Subcutaneous Tissue Transient Thermal Profiling Under RF-energy Pulsed Wireless Supply to 3W-8W Rated LVAD in the Living and Cadaver Models

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Abstract

Left Ventricular Assist Devices (LVADs) are used as a bridge to cardiac transplantation, and for long-term support in patients with advanced Heart Failure. LVADs are relatively high-power demanding implanted devices (>3W), provided via a percutaneous driveline (cable) from an external supply. However, incidence of driveline infection is a severe and frequent drawback. Wireless Pulsed Energy Transmission (WPET) transcutaneous system is aimed to mitigate tissue-heating effects over conventional non-pulsed Transcutaneous Energy Transfer Systems (TETS). We comparatively assess the transient thermal profile of WPET in living and cadaver porcine models. This study focuses on the transient thermal analysis of the subcutaneous tissue heating effects, in a dual-channel WPET (pulsed transmission mode) and conventional continuous mode TETS systems.

1. Introduction

Heart failure (HF) is a clinical syndrome, and patients with advanced heart failure have a reduced ability of the heart to pump and impaired blood circulation through the body. Heart Failure (HF) can be considered a global pandemic, affecting more than 64 million people worldwide in 2017 [1]. The prevalence of symptomatic HF in the adult population is 1%-3 %, increasing to 20% over 75 years of age. In end-stage HF, one-year mortality is 30% [2]. In HF refractory to drug therapy, cardiac transplantation is an option, although strictly limited by donor availability.

Left Ventricular Assist Devices (LVADs) are small electrically powered implanted blood pumps connected to the heart and aorta. Initially used to 'bridge' to transplantation, LVADs are increasingly used as long-term 'destination' therapy. LVADs significantly improve quality-of-life and survival rates in patients with end-stage HF patients [3].

The power demand of LVADs is high (5W-40W) and necessitates a percutaneous driveline to an external power supply. However, driveline site infection is a serious issue, requiring hospitalization and prolonged antibiotic therapy. Driveline related complications also lead to premature LVAD failure and increased patient mortality [4-6].

A wireless power transmission (WPT) in implantable medical devices is becoming increasingly relevant in the medical device industry [7]. A wireless power solution would eliminate the driveline, improve the quality of life for the patient, reduce hospitalisation and increase patient survival. However, the main limitation to WPT use is the related tissue heating effect from the radiofrequency coils leading to local tissue damage. Even at relatively low power transmission levels (4W), the heating effect in the implanted receiver element (coil) would exceed 2°C above baseline body temperature, leading to tissue injury.

We have addressed this issue and developed a novel Wireless Pulsed Energy Transmission (WPET) system for LVADs, using high-energy pulses transmitted in a relatively short time interval, followed by an idle time to reduce the temperature of the tissue by capillary blood thermal perfusion action around the implanted coil. Thus, WPET transdermal energy supply systems are aimed to mitigate tissue-heating effects over conventional non-pulsed Transcutaneous Energy Transfer Systems (TETS). In this study, we assess the transient thermal profile of WPET in living and cadaver porcine models against the conventional continuous transmission TETS. Thus, this study complements our previously reported work for further characterisation of WPT solution for LVADs [8,9].

2. Methods

This section describes the prototype WPET system, the experimental setup, and the protocol design for studying the porcine model's thermal effects on *in vivo* and cadaver measurements under the same experimental condition. Dual-channel WPET pulsed and continuous TETS systems were developed to investigate the subcutaneous tissue transient heating profiling for several ratings of RF-power losses between the primary and the implanted coils. Twelve Negative-Temperature-Coefficient thermistors were adhered at the surface of the implanted coils to monitor the thermal profiles for 3W, 6W, and 8W rated

ISSN: 2325-887X DOI: 10.22489/CinC.2023.418

LVADs. The implanted coils (channel-1 and channel-2) are placed at about 6-10 mm underneath the skin surface [9]. RF-transmission pulse duration ranged from 30ms to 480ms, and idle time (no-transmission) from 5s to 120s. Temperature change of the tissue were sensed by the 12-thermistor.

2.1. Radiofrequency power loss effects

To investigate the heating effect both in pulsed and continuous transmission system resulting from inefficiency in electromagnetic power loss between transmitter and receiver coils in 2-channel WPET systems is developed. Figure 1 showed a schematic diagram of a 2-channel system. Each channel has a pair of coils: an external coil and an implanted coil.

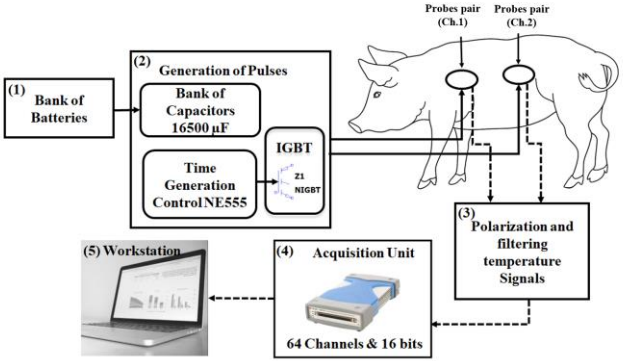


Figure 1. Schematic block diagram of the 2-channel WPET system and porcine model setup [9].

Each WPET coupling coil element is attached with 12 adhered negative temperature coefficient (NTC) thermistors [8, 9]. Thermistors had hair-thin wires (80 µm) connected to very-high input impedance instrumentation amplifiers at the operating RF (200 kHz).

2.2. *In-vivo* and cadaver model studies

The *in-vivo* measurements were carried out in 18 pig cases (average weight 50 kg; average body temperature 37°C, male and female) under the same measurement conditions with various power levels, pulse width and idle time (No transmission). Note that the results in Section 3 are based on the received power level for the LVAD application. The porcine study was endorsed by the Agri-Food and Bioscience Institute (AFBI) and the Animal Welfare & Ethical Review Board, and a project licence (PPL 2900) was obtained, under the Animals (Scientific Procedures) Act, from the Department of Health, UK.

2.3. Transient heating effect profiles (ΔT)

The transient heating profile of the subcutaneous tissue was evaluated from the implanted coil. The recorded 12-NTC thermistor signals used to calculate average temperature of the tissue. Note that recorded thermistor signals are subtracted from the body's baseline temperature, to estimate the transient thermal profile (ΔT) of the tissue with 3, 6 and 8W of LVADs.

3. Results and Discussions

3.1 Thermal profile vs LVAD power level

Here the thermal profile data analysis obtained from the implanted (approx. 6-8 mm beneath skin surface) coils; channel 1 & channel. 2 (see Figure 1), in both *in-vivo* (alive) and cadaver experimental stages of the pig model under same experimental condition.

The average transient thermal profile of the *in-vivo* model at 3, 6, and 8 watts power levels, for both in pulsed and continuous transmission heating effects, ΔT (°C), are presented in Table1. There, it can be observed that the pulsed transmission protocol showed a lower thermal profile than the continuous transmission protocols. This tendency is stronger as the level of operating power increases (from 3 W to 8 W). Table 2 presents the comparative thermal profile for the cadaver model stage (no blood circulation) study, for both in pulsed and continuous transmission protocols, and for the particular operating LVAD power rate of 8 W. There, the mean temperature increase (ΔT) in 12 minutes, is at least twice larger than mean ΔT values in Table 1, for the 8W power level.

Table 1. Transient thermal profile of pulsed and continuous transmission (Ch.1 and Ch.2), in the *in-vivo*, model stage, for 3, 6 and 8 watts power rates LVADs.

Power (W)	**Pulsed** ±SD (ΔT) ***In-vivo***		**Continuous** ±SD (ΔT) ***In-vivo***	
	Ch.1(°C)	Ch.2 (°C)	Ch.1 (°C)	Ch.2 (°C)
3	0.85±1.75x 10^{-2}	1.19±1.78x 10^{-2}	0.99±3.05x 10^{-5}	1.19±3.08x 10^{-5}
6	1.58±1.60x 10^{-2}	1.86±2.01x 10^{-2}	1.92±2.86x 10^{-5}	2.22±4.49x 10^{-5}
8	0.40±1.93x 10^{-1}	0.49±2.41x 10^{-1}	0.64±3.52x 10^{-1}	0.73±3.55x 10^{-1}

Table 2. Transient thermal profile of pulsed and continuous transmission (Ch.1 & Ch.2) in cadaver model.

Watts	**Pulsed.** ±SD (ΔT)		**Cont.** ±SD (ΔT)	
	Ch.1(°C)	Ch.2 (°C)	Ch.1 (°C)	Ch.2 (°C)
8	0.88±4.46x 10^{-1}	1.15±5.63x 10^{-1}	1.56±7.68x 10^{-1}	2.00±9.77x 10^{-1}

3.2. Thermal profiles analysis for 8W case

In-vivo and cadaver temperature measurements from channels 1 and 2, were recorded for both modes of pulsed transmission protocols and their respective continuous transmission protocols. Figures 2 and 3 depict the transient

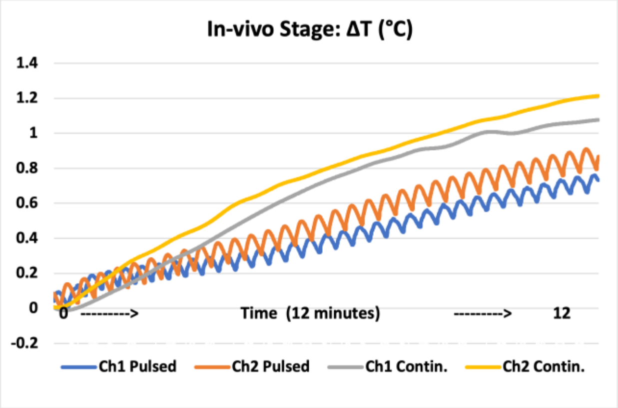


Figure 2. *In-vivo* transient thermal profile (Δ*T*) for 8W.

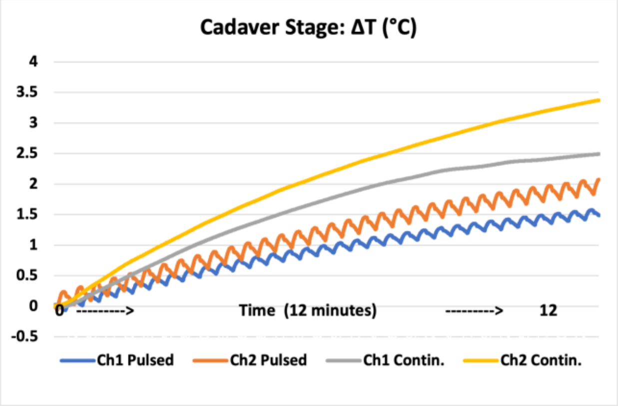


Figure 3. Cadaver transient thermal profile (Δ*T)* for 8W.

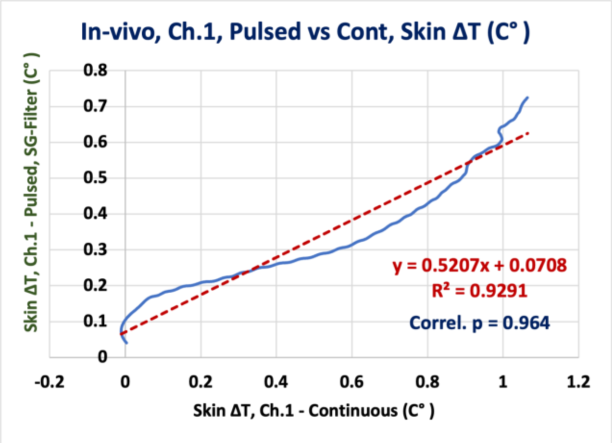


Figure 4. Scatter plot and linear regression model for ***in-vivo*** model **Ch.1:** Pulsed vs. Continuous.

thermal profile of channel 1 and channel 2, in pulsed and continuous transmission protocols. In both cases, the channel 1 shows a lower temperature than channel 2. The average temperature increase (Δ*T)* rises to 0.8°C and 0.9°C for channel 1 and channel 2 but in continuous transmission the temperature increase is considerably higher: 1.1°C, and 1.2°C respectively.

The cadaver ΔT trend shows a higher profile than the *in-vivo* model. Thus, it reveals that blood perfusion plays a significant role in reducing thermal damage due to tissue heating effect, both with pulsed and conventional continuous transmission protocol. In the *in-vivo* model, the continuous protocol presented a higher temperature change (ΔT) profile than the pulsed transmission. Thus, the idle (no transmission) time of the pulsed system allowed to reduce the temperature of the tissue.

In order to find a linear regression model of pulsed versus continuous in a scatter plot of pairs of continuous and corresponding pulsed ΔT, for both Ch1 and Ch2, the pulsed thermal time series (see orange and blue raw waveforms in Fig. 2 and Fig. 3) were first smoothed using a 2nd order, 80 ms window size Savitzky–Golay FIR filter, before inputting it to the y-axis of a scatter plot versus respective continuous ΔT series (x-axis), of same channel and porcine model type (*in-vivo*/cadaver); see Figure 4 to Figure 7. Thus, linear model slopes and their coefficient of determination (R^2) values computed.

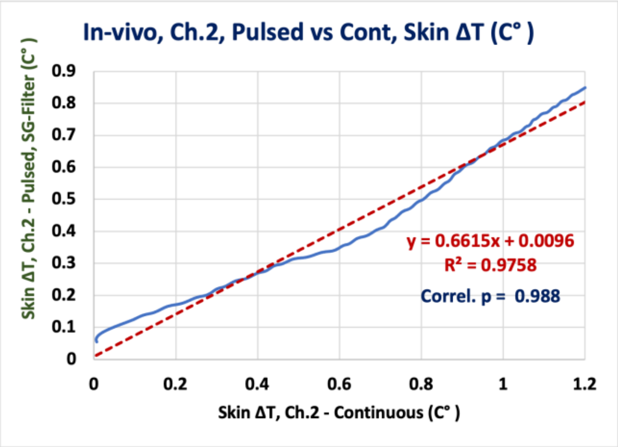


Figure 5. Scatter plot and linear regression model for ***in-vivo*** model **Ch.2:** Pulsed vs. Continuous.

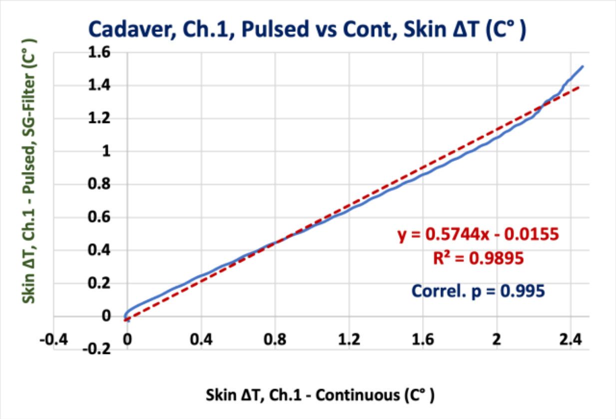


Figure 6. Scatter plot and linear regression model for **cadaver** model **Ch.1:** Pulsed vs. Continuous.

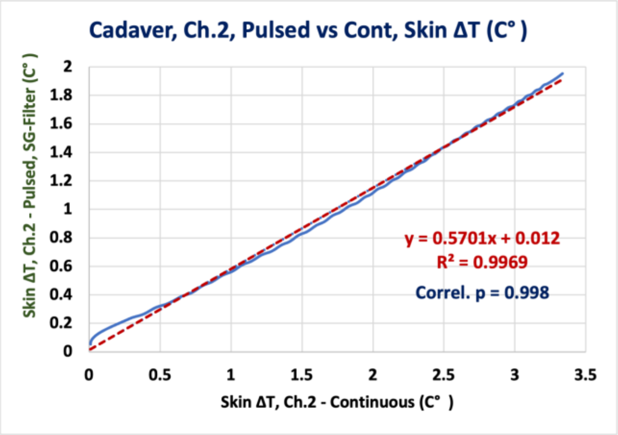
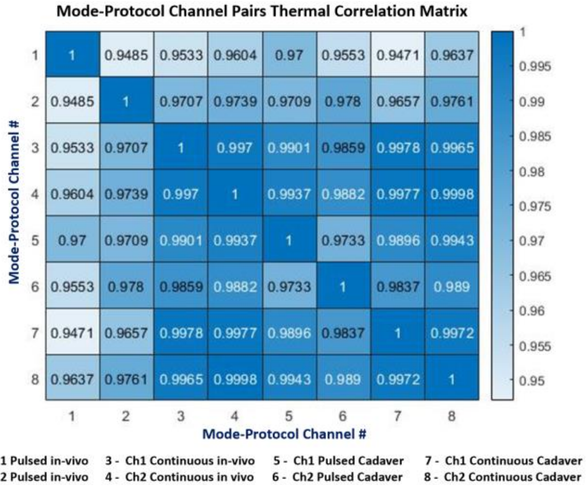


Figure 7. Scatter plot and linear regression model for **cadaver** model **Ch.2:** Pulsed vs. Continuous.

3.3. Thermal correlation matrix pattern

Correlations between pairs of "channel #" mode-protocol (total of 8 channel modes), were assessed by Pearson correlation coefficients to construct a correlation matrix [10]. Figure 8 presents the correlation coefficient between the 8 protocols for in vivo and cadaver models, for both continuous and pulsed power (8 W) transmission modes, and thermal profile of the subcutaneous coil/tissue. The correlation matrix is used to visualise the distribution pattern of correlation between pairs of mode-protocol within the 8 sets of data obtained, with the darker shades indicating stronger positive correlations, thus, depicting the strength of the correlation between each channel-mode paired temperature profiles; as a WPT system fingerprint.



Mode-Protocol Channel Pairs Thermal Correlation Matrix

	1	2	3	4	5	6	7	8
1	1	0.9485	0.9533	0.9604	0.97	0.9553	0.9471	0.9637
2	0.9485	1	0.9707	0.9739	0.9709	0.978	0.9657	0.9761
3	0.9533	0.9707	1	0.997	0.9901	0.9859	0.9978	0.9965
4	0.9604	0.9739	0.997	1	0.9937	0.9882	0.9977	0.9998
5	0.97	0.9709	0.9901	0.9937	1	0.9733	0.9896	0.9943
6	0.9553	0.978	0.9859	0.9882	0.9733	1	0.9837	0.989
7	0.9471	0.9657	0.9978	0.9977	0.9896	0.9837	1	0.9972
8	0.9637	0.9761	0.9965	0.9998	0.9943	0.989	0.9972	1

1 - Ch1 Pulsed in-vivo
2 - Ch2 Pulsed in-vivo
3 - Ch1 Continuous in-vivo
4 - Ch2 Continuous in vivo
5 - Ch1 Pulsed Cadaver
6 - Ch2 Pulsed Cadaver
7 - Ch1 Continuous Cadaver
8 - Ch2 Continuous Cadaver

Figure 8. Thermal correlation matrix for 8W power rate.

4. Conclusions

In this study, the thermal profile differences due to the type of transmission has been characterised quantitatively; evidencing a lower rise in temperature (ΔT) for pulsed transmission versus continuous transmission, regardless of WPT skin-coupling channel or living/cadaver model mode, as revealed by all four linear regression models: slopes < 0.66, with good coefficient of determinations values ($R^2 > 0.92$). The latter analysis perspective corroborates the 30% lower heating effect of pulsed transmission (WPET) advantage over conventional continuous transmission TETS, as previously reported [9].

Acknowledgments

This study was funded by Heart Research UK (HRUK), UK, grant reference number RG2678.

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