Harnessing Dermal Blood Flow to Mitigate Skin Heating Effects in Wireless Transdermal Energy Systems for Driving Heart Pumps

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Abstract

This work focuses on the thermal analysis of a transdermal wireless radiofrequency (RF) energy transfer system, to power artificial heart pumps, particularly left-ventricular assist devices (LVADs). We aim to understand the blood perfusion factors to mitigate the skin heating effects and thermal injury to subcutaneous tissue under the RF coupling area. A 2-channel RF power loss emulator (RFPLE) system was developed to conduct a study independent of the wireless RF supply coupling method. The heating coils were implanted subcutaneously 6-8 mm beneath the porcine model skin. Heating effects due to RF coupling inefficiency power losses for conventional and our novel pulsed transmission waveform protocol were emulated. The thermal profiles were studied for varying levels of LVAD power requirement. An in-silico model was developed in parallel with the in-vivo experiments to aid the interpretation of results.

1. Introduction

Heart failure (HF) remains a growing public health problem despite advances in drug and device therapy [1]. In 2019, almost 17.9 million people died from cardiovascular diseases representing 32% of all global deaths reported by the World Health Organization (WHO). However, in advanced heart failure, refractory to maximal drug and device therapy therapeutic options are limited. Cardiac transplantation remains an option, but a limited supply of donors results in less than 5000 procedures performed worldwide each year. Artificial heart pumps (left ventricular assist devices, LVAD) are used as a bridge to transplant and increasingly as destination therapy. [1-3]. The power requirement of LVADs is high (5W-40W), necessitating an external battery connected to the LVAD via a percutaneous driveline. The driveline passes through the skin, at which point infection frequently occurs. Driveline site infection is a serious problem, requiring hospitalization and prolonged antibiotic therapy. In some cases, a systemic infection can occur, requiring removal or replacement of the driveline. In addition, driveline related complications are associated with poor quality of life, premature LVAD failure and increased patient mortality [4].

A Wireless Power Transmission (WPT) solution would eliminate the driveline, improve the quality of life for the patient, prolong LVAD lifespan, reduce hospitalisation and increase patient survival. However, the main limitation to WPT use is the tissue heating effect from the radiofrequency coils leading to local skin damage. Even at relatively low power transmission levels (5W) the heating effect of the subcutaneous receiver element (coil) would exceed 2°C above baseline body temperature, leading to tissue injury.

To address this issue, we developed a novel wireless transdermal energy system for LVADs, using high-energy pulses transmitted in a relatively short time interval, followed by an idle (cooling) time to reduce the temperature of the tissue by capillary blood flow around the implanted coil [5]. This study complements previous work [6] and provides experimental (*in-vivo*) and numerical (*in-silico*) methodologies for the development of advanced WPT solutions.

2. Methods

We previously reported our novel RF wireless power transmission system consisting of multi-channel electromagnetically coupled transmitter (external) and receiver (implanted) coil modules [5], [6].

2.1. Radiofrequency power loss emulation

A Radiofrequency Power Loss Emulator (RFPLE) system was developed, as shown in (Figure 1). This allowed us to study subcutaneous blood circulation cooling

effects in a porcine model at varying power levels independently of the wireless power supply coupling method. This enabled analysis and modelling of the skin tissue thermal profile data under a wide range of power transmission levels while ON-pulse-transmission (50W-700W), ON-pulse durations (30ms-480ms) and blood perfused cooling OFF-time durations (5s-120s). Thus, the implemented RFPLE system enabled the study of the heating effects for both: (a) our novel pulsed transmission protocols, and (b) conventional continuous transmission mode, for similar power delivery levels. Furthermore, this permitted comparison of related heating coefficient metrics from the recorded temperature data of the subcutaneous heating element, both in the living model and in the cadaver (placebo) model of 6 porcine cases. Then, using COMSOL finite elements multiphysics software, an *in-silico* model was developed, permitting the characterisation of the subcutaneous blood circulation cooling factors.

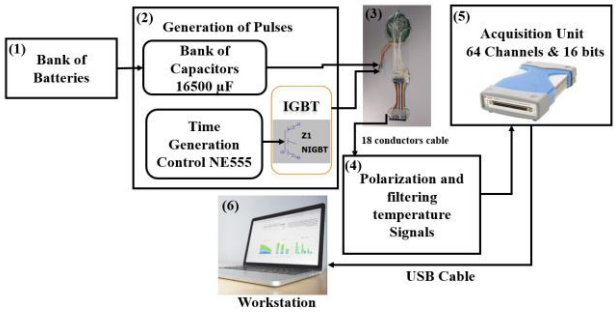

Figure 1. Schematic block diagram of the RFPLE system.

2.2. *In-vivo* studies

A project license (PPL 2900) was obtained from the Home Office. The in-vivo study using the RFPLE prototype was carried out in 6 pig models (average weight 50kg; average body temperature 37°C) under same measurement conditions. Each pig was sedated, anaesthetised and, before the placebo experimental stage, euthanised following procedures described in [6], under project licence PPL 2900, from the Home Office. Two subcutaneous pouches were surgically created on the left side of the pig, as shown in Figure 2, and four heating and thermal-sensor probes (external and implant) were inserted (2 channels).

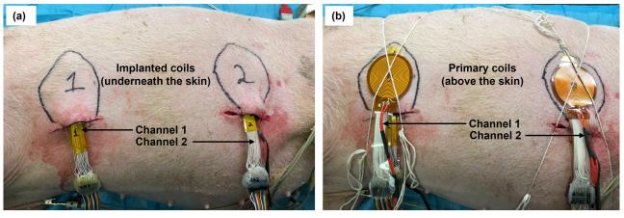

Figure 2. (a) and (b) post-surgery images of *in-vivo* studies.

2.3. *In-silico* studies

Finite element analysis (COMSOL Multiphysics 5.6) was used to simulate the heating effects in the subcutaneous tissue regions due to resistive loss of the coils. The simulation was performed by using magnetic fields (mf), heat transfer (ht) in solids and biological media, events module, and coupling of multiphysics modules. A two-dimensional axisymmetry geometry was constructed in COMSOL, as illustrated in Figure 3. Moreover, 2D axisymmetry geometry significantly reduced the computational time. The model has 149926 (plus 34907 internal) degrees of freedom (DOFs) to be solved. The coils and surrounding regions of coils domains had a higher mesh density to increase the accuracy of the simulation, in particular the adjacent region of the coils. The frequency-transient study was set from 0-600 seconds at f = 200kHz, and MUMPS direct solver was chosen. The following bioheat equations were solved in the subcutaneous tissue region to estimate the temperature.

$$C\rho\frac{\partial T}{\partial t} = \nabla\cdot(K\nabla T) + Q_s + Q_{SAR} + Q_m - P_b(T - T_b) \qquad (1)$$

Where T is the temperature, C is the specific heat, ρ is density of the tissue and K is the thermal conductivity. The heating sources are Q_s, Q_{SAR} and Q_m. The heating term Q_s is represented the resistive heat from the coils. We ignored Q_{SAR} as the specific absorption rate (SAR) is significantly lower at 200kHz. Q_m is the metabolic heat source depends on physiology of the body and P_b is the blood perfusion.

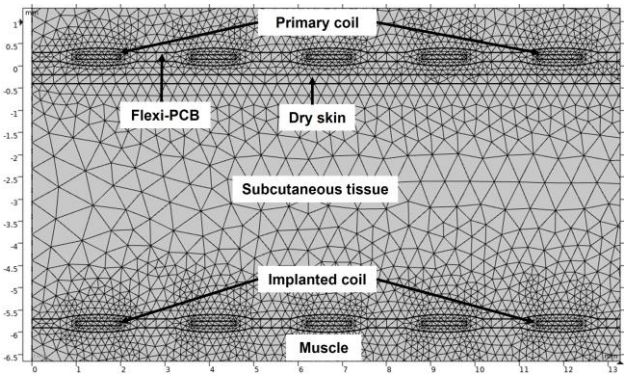

Figure 3. 2D axisymmetry geometry with meshes.

2.4. Thermal heating coefficient estimation

The blood thermal influence was evaluated to estimate the thermal heating coefficients from the thermistors of the implanted coils placed in the subcutaneous tissue for both the *in-vivo* (alive) and cadaver (placebo with the same pig case of the *in-vivo* stage) porcine model experimental test stages. For each protocol, the mean value and standard deviation (SD) of twelve distributed NTCs (thermistor) sensors mounted on the

surface of each heating element (coil; total: 2 per channel), in the subcutaneously implanted coil, for each channel, was used for estimating the thermal heating coefficient throughout the pulsed or continuous transmission protocols duration of 10 to 20 minutes. The mean temperature variations (ΔT) throughout the protocol provided the tissue heating coefficient (°C/s).

3. Results and discussions

This section presents the thermal profile data analysis obtained from the implanted (approx. 6-8 mm beneath skin surface) probes; channel 1 & channel. 2 (see Fig. 2(a)), in both *in-vivo* (alive) and cadaver experimental stages of the six pig cases. Then the *in-silico* model analysis results for the thermal profile in the subcutaneous tissue associated with inductive RF power loss heating effects both for: (a) pulsed and (b) continuous (conventional) transmission protocols.

3.1. *In-vivo* temperature measurements

In-vivo temperature (as a result of emulated RF power loss in the implanted elements) measurements from channels 1 and 2, were recorded for both modes of pulsed transmission protocols and their respective continuous transmission protocols, as described in the Methods section, on the six pig cases, under same measurement conditions. The received electric power levels were 2.8W, 3.5W, 5W, 6W and 8W; representing LVADs power rating levels. The recorded voltage drop across the heating elements in pulsed mode was used to derive the input voltage for the associated continuous mode; by equating the delivered energy per pulsed transmission cycle.

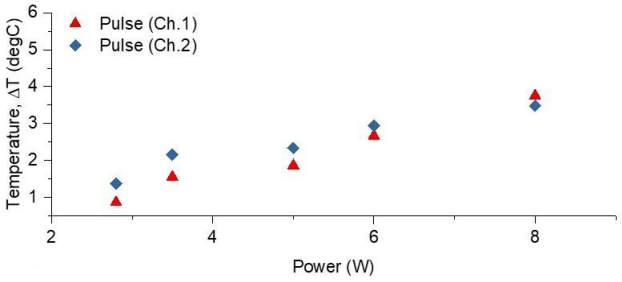

Figure 4. Maximum average temperature (Δ*T*) in the subcutaneous tissues vs. power delivered to the load in pulsed transmission protocols.

Figures 4 and 5 show the maximum averaged temperature increase for various delivery power loss levels in pulsed and continuous transmission modes. Note that channel-2 temperatures presented slightly higher values in both pulsed and continuous transmission than channel-1. . This could be due to higher blood perfusion (cooling) in skin areas near the heart; as is channel 1. The maximum temperature rises to 3.5°C at the 8W delivery power loss level in pulsed transmission; however, the temperature rises to 5°C for continuous mode transmission; under the

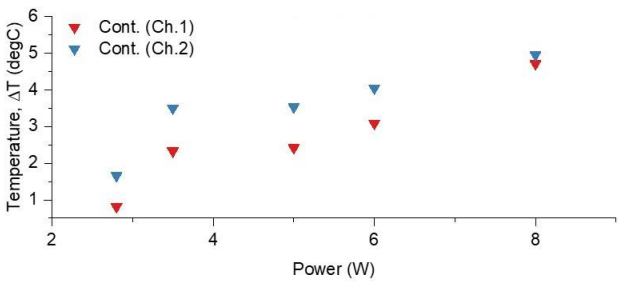

Figure 5. Maximum average temperature (Δ*T*) in the subcutaneous tissues vs. power delivered to the load in continuous transmission protocols.

same conditions. Moreover, the temperature rises from 0.5°C to 2°C until 5W is delivered to the load in pulse transmission. Nevertheless, continuous transmission temperature rises from 0.5°C to 3°C until 5W LVADs. Thus, pulsed transmission increased temperature by less than 2°C than continuous transmission for 8W LVADs.

The thermal heating coefficients were estimated from the average temperature data in channel 1 and channel 2, for both pulsed and continuous transmission protocols. Table.1 shows the estimated thermal profile coefficients from the *in-vivo* measurements under the same experimental conditions. There, the estimated thermal coefficients show that the values for pulsed transmissions and continuous transmission (10E-4) are almost similar for low power rated LVADs (5W). However, the 8W load's estimated thermal coefficient for continuous transmission is at least an order higher (10E-3) than in the pulsed transmission. This explains the reduced thermal effect with pulsed transmission protocols for high LVAD power rate; evidencing that pulsed transmission provided more time to reduce temperature through blood perfusion.

Table 1. Thermal heating coefficient (mean ± SD; N=12) in various power levels *in-vivo* measurements.

Power level (W)	**Channel 1 (°C/s)**	**Channel 2 (°C/s)**
3.5 (pulse)	5.69E-4 ± 1.03E-5	5.80E-4 ± 1.08E-5
3.5 (cont.)	6.91E-4 ± 7.58E-6	9.49E-4 ± 1.16E-5
5.0 (pulse)	6.76E-4 ± 7.47E-6	6.70E-4 ± 1.43E-5
5.0 (cont.)	7.46E-4 ± 7.70E-6	1.03E-3 ± 2.06E-5
8.0 (pulse)	8.75E-4 ± 2.00E-5	7.23E-4 ± 2.78E-5
8.0 (cont.)	1.09E-3 ± 3.73E-5	1.28E-3 ± 2.64E-5

3.2. Cadaver temperature measurements

Thermal profile data, for each pig during the cadaver experimental stage was gathered for pulsed and continuous transmission modes to investigate the tissue heating effects

in the absence of blood perfusion. Figure 6 shows the calculated mean temperature change (ΔT) at the implanted element (channel 1 and channel 2) *in-vivo* and during cadaver stages, for the 5WLVADs. The *in- vivo* mean ΔT in pulsed transmission mode (Ch.1 and Ch.2) was 2°C. The mean ΔT was between 5°C and 6°C for the cadaver stage. The mean ΔT for continuous transmission was the highest in channel 2 (about 7°C; cadaver stage). In both cases, the temperatures are higher than the pulsed transmission protocol. Thermal analysis results showed that pulsed mode generates less heat than continuous. Thus, blood perfusion is a key factor to reduce the skin tissue heating effect.

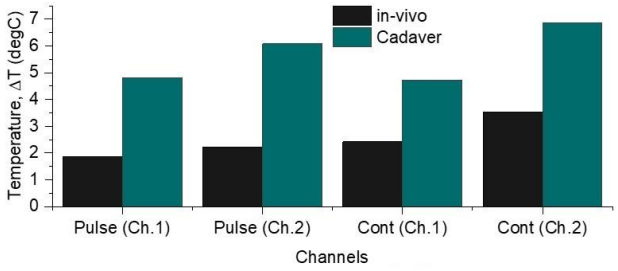

Figure 6. Maximum averaged temperature in-vivo and cadaver measurements for 5W LVADs power rating.

3.3. In-silico temperature model

Figure 7 shows the simulated temperature profile in the subcutaneous tissue in pulsed transmission protocol for 5W and 8W power levels LVADs.

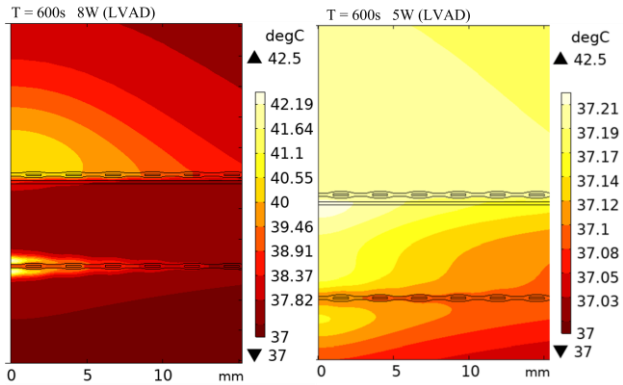

Figure 7. Simulated temperature inside the tissue at 600s.

The initial temperature of the tissue was 37°C. However, the room temperature (25°C) was much lower than the tissue temperature. As the energy is transmitted, current started to flow in the RF power coupling elements. Due to resistive loss the heat dissipation was occurred in the tissue domain. Blood perfusion in the tissue reduces the temperature and prevents thermal damage of the tissue. The simulation results showed that the temperature across the centre of the coil is higher than in other parts of the coil. The current density is expected to be higher at the coil's centre. The higher density of current generates more heat and dissipates into the tissue. The simulated maximum temperature rises to 5.19°C for 8W LVADS and 0.21°C for 5W LVADs from the baseline temperature. Thus, the *in-silico* results showed an agreeable thermal profile with the *in-vivo* measurements.

4. Conclusions

Evidence-based characterisation of skin thermal effects due to power dissipation of implanted electronic systems are of increasing importance [7]. In this study, which is complementary to our previous work within the same project [6], we have characterised blood flow cooling factors and proposed methods for harnessing this important element using a novel power-loss emulation system for designing safe high-power rated WPT systems.

Acknowledgments

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