Safe Temperature Limits in Wireless Power Transfer for Ventricular Assist Devices

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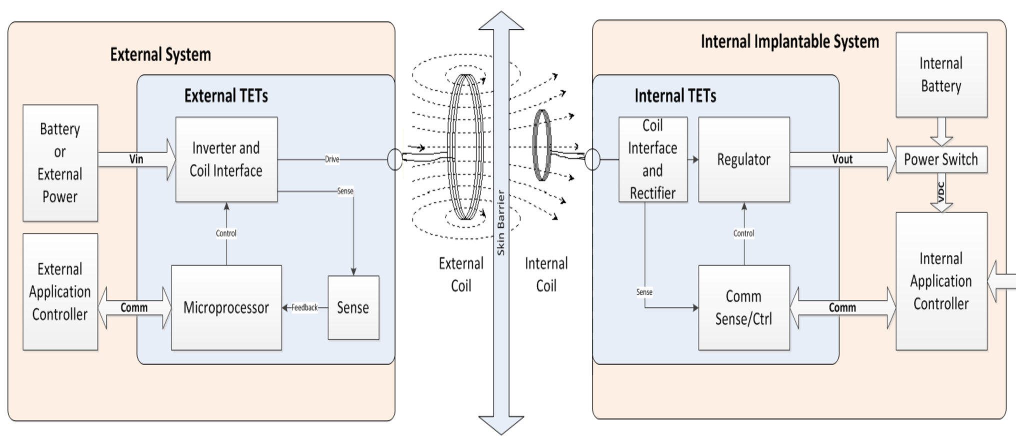
Introduction

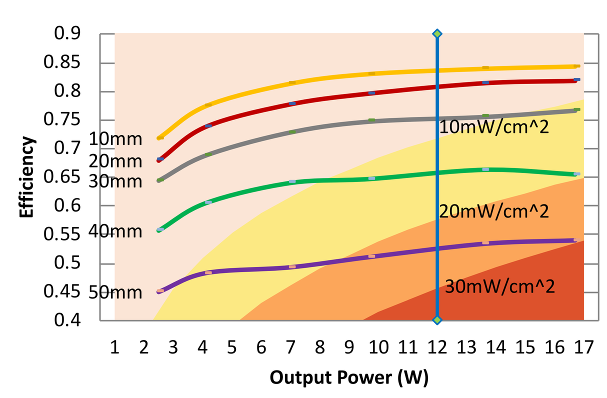
- Ventricular assist devices (VADs) require a percutaneous driveline
- TETS reduces risk of infection however, tissue heating must be managed
- Previous studies correlated power loss, (heat flux) to tissue heating with deep implants [1,2,3]
- An *in vivo* swine model was used to correlate heat flux with tissue heating for shallow implant (just under the skin)
- Power and drive frequencies were varied to determine the impact to tissue heating.

TETS System Design

- Consists of Primary (external electronics, coil) and Secondary (Implant coil and implant electronics)
- Provides power for implants from 6W – 12W (capable of up to 80W), suitable for LVADs [4,5]
- Designed for high efficiency



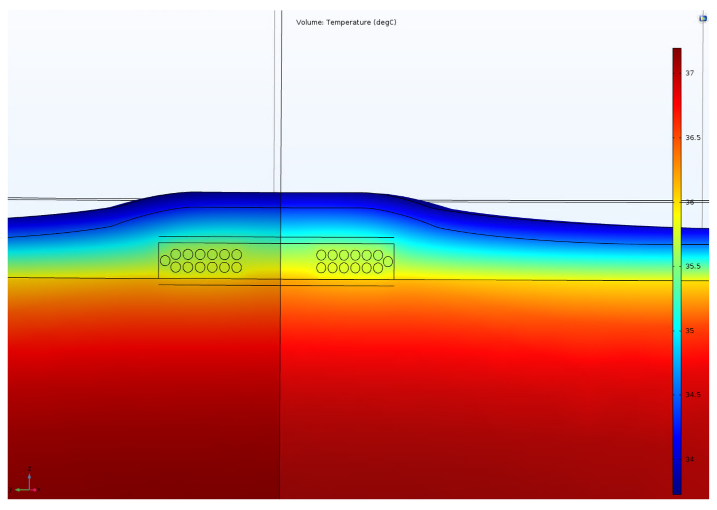
Transcutaneous Energy Transfer System – Wireless power through skin



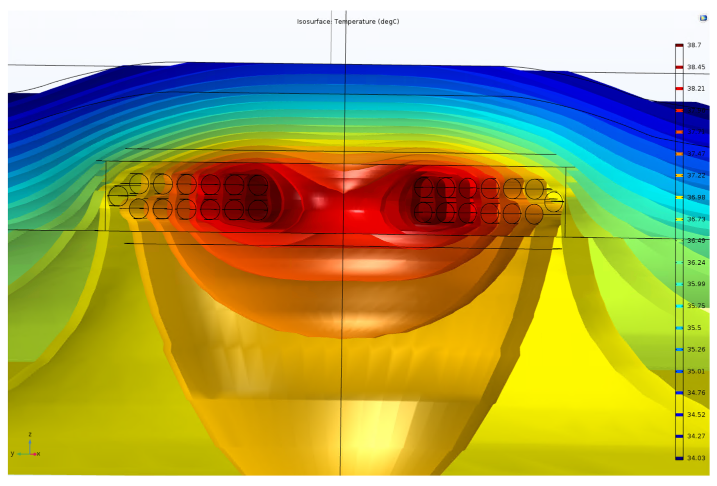
Efficiency vs Output power for varying coil spacing

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 nearest to the implant coil
- Correlated to animal implant studies



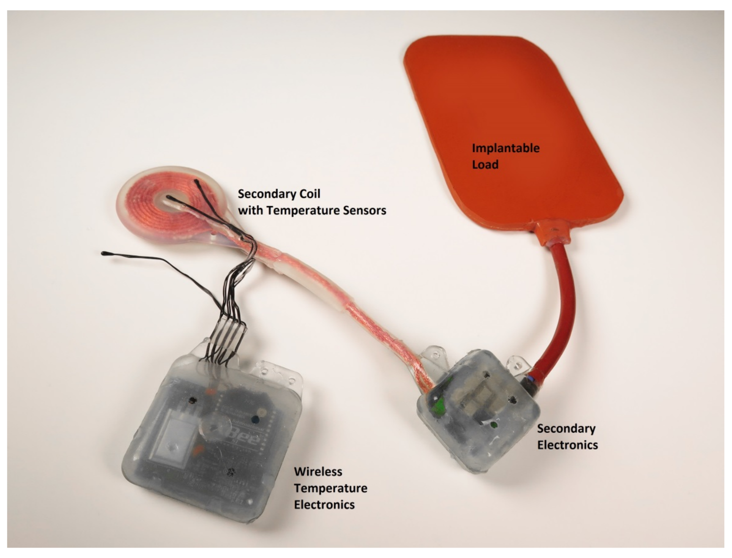
TETS Tissue Model : Baseline temperatures before current excitation in the coils



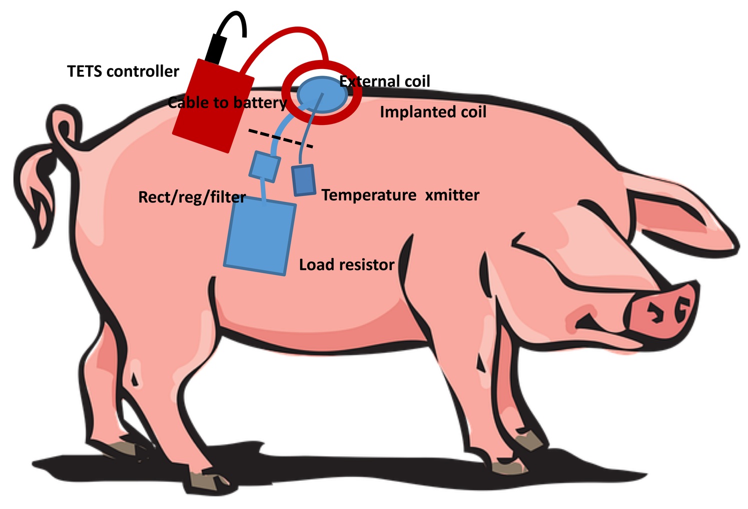
TETS Tissue Model: Coil and surrounding tissue temperature with 0.965A RMS current

System Designed for Animal Studies

- TETS system designed to correlate heat flux to tissue heating
- TETS coil designed for implant under the skin equivalent to human sizes [7]
- Secondary electronics potted for implant
- Implantable heat blanket used to simulate LVAD 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 wirelessly to external data collection system



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



Placement of components for *in-vivo* testing

Relevant Financial Relationship Disclosure Statement

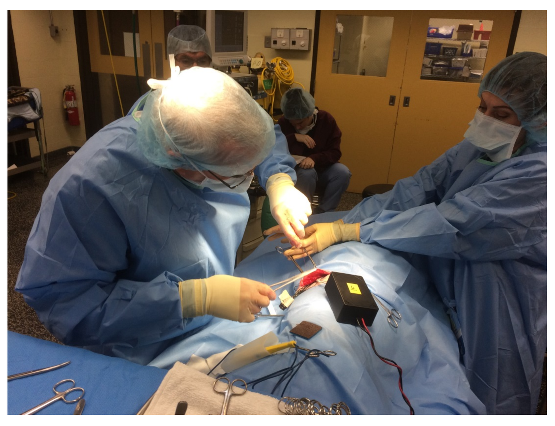
I will not discuss off label use and/or investigational use of any drugs/devices.

The following relevant financial relationships exist related to this presentation:

L. Lucke: Minnetronix, Inc.; Employee. **A. Bartnik:** Minnetronix, Inc.; Employee. **W. Weiss:** Penn State Hershey Medical Center; Employee. **B. Doxtater**: Penn State Hershey Medical Center; Employee. **J. Reibson:** Penn State Hershey Medical Center; Employee. **A. McCabe:** Minnetronix, Inc.; Employee

In-vivo Testing

- 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



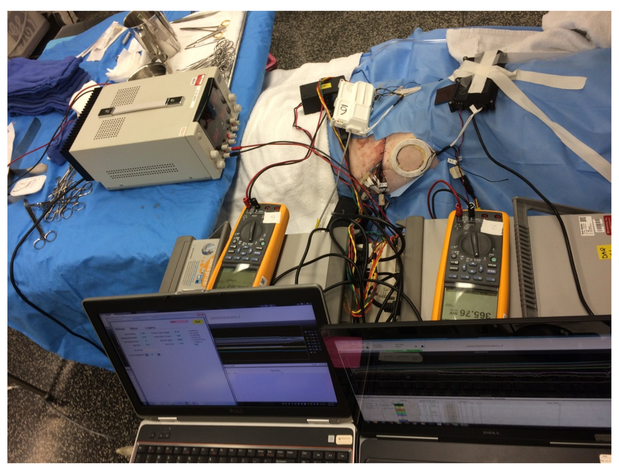
In-vivo implantation

Temperatures Measured	Frequency	Power (W)	Heat Flux (mW/cm^2)
Implant Coil	1MHz	12	5.6, 6.1
Implant Coil	1MHz	6	5.8, 6.6, 7.4
Implant Coil	200kHz	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

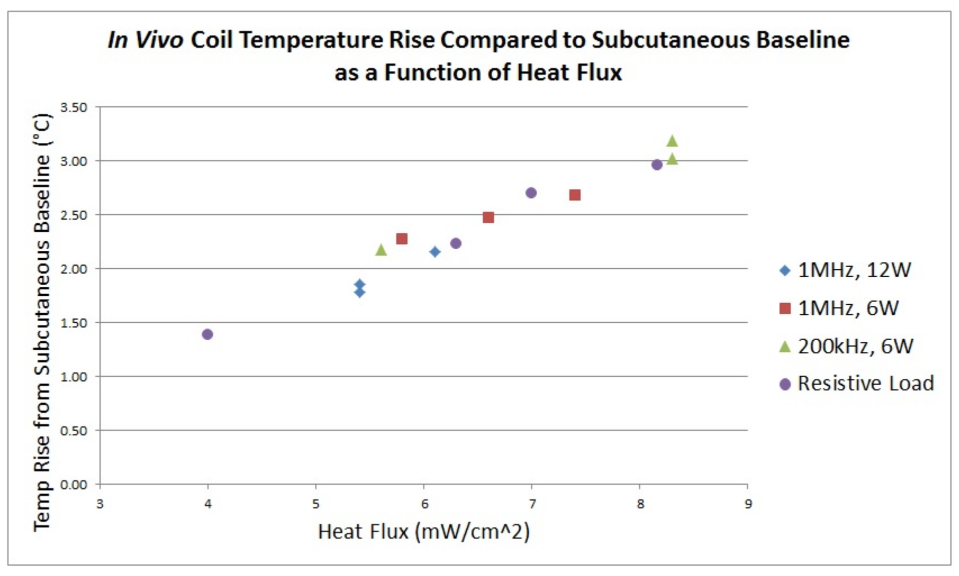
Animal Study Summary



In-vivo temperature data collection

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/cm^2 for implants just below the skin
- 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



Temperature Rise vs. Heat Flux

Conclusion

- Heat flux necessary to heat tissue for implants just under the skin much lower than previously published studies for deep implants.
- Developed a model for simulation for tissue heating
- Heat flux of 5.5mW/cm^2 correlates to 2°C tissue temperature rise
- Coil heat flux, specifically I2R heating across the surface of the coil, is the primary contributor to tissue heating, where I is the RMS current through the implant coil and R is the coil impedance at the drive frequency
- Negligible heating from secondary concerns such as frequency of signal [6] or amount of power transferred
- Power sufficient for LVADs can be transferred using TETS system when heat flux is limited to safe levels.

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
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[6] L. Lucke, V. Bluvshtein, "Safety Considerations for Wireless Delivery fo Continuous Power to Implanted Medical Devices", IEEE EMBC Conference, Aug. 2014
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