Safety Considerations for Wireless Delivery of Continuous Power to Implanted Medical Devices

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Abstract— **Wireless power systems for use with implants are referred to as transcutaneous energy transmission systems (TETS) and consist of an implanted secondary coil and an external primary coil along with supporting electronics. A TETS system could be used to power ventricular assist systems and eliminate driveline infections. There are both direct and indirect safety concerns that must be addressed when continuously transferring power through the skin. Direct safety concerns include thermal tissue damage caused by exposure to the electromagnetic fields, coil heating effects, and potential unwanted nerve stimulation. Indirect concerns are those caused by potential interference of the TETS system with other implanted devices. Wireless power systems are trending towards higher frequency operation. Understanding the limits for safe operation of a TETS system across a range of frequencies is important. A low frequency and a high frequency implementation are simulated to demonstrate the impact of this trend for a VAD application.**

I. INTRODUCTION

Over 5000 patients are living with ventricular assist devices (VADs) [1] which require a driveline cable through the skin. Driveline infections have been a constant area of concern especially as quality of life problems have become more prominent with VAD patients [2, 3]. To eliminate the percutaneous cable, a wireless power transfer system through the skin, referred to as a transcutaneous energy transmission system (TETS) is necessary. A TETS based total implantable system has been demonstrated to be effective for the pulsatile LionHeart VAD [4, 5].

Wireless power transfer implementations have also been evolving for the consumer market with multiple emerging standards [6, 7]. To take advantage of the new technology it is important to understand the safety issues associated with continuously powering an implantable device such as a VAD. Unlike commercial wireless power transfer systems, a TETS system for a VAD must be used by the patient perpetually. Few electronic systems have been implemented for constant power delivery into a patient. This paper will focus on direct and indirect safety risks impacted by the operation of the TETS system. Direct risks include acute and chronic tissue damage, as well as nerve and or muscle stimulation. Indirect concerns include TETS system interference with other implanted medical devices. This includes signal interference as well as potential heating concerns caused by the metal within the implanted device.

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TETS systems have been studied regarding direct injuries from tissue heating [8]. Exposure limits have also been considered for commercial wireless power transfer systems [9, 10]. Relatively little work has been done on the indirect safety risks of TETS systems.

The two primary implementations for wireless power transfer systems for commercial applications include inductive resonant systems and inductive highly resonant systems with at least two standards emerging. The earliest inductive resonant wireless power transfer standard is the Qi standard [6]. The original standard supports 100-205 kHz systems at 5W. The earliest inductive highly resonant standard was the A4WP standard which supported systems operating at 6.78 MHz [7]. The inductive highly resonant systems generally require higher frequencies to operate effectively. Updates to these standards are proposing support for the 13.5 MHz transmission band as a means to more efficiently transmit power.

The move to higher frequencies may not be as advantageous for a TETS systems used with an implantable VAD because of the indirect and direct safety issues. In this paper we review the standards for direct and indirect safety risks associated with TETS systems. We demonstrate potential issues with the different wireless power transfer implementations

II. TETS OPERATION

In a TETS system alternating current in a primary coil generates a magnetic field that induces an alternating field in a secondary coil to transfer the power. The ratio between captured magnetic flux by the secondary coil and flux generated by the primary coil is called the coupling factor. Typical coupling factors for TETS systems range from 5-30%. These low coupling factors indicate that large fields and high magnetic flux intensity are needed to transfer the power even over relatively small distances. Due to these factors, it is important to understand the electrical and magnetic field limits for safe operation with high magnetic flux intensities.

A TETS system can cause direct thermal tissue damage from coil heating due to power losses in the coils or by exposure to the electromagnetic fields. Both magnetic and electrical fields (H-fields and E-fields) are generated in a TETS system. Since a TETS system operates as a loop antenna, the generated E-fields are small and are mostly shielded by the body [11]. As such, radiated electric fields will not be considered further although induced electric fields must still be considered as a potential source of heating.

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It is important to understand how magnetic fields interact with the human body. Human tissue is non-magnetic. This means that the magnetic field radiation pattern is not altered as it encounters tissue and can penetrate deep in the body without direct attenuation. On the other hand, tissue is conductive. Because an alternating magnetic field can induce current in a conductor, the coils in a TETS system can generate local eddy currents which can interact with tissue. The induced current density increases with frequency. At low frequencies (<100 kHz) the body appears transparent to magnetic fields and at high frequencies (>10MHz) magnetic fields are attenuated by the body [12].

The magnetic fields that interact with tissue can cause either unwanted stimulation or thermal heating. At frequencies below 100 kHz, induced currents at thresholds greater than 100 to 1000 mA/m^2 can directly cause nerve and/or muscle stimulation to occur [12]. This effect is reduced as the frequency is increased until it can be ignored for frequencies above 5-10 MHz. As frequencies increase, the current density increases causing an induced field that can cause thermal heating. Another source of thermal tissue damage is heat transfer from the inductive coil itself. As coil current and frequency go up, resistive losses increase.

The magnetic fields in a TETS system, whether implemented with an inductive resonant or inductive highly resonant system can be significant near the coils or between the coils as shown in Figure 1.

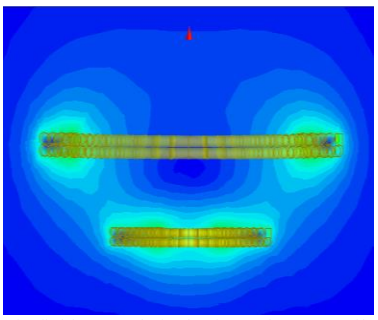


Figure 1: Magnetic field strength for horizontal TETS coils separated by 3 cm, higher strength field represented by lighter color

The characterization of the strength of the magnetic field is roughly dependent on the distance, d, from the primary coil, and the frequency, f, of operation. A TETS system operates in near field conditions because the frequency of operation relative to coil geometry is low. The decay of the magnetic field in this region is proportional to $1/d^3$ [13]. The close proximity of tissue to coils in a TETS system can cause exposure to large magnetic fields and the corresponding induced electric fields.

Although the magnetic fields are most intense near the coils, they are still prevalent at some distance from the coils. These fields can cause indirect safety risks by coupling to other implanted devices. The magnetic fields interact with implanted devices via both non-thermal and thermal mechanisms. Nearby implantable medical devices (IMDs), and their conductive leads, could be susceptible to induced signals caused by coupling to the time varying magnetic field and the induced eddy currents. As a result, thermal tissue damage can occur from a nearby IMD which experiences inductive heating. The induced currents can also cause improper operation of the IMD.

The magnetic field effects are summarized in Table 1.

Thermal	Non-Thermal
Direct tissue heating	Nerve/muscle stimulation
Coil resistive losses	'Noise' injection in IMD
Inductive heating of IMD	Suppressed or unexpected operation of IMD

Table 1: Summary of Magnetic Field Effects

III. Established Limits

Direct safety risks are covered in several design standards. Human exposure to electromagnetic fields is addressed in standards that impact tissue heating and nerve stimulation. These standards vary between the United States (US) and the European Union (EU). In the US, human exposure guidelines are published by ANSI/IEEE C95 [14]. In the EU, ICNIRP publishes the guidelines [15]. Exposure limits are listed based on occupational and general public exposure. Guidelines for the general population apply stricter limits that are more appropriate for a TETS system. These limits are summarized by Christ et al. [10].

Basic restriction limits in the standards are written in terms of specific absorption rate (SAR) and induced electric field. Thermal limits can be framed in terms of SAR. SAR considers the basal metabolic rate of a human to be 1W/kg. If the body is exposed to larger rates of heat transfer than the basic metabolic rate, thermal tissue damage can occur [16]. Muscle and nerve stimulation thresholds in the standards have been determined using induced electric field limits. The stimulation thresholds are only applicable below approximately 5-10 MHz. These thresholds are meant to avoid identified minor and short-lived effects on the central nervous system. At the higher frequencies, the SAR levels are the appropriate levels to measure. The standards also supply reference levels; however, these reference levels can lead to overly conservative results [10].

The indirect safety risks are mitigated by understanding the compliance standards for IMDs. Implanted device susceptibility limits are based on biological exposure guidelines for the general public, i.e. IMDs have to endure at least the same amount of exposure as the human body. Therefore, if the TETS system emissions are lower than the IMD immunity levels; it can be assumed that the TETS system can be successfully used in conjunction with the IMD. In the US, exposure limits are contained in ANSI/AAMI ISO 14117 [17] or ISO 14708 [18]. In the EU, a family of standards covers different types of devices. These include EN45502 and the ISO 14708 series [18, 19]. At the most stringent test level, the IMD is expected to work as intended with no loss of function. If the IMD does not have leads, then only inductive heating is considered and average limits should be used. If the IMD has leads, then both thermal effects (average limits) and induced current (peak limits) effects should be considered. The standards and thresholds are summarized in Tables 2 and 3.

IMD	U.S. FDA (AAMI)	EU AIMDD (EN)	Int'l ISO
General	--	45502-1	14708-1
Cardiac Pacemakers	14117	45502-2-1	14708-2
Cardiac Defibrillators	--	45502-2-2	14708-6
Circulatory Support	--	--	14708-5
Neuro stimulators	--	--	14708-3
Infusion Pumps	14708-4	--	14708-4

Table 2: IMD Standards

IMD	U.S. FDA H-field A/m rms	EU AIMDD H-field A/m rms	Int'l H-field A/m rms
General	--	15000/f	15000/f
Cardiac Pacemakers	15000/f	15000/f	15000/f
Cardiac Defibrillators	--	15000/f	15000/f
Circulatory Support	--	--	15000/f
Neuro stimulators	--	--	1590/f (A) 15900/f (B)
Infusion Pumps	1590/f (A) 15900/f (B)	1590/f (A) 15900/f (B)	1590/f (A) 15900/f (B)

Note: f = 100 kHz – 30,000 kHz
A-level: Exposure is probable, frequent, and unavoidable. Operation is expected to be normal.
B-level: Exposure is possible, infrequent and for short duration. Operation is free from damage and unacceptable risk.

Table 3: IMD H-field Limits

In addition, European Standard EN45502-1 limits surface temperature of an implanted device to 2°C above the body temperature of 37°C [19], although there are no sanctioned assessment or measurement methods. Correlation between dissipated power and tissue temperature rise is complicated and depends on factors like implant region (good or poor circulation) and implant size. Simplified design methods have been derived from animal studies and rely on heat flux calculations set by observed animal trial results [20, 21].

IV. Methods and Results

The frequency of operation of a TETS system may have an impact on the ability to manage the direct and indirect safety risks, particularly for the high power transfer needed by VADs. Previous work analyzed direct safety risks [22]. In this paper a high frequency and a low frequency TETS system are compared for the direct and indirect safety risks as defined by the limits in the standards.

Current VADs require power transfer of up to 20 W. Two TETS system finite element models were set up to transfer 20 W of power with an input voltage of 15V and output voltage of 18V. The first system ran at 650 kHz and had a voltage source topology, which creates worst case coil current at lowest coupling or furthest separation of the coils. The second system ran at 13.5MHz and had a current source topology, which creates worst case coil current at highest coupling or when coils are close together. Both systems used identical coils with a primary inductance of 8 uH and a secondary inductance of 5.5 uH. At 650 kHz, the coils resistance measured 79 mOhms and the system had a Q of 300. For the 13.5 MHz system, the resistance was reduced to 1.3 ohms to ensure a Q of 350 which was similar to the 650 kHz example. The worst case current in the primary and secondary coils is shown in Table 4.

Simulated System	Primary Current (A)	Secondary Current (A)	Coil Spacing (cm)
650 kHz	5.2	4.4	2
13.5 MHz	0.7	1.1	0

Table 4: Primary and Secondary Currents

The external coil outer diameter was set to 82mm and the internal coil outer diameter was set to 44mm. The maximum coil spacing was set to 20mm. The implanted coil was encapsulated between a simplified tissue model consisting of 2 mm of skin and the following stack: 10 mm of muscle, 10 mm of bone, and 30 mm of lung tissue as shown in Figure 2. Although not a complete human body model, it was sufficient for test purposes as the field energies are concentrated between the coils. The 650 kHz system was built and tested using the CardioMan device to verify the models field strength measurements [22].

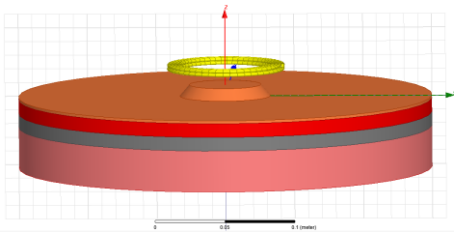


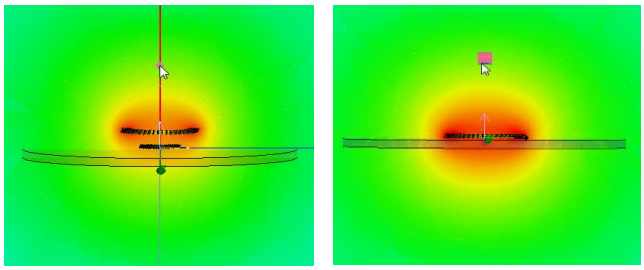
Figure 2: Finite element model for TETS simulation

The direct safety risks can be measured in terms of induced E-field and SAR. The E-field and SAR were determined using the finite element models. The SAR measurements were localized over 10g. The E-field limits are only applicable for the 650 kHz model. For frequencies over 10 MHz, only the SAR is considered as no electrical stimulation occurs at this frequency. The results are shown in Table 5. It is clear that the higher frequency design is significantly over the SAR limit.

Simulated System	ICNIRP 2010 E-Field Limit	Measured E-field Result	IEEE 2005 SAR Limit	Measured SAR Result
650 kHz	83 Vrms/m	32 Vrms/m	2 W/kg	0.2 W/kg
13.5 Mhz	n/a	n/a	2 W/kg	16 W/kg

Table 5: E-field and SAR Results

The indirect safety risks are dependent on the H-field emission and the H-field results are dependent on the distance of the coils from the IMD. It is necessary to simulate the H-fields and determine the distance from the coils until the H-fields reach the acceptable levels. The simulations for the H-fields are shown in Figure 3. Nearest the coils, the H-fields violate the limits in the standards. The 'safe' distance for each example is summarized in Table 6 and shown in Figure 4. For the H-field limits, ISO 14708-3 was chosen as a representative standard for comparison. The B-level limits in this standard are very close to limits in the general ISO 14708-1 standard. In this example, the higher frequency design requires more separation.



(a) (b)

Figure 3: H-field simulation for (a) 650 kHz and (b) 13.5 MHz

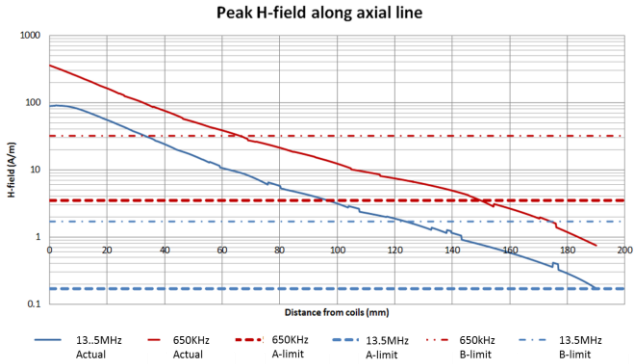


Figure 4: H-field Results for both models.

H-Field Limits	Applicable Standard	650 kHz Safe Distance(mm)	13.5Mhz Safe Distance(mm)
A-level	ISO14708-3	140	190
B-level	ISO14708-3	68	116

Table 6: H-field Results

It is difficult to predict the temperature rise of the coil although it is possible to measure the heat flux from each example. The effective resistance at frequency for each coil can be measured. Combining this measurement with the current in the coils from Table 4 and knowing the surface area of the coils, the heat flux can be estimated as shown in Table 7. Combining the heat flux results with the SAR results can be used as an indicator for the temperature rise of the tissue. The LionHeart system demonstrated no known coil heating issues [5]. The higher heat flux and much larger SAR generated by the high frequency implementation are an indication of a thermal safety risk.

Model	Resistance Secondary	Surface Area	Heat Flux Secondary
650 kHz	0.079 ohm	35.3 cm^2	9.4 mW/cm^2
13.5 MHz	1.3 ohm	35.3 cm^2	22.3 mW/cm^2

Table 7: Heat Flux Results

The LionHeart system demonstrated that coils could be built using stranded wire to meet the simulated resistance levels for the lower frequency systems. For the higher frequency systems, the coils proposed by this example generally need to be built as copper strips as shown in [23], thus requiring more complex implant packaging.

V. Summary

New wireless power technology uses increasingly higher frequency levels which may prove challenging for a TETS system designed for continuous delivery of power for VADS. In this paper, two TETS systems were compared for a continuous power delivery system suitable for a VAD implantable. The higher frequency system did not meet the SAR limits and requires a larger separation from other implanted devices for safe operation. The higher frequency system also generates more than twice the heat flux. The lower frequency system met the required limits. As wireless power transfer systems continue to evolve for the commercial environment, they will have to be carefully evaluated for powering implanted medical devices.

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