Controlling an LVAD Wireless Power System for Temperature Studies

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Introduction

Current ventricular assist devices (VADs) require a percutaneous driveline which is susceptible to infections. While a TETS reduces risk of infection, power losses in the implant coil can contribute to tissue heating and must be managed.

Translating the power losses into tissue heating is important. In this work we developed a TETS capable of transferring power suitable for a VAD system for implant under the skin. We developed a method for measuring the tissue heating. We correlated the power loss with tissue heating.

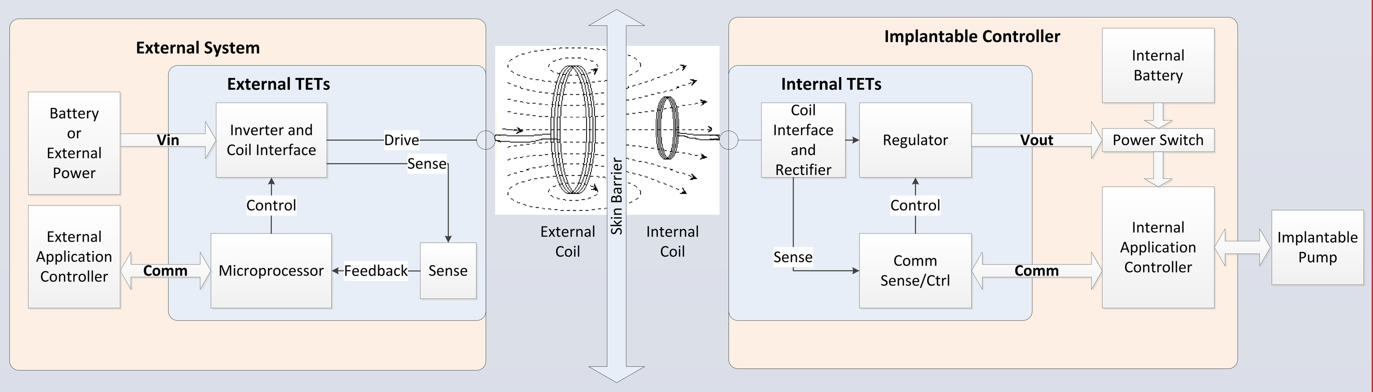
Previous studies correlated power loss (heat flux) with deep tissue implants [1,2,3]. These studies showed that tissue temperature would increase by only 2° C with heat flux of 45 mW/cm². This work did not provide information for subcutaneous implants under the skin.

The goal of this work was to understand how a TETS contributes to tissue heating

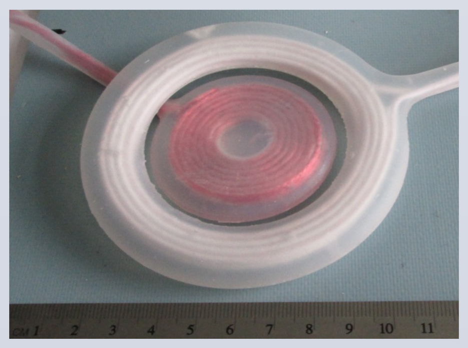
- Determine the correlation between power loss and tissue heating for shallow implants - under the skin.
- Determine the source of tissue heating:
  Conducted or Induced (frequency based) [4]
- Determine the impact of the amount of power transferred
- Develop a model for tissue heating
- Confirm the results using an appropriate animal study model

TETS System Design

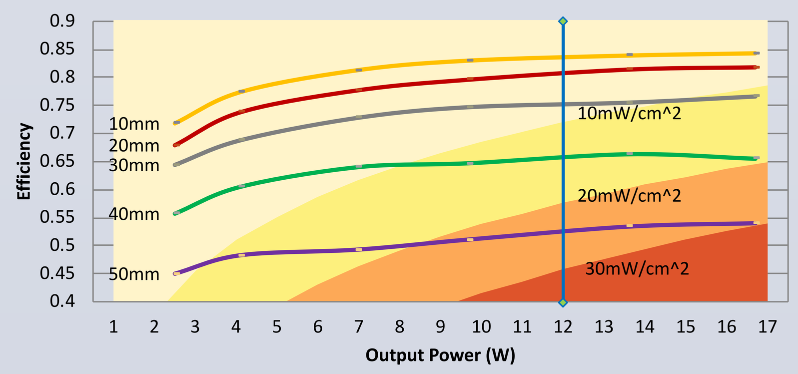
- Consists of Primary (external electronics, coil) and Secondary (Implant coil and implant electronics)
- Based on the LionHeart fully implantable LVAD design used in 36 human implants with no TETS failures
- Provides power for implants from 6W – 12W (capable of up to 80W), suitable for VADs [5,6]
- Added methods for real time control of temperature based on the heat flux generated by the secondary coil



TETS System Diagram



VAD TETS Coils



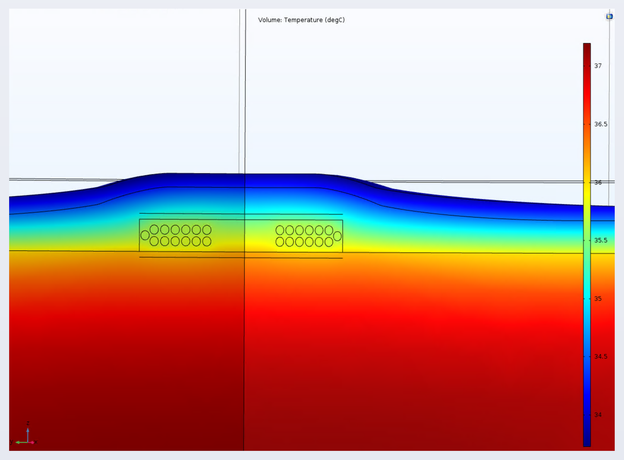
TETS Efficiency, Output Power, and Heat Flux

Performance Specifications	
Input supply voltage	12-15 VDC
Output voltage	18 VDC
Power delivered	0-12 W (Capable of up to 80 W)
Primary coil diameter	95 mm
Secondary coil	55 mm
Min. coil separation	0 mm
Max. coil separation	30mm

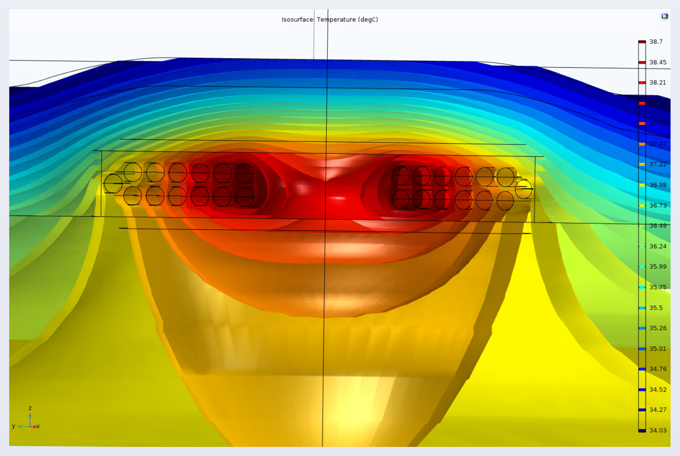
TETS Animal Study System

Finite Element Simulation

- Used to predict tissue heating in the sub-clavicular region
- TETS coil implanted under the skin
- Skin, subcutaneous fat, and muscle were incorporated into the model
- Perfusion characteristics and convective heat loss at skin included in the model
- Prediction of heat flux and temperature rise of surrounding tissue as power is transferred to the implant coil – heating occurs most significantly at the center of the implant coil
- Correlated to animal implant studies
- Can be used to explore design alternatives



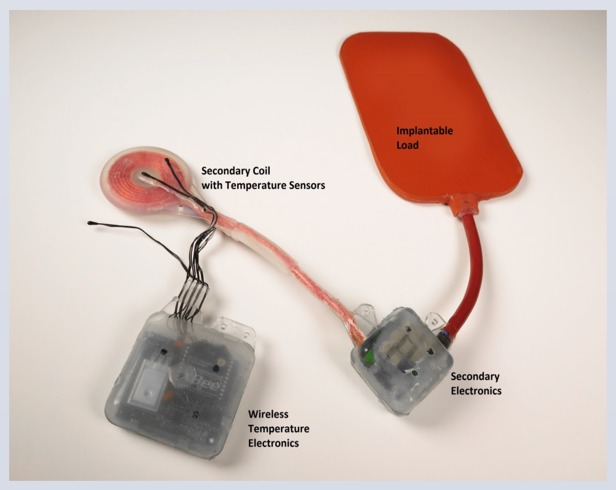
TETS Tissue Model : Baseline temperatures before current excitation in the coils



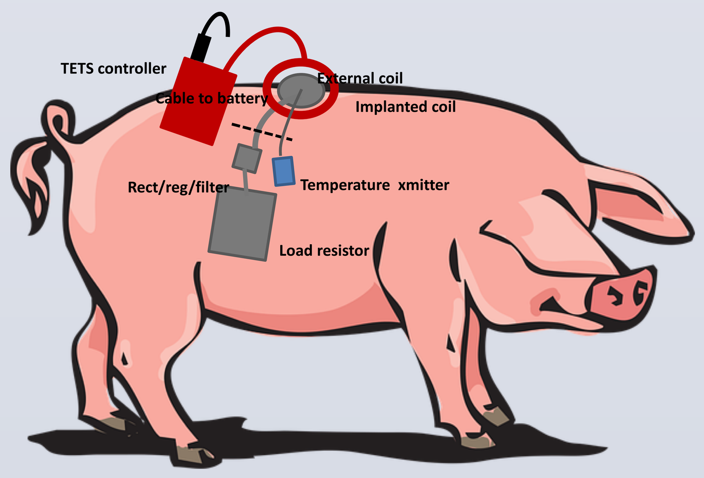
TETS Tissue Model: Coil and surrounding tissue temperature with 0.965A RMS current

Animal Study Design

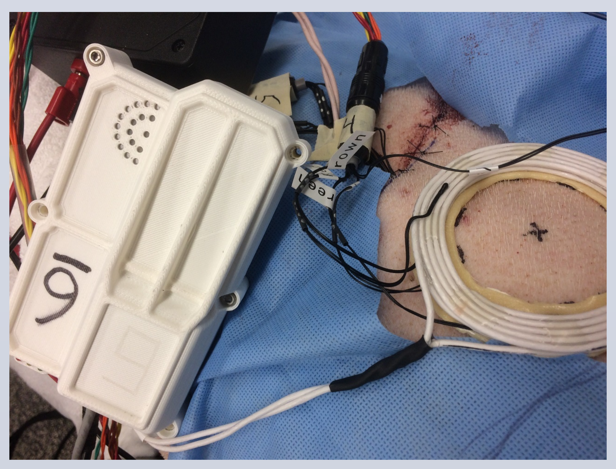
- TETS designed to correlate heat flux to tissue heating
- TETS coil designed for long term implant under the skin (size, location) based on market research studies [7]
- Secondary electronics designed for short term implant
- Implantable heat blanket used to simulate VAD load
- Temperature collection system using thermistors designed to collect real time data with temperature collected nearest to the coil on both the top and bottom (not shown) of the coil as well as in nearby tissue
- Temperature data communicated to external data collection system



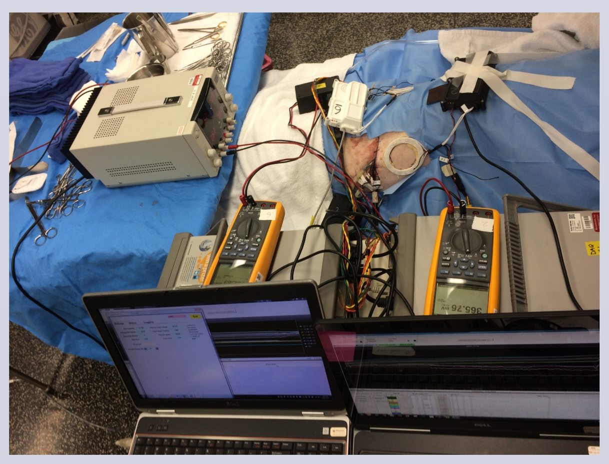
Coil, secondary, and load for animal studies, wireless temperature collection



Placement of components for *in-vivo* testing



Implanted system with external coil and controller



Implanted system with data collection system

In-Vivo Test Results

- Utilized a swine model as it provided a good proxy to shallow depth human implant
- Data collected across a range of parameters: Load (power transferred), heat flux, and frequency of signals used for transfer
- Method was used to vary the heat flux generated by the coil
- Temperature sampled frequently
- Temperature Data collected at 5 sample points
  - Center proximal to the coil, center distal to the coil
  - Offset proximal to the coil, offset distal to the coil
  - 5 cm from coil in nearby subcutaneous tissue
- Temperature collected from resistive load for comparison
- Completed 30 day biocompatibility study

Temperature Measurement Location	Frequency	Power (W)	Heat Flux (mW/cm²)
Implant Coil	1 Mhz	12	5.6, 6.1
Implant Coil	1 Mhz	6	5.8, 6.6, 7.4
Implant Coil	200 kHz	6	5.6, 8.3
Resistive Heater	n/a	n/a	6.4, 7.2, 8.2

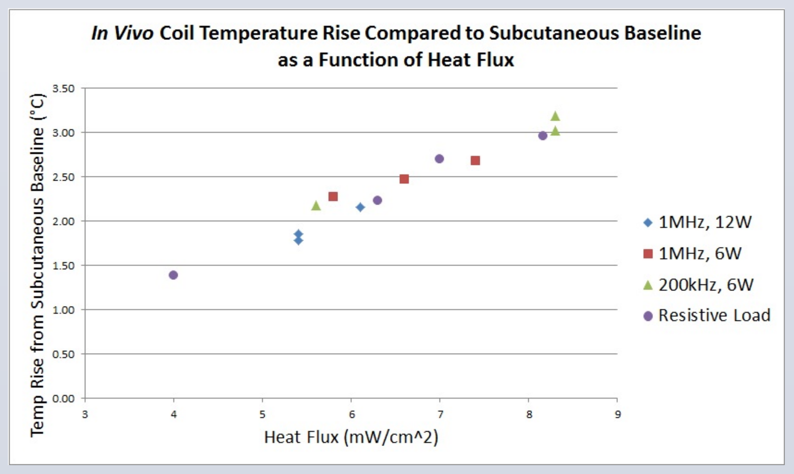
Summary of Test Parameters

No.	Tag	Breed	Surgery	Surg Weight	Days	Necr. Weight	Early Term	Powered	Description	Coil heat flux
1	2629	Yucatan	3/18/2015	NA		NA	acute	no	Acute fitting of electronics	n/a
2	2626	Yucatan	NA	NA		92 lbs	NA	no	Jacket fiting/adhesive testing	n/a
3		Yucatan	7/21/2015	NA	16	NA	yes	no	incision dehiscence, infection	6.7 @ 15mm
4	39115	Yucatan	7/21/2015	76 lbs	34	~85 lbs	yes	no	implant migration through incision, infection	5.7 @ 15mm
5	40017	Yucatan	8/4/2015	59 lbs	17	63 lbs	yes	no	incision dehiscence, infection, heat pad migration through incision	24.5 @ 15mm
6	40025	Yucatan	8/4/2016	59 lbs	20	66 lbs	yes	no	implant migrating through JP drain hole, infection	24 @ 15mm
7	7868	Yucatan	2/2/2016	57 lbs	42	66 lbs	yes	yes	Thermistor migration through skin, not related to incision	5.56 @ 15mm
8	7882	Yucatan	3/1/2016	57 lbs	37	64 lbs	yes	yes	Internal electronic failure	5.6 @ 15mm
9	9813	Hanford	5/12/2016	86 lbs	131		no	yes	Internal electronic failure/move to acute study	16.5 @ 15mm
10	2186	Hanford	6/7/2016	79 lbs	104		no	yes	Internal electronic failure/move to acute study	16.3 @ 15mm
11	9807	Hanford	6/8/2016	83 lbs	90		no	yes	Internal electronic failure/move to acute study	17.9 @ 15mm
12	203	Hanford	2/16/2017	79 lbs	NA		acute	no	acute temperature study	varied
13	260	Hanford	2/21/2017	92 lbs	NA		acute	no	acute temperature study	varied
14	243	Hanford	3/7/2017	99 lbs	NA		acute	no	acute temperature study	varied

Completed Animal Studies

Results

- Linear correlation between heat flux and tissue temperature rise
- Independent of frequency of signal used for power transfer from 200 kHz to 1 MHz
- Independent of load power from 6-12W
- Temperatures on the implant increased from 1.4°C to 3.2°C from 4 to 8.5 mW/cm² for implants just below the skin
- Heat flux of 5.5 mW/cm² correlates to 2°C tissue temperature rise much lower than for deep implants
- Absolute tissue temperature rise during power transfer ranged from 37.6 to 39.5°C at the implant coil
- Determined that the coil packaging did not cause biocompatibility issues in a chronic 30 day study based on histology results.



Temperature Rise as a Function of Heat Flux

References

[1] C. Davies, “Adaptation of tissue to a chronic heat load”, ASAIO Journal 40(3)., 1994
[2] D. Prutchi, “Analysis of Temperature Increase at the Device/Tissue Interface for Implantable Medical Devices Dissipating Endogenous Heat”,Impulse Dynamics, 2013
[3] Bossetti, Chad. Design and evaluation of a transcutaneous energy transfer system. Diss. Duke University, 2009
[4] L. Lucke, V. Bluvshtein, "Safety Considerations for Wireless Delivery of Continuous Power to Implanted Medical Devices", IEEE EMBC Conference, Aug. 2014
[5] V.Bluvshtein, L.E. Lucke, W.J. Weiss, "Wireless Power Transmission for Ventricular Assist Devices", ASAIO Annual Conference, June 2013
[6] L. Lucke, J. Mondry, S. Scott, W. Weiss, "A Totally Implantable Controller for Use with Rotary LVADs", June 2014
[7] L. Lucke, V. Bluvshtein, M. Stoll, W. Weiss, "User Studies and The Design of a Completely Implantable VAD System", ASAIO Annual Conference, June 2015

Disclosures

Minnetronix SBIR grants with Penn State were used to develop TETS system

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