, and heat conductively transferred to the body. Thermal radiation caused by the RF energy from the wireless power transfer could also generate heat across the conductive tissues inside the body. However, the key finding that has been repeatedly demonstrated through animal experimentation is that the FREE-D system did not generate a temperature rise inside the body.

Although the wireless power was enabled during the long-range experiment, the battery power never contributed to the load. The VAD power fluctuated due to the animal's healthy heart changing the mechanical load presented to the VAD at every systolic and diastolic cycle. The efficiency also changed not only because of the changing load power, but also because of the animals' chest expansion and contraction as they breathe, thus the distance between the coils was constantly changing by a couple of centimeters. The dynamic tuning techniques allowed for the

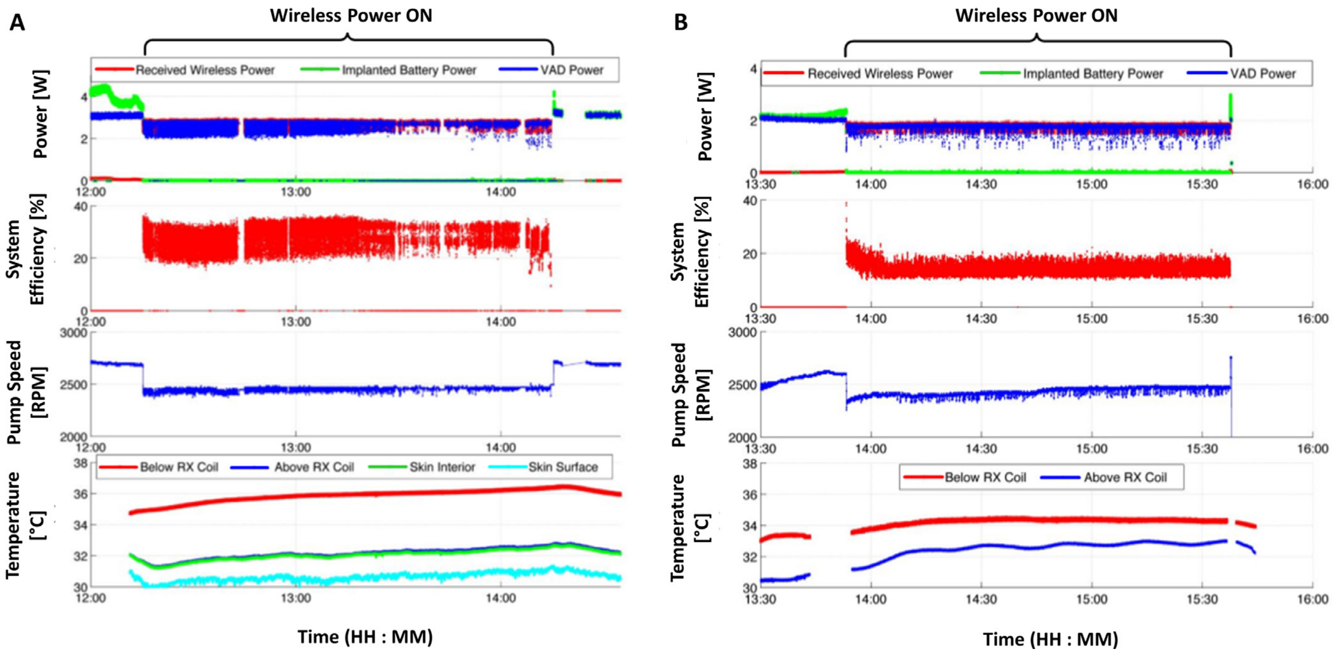

Figure 5 In-vivo FREE-D system performance measurements for short- and long-range configurations. For both experiments, the adaptive tuning techniques allow for the system to maintain seamless wireless power delivery, without any backup battery assist. The VAD power and system efficiency fluctuations were attributed to systolic and diastolic cycles or expansions and contractions of the chest of the animal as it breathed. Measurements of wireless power delivered to the receiver, backup battery power, load power, pump speed, wireless power transfer efficiency, and temperature rise during (A) short-range and (B) long-range configurations in an in-vivo experiment.

system to maintain seamless wireless power delivery, without any backup battery assist.

We could successfully supply the wireless power on the implanted device on animals at a distance of 50 cm away on either the right or left side, accomplishing 1-meter-distance wireless power delivery.

Discussion

These results show that the FREE-D system can transfer wireless power up to a 1-meter distance in all directions, which can lead to improvement in quality of life of patients with an implanted device.

To extend the range of the wireless power from the transmit coils directly connected to the transmitter to the implanted receive coil, the FREE-D system consists of external coils between them as relay coils, with the one near the skin, for example, in a form of the vest-worn (vest-coil; Figure 1B). Other relay coils or transmit coils can ultimately be hidden inside the wall, floors, couches, tables, and beds. Although it may not be practical for the patient to completely remove the vest-coil everywhere inside the household because of technological limitations in

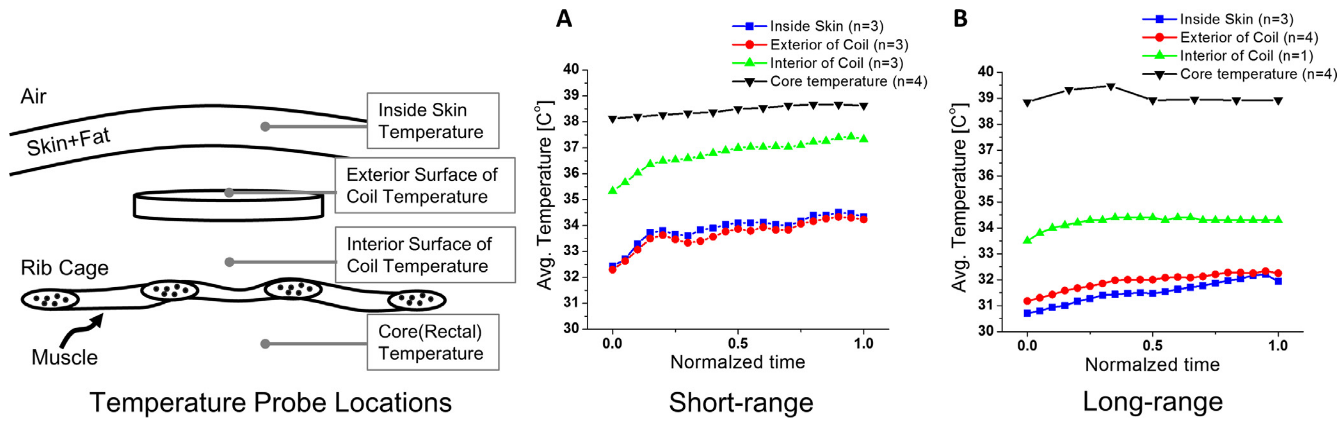

Figure 6 Average temperature changes at 4 different locations between (A) short-range and (B) long-range configurations. Thermocouples were placed at 4 different locations: inside the skin above the receive coil; directly above the receive coil; directly below the receive coil; and core temperature. The greatest temperature rise occurred at directly above the receive coil. Temperature measurements never exceeded the maximum allowable temperature deviation of the body, 2°C, for an implanted device inside the trunk.

transmitting power from a large transmit coil to a small, implanted receive coil, the unique advantage that the bulky transmitter circuit does not need to be carried around, allowing the patient maximal mobility throughout their household and unconstrained by heavy body-worn batteries and circuitry. The patient may be able to move freely throughout their home while receiving power from large transmit coils placed strategically around the home (Figure 1C), rather like WiFi for internet. With external coils placed beneath the patient's bed, the patient may be able to remove the vest-coil while sleeping at night. For outside activities, patients can simply go out with the vest-coil connected to body-worn batteries and circuitry. Thus, the FREE-D technology works just like how the current WiFi signal works for internet access. As the signal is strongest in and around the house (porch, backyard, garden area) there is seamless and uninterrupted access to WiFi. As one drives away from the home, the signal becomes weak and fades, making one reliant on cellphone towers to allow data access. However, in case of the VAD, one would simply carry the vest-based portable coil and its batteries to have freedom of movement (just as current VAD patients rely on batteries when outside the house or in a restaurant or when shopping or in recreational areas). The vest-based system can be externally powered via car charger or any wall outlet if needed.

In our design considerations, we did an informal survey of all household chores that would need full freedom from an external vest coil. Such tasks would include daily routine hygiene tasks, such as showering and bathing, and recreational activity, such as swimming or physical activity, that lead to excess body sweat. When considering all such activities in a healthy adult, these activities rarely exceed 1 hour (data not presented). Thus, we believe an implanted battery time of 90 to 120 minutes should provide a balance between total freedom of movement and conservation of the implanted battery life to prevent multiple replacements. With a nominal power consumption of <5 W, the size of the implanted battery can be as small as about 50 to 60 mm in width and height and 5 mm in thickness (see Figure S4 online) for 2-hour use.

The FREE-D system uses the 13.56-MHz industrial, scientific, and medical (ISM) frequency band. At this frequency, and at the power level of approximately 1 to 5 W in in-vivo experiments, the primary safety and regulatory concern was the specific absorption rate (SAR). SAR limits are in place to limit the extent that RF energy can cause tissue heating.[7,15,16] However, proper techniques for measuring SAR in vivo have not yet been established at these sub–30-MHz frequency bands. A related metric acknowledged by both the FDA and FCC requires that the maximum temperature rise from induced RF energy inside the trunk of the body does not exceed 2°C. Therefore, in this work, we relied on direct temperature measurements to demonstrate that the FREE-D system operates within the maximum allowable temperature rise of 2°C in its current embodiment.

Earlier studies on fully implantable systems have shown significant reductions in overall infection rate.[1,2] This is in spite of the fact that a very sick cohort of patients was selected for both of these studies. A more likely inference from those studies is that eliminating an externally communicating drive-line does have an impact on overall infection rates in recipients of VADs and TAHs. Over the years, there have been significant discussions in the VAD community oriented toward reducing the number of adverse events by eliminating drive-lines for power delivery. We sincerely hope that the current study will help to swing the pendulum in favor of eliminating the drive-line in future pump designs.[17,18]

Disclosure statement

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Supplementary data

Supplementary data associated with this article can be found in the online version at www.jhltonline.org/.

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