High Frequency Transcutaneous Transmission using Stents Configured as a Dipole Radiator for Cardiovascular Implantable Devices

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Abstract — In this work we explore the use of stents as radiating structures to support transcutaneous wireless telemetry. Stents are well established Food and Drug Administration (FDA) approved structures with a matured surgical delivery technique. Incorporating stents with a miniature implantable sensory device allows for internal monitoring of nearly any location within the cardiovascular system. We assembled an implantable stent-based transmitter by integrating a 2.4 GHz wireless transmitter, battery, and two stents configured as a dipole radiator. The radiative properties of the dipole stents was quantified through free space, \textit{ex vivo} experiments on excised tissue, and \textit{in vivo} studies on porcine subjects. The \textit{in vivo} results from various receive distances (10 cm to 1 m) showed a 33-35 dB power reduction while implanted at a 3.5 cm depth within the chest. This validates the ability of using stents to wirelessly transmit data from deep within a living body.

Index Terms — Biomedical applications of electromagnetic radiation, biomedical monitoring, biomedical telemetry, and implantable biomedical devices.

I. INTRODUCTION

Numerous cardiovascular disease syndromes are well understood but clinical means to extract the necessary information for diagnosis is limited [1]. In order to accurately obtain internal cardiac measurements such as pressure and blood flow, it is oftentimes necessary to perform an invasive surgical procedure. During this surgery, a cathether, with a wired pressure sensor on the tip, is inserted into a vessel and guided to the desired location. This pressure sensor catheter relays data through a direct connection to an external data acquisition unit. A catheter left in the body can only be used for short-term monitoring and a fully wireless miniature implantable device is required for long-term internal data acquisition.

Recent work has been done in the development of an implantable cardiac pressure sensing device. Amongst the developers of implantable hemodynamic monitors (IHM), Medtronic, Inc. leads the field with designs including the IHM-0, IHM-1, and IHM-2 (Chronicle\textsuperscript{®}) [2]. The main drawback of these Medtronic IHMs is that they consist of a large device, developed for implantation in a pectoral pocket of the patient’s upper left side of the chest, and requires a lead running from the IHM to the measurement site [3]. These devices lack the versatility of placement and thus are typically only used in the chest area within or around the heart. This suggests the need for a miniature implantable sensor that can be implanted in any vessel to provide measurements without the need for any wires or external connections.

Stents are hollow cylindrical devices typically implanted within vessels to leave a patent lumen and maintain flow through the conduit. Stents are widely used in the medical field and their well established delivery methods allow for placement in nearly any vessel or other anatomic conduit in the body. The integration of a miniature cardiac pressure monitor with a stent would take advantage of the maturity of stent technology and its delivery procedure. The idea of using the stents themselves as radiating antennas has never been implemented for wireless miniature implantable cardiac pressure or hemodynamic monitors.

Another application of this work is monitoring the condition and operation of the stents themselves. Stents have a variety of applications and are most widely used in treating obstruction of blood flow in the cardiovascular system. A common problem with stents is re-occlusion, although current technologies attempt to alleviate this problem by incorporating drug-eluting coatings as well as using careful consideration when choosing base materials. Even with these preventative measures, re-occlusion can still occur without warning since little is known about the performance of stents after initial placement. A miniature implantable device integrated with a stent that monitors pressure, blood flow, and other characteristics in the surrounding area would provide clinicians with some idea of how well the stent is faring in the implanted environment.

This work explores the wireless capabilities of Formula 418\textsuperscript{®} Balloon Expandable Stents provided by Cook Medical. These medical grade stents can be used as a platform to provide transcutaneous telemetry capabilities for a variety of implantable internal cardiac monitors. The device incorporates two stents sized according to biomedical needs, which act as both the holder and a dipole antenna for the implant. With the use of preexisting FDA approved stents as radiating structures, we assembled a fully wireless miniature stent-based transmitter and performed \textit{ex vivo} and \textit{in vivo} experiments to validate and quantify transmission from an implanted setting deep within a body.
We incorporate stents into our device allowing us to secure the implant in a vessel and take advantage of well established surgical delivery methods. We integrated two Formula 418™ Biliary Stents, provided by Cook® Medical, with a MAX2753 voltage controlled oscillator (VCO) from Maxim Integrated Products. We milled out a printed circuit board from a Rodgers Duroid substrate and integrated the µMAX/8 VCO chip along with the stents as shown in Fig. 1. To prevent any undesired electromagnetic wave propagation induced by external wires, we integrated a lithium-ion battery with our stent-based transmitter.

From antenna theory, a dipole optimally radiates at a frequency where its total length is half a wavelength. The two 15 mm stents will produce a 30 mm dipole and the optimal operating frequency in free space is 5 GHz, which was verified through lab testing. After implantation, the tissue dielectric causes the optimal frequency to drop and we chose to operate at 2.4 GHz, which lies within the industrial, scientific, and medical band (ISM). In addition to the benefit of using an unlicensed band available for medical purposes, this lower frequency sees less tissue induced power reduction but still maintains an efficient antenna radiation performance.

III. HIGH FREQUENCY SIMULATION MODELS OF IMPLANTED STENT-BASED ANTENNAS

To provide a rough approximation of the interaction of our stent-based radiating antennas with the human body, we used HFSTM, a 3D full-wave electromagnetic field simulator developed by Ansoft Corporation. To model the stents, we used two stainless steel hollow cylinders with a length of 15 mm, diameter of 5 mm, and thickness of 150 µm, which matches the material and dimensions of a fully expanded Formula 418® stent. We covered the stents with a thin 4 µm layer of parylene to prevent direct shorting to the conductive tissue. The two cylinders were positioned in a dipole configuration with a 5 mm gap in between. The stent-based dipole antenna in free space was simulated to have a realized gain of -1.6 dBi, an efficiency of 44.5 %, and an input impedance of 21 – j65 Ω. These results show that the unaltered stents perform reasonably well as antennas when simulated in free space.

As a first order approximation model of the implanted environment, the stent-based dipole was placed within a section of tissue with dielectric properties set to that of muscle. We expect this model to be very rough because it does not account for various aspects including the entire body and different layers of heterogeneous tissue and bone but does provide a reasonable approximation of the near-field interactions. At 2.4 GHz, human muscle tissue has a measured conductivity of 1.705 S/m and a relative permittivity of 52.791 [4-6]. The thickness of the muscle section was set to 18 cm which matches that of a typical male human chest [7]. The stents were positioned 3.5 cm from the front side of the tissue model to roughly represent the distance from the heart to the surface of the chest. The muscle extends 10 cm on either side of the implanted antenna and 5 cm above and below. We then positioned an external receive antenna at specific distances away from the front surface of the tissue model. The reason we included both antennas in a single simulation was to help
capture some of the possible near field interactions between the antennas. The complete setup is shown in Fig. 2(a) and was used to simulate the affects of the tissue on transcutaneous power transfer. The antenna pattern of the stent-based dipole, plotted in Fig. 2(b), deviated from a typical donut shape after implantation in the section of muscle. This difference can be explained by asymmetric positioning within the muscle box. We then removed the tissue section, while keeping all other aspects constant, and reran the simulations. The difference in power transfer between the two sets of simulations represents the isolated effects of only the tissue. At distances of 10 cm, 20 cm, and 50 cm, the power reduction from the tissue was simulated to be 42.8 dB, 46.3 dB, and 44.9 dB respectively.

**IV. EX VIVO AND IN VIVO EXPERIMENTS**

For initial testing, we developed a model for blood using a 140 mM/L NaCl solution to roughly model the electrolyte concentration. The stent-based transmitter was immersed in the solution and positioned about 4 cm behind the front of the plastic saline solution container. An external horn antenna was placed at various distances from the front side of the saline solution container and the received power was measured.

After quantifying transmission through the saline solution model, we performed ex vivo tests using excised sections of porcine tissue. We first performed a set of measurements with a 5 cm thick section of muscle placed behind the implant. A 5 cm thick section of ribcage and muscle was then placed in front of the stent transmitter to model the porcine chest and the measurements were repeated. The difference of the power received from the two experiments represents the attenuation and power reduction through the section of ribcage and muscle.

To achieve the most accurate experimental measurements of power transfer, we performed in vivo studies on a 32 kg domestic pig, as shown in Fig. 3. The surgical procedure follows our Purdue Animal Care and Use Committee (PACUC) approved protocol (PACUC No. 08-019). Anesthesia induction is done with a combination of Telazol (250 mg tiletamine and 250 mg zolazepam), ketamine (250 mg), and xylazine (250 mg). Anesthesia will be maintained with inhalation anesthetics composed of Isoflurane (1.5 – 4.0 % oxygen) administered from a machine with vaporizer and waste gas ventilation system. Throughout the procedure, muscle tone, reflexes, respiration, temperature, ECG, and blood pressure are carefully monitored.

The surgical procedure began with an incision in the right side of the chest down to the level of the jugular vein, which was about 2 cm beneath the surface. The 1 cm tall battery-operated device was then placed right beside the jugular vein, so the final position of the radiating stents was 1 cm beneath the surface of the chest. After implantation, we sutured the layers of muscle and skin and then performed measurements of the power transmitted from the chest. After the first set of tests, we removed the sutures, extracted the device, and deepened the incision. The next implantation positioned the stents about 3.5 cm beneath the surface. After closing the opening with sutures, we recorded another set of power measurements. The same procedure was repeated on the left side of the porcine chest. Fig. 3 shows a radiograph of our stent-based transmitter placed beside the heart along with the porcine chest.

**V. DATA ANALYSIS**

The results from our in vivo studies showed the ability to receive signals from a transmitter implanted deep within a living porcine body. In our test setup, the spectrum analyzer used for reception was fed by an 8 dBi horn antenna and 24 dB low-noise amplifier (LNA). To obtain data of the power delivered to a specific location from our -8.5 dBm stent-based transmitter, we subtracted out the gains of the horn antenna and LNA. Results of our in vivo studies are shown in Fig. 4(a) where we plot the power delivered to specified locations away from the surface of the porcine chest. These measurements were performed at the two implantation depths of 1 cm and 3.5 cm. At the greater depth of 3.5 cm, the power delivered to our receive antenna placed at distances of 10 cm and 1 m was 70.7 dB and 87.8 dB respectively. A comparison between the two curves shows that the additional 2.5 cm of tissue at the greater implantation depth resulted in an additional power reduction of 19.5 dB.
Comparing the measurements from the simulations, saline solution, ex vivo, and in vivo experiments, to those in free space, we determine the amount of loss induced by just the saline solution or porcine tissue. The data, plotted in Fig. 4(b), shows that all of our models predicted significantly different results than what we measured in the in vivo tests. These discrepancies could be attributed to various differences including the fact that the simulations, saline model, and ex vivo experiments all lacked a model of the entire body and a full set of heterogeneous tissue layers. The in vivo studies showed that after implantation in a live test subject, the receive power, when compared to the free space case, diminished by about 33-35 dB at a 3.5 cm implantation depth over transmission distances of 10 cm to 1 m.

VI. Conclusion

This work has validated the use of stents as a platform for wireless miniature implantable cardiac monitoring devices. We have shown the ability to use stents as radiative antennas for wireless telemetry. A fully wireless 35 mm x 5 mm (when expanded) stent-based transmitter was assembled and implanted in live animal experiments following our PACUC approved protocol. The efficiency of the stent-based antennas was measured and the power loss was quantified for transmission through free space, saline solution, and porcine tissue in both ex vivo and in vivo studies.

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REFERENCES


