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Charging Current Characteristics and Effect of Casing Material in Wireless Recharging of Active Implantable Medical Devices Using Transcutaneous Energy Transfer System

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ABSTRACT: Batteries inside an active implantable medical device (AIMD) need to be replaced every few years. However, rechargeable batteries can enhance the life of such devices to a large extent. Transcutaneous Energy Transfer System (TETS) is a promising method for recharging these batteries inside medical devices. These devices are generally made of metal casings to avoid fluid ingress and provide better mechanical strength. However, the metal cases when being present in the path of electromagnetic energy induces eddy current thus producing excessive temperature rise due to thermal loss. Thus, the selection of an interface casing material plays a significant role in the performance of the wireless recharging. In this paper, the performance of a transcutaneous energy transfer system for recharging an AIMD with different axial gaps and casing materials is reported. The effect of these variations on the output voltage, recharge current, and efficiency of operation was quantified. It has been found that, with TETS the charging current of 0.3 A to 0.5 A can be obtained to charge the implanted battery within 180 minutes. It was found that the induced voltage in the secondary coil is substantially reduced with the presence of titanium casing compared to epoxy encapsulation. Thermal studies were performed with titanium casing material of various thicknesses. The casing temperature rose to above 70°C within the first 10 minutes for 0.5 mm thickness and within 50 minutes in the case of 0.25 mm. With epoxy encapsulation, the casing temperature rose to only 30°C. The charging voltage of 5 V and charging current of more than 0.3 A were obtained with epoxy encapsulation. A polymeric material casing or epoxy encapsulation is the best choice in the interface region to get a high recharging current in the case of wireless recharging of implantable medical devices. With the proposed design modification, wireless energy transfer and recharging implanted batteries shall be done in a more energy-efficient manner with less thermal damage to nearby tissues.

1. INTRODUCTION

Active implantable medical devices (AIMDs) such as implantable infusion pumps, defibrillators, and pacemakers need medical-grade batteries for their continuous operation [1]. The life of these devices is primarily depending on the durability of the batteries used. Primary cells with lithium ion and lithium polymer chemistry having high power density, stability, and longevity are used for powering these devices [1, 3]. The life of these devices is now more than five to six years thanks to the advancements in chemical technology [5]. However, for life-saving medical devices, the replacement of batteries remains a challenge and discomfort to the patients [1, 4, 5, 29]. Introducing suitable technical solutions for improving the longevity of medical batteries remains an unmet clinical need.

Recently, rechargeable batteries are slowly taking over the primary cells in every field of technology [2, 3]. Much research has focused on energy generation by using physical, chemical, mechanical, and electrical phenomena of the inner body to resolve the energy issue of implantable devices. A technique of transfer of energy by ultrasound generated by a 64-channel high-voltage driver is discussed in [6]. However, the transmitted power using ultrasound so far is insufficient for driving the existing IMDs. Moreover, the size of the receiving transducer is large, which is not suitable for implantation. A method of combining focused ultrasound with a miniaturized 1–3 piezoelectric composite receiving transducer to produce higher electrical power was discussed in [32]. An output power of 60 mW at a distance of 150 mm is obtained with this technique. The application of glucose as a catalyst to oxidize noble metals or carbon was provided in [7]. In another technique, light was used for the transfer of energy across the skin [8]. Light impinges on a photovoltaic device through an optical fiber going from the photovoltaic device to just beneath the patient's epidermis. A photovoltaic converter inside the implantable device provides a small electric potential for powering the device. A design of capacitive wireless charging (CWC) for implantable medical devices using a film-type electrode is provided in [30] in which the energy is passed through the tissue dielectric kept between two thin film electrodes. Experiments show that up to 43.5% of the energy can be transferred at 308 MHz with 70 mW input energy.

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However, these energy transferring and harvesting methods could produce very low instant energy output levels, which has restricted them from being used as a direct energy source. Recharging the internal batteries through wireless energy transfer adds benefit to its usage [9]. Recharging an inbuilt battery in a consumer product is a straightaway solution as the battery terminals can be assessed and connected to a wall electrical socket through a proper charger or can be done with the modern wireless chargers. The problem becomes very tricky in the case of an implanted medical device, as neither any openings are available for battery assessment, nor providing a permanent charger through tissue is possible without the risk of infection. For medical devices such as ventricular assist device (VAD) and total artificial heart (TAH) a cable that connects to the implanted device is taken out through a small puncture in the skin and connected to the external controller and battery pack. From clinical trials, it is found that a major failure mode that limits the survival rate of patients implanted with the VAD was the infection due to these percutaneous wires [11, 12]. Transcutaneous energy transfer system (TETS) shows a promising solution in this scenario, where a battery within an implanted medical device can be recharged across skin and tissue of varying thickness [10]. TETS system consists of a transmitter coil and a receiver coil tuned to operate at a resonant frequency [13, 14]. The receiver coils are usually embedded within the medical device and are connected to a high-frequency rectifier. The rectified DC voltage is amplified and connected to a single lithium-ion battery for recharging. As described in [15, 16], wireless recharging shall be utilized to recharge the battery and increase the life expectancy of the device to more than 10 years.

In [26], the authors have proposed a low-frequency wireless power transfer technology (LF-WPTT) using rotating rare-earth permanent magnets. The LF-WPTT was able to deliver 2.967 W power at a 117.1 Ω resistor over a 1 cm distance with 50% overall efficiency. In [27], a wireless battery recharging circuitry developed for an implantable pressure sensor is presented which consists of an RF/DC rectifier, voltage limiter, and constant-current battery charger with 150-mV end-of-charge hysteresis. Wireless recharging tests confirmed that a constant recharging rate of 200 μA could be sustained at implant depths up to 20 cm, but with low power transfer efficiency $<$ 0.1% due to small implant coil size. Another wireless recharging system [28], for implantable bladder pressure chronic monitoring application consists of an external 6-turn 15-cm-diameter powering coil and a silicone-encapsulated implantable 18-turn spiral coil with a dimension of 7 mm $\times$ 17 mm $\times$ 2.5 mm, which encloses a 3-mm-diameter 12-mm-long rechargeable battery, two ferrite rods, an Application Specific Integrated Circuit (ASIC), and a tuning capacitor. Analyses and experiments demonstrate that with the two coils aligned coaxially or with a tilting angle of 30° and 6 cm offset in coils axes, an external power of 3.5 W and 10 W is required, respectively, to achieve a large coupling distance of 20 cm at an optimal frequency of 3 MHz. A recently developed Qi energy transfer system is deployed in [35], in which a novel Qi smart charger compatible with WPC-compliant power transmitters was presented. The proposed charger contains a microcontroller and a Bluetooth low-energy transceiver for real-time supervision and control of the system with smartphones, computers, or tablets.

The electrical power needed by lifesaving medical devices such as VADs and TAH are in the range of 5 to 30 W continuously [17, 18]. In such situations, TETS shall be operated to power the device continuously rather than recharging the battery intermittently. Many researchers have reported the design and development of TETS for high-power medical devices where continuous delivery of electrical energy occurs [14–16, 19]. The characteristics of the system such as voltage gain, efficiency, load variations, and coil separation were given in [15, 16, 33]. The coils were kept near the abdomen and were encapsulated in medical-grade epoxy. The studies were primarily focused on the effect of distance between coils [34].

However, for low-power active implantable medical devices (AIMDs), the power less than 1 W is required where the battery recharging at an interval of a few days is preferred [9, 31]. The recharging happens only for a few hours and is repeated at regular intervals. For low-power medical devices, with intermittent battery recharging, the performance of the TETS was not fully studied. Unlike Left Ventricular Assist Device (LVAD) and TAH, low-power medical devices are self-contained single units with the electronics and battery encapsulated in a metallic casing. The presence of metallic casings seriously affects the output voltage generated within the secondary coil due to the shielding effect [20]. The presence of metal in the path of electromagnetic waves creates eddy currents. The eddy currents produce excessive heat and increase the temperature of the device beyond acceptable limits [21, 22]. This excessive heat needs to dissipate through the tissue without any damage. Hence, a proper selection of the casing material and its thickness becomes an important part of the TETS design process for low-power implantable medical devices. The effects of various factors such as

a. Axial separation gap
b. Casing material

need to be studied in detail to develop a proper TETS design process for low-power battery recharging purposes.

In this paper, the performance of TETS for intermittent recharging of a battery inside an AIMD is provided. A 3.7 V, 1000 mAh lithium-ion battery inside an implantable medical device is considered for the study. Experiments are conducted on a test jig with various separations, tissue thickness, and casing material. Section 2 discusses the methodology employed in the study. Section 3 discusses various tests performed and their results. Section 4 discusses the results obtained through various experiments followed by the conclusion.

2. METHODOLOGY

In this paper, the recharging of a single battery suitable for an AIMD is chosen to demonstrate the effect of a transcutaneous energy transfer system. As shown in Fig. 1, the TETS consists of a transmitter coil and a receiver coil tuned to operate at a resonant frequency. The receiver coils are embedded within the medical device and are connected to a high-frequency rectifier. The rectified DC voltage is regulated and connected to

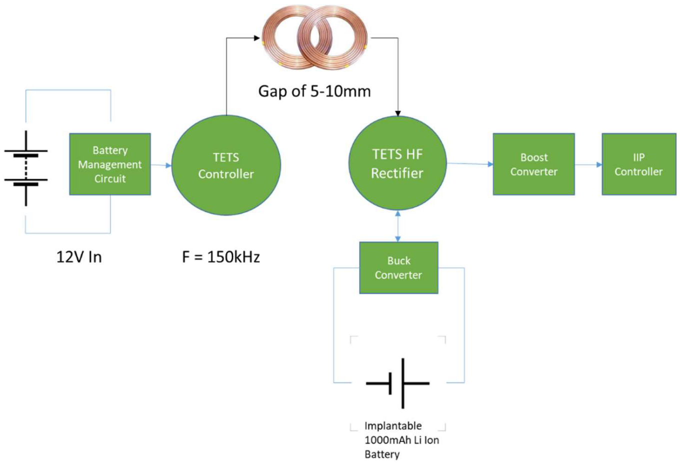

FIGURE 1. TETS configuration for AIMDs.

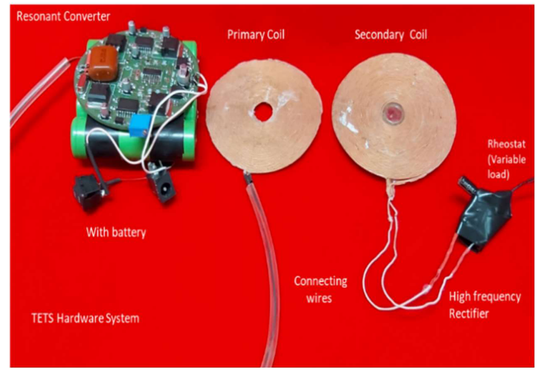

FIGURE 2. Fabricated TETS system suitable for an AIMD.

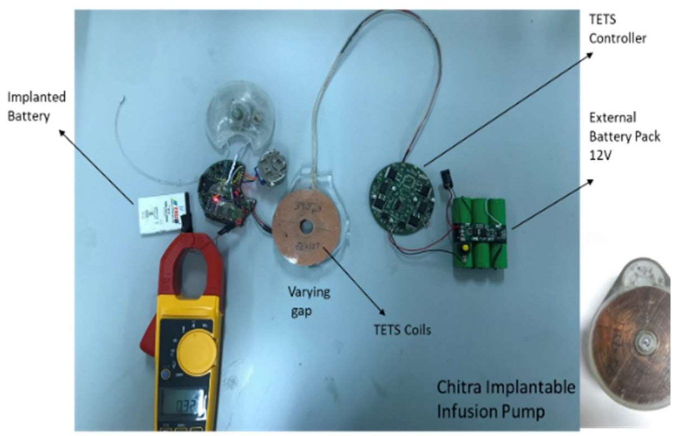

FIGURE 3. TETS circuitry is connected to a rechargeable lithium-ion battery.

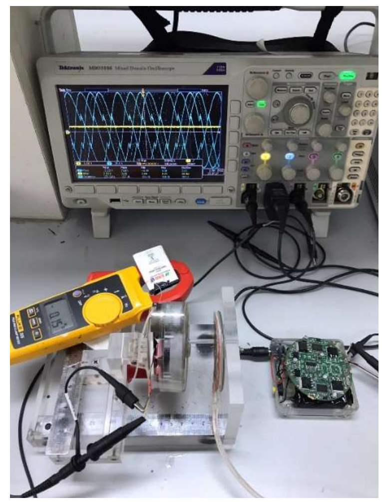

FIGURE 4. Test jig for measuring TETS performance.

a single Li-ion battery for recharging. AIMDs usually need a power of up to 1 W for its operation. A single Li-ion battery of 3.7 V, 1000 mAh with a charging interval of three to four days is preferred for most of the implanted medical devices. The transmitter circuit consists of a 12 V battery connected to a TETS controller and a primary side coil through a battery management circuitry. The battery pack can be recharged from household wall outlets using a common power adapter. The AIMDs are kept beneath the skin and tissues to a depth of a few millimeters. The primary coil and secondary coil are placed face to face across the skin while charging. The electrical power has to be transferred with good efficiency across the skin and tissues without overheating the tissues in between.

The fabricated electronic hardware for transferring the electrical power across the skin is shown in Fig. 2. It consists of a battery pack, a primary side full bridge resonant converter, a primary coil, a secondary coil, and a high-frequency rectifier [23]. The output of the high-frequency rectifier is connected to a 3.7 V, 1000 mAh lithium-ion battery through a battery charger module. The secondary coil is kept within the device casing.

The exploded image of the implantable device is shown in Fig. 3. The battery is connected to the device controller. For testing the TETS performance, the primary coil was kept over the secondary coil. A hall-based clamp on the current sensor Fluke 302+ with an accuracy of 1.8% of its measuring value was attached to the battery for measuring the charging current. Recharging voltage is measured using an industry standard Fluke 17B+ multimeter as shown in Fig. 3.

For studying the charging characteristics of the system, the TETS system is mounted over a test jig as shown in Fig. 4. The test jig has a fixed arm and a moving arm. The moving arm can change its position in the X direction and Y direction. The orientation of the arm can also be changed to different angles. The arms are graduated to measure the distance moved. The primary coil is mounted over the fixed arm, and the device with the embedded coil is kept in the movable arm. Experiments were conducted to understand the effect of axial gap and casing material of AIMD.

(a) (b) (c) (d)

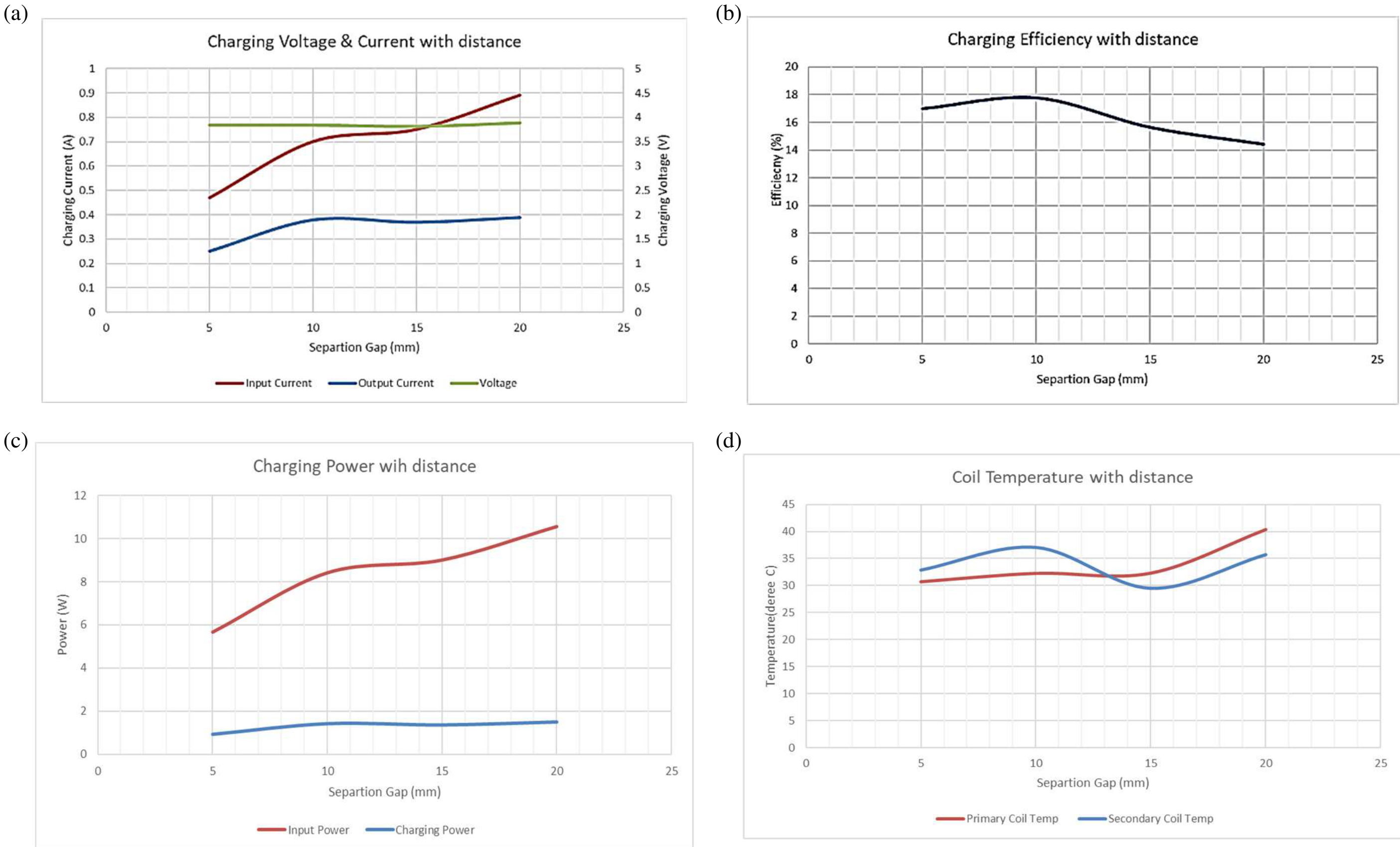

FIGURE 5. Effect of the axial gap on TETS performance, (a) charging voltage & current, (b) efficiency, (c) charging power, (d) coil temperature.

To understand the effect of the axial gap over the charging, the TETS was turned on after setting various gaps between the fixed arm and the movable arm. The frequency of operation of the TETS was adjusted to get the maximum charging current at each axial gap. The arm was adjusted to get the performance for separation in the range of 5 mm to 20 mm in steps of 5 mm. A thermal sensor PT100 thermal couple having an accuracy of $\pm 0.05°$C was attached to the coils to measure the temperature rise during charging. TETS was turned on, and parameters such as input voltage, input current, voltage across the input of the battery charger, battery charger output voltage, charging current, coil temperature, and time were noted down until the battery was fully charged. Input power, output power, and efficiency of TETS were calculated from the observed values.

AIMDs need to be encapsulated in a suitable material to prevent the ingress of liquids and prevent shock, vibration, acoustic energy, etc. ISO 14708 provides various guidelines for testing the mechanical integrity of the device. The device should be able to operate at different pressure conditions and should withstand drop from a height as well to get regulatory clearances. Due to its high strength and low weight, titanium is the preferred material for creating the casings for medical devices. However, when wireless recharging is employed, metallic enclosures will heat up due to eddy current formations. The eddy currents reduce the efficiency of the system drastically. In traditional electrical engineering practices, eddy current is reduced by providing thin laminations and stacking it thus introducing high resistance to current flow. Another strategy can be to use polymers [24, 25] as the casing material. Hence, identifying the influence of the casing material on the performance of TETS is very much required for selecting the material and its thickness for the use as a casing material for implantable devices.

In this experiment, the effect of casing material was studied for various thicknesses of titanium material, with medical-grade epoxy as the casing material. Casings of thickness varying from 250 micrometers to 500 micrometers were fabricated and tested.

3. RESULTS

3.1. Effect of Axial Gap

Experiments were conducted on two different prototypes, and average values are plotted in Fig. 5. Fig. 5(a) shows the variation of charging current, voltage in the battery, and the charging current drawn in the primary transmitting coil. For all axial gaps, the charging voltage obtained was $3.84\,\mathrm{V}+/-0.033\,\mathrm{V}$. The charging current to the battery was $0.34\,\mathrm{A}+/-0.065\,\mathrm{A}$. The input current to the converter has an average value of 0.70 A with a standard deviation of 0.174 A. Fig. 5(b) shows the drop in efficiency with the axial gap. The overall efficiency of the system lies between $16.20+/-1.5\%$. The average power in the primary side and secondary side circuits was $8.4+/-2.04\,\mathrm{W}$

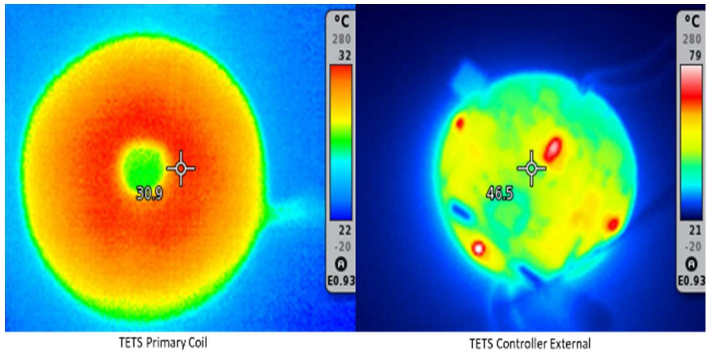

FIGURE 6. Thermal analysis of TETS.

and 1.32+/−0.26 W as shown in Fig. 5(c). The charging power remains almost the same with distance whereas the input power increases with an axial gap. This increase in power accounts for the loss in overall efficiency with axial gap.

The power lost across the coils is converted to heat. Fig. 5(d) shows the rise in temperature in the primary coil and secondary coil during the battery charging. The primary coil temperature and secondary coil temperature were 33.9+/−4.3°C and 33.8+/−3.3°C, respectively. These experiments are carried out with air present in the axial gap. To understand the performance in a real clinical situation, energy transfer across tissue needs to be studied.

The temperature rise of the TETS system was studied by observing the temperature at the primary coil and the primary side electronics. Since the secondary coil is implanted within the infusion pump, exact measurement of temperature rise in the coil cannot be taken. However, it is assumed that the temperature rise of the secondary side will be less than the primary as it handles less power. The temperature rise of the system during charging at different axial gaps is shown in Fig. 5(d). However, it shows only the point of temperature rise. An overall thermal rise of the system was obtained by using a Testo 870 thermal analyzer at the end of the experiment. After the complete charging, the thermal imager obtains the thermal image of the system as shown in Fig. 6.

3.2. Effect of Casing Material

Medical devices are in general made up of metal enclosures preferably titanium to enable hermetic sealing through laser welding. This in turn helps in avoiding ingress protection as well as protection from mechanical shock. The enclosure must easily transfer heat and withstand the pressure variations due to altitude. However, the presence of metal enclosure is an hinderance to the deployment of the wireless energy transfer due to the loss of energy through eddy currents. Hence, the research on various methods to improve the transfer capability without compromising the mechanical and thermal properties is very much essential. To study the influence of the casing material on the charging properties, the medical device cases are fabricated with titanium of different thicknesses, polymers like medical grade epoxy, Delrin combination, and titanium polymer combination. Casings of thickness varying from 250 micrometers to 500 micrometers were tested. The results of the tests are shown in Fig. 7.

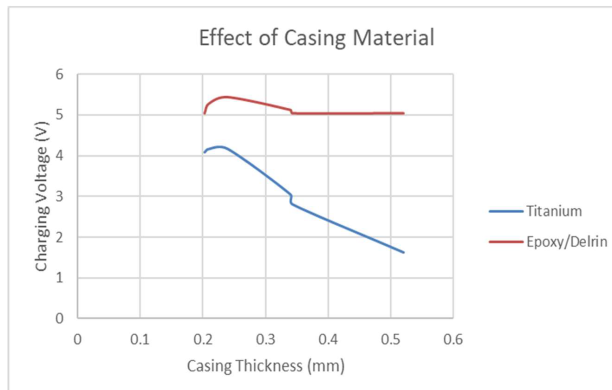

FIGURE 7. Effect of various casing materials and thicknesses.

The fabricated devices with different casing materials were tested with the TETS for recharging the internal battery at a gap of 15 mm. The temperature rise on the device was measured using a thermocouple attached to the casing material. TETS was turned on, and the input current, charging current, charging voltage, and temperature were monitored as shown in Fig. 8.

4. DISCUSSION

In this paper, experiments were conducted to study the effect of axial gap and the effect of casing material on the performance of TETS for powering a battery inside an AIMD. The results of the experiment are summarized in Table 1. It can be seen from Fig. 5, that the charging characteristics are very much dependent on the separation between the device and the primary coil. For the axial gap from 5 mm to 20 mm, a charging current in the range of 0.3 A to 0.5 A was obtained. The average charging current of 0.350 A was obtained for a gap of 15 mm. With the charging current, the battery can be recharged in 2.5 hours.

The average overall efficiency of the system during the charging is found to be 16% and varied by 2% with separation. However, the lower efficiency was not reflected as such in the thermal dissipation of the coils. Thermographic analysis of the coil shows a uniform distribution of temperature surrounding the coil. The average coil temperature is less than

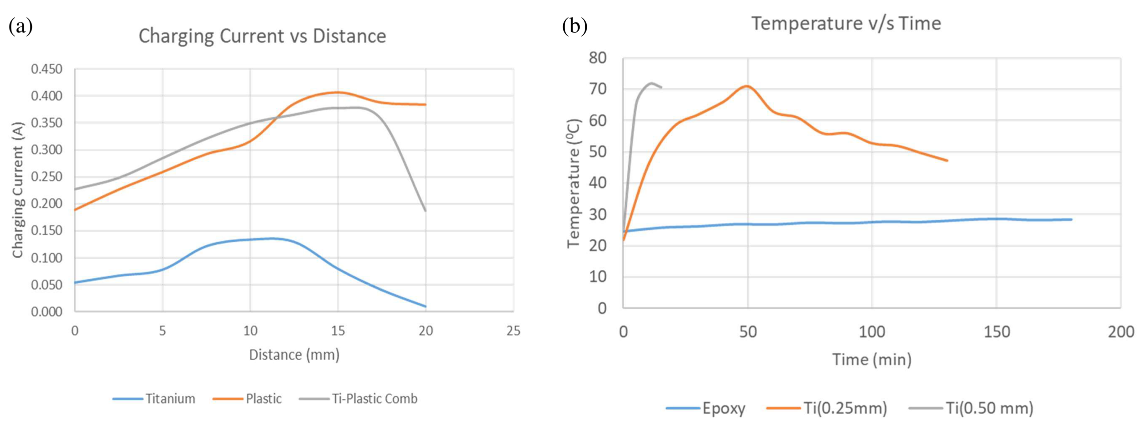

FIGURE 8. Effect of various casing materials on battery recharge. (a) Charging current, (b) temperature.

TABLE 1. Summary of TETS performance for lithium-ion battery recharge.

Gap (mm)	Input Current (A)	Output Current (A)	Output Volt (V)	Pri. Coil Temp (°C)	Sec. Coil Temp (°C)	Input Power (W)	Output Power (W)	Efficiency %
5	0.47	0.25	3.84	30.7	32.88	5.65	0.94	16.98
10	0.7	0.38	3.84	32.25	37.02	8.4	1.44	17.76
15	0.75	0.37	3.81	32.29	29.54	8.99	1.38	15.65
20	0.89	0.39	3.89	40.33	35.7	10.54	1.52	14.43

34°C. However, hot spots were identified in the primary circuit hardware. A temperature of up to 80°C was observed in power diodes. The low level of efficiency may be due to the loss in the primary circuit, which needs to be dissipated with appropriate methods. The primary circuit is supplied with a high input voltage for charging a lithium-ion battery. This selection of the primary side voltage is dependent on the voltage of the battery pack of VAD and TAH. In those cases, batteries are stacked to get a high voltage to limit the overall current passing through the circuitry. This would have been an overkill for charging a battery of low-power implantable devices such as pacemakers and infusion pumps. Hence, an improved primary side design with lower supply voltage may be considered for improving the overall efficiency of the system.

The casing plays a major role in preventing damage to the implantable device. For better strength, titanium is the preferred material for the casing. However, in the case of AIMD with a rechargeable battery, the heating of the casing needs to be prevented. Metallic enclosures create a shielding effect and prevent the electromagnetic fields from penetrating the coils present inside the device. Due to the shielding effect, the voltage developed in the secondary coil was reduced substantially. Experiments were conducted with various materials for the casing to quantify the heating and the voltage produced on the secondary side. As shown in Fig. 7, with a titanium thickness of 0.5 mm, the output voltage is less than 1.5 V.

As shown in Fig. 8(a), the charging current varies with different casing materials. The maximum charging current of 0.3 A is obtained for plastic casing whereas the charging current of less than 0.1 mA is obtained with 0.2 mm titanium. However, with that charging current, the temperature of the titanium plate increases to more than 70°C within 10 minutes of charging. When the thickness decreases to 0.2 mm, the output voltage increases to 4 V. However, in this condition, the temperature in the titanium casing slowly rose to 70°C within fifty minutes of charging. The overall temperature was greater than 50°. The system was also tested with 1 mm thick medical-grade epoxy as the encapsulation material. It was found that a voltage higher than 5 V is obtained as output of the secondary coil. The overall temperature measured on the face of the epoxy surface lies within 30°C.

5. CONCLUSION

In this paper, the effect of coil separation, casing material, the effect of tissue, and temperature rise during the recharging of a single lithium-ion battery of an AIMD through transcutaneous energy transfer is presented. The TETS consists of a primary coil kept over the skin and a secondary coil kept within the medical device. The primary coil was fed with an alternating current produced by a full bridge resonant converter. The primary coil and secondary coil were connected to compensation capacitors and made to operate at resonance. A full bridge rectifier converts the output of the secondary side to a DC voltage suitable for charging a single lithium-ion battery. It was found that environmental parameters such as tissue thickness and casing material affect the performance of the TETS such as the efficiency, charging current, and thermal rise.

To characterize the system, experiments were conducted on recharging a 3.7 V 1000 mAh battery kept within an AIMD under varying coil-to-device axial gap and casing material of the device. It was found that, with the TETS, a charging current of 0.3 A to 0.5 A can be obtained which could charge the implanted battery within 180 minutes. An average efficiency of

16% is obtained with a maximum temperature of 33°C with air between coils. A stable charging voltage was obtained at 3.84V+/−0.033 V with very little variation with axial gap. The secondary side charging power varies within 1.32+/−0.26 W for changes in separation. The charging power remains almost the same with distance whereas the input power increases with the axial gap. The average charging current of 0.350 A was obtained for a gap of 15 mm. With the charging current the battery can be recharged in 2.5 hours. This gives an indication for the clinician to appropriately select the site of implantation of the medical device which gives the best charging characteristics.

Casing material has a significant influence on the efficacy of wireless power transfer. This paper addresses the issue by quantifying the energy loss and suggesting means of improvement through an enclosure redesign. To study the influence of the casing material on the charging properties, the medical device cases are fabricated with titanium of different thicknesses, polymers like medical grade epoxy, Delrin combination, and titanium polymer combination. Casings of thickness varying from 250 micrometers to 500 micrometers were tested. Results show that the induced voltage in the secondary coil is substantially reduced with the presence of 0.5 mm titanium casing compared to epoxy or polymer encapsulation. There was a slight improvement in induced voltage and recharge current obtained with a titanium thickness of 0.25 mm in the interface. However, the casing temperature rose to above 70°C within the first 10 minutes for 0.5 mm thickness and within 50 minutes in the case of 0.2 mm. When the interface region is made with epoxy or a polymer like Teflon, a charging current of more than 0.3 A and a charging voltage of 5 V are obtained. Hence, it is advised to have a polymeric encapsulation or epoxy encapsulation as the best choice in the interface region to get a high recharging current in the case of wireless recharging batteries inside the implantable medical devices.

The study focused mainly on the charging characteristics of an implantable battery with wireless energy transfer system. Air is considered as the medium for the study purpose. It is believed that the primary factor which affects the energy transfer through electromagnetic principle is the relative permeability of the medium. As the relative permeability of human tissue is the same as that of the air, no change in the energy transfer characteristics is expected. However, as the thermal conductivities of both the mediums are different, a difference is expected. Air is a poor thermal conductivity which is approximately equal to 25 mW/mK, and human flesh has conductivity in the range of 200 mW/mK to 500 mW/mK based on its constituents such as the presence of fat, skin, muscle. Since human flesh has a better conductivity, it is expected to conduct the heat faster than air and provide less thermal rise.

Thus, with the proposed design modification, wireless energy transfer and recharging implanted batteries shall be done in a more energy-efficient manner with less thermal damage to nearby tissues. To understand the performance in a real clinical situation, energy transfer across tissue with the influence of misalignments needs to be studied as future work. It is believed that the study can provide value addition to the medical device development community by providing insights into the losses happening through wireless energy and alternative solutions to be sought in active implantable medical device casing design.

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