Harnessing Dermal Blood Flow Thermoregulation for Mitigating 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 systems, to power artificial heart pumps, particularly left-ventricular assist devices (LVADs), aiming to understand the blood perfusion factors, mitigate the associated skin heating effects and thermal damage of the subcutaneous tissue under the RF coupling area. A 2-channel RF power loss emulator (RFPLE) system was developed to conduct a study independently of the wireless RF supply coupling method being adopted and their associated inefficiency. In this approach, the heating coils were implanted subcutaneously 6-8 mm below the body surface of the porcine model skin. Thus, heating effects due to RF coupling inefficiency power losses, for conventional and for our novel pulsed transmission waveform protocols were emulated and the experimental skin tissue thermal profiles studied for various levels of LVAD power drive; by estimating the heating coefficient for the porcine model measurement (in-vivo and placebo), along with an in-silico model to support their interpretation, providing reliable experimental and numerical methods for effective wireless transdermal LVAD energisation advanced solutions.

1. Introduction

Heart failure (HF) is a global health issue and remains a growing public health problem despite drug therapy and medical device technology advances [1]. In 2019, almost 17.9 million people died from cardiovascular diseases (CVDs), which represent 32% of all global deaths reported by the World Health Organization (WHO). However, considerable progress has been made in understanding HF, its advanced stage and the various treatment options. The implantation of artificial heart pumps, such as Left Ventricular Assist device (LVAD) or Total Artificial Hearts (TAH), are increasingly used for patients with advanced HF [1-3]. LVADs essentially supersede the heart's pumping function and significantly improve the survival rate of the patients [3]. More specifically, LVAD sits next to the heart's left ventricle with a tube that bypasses the blood to the aorta. Nevertheless, in all cases, an LVAD requires a relatively high-power supply, between 5W and 40W. The current practice to get the required LVAD power rate is by connecting the LVAD and an external power source through the skin (percutaneously) via a driveline cable, requiring skin piercing to connect the power source and the LVAD. Moreover, compromising the skin's natural defense limitations around the driveline leads to infection, resulting in recurrent hospital admissions and life-threatening sepsis, LVAD failure and premature death [4].

Wireless Power Transmission (WPT) solutions across the skin could eliminate the use of the driveline for energising the implanted LVAD. However, there are significant heating effects in the skin tissue around the radiofrequency coupling elements of the WPT system, leading to local skin tissue damage. This issue remains the main blocking issue with current WPT technology. When used in LVAD demand exceeding 5W, the heating effect of the subcutaneous receiver element (coil) would reach prohibitive levels exceeding 2°C above the baseline body temperature, leading to irreversible thermal 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 interval of time, followed by an idle (cooling) time to reduce the temperature of the tissue by capillary actions, for example, blood perfusion in the vicinity of the implanted coils [5]. This study is complements previous work [6] and provides reliable experimental (*in-vivo*) and numerical (*in-silico*) methods for the development of advanced TETS solutions.

2. Methods

The research subject system is our novel transdermal RF energy supply concept system, which consists of multi-

channel electromagnetically coupled transmitter and receiver (implanted) coil modules previously [5], [6].

2.1. Radiofrequency power loss emulation

A Radiofrequency Power Loss Emulator (RFPLE) system prototype was developed having a block diagram as shown in Figure 1, in order to conduct a study on the cutaneous blood circulation cooling effects in the porcine model at various power loss levels, independently of the wireless power supply coupling method being used and their associated inefficiency, thus, enabling analysis and modelling of the skin tissue thermal profile data under a wide range of power loss 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 same power delivery level, and comparatively assessing related heating coefficient metric 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 Multiphysics software, an *in-silico* model enabled evidence-based knowledge-mined characterisation of the subcutaneous blood circulation cooling factors.

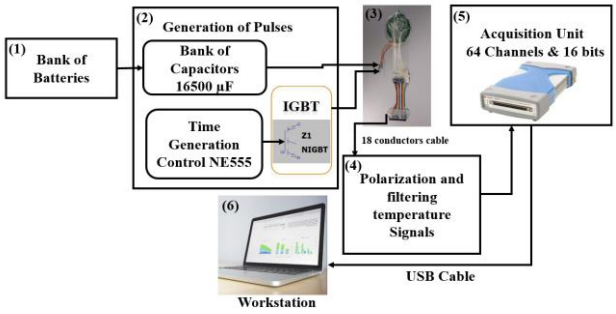

Figure 1. Schematic block diagram of the RFPLE system.

2.2. *In-vivo* studies

The *in-vivo* study using the RFPLE prototype was carried out in 6 pig cases (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 as described in [6], under project licence: PPL 2900, from the Department of Health. 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).

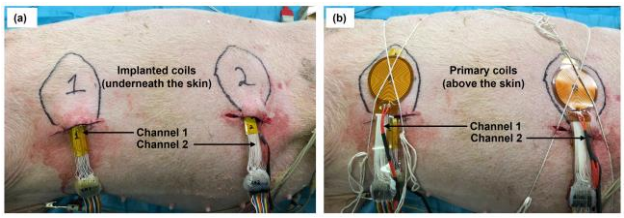

Figure 2. (a) and (b) post-surgery images of *in-vivo* studies.

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.

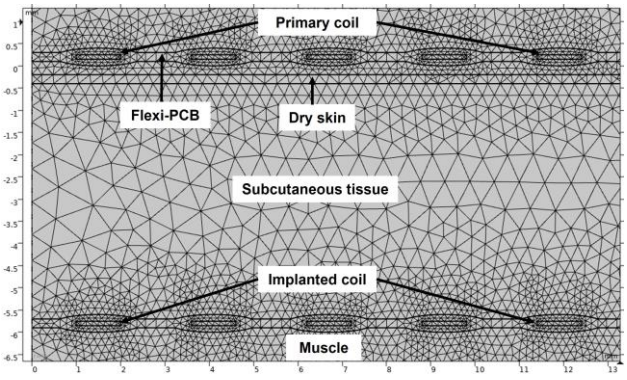

Figure 3. 2D axisymmetry geometry with meshes.

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 underneath of 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 (thermistors) sensors mounted on the surface of each heating element (coil; total, 2 per channel), in the subcutaneously implanted coil, for each individual 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 profiles data analysis results obtained from the implanted (approx. 6-8 mm) 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 to inductive RF power loss heating effects for pulsed 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 of 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.

Figures 4 and 5 show the maximum averaged temperature increase for various delivery power loss levels, both in pulsed and continuous transmission mode protocols. Note that channel 2 temperatures, in both pulsed and continuous transmission presented slightly higher values 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 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

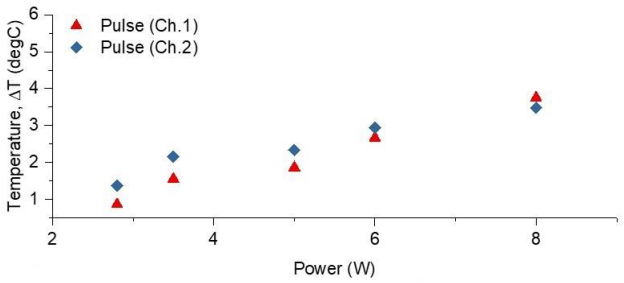

Figure 4. Maximum average temperature (Δ*T)* in the subcutaneous tissues vs. power delivered to the load in pulsed transmission protocols.

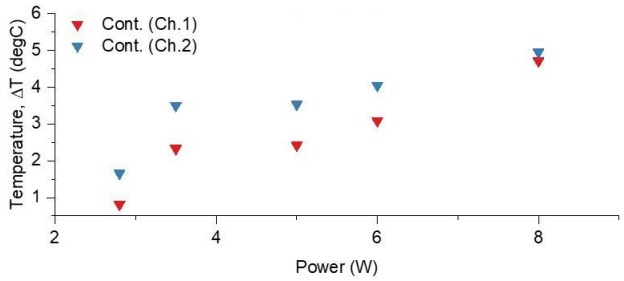

Figure 5. Maximum average temperature (Δ*T)* in the subcutaneous tissues vs. power delivered to the load in continuous transmission protocols.

transmission temperature rises from 0.5°C to 3°C until 5W LVADs. Thus, pulsed transmission generated less than 2°C heat than continuous transmission for 8W LVADs.

The thermal heating coefficients were estimated from the average temperature data in channel 1 and channel 2, in 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, in the 8W load, the estimated thermal coefficient in the continuous transmission is at least an order higher (10E-3) than in the pulsed transmission. This accounts for 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 level of LVADs *in-vivo* measurements.

Power level (W)	**Ch. 1 (°C/s)**	**Ch. 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

The thermal profile metrics data, at each pig respective cadaver stage, was gathered for both pulsed and continuous transmission modes to investigate the tissue heating effects in the absence of blood perfusion. Figure 6 shows the computed mean temperature change (ΔT) at the implanted element (channel 1 and channel 2) *in-vivo* and cadaver stages, for the 5W delivery level. The *in- vivo* mean ΔT in pulsed transmission mode (Ch.1 and Ch.2) was of 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. It is clear that pulsed transmission generates less heat than continuous transmission. Thus, blood perfusion factors can help to reduces the skin heating effect.

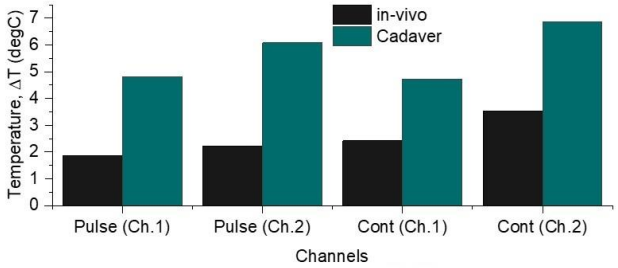

Figure 6. Maximum averaged temperature *in-vivo* and cadaver measurements for 5W LVADs.

3.3. *In-silico* temperature model

Figure 7 shows the simulated temperature profile inside the subcutaneous tissue region in pulsed transmission protocol for 5W and 8W LVAD power ratings. The initial temperature of the tissue was considered at 37°C. However, the ambient temperature was much lower than the tissue temperature (25°C). As the RF pulsed energy is transmitted, current flows in the RF power coupling elements and power losses heat is dissipated into the surrounding media. However, blood perfusion in the subcutaneous tissue reduces the temperature and prevents the tissue from thermal damage.

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 current generates more heat and dissipates it into the tissue. The simulated maximum temperature is 42.19°C; for 8W rating. Interestingly, the temperature rises slightly for 5W rating. Thus, the *in-silico* result is agreeable with the *in-vivo* measurement.

4. Conclusions

Evidence-based characterisation of skin thermal effects due to power dissipation of implanted electronic systems is

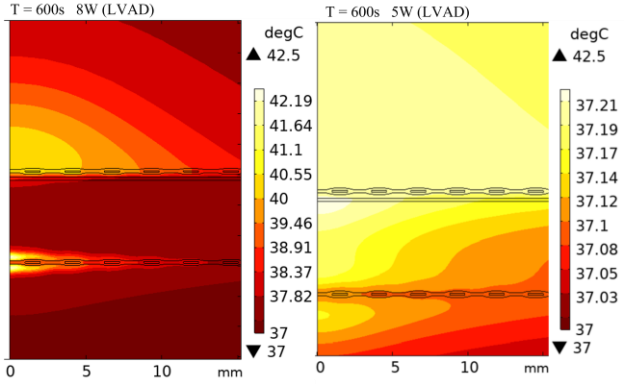

Figure 7. Simulated temperature inside the tissue at 600s.

of increasing importance [7]. In this study, which is complementary to our previous work within the same project funding [6], we have characterised blood flow cooling factors and proposed methods for harnessing this important capacity using a novel power-loss emulation system for designing safe high-power rated TETS with mitigated dermal tissue heating effects.

Acknowledgments

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