Program Digest, 2019 IEEE International Ultrasonics Symposium (IUS)
Glasgow, Scotland, October 6-9, 2019

Ultrasound-Based Post-Endovascular Aneurysm Repair (EVAR) Monitoring Device

Eric S. Young
Department of Electrical and Computer Engineering
NC State University
Raleigh, NC USA
esyoung3@ncsu.edu

F. Yalcin Yamaner
Department of Electrical and Computer Engineering
NC State University
Raleigh, NC USA
fyyamane@ncsu.edu

Ömer Oralkan
Department of Electrical and Computer Engineering
NC State University
Raleigh, NC USA
ooralka@ncsu.edu

***Abstract*— A diverse set of stimulators, transducers and data transceivers can be integrated into medically implantable devices using ultrasonic power. An application for such a device is postoperative monitoring of abdominal aortic aneurysm repair. Endoleaks are a potentially serious, but correctible, complication of aorta repair. A miniscule ultrasonic powered device incorporated into the stent-graft for endovascular delivery could provide on demand diagnostic information about the presence of endoleak by monitoring the dimensions of the aneurysm sack in real time. To power this device, a wireless ultrasonic power recovery scheme is demonstrated in oil using a single-element capacitive micromachined ultrasonic transducer, and a circuit made with commercially available discrete components. The 2-mm diameter element, a diode rectifier bridge and inductor-based boost circuit form the power conversion circuit delivering over 1 mW to the load. Other aspects of the implantable device are a pulse echo measurement of the diameter of the vessel lumen, and a data transmission method that encodes clock, data and transmission framing information in biphasic ultrasonic pulses and takes advantage of the wideband characteristics of the CMUT. This proof of concept is guiding the design of an integrated circuit implementing the key elements of the implantable device.**

Keywords*— *ultrasonic or wireless power; medical implantable device; ultrasonic communication; capacitive micromachined ultrasonic transducer; CMUT

I. INTRODUCTION

A diverse set of stimulators, transducers and data transceivers can be integrated into micro-scale medically implantable devices. Ultrasonic power transfer provides substantially higher power density and reaches much deeper in tissue compared to alternative sources using inductive coupling or radio frequency. A key advantage of ultrasonic technology over the competing radio-frequency (RF) technology is that the maximum allowed power level in tissue for diagnostic ultrasound is 7.2 mW/mm^2 or about 70x higher compared to RF energy limits. Other advantages are the attenuation of ultrasonic signals in tissue is far less than RF, and the wavelength of the ultrasonic energy in tissue is on the order of millimeters. These advantages translate to a small device size and excellent range in biological systems. Recent work has demonstrated the use of piezoelectric technology for power transfer and charging of miniscule "Neural Dust" motes [1], [2]. The capacitive micromachined ultrasonic transducer (CMUT) provides advantages in size, integration, cost, and fabrication.

One application for an ultrasonically powered implantable device is postoperative monitoring of abdominal aortic aneurysm (AAA) repair. Endoleaks are a potentially serious, but correctible, complication of AAA repair and develop in about one third of the 30,000 procedures done in the US. Endoleak is usually determined in routine followup by radio-contrast dye injection into the aorta with CT imaging. This is an invasive procedure requiring use of a full cardiac catheterization lab. A miniscule ultrasonically powered device integrated into the Endo-Vascular Aneurysm Repair (EVAR) stent-graft, and delivered transcutaneously, could provide on demand diagnostic information about the presence of endoleak, based on measurements of the aneurysm sack dimensions, and of the stent-graft inside the vessel lumen.

II. APPROACH

A. Overview

The objective of this research is to develop an implantable, wirelessly powered electronic microdevice for recording and transmitting clinically relevant data, using CMUT technology. The stent-graft device used for repair of abdominal aortic aneurysm makes an excellent use case for this implantable device. An in-situ monitoring system integral to the stent-graft and capable of detecting endoleak shortly after initial placement or on routine follow-up would improve overall healthcare costs and outcomes for EVAR procedures. This device would have to be small enough to fit in the endovascular delivery system, and its electronics would be powered from a reservoir capacitor that is charged wirelessly on-demand. Therefore, the key elements the implantable must incorporate are wireless power delivery, distance measurement and encoding of distances in the aorta, and wireless data transfer to an external unit. To investigate the strategies to address these needs prior to committing to an integrated circuit design implementation, we used commercially available discrete surface mount components. Through these implementations we were able to

---

This work was supported by the National Science Foundation under Grant 1160483 as part of a Center-to-Centre collaborative partnership.

demonstrate ultrasonic power delivery, pulse-echo ranging with a real EVAR kit, and biphasic pulse communications.

B. Wireless Power

A key feature of the implantable device is wireless power delivery. The stored energy need only last as long as it takes to make the clinical measurements and transmit the data. A wireless ultrasonic power recovery scheme is demonstrated in oil using a single element CMUT and a circuit made with, commercially available diodes, transistors, an inductor and a comparator with open drain output for the boost regulator. The 2-mm diameter CMUT element, a diode rectifier bridge and an inductor-based boost circuit form the power conversion circuit. In these experiments, the bias voltage for the CMUT is supplied externally, but there are special devices under development which will store the charge in the dielectric. Concerning this aspect, several techniques are reported in the literature for storing charge on electrets [3], [4].

The inductor-based boost circuit is selected over charge-pump doubler because it has the potential to provide power at a wide range of output voltages when operating in discontinuous conduction mode. This is precisely the situation we expect when charging a storage capacitor element. The operation, which is hysteretic based on the input voltage, can be briefly described as follows. During the positive phase of the voltage at T2, the switch S1 is on and the inductor current increases. During the negative phase of T2, the switch turns off and the inductor discharges current to the output through D4. The inductor current is supplied by D3 during the negative phase.

C. Wireless Communication

A key aspect of the implantable device is the transmission of data collected during pulse-echo ranging to the external unit for diagnostic analysis and periodic monitoring. It is desirable for translation into the clinical setting to use a common bus standard, such as serial peripheral interface (SPI) and convert this standard to a "one-wire" differential protocol to drive the CMUT and generate pressure waves. The pressure waves will then be received by a second CMUT, converted to electrical signals and decoded to convert them back to the SPI signals. The broadband characteristics of the CMUT are key to the use of an industry standard "IsoSPI™" protocol we selected, which is implemented in the protocol device (LTC6820, Analog Devices, Norwood, MA, USA). This "cable driver" communication concept uses single biphasic pulses with phase indicating polarity; and two distinct frequencies are used to communicate data and frame information.

III. RESULTS

On the power recovery circuit, we investigated two different sizes of CMUT elements, variations in transducer excitation. frequency, CMUT bias voltage, circuit component selection, and active vs. passive rectifier design. The highest power achieved (1.1 mW) used the active rectifier at bias voltages approaching CMUT collapse, and at excitation frequencies (1.2 MHz) where we find the center frequencies of the transmitter and the CMUT match. During our experiments, the current supply for the boost circuit (LMV7235, Texas Instruments, Dallas, TX, USA) was provided separately, but could be supplied from the boosted output or from a rectified input.

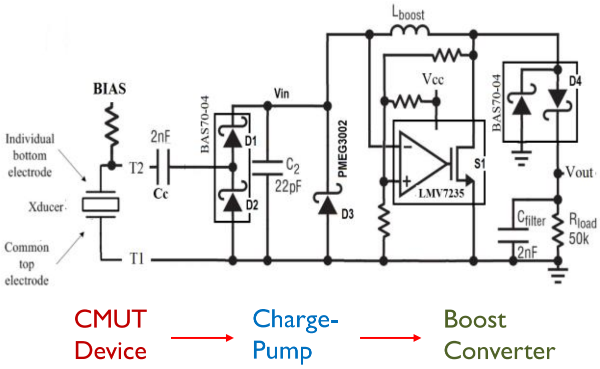

Figure 1. Acoustic power converter circuit for ultrasonic energy received by the CMUT.

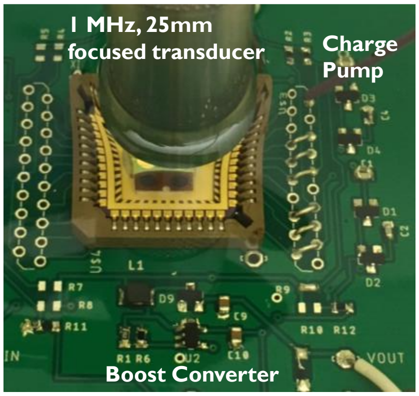

Figure 2. Board implementing acoustic power converter, shown with a 1 MHz focused transducer insonifying the CMUT.

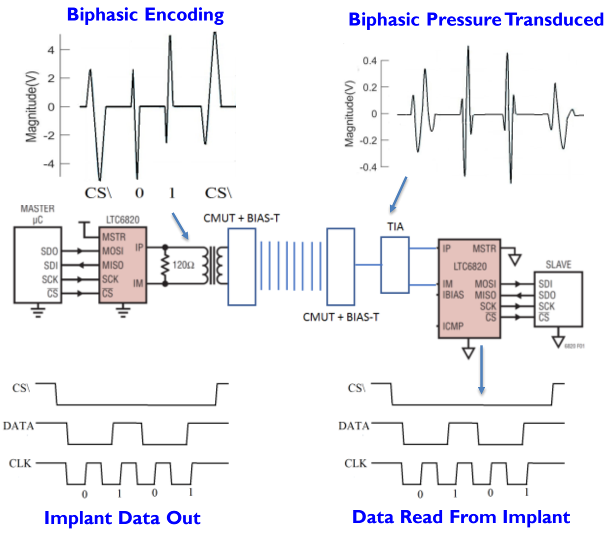

Figure 3. Signal flow for bi-phasic ultrasonic communication between two CMUT elements showing typical encoding and transmission waveforms.

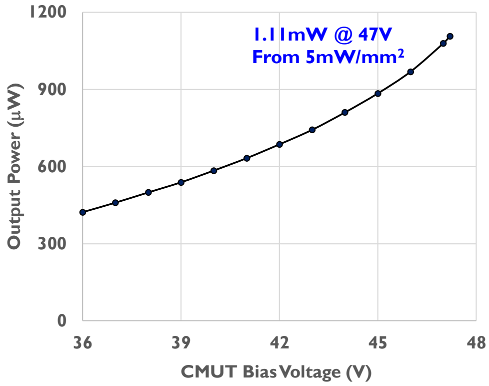

Figure 4. Output Power at 1.2MHz as a function of CMUT bias voltage with 15mW incident power. A separate study of frequency response showed a peak power output at 1.2MHz

The wireless communications concept is demonstrated in an oil tank with two CMUTs, one for transmit and the other for receive. The frequency response of the CMUT (conventional operation) was compatible only with the chip-select feature of the protocol chip. We demonstrated correct decoding of the biphasic pulse as shown in Figure 5. Compared to the on-off shift keying techniques, the anticipated advantages of using this single-pulse system with phase indicating polarity is 1) increased data rate, as high as 500 kHz with data signal frequency of 3 MHz, and control signal frequency of 1 MHz, assuming the two types of pulses can be spaced at 2 μs ; 2) better immunity to multipath interference, which could be a complication where highly echogenic structures such as bone are near the implant; and 3) power efficiency because the communications can be concluded using a smaller number of pulses, less time and thus less energy.

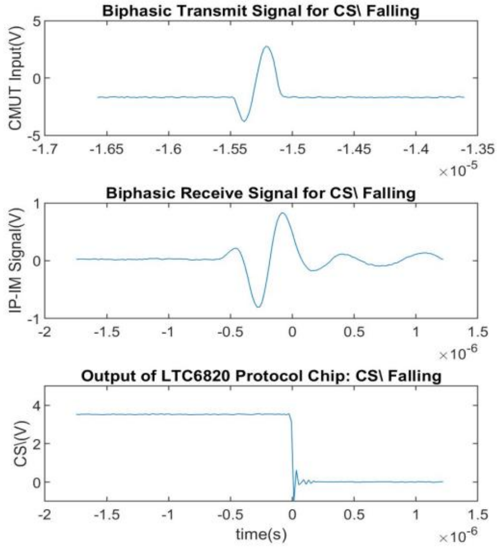

Figure 5. Ultrasonic communication waveforms demonstrating decoding of biphasic pulse into falling chip select.

The pulse-echo response to the EVAR stent-graft was captured to investigate the echogenicity of the device and the likelihood of measuring a differential distance across the EVAR and potentially across the aneurysm sac. The setup for this experiment was similar to the pitch-catch used for the data communication. The metal stent structure is found to be highly echogenic. Investigations into the best way to represent these data for encoding and transmission are moving forward.

IV. CONCLUSIONS

We demonstrated key concepts for an implantable intravascular ultrasound device to monitor/diagnose endoleak in endovascular aneurysm repair stent-grafts. In benchtop studies using externally biased CMUTs and off-the-shelf discrete components, we demonstrated:

- Greater than 1 mW power recovery from a 3 mm^2 device with incident ultrasound intensity of 5 mW/mm^2, which is less than the I_{SPTA} limit of 7.2 mW/mm^2
- Ultrasonic biphasic communication concept with potential for high data rate
- Pulse-echo ranging from sensor to EVAR structures.

Our future efforts will focus on integrating the functionality of this device into a single integrated circuit chip, and demonstration of measurements in porcine animal models.

ACKNOWLEDGMENT

This work was supported by the National Science Foundation under Grant 1160483 as part of a Center-to-Centre collaborative partnership with NUI Galway, Ireland and Queens University, Belfast, Northern Ireland, in particular Manus Biggs and Sean Cummins. The authors thank Cook Medical for providing the EVAR samples used to investigate the pulse-echo ranging capability.

REFERENCES

[1] T. C. Chang, M. J. Weber, J. Charthad, S. Baltsavias and A. Arbabian, "Scaling of ultrasound-powered receivers for sub-millimeter wireless implants," in IEEE Biomedical Circuits and Systems Conference (BioCAS), Torino, 2017.

[2] D. Seo, "PhD Thesis - Design of Ultrasonic Power Link for Neural Dust," UC Berkeley, Berkeley, 2016.

[3] M.-C. Ho, M. Kupnik and B. T. Khuri-Yakub, "PRE-CHARGED CMUTS FOR ZERO-EXTERNAL-BIAS OPERATION". US Patent 2013/0088118A1, 11 April 2013.

[4] V. Leonov, P. Fiorini and C. V. Hoof, "Rapid corona charging and stability of positive charge stored in SiO2/Si3N4 electrets," in 12th International Symposium on Electrets, 2005.

[5] T. C. Chang, M. Weber, J. Charthad, A. Nikoozadeh, P. T. Khuri-Yakub and A. Arbabian, "Design of High-Efficiency Miniaturized Ultrasonic Receivers for Powering Medical Implants with Reconfigurable Power Levels," in 2015 IEEE International Ultrasonics Symposium Proceedings, 2015.