# Dynamic Evaluation of a Digital Wireless Intracranial Pressure Sensor for the Assessment of Traumatic Brain Injury in a Swine Model

Xu Meng, Student Member, IEEE, Kevin D. Browne, Shi-Min Huang, Student Member, IEEE, Constance Mietus, D. Kacy Cullen, Mohammad-Reza Tofighi, Senior Member, IEEE, and Arye Rosen, Life Fellow, IEEE

Abstract—The monitoring and control of increased intracranial pressure (ICP) are the major requirements for the diagnosis and treatment of patients suffering from traumatic brain injury (TBI) or hydrocephalus. Widely used commercially available ICP measuring devices require the use of a tethered fiber optic probe, which can cause complications, such as infection and hemorrhage. The use of a probe also prohibits immediate (at the time of induced injury) and long-term measurements of ICP. Therefore, we have developed and tested a small fully embedded wireless ICP sensor, incorporating a novel antenna and packaging arrangement. Evaluations were performed in-vitro and in-vivo to demonstrate the robustness of this microwave pressure-monitoring system. This is the first report of in-vivo tests in a dynamic study of continuous (every 6 s) wireless ICP measurements in a swine model of closed-head rotational-acceleration induced TBI using a digital device. In particular, our device measured extreme changes in ICP immediately upon rapid head rotation that persisted for hours after the injury. The readings matched well those obtained from a commercially available tethered monitor. Our device can be utilized in the future as a tool to diagnose and track long-term ICP changes.

*Index Terms*—Digital wireless implants, intracranial pressure (ICP), rotational head injury, slot antenna, traumatic brain injury (TBI).

#### I. INTRODUCTION

T HE utilization of microwave/RF technologies in biomedical applications is rapidly changing the landscape of the medical industry and currently improving healthcare around the world [1]–[3]. Improved components and the continued down scaling of electronic subsystems are fueling research and development in the area of biomedical wireless implants [4]–[6], which are expected to improve patients' comfort and reduce healthcare costs.

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X. Meng and A. Rosen are with the School of Biomedical Engineering, Drexel University, Philadelphia, PA, 19104 USA (e-mail: xm26@drexel.edu; ar86@drexel.edu).

K. D. Browne, C. Mietus, and D. K. Cullen are with the Department of Neurosurgery, Center for Brain Injury and Repair, University of Pennsylvania, Philadelphia, PA, 19104 USA (e-mail: kbrowne@mail.med.upenn.edu; mietus@mail.med.upenn.edu; dkacy@mail.med.upenn.edu).

S.-M. Huang is with the Department of Electrical Engineering, Drexel University, Philadelphia, PA 19104 USA (e-mail: sh592@drexel.edu).

M.-R. Tofighi is with Capital College, Pennsylvania State University, Middletown, PA, 17057 USA (e-mail: mtofighi@psu.edu).

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As the interest grows in incorporating wireless communication technology in medical research and healthcare, several groups have introduced systems and devices for the wireless acquisition of various physiological conditions or other information from inside the body. Some examples are: an implant-base wireless pressure sensing paradigm for long-range and continuous intraocular pressure (IOP) monitoring of glaucoma patients [7], a fully wireless active platform for monitoring parameters in the vascular system (cardiac pressure) [8], an implantable wireless neural recording system to measure local neural activity and transmit action potential occurrences to an external interface [9], and an acute and chronic bladder pressure monitoring system using low-power wireless micromanometer [10]. In the past several years, our group has devoted significant efforts to the wireless measurement of intracranial pressure (ICP) [11]–[14]. ICP is the pressure inside the skull, which contains the brain, cerebrospinal fluid (CSF), and blood. The monitoring of ICP is of great importance in the medical management of patients who have suffered a traumatic brain injury (TBI) due to head impact and/or acceleration, as well as patients suffering from neurological disorders such as hydrocephalus. It is reported that each year 1.7 million people in the US sustain TBI, a contributing factor to roughly one-third (30.5%) of all injury-related deaths in the US [15]. Hydrocephalus affects hundreds of thousands of Americans from infants to adults. It is estimated that one to two of every 1000 babies are born with hydrocephalus [16]. Increased ICP in such patients can lead to permanent brain damage, disability, or death. Moreover, ICP is a significant parameter in the management of various cerebral disorders and trauma, and serves as an indicator of brain tissue and cerebral vascular status. Therefore, an understanding of the underlying causes and the effects of potential treatments in ICP management for various neurological disorders is necessary to choose the best treatment options and develop mitigation strategies.

Current "tethered" capabilities for monitoring ICP present considerable logistical, medical, and technological challenges to research, as well as effective surgical interventions. Such devices use a tethered probe that penetrates the brain, and therefore, can only remain implanted for relatively short time periods considering the wires, cables, or catheters emanating from the patient's head. Besides, the use of wires can increase the risk of complications, such as infection, hemorrhage, and malfunction of the device. The widely used Camino catheters for ICP measurement have been extensively studied [17]–[20]. One of the studies on Camino catheters in clinical practice reported complications including 0.7% infection, 5.1% intraparenchymal hematoma, and 23.5% technical aspects [21]. In addition, incidences of improper placement and dislodging of the device were reported by other groups [20], [22]–[24]. A small fully embedded wireless ICP device with subdural placement will simplify the surgery procedure, whereas reducing the infection rate, the risk of hemorrhage, and the degree of tissue injury. Such a device may also simplify clinical management and research protocols by offering a means for semi-invasive and long-term ICP measurements following brain injury.

A prototype of an analog wireless implantable intracranial pressure (AICP) monitoring device operating at the industrial-scientific-medical (ISM) band of 2.4 GHz was previously proposed, developed, and tested by the authors [11], [12]. In the completely implantable wireless AICP device, the ICP information from the sensor varied the oscillation frequency of a 700-kHz Schmitt trigger oscillator modulating a 2.4-GHz RF oscillator, coupled to a printed inverted-F (PIFA) antenna [11]. The device was housed in a titanium case over the skull. A 6-mm-diameter skull burr hole was required for the nozzle that accommodated a sensor. The implanted PIFA antenna was characterized in terms of its reflection coefficient  $(S_{11})$ , resonance frequency  $(f_r)$ , and transmission coefficient through the phantom  $(S_{21})$  at 2.45 GHz [11], as well as its drift over time and with temperature change. In-vitro and in-vivo evaluations were carried out to demonstrate the feasibility of microwave pressure monitoring through scalp, device integrity over a long period of time, and repeatability of pressure measurements [12]. In a long-term study, the device was successfully implanted in dog, and the data were collected from the implant in a regular basis for 45 days. The results did not indicate any immunological reaction or organ dysfunction [25].

For the study of TBI, dynamic ICP measurements before and after the injury in a completely closed-head environment may have a significant research value, particularly in the acute postinjury period. With current technology, in experimental (animal) models of TBI, a tethered fiber optic probe has to be removed before injury is induced (if inserted before the injury at all) in order to avoid significant focal injury at the point of probe insertion. Moreover, its reinsertion can be done only after the animal's vital signs have stabilized. However, the act of breaching the cranium after the injury affects the fidelity of ICP measurements. Moreover, proposed noninvasive intracranial pressure (NICP) solutions, such as the pulsatility index method based on the use of trancranial Doppler, argued by Figaji *et al.* [26] has been shown to be insufficient for accurate ICP estimation.

Recently, the dynamic evaluation of the AICP was successfully performed using our swine model of closed-head TBI, demonstrating the ability of this system to monitor post-injury ICP changes [14]. However, monitoring by the AICP required personnel involvement such that a receiver had to be always held in close proximity of the head. Therefore, the results could not be recorded continuously and efficiently. A novel digital wireless intracranial pressure (DICP) device encompassing more features such as the ease of interfacing to the existing computer platforms, sensor calibration, multidevice operation, power management, and control was developed [13] to further satisfy conformance with the current trends in healthcare-related technology. The preliminary *in-vitro* evaluations of such DICP device (unpackaged device with only silicone coating for water tests) including the pressure tests (air and water), temperature sensitivity tests (air), and signal strength tests (air) were previously reported to demonstrate its performance [13].

This paper provides for the first time the results of the DICP device's utilization for dynamic ICP monitoring in a swine model of TBI. The animal's ICP was continuously recorded for both pre- and post-injury without necessitating personnel intervention, requiring particular receiver placement, or concerns for device malfunction due to rotational injury. The device also features a combination of novel antenna implementation and packaging/sealing material, for achieving high radiation efficiency through the scalp and maintaining low sensitivity to packaging variability, whereas making it very robust for use in rotational head injury studies.

The configuration of the device, and the characterization of the antenna and encapsulating material are provided in Section II. In Section III, the in-vitro experimental setups for the device and antenna are described, and the results are provided. Section IV presents the main emphasis of this paper, where the new DICP device is employed to measure ICP changes induced by closed-head rotational TBI in swine. A description of the method of inducing the nonimpact TBI, in-vivo investigational procedures, and obtained measured results correlated with gross pathology are presented in Section IV. It is followed by a discussion of the results in Section V. This first report of the test results of the DICP device's utilization to study TBI-induced ICP changes (dynamic measurements) in a large animal such as a pig demonstrates the usefulness of the DICP device, its dynamic performance, and the robustness of the used system.

#### II. DEVICE CONFIGURATION AND DESIGN

#### A. Device Configuration

The device configuration is illustrated in Figs. 1 and 2. A titanium sheet (21 mm  $\times$  25 mm) with an open nozzle (titanium) on one side (5.1-mm diameter and 5-mm length) was fabricated. All the electronics sit on the other side of the sheet, and a coin battery is located between the circuitry and antenna, as shown in Fig. 1(b). The sensor is recessed 1.5 mm from the end of the nozzle and connected to the board through two small coaxial cables (UT-34, Micro-coax Inc., Pottstown, PA). The sensor is thus protected from direct contact with the brain as it swells during or after the injury. A very small amount of silicone is applied for attaching the different layers to form one unit and the entire device is fully encapsulated by a medical grade epoxy (EPO-TEK 302-3M, Epoxy Technology Inc., Billerica, MA). The final size of the DICP device is  $22 \text{ mm} \times 26 \text{ mm}$  (Figs. 1 and 2). The DICP circuitry and antenna design will be explained in Sections II-B and II-C.

The device features a subdural placement where the sensor is in contact with the CSF, which circulates in the subdural or subarachnoid space, as previously described [13], [14].



Fig. 1. DICP device. (a) 3-D schematic view. (b) Layer view.



Fig. 2. (a) DICP device configuration (top view) communicating with a USB based receiver. (b) DICP device bottom view with zoomed sensor view.

# B. DICP Device Design

A modified eZ430-RF2500T target board (end device), incorporating the capacitive microelectromechanical system (MEMS) sensor (Murata Electronics Oy, Vantaa, Finland) and a 3-V lithium coin battery (CR2032, 220 mA·h, 20-mm diameter, Panasonic, Secaucus, NJ), is used as a standalone wireless device [13].

The wireless DICP network application includes MSP430 microcontroller and CC2500 low-power wireless radio (Texas Instruments Incorporated, Dallas, TX). The communication is based on a Texas Instruments Incorporated's SimpliciTI network protocol. The original board ( $20 \text{ mm} \times 30 \text{ mm}$ ) is reduced by carefully cutting off and removing the printed circuit board (PCB) area hosting the board's existing chip antenna. The reduced size is 20 mm  $\times$  22 mm. The DICP device communicates with an access point connected to a PC, sending the pressure and temperature information. Prior to packaging (Fig. 2), the device (target board) is programmed using a USB debugging interface, connected to the device through a JTAG connector by a C program compiler running on the PC. After programming the device, the connector is also removed. The MSP430 microcontroller measures the capacitor and sends the information through the CC2500 radio. The CC2500 can be programmed from -30to 0 dBm and for communication within the 2400-2483.5-MHz ISM frequency band. A terminal emulator application, which can act as a serial console, reads and saves the incoming data received by the access point through an available UART to a PC COM port. The transmitted data include the device temperature from the MSP430's internal temperature sensor (2 B), the device battery and capacitors' voltage at the end of the count (2 B), the sensor and reference counts (4 B). This information is transmitted by the CC2500's standard packet consisting of preamble, synchronization word, length byte, address byte, data, and cyclic redundancy check (CRC) bytes. These data, together with the measurement date and time, are repeatedly saved in a text file.

For the current measurement purposes, the sensor located at the end of nozzle [see Fig. 2(b)], along with a resistor (R =10 M $\Omega$ ), is connected to MSP430 I/O ports. The ports can be set for input, output, or open (high impedance) state. The measured capacitor is initially charged to  $V_{cc}$  when an internal timer simultaneously starts its count. Subsequently, the capacitor discharges to a set value (programmed to  $V_{cc}/4$ ), which creates an event that causes the timer to stop. This process is performed and the count values, along with the reading of the MSP430 internal temperature sensor, and its battery level, are sent to the access point, which sends these data along with the measured signal strength to the PC. In the current application, the clock frequency  $(f_c = 1/T)$  of the microcontroller is programmed to run at 12 MHz and the capacitor measurement is performed about once every 6 s. For the majority of this time, the CC2500 is in its sleep mode and MSP430 is in the low power mode 3 (LPM3), with an overall current consumption of 1.3  $\mu$ A. The capacitor measurement lasts about 0.8 ms, and the events of MSP430 and the radio operation for sending the sensor information takes about 4.7 ms. The average current consumption is about 18.3  $\mu$ A. The CC2500 transmits data at 250 kb/s. Processing of the received information can be done based on a count model explained in [13], where the timer counts for the reference and the MEMS capacitors are used for measurement and calibration of the ICP. However, due to an observed sizeable change of the reference capacitor (surrounded by the epoxy) due to extensive stress at high pressure (above 80 mmHg) in the water (not tested in [13]), the reference is not used for calibration. Therefore, the processing method in this study, as described below, is slightly different from [13], allowing us to overcome the 80-mm · Hg range limitation.

Considering the exponential form of the capacitors' discharge from  $V_{cc}$  to  $V_{cc}/4$ , the read timer count  $(N_X)$  is modeled as

$$N_X = N_C + (R \times \ln(4)/T) \times (C_X + C_S) \tag{1}$$

where the second term is the capacitor count due to the actual discharge, T is the clock period,  $C_S$  is the stray (parasitic) capacitance of the circuit effectively added to the  $C_X$ , and  $N_C$  is the number of clock cycles from the time that the discharge event occurs to the time that the counter is read. At two different pressure values, the sensor will demonstrate different  $C_X$  values, which correspond to different  $N_X$  values. Therefore, at a fix clock setting

$$\Delta N_X = (N_{X2} - N_{X1}) = \Delta C_X \times R \times \ln(4)/T \qquad (2)$$

where  $\Delta N_X$  is proportional to the  $\Delta P$ , which is the difference between the two pressure values. The pressure is obtained based on the number of clock cycles calibrated at zero pressure  $N_{X0}$ in water and pressure sensitivity given by  $\Delta N_X / \Delta P$ .

# C. Antenna Design and Packaging Considerations

Medical grade silicone rubber has been commonly used for protecting implant circuitry embedded in biological media. However, gradual absorption of water in silicone can lead to a sizable drift in the antenna performance, in particular its resonance frequency [11]. Moreover, we found that the silicone rubber was problematic during implantation, and a more rigid sealing was needed to sustain adherence of the device to the skull. Therefore, it was decided that the whole device be encapsulated by the medical grade epoxy mentioned before (EPO-TEK 302-3M). This is a two-component biocompatible epoxy with desirable adhesion property to a variety of materials. It is transparent and exceptionally hard after being properly cured. Unlike our previously assembled devices [12], [13], for which the antenna and the whole device were coated and sealed in different steps, in here, all coatings were done in one step. The main reason for this was that the epoxy had a very low viscosity and a one step handling was deemed more desirable. The device, after circuit integration, was dipped in the epoxy. This step of the process was important in proper prediction of the antenna's performance. Therefore, it was necessary to measure the complex permittivity of the epoxy at the operating frequency, as will be explained below.

Complex Permittivity of Epoxy: The manufacturer-provided dielectric parameters for the epoxy were  $\varepsilon_r = 3.39$  and  $\tan \delta = 0.0061$ , specified at 1 kHz. Due to the unavailability of the complex permittivity at microwave frequency, it was measured using the cavity resonator method. The measurements were performed at Material Sensing & Instrumentation Inc., Lancaster, PA, using its 2.4-GHz cylindrical cavity operating at TM<sub>010</sub> mode. A cylindrical shape epoxy specimen was prepared by filling a hollow tubing mold with 11.07-mm diameter and letting it cure for two days at room temperature. The specimen was ground down to the exact height of the cavity (50 mm) using a fine grinder for placement at the center of the cavity. The measured dielectric constant and loss tangent were  $\varepsilon_r = 2.88$  and  $\tan \delta = 0.023$  at 2.33 GHz (the resonance frequency of the loaded cavity).

Annular Slot Antenna: A different type of antenna (Fig. 3) was used for the implant in this study, and its performance was carefully characterized through simulation. The motivation for this modification was twofold. First, authors previously observed that the resonance frequency of the PIFA, which was essentially a folded microstrip metallization with a grounded end, was very sensitive to the biocompatible coating thickness (optimally chosen about 0.4 mm) [11]. Second, the radiation efficiency of the PIFA was not the best obtainable. As studied in [27], the radiation efficiency of this antenna for an 8-mm-thick scalp phantom is only in the order of a tenths of percent (0.2%-0.4%) at 2.4 GHz. Therefore, in [27], it was suggested that an essentially complementary structure be used, where the microstrip and grounding pin were replaced by a slot and an open circuit, respectively. This modification would prove to provide a sizable increase in the radiation efficiency, achieving an efficiency of around 0.5%-1.0% (depending on the coating thickness) [27]. Nonetheless, further simulation studies revealed that the modified antenna's resonance frequency be-



Fig. 3. Annular slot antenna used in this study. Coaxial feed is penetrated from the backside. The back plane is not metallized [27].

comes very sensitive to the side and back coating of the antenna board. Noting that the antenna sizes of 5 mm  $\times$  4 mm for the PIFA and 6.5 mm  $\times$  6.5 mm for the complementary slot were significantly smaller than the available device area (Fig. 1), it was decided to exploit this entire area for antenna implementation. Moreover, this would serve as an extra protection for the battery, then placed completely behind the antenna board.

Annular slot antennas have been popular as applicators for microwave heating applications. They offer a symmetric beam and their performance is almost insensitive to the location of feed along the slot. Nonetheless, compared to the folded PIFA, spiral, or meandered antennas, they may be comparatively large for implant applications. Fortunately, an annular slot (Fig. 3) could properly fit in the available area, while providing superior radiation efficiency and low sensitivity to biocompatible coating thickness. To compare with previous work [11], [25], the performance characteristics of this antenna were evaluated with respect to 50- $\Omega$  reference, as will be explained below. However, as explained later, it had to be matched to non-50  $\Omega$ , when placed in the device.

Fig. 4 illustrates the simulated performance of the rectangular annular slot antenna with varying thicknesses of epoxy coating (d) in terms of resonance frequency  $(f_r)$ ,  $S_{11}$  at 2.45 GHz,  $S_{11}$ at  $f_r$ , radiation efficiency, and fractional 10-dB bandwidth. Ansoft HFSS was used for the simulation with the entire device, as shown in Fig. 1, and is placed under a 8-mm-thick scalp.  $S_{11}$  versus frequency for various d values are plotted in Fig. 5. Compared to the folded PIFA, the annular slot's performance is superior in all aspects, namely: 1)  $S_{11}$  at 2.45 GHz remains below -10 dB for a wide range of d; 2) -10 -dB bandwidth is much higher (5% for the PIFA [11] versus 26% for the annular slot, with a coating thickness of 0.43 mm); and 3) radiation efficiency is much higher. To clarify the latter, for d = 0.43 mm and 8-mm-thick scalp, the radiation efficiency for the PIFA [27], complementary slot [27], and annular slot in this paper are 0.2%, 0.8%, and 1.2%, respectively. The radiation efficiency reaches about 2% for a coating thickness of 1.5 mm [see Fig. 4(b)].

Antenna Matching: As mentioned earlier, the existing chip antenna on eZ430-RF2500T, together with a board area hosting it, was removed. Furthermore, a portion of the matching circuit dedicated to the chip antenna was also removed [see Fig. 6(a)]. Note that the original chip antenna was intended for operation in air, not tissue. Therefore, its replacement by an implanted antenna, and a modified impedance matching circuit were necessary. From the datasheet of the chip antenna (Würth Elek-



Fig. 4. Simulated antenna characteristics with varying thickness of epoxy coating (d) for: (a)  $S_{11}$  at 2.45 GHz,  $S_{11}$  at  $f_r$ , and  $f_r$  and (b) radiation efficiency and fractional bandwidth (10 dB).



Fig. 5.  $S_{11}$  versus frequency for various d values.

tronik, Waldenburg, Germany) and eZ430-RF2500T, the desired impedance of the replacement annular slot was estimated as  $84 + j4 \Omega$  at an operating frequency of 2.45 GHz. Consequently, it was decided to modify the replacement annular slot's radiation impedance by an added *LC* matching network to the value mentioned above [see Fig. 6(b)]. In doing so, the length of the coaxial cable (Fig. 1) was also taken into account for more accuracy.

## III. DICP DEVICE In-Vitro TESTS

#### A. Experimental Setups

Different tests were carried out on the DICP prototype (12-MHz clock frequency) to establish the performance of the device, such as pressure sensitivity, temperature sensitivity, and zero pressure drift over time. The device was tested in a water



Fig. 6. (a) Schematic of the eZ430-RF2500T's original chip antenna with its matching circuit. (b) Its replacement by the annular slot antenna with an added LC matching network.



Fig. 7. (a) Schematic of the hydrostatic pressure measurement with the DICP device. (b) Schematic of zero pressure drift test.

bath under different pressures (fixed temperature) and various temperatures (fixed pressure).

In-vitro hydrostatic pressure tests were conducted in the presence of a Camino catheter (Camino 1104B, Integra Life Science, Plainsboro, NJ) to calibrate our device. The goal of the DICP test was to establish a zero baseline corresponding to  $N_{X0}$ and establish a relationship between the measured  $\Delta N_X$  and the pressure difference  $\Delta P$  obtained by the Camino catheter.

Fig. 7(a) illustrates the schematic of the hydrostatic pressure test setup. The device stayed stationary at the bottom of the pressure chamber, and a graduated water column was connected to the chamber. The standard Camino ICP catheter was placed 5 mm  $\cdot$  Hg lower (6.8 cm higher) than where the sensor was to verify the applied pressure. The chamber was held stationary inside a water bath at a fixed temperature (37 °C), and its pressure varied through a graduated water column similar to [12].

One of the complications of the ICP monitoring is the device drift. To avoid overestimating or underestimating the ICP readings due to the drift, it is important to investigate the drift of the DICP device at zero pressure. In order to better mimic the animal study condition in terms of the exerted pressure on the device, as shown in Fig. 7(b), only the nozzle part (including sensor) was immersed in the water, and the rest of the device stayed out of the water.



Fig. 8. (a) DICP device pressure sensitivity test result. (b) DICP device temperature sensitivity test result.

# B. Tests Results

As described in Section II, the electronics and battery were encapsulated in the medical grade epoxy. However, the nozzle and the area surrounding the sensor membrane were sealed by silicone due to its ease of the handling (it was difficult to apply the low viscosity epoxy to the sensor without the risk of affecting its membrane). The entire device was further coated with biocompatible parylene. Parylene coating not only protects the device from damaging effects of corrosive body fluids, organic agents, electrolytes, acids, and so on, but also acts as a barrier to the passage of any contaminants from the device to the body.

The device was first tested at zero pressure and fixed temperature (37 °C) for two days based on the length of time anticipated for the animal study [see Fig. 7(b)]. The mean counts at 0 mm  $\cdot$  Hg were 4638 with a standard deviation of ±2.689 counts, which corresponded to ±3.3 mm  $\cdot$  Hg zero pressure drift.

The hydrostatic pressure tests were performed in the pressure range of 0–120 mm  $\cdot$  Hg [see Fig. 7(a)] with a step of 10 mm  $\cdot$  Hg, and the results are shown in Fig. 8(a). The sensitivity of the measured counts for the sensor versus pressure, over the entire pressure range, was calculated as 0.803 count/mm  $\cdot$  Hg. The measurement error (standard deviation) was 0.722 count, corresponding to a pressure error of 0.90 mm  $\cdot$  Hg.

Temperature variation tests were performed in the range of 23.9 °C–34.4 °C (75°F–94°F) in water to determine the effect of temperature on the device [see Fig. 8(b)]. The device exhibited an average temperature sensitivity of 1.480 counts/°C (0.822 count/°F), corresponding to a 1.843 mm· Hg/°C (1.023 mm· Hg/°F) pressure reading drift, obtained by hydrostatic measurements at a pressure of 0 mm · Hg. The reason for the increase in temperature sensitivity compared to the preliminary evaluation of the DICP device [13] is that, for better sealing, the sensor's glass–silicon interface is coated first by a small amount of epoxy and then by silicone as opposed to the silicone only coating in the previous study. The sensor is sensitive to the temperature coefficient of the surrounding materials, such as the epoxy, which is very hard and can exert varying level of stress on the sensor when temperature varies.



Fig. 9. Signal strength test setup and result. The signal strength is evaluated in the radial direction with respect to the cylindrical container and in its line of sight.

### C. Signal Strength and Range

The DICP was placed in a container approximately 13.5 cm in diameter and filled with water of 4.5 cm in height. The antenna was kept 8 mm below the surface of the water shown in Fig. 9.

Fig. 9 also illustrates the signal strength for the device with the annular slot antenna, evaluated at steps of 1.02 m. The container was kept at one corner of a hallway at a height of about 1 m from the floor. With the default radiated power of 0 dBm for CC2500, the range of reading was approximately 18 m, compared to the range for the DICP device with the PIFA antenna of about 11.7 m.

#### IV. DICP DEVICE In-Vivo TESTS IN ANIMAL MODEL OF TBI

#### A. Method

Animal studies were conducted in accordance with the policies set forth by the University of Pennsylvania's Institutional Animal Care and Use Committee (IACUC) and followed the National Institutes of Health "Guide for the Care and Use of Laboratory Animals."

Yorkshire swine were anesthetized, and the ICP monitoring device was implanted approximately 24 h prior to the injury. The implantation required a minimally invasive surgical procedure with the device placed over the skull with a 5.1-mm-diameter transcranial burr hole to allow sensor contact with the CSF. Titanium self-tapping screws were used to fasten the flange of the case and dental cement was applied around the perimeter to further secure the device housing to the skull.

On the day following the implantation, nonimpact TBI was induced via rapid head rotational velocity/acceleration using a HYGE pneumatic actuator (HYGE Inc., Kittanning, PA) The HYGE device is driven by pressurized nitrogen and converts linear motion into angular motion through custom-built linkage assemblies. Animals were secured to the device via a padded snout clamp attached to the custom linkage and the head was rapidly accelerated in the sagittal plane such that the center of rotation was located at the cervical spine (Fig. 10). An angular rate sensor (Applied Technology Associates Inc., Albuquerque, NM) was attached to the linkage sidearm to measure rotational



Fig. 10. Schematic depicting the position of the pig on the HYGE device.



Fig. 11. DICP device measurements in pig for two days.

velocity, and signals were captured using a PC-based data acquisition (f = 8 kHz). Accelerations were computed by differentiation of the rotational velocity signal [28]. A peak angular velocity of 105–138 rad/s (occurring over approximately 12 ms) was provided to deliver a biomechanical insult associated with moderate-to-severe TBI—sufficient to cause a measureable increase in ICP. Animals were sacrificed within 6-h post-injury and the brains were processed for gross pathology.

#### B. In-Vivo (Animal) Study Results

After the implantation, the device exhibited an instability period in the first 4–5 h (Fig. 11), potentially due to surgical considerations or air between the sensor tip and the CSF (see Section V). After device stability was reestablished, baseline ICP readings were relatively consistent over the 12 h prior to the injury at 15.6  $\pm$ 5.3 mm · Hg (mean  $\pm$  standard deviation). We found that closed-head rotational TBI induced a rapid and extreme ICP spike occurring directly upon injury (max ICP > 115 mm · Hg) (Fig. 11). Notably, device integrity and positioning remained suitable for dynamic post-injury ICP readings, which is impressive given the forces necessary to generate the rapid head rotation in the swine (peak angular acceleration of over 50 000 rad/s<sup>2</sup>). The acute elevation in ICP generally lasted for 40–60 min, followed



Fig. 12. Results from three independent ICP trials of digital and analog devices. Trial (1) is for the DICP (1) device, i.e., the one described in this paper with the entire ICP results provided in Fig. 11. Trial (2) is for a preliminary DICP device (i.e., DICP (2), an earlier version with a larger housing, not shown in this paper). Trial (3) is for an AICP device [AICP (1)] [14].

by a gradual decline to maintain a persistently elevated level over several hours post-injury.

To the best of our knowledge, this trend of an immediate ICP spike followed by persistently elevated levels has not been previously observed following closed-head TBI. To confirm our measurements, the Camino ICP monitor was introduced into the parenchyma 3 h after the injury (placed contralateral to the DICP device). Camino measurements showed a pressure range of 22–26 mm  $\cdot$  Hg and during that period, our DICP measurements recorded a mean 23.79 mm  $\cdot$  Hg with a standard deviation of  $\pm 2.94$  mm  $\cdot$  Hg.

Two other independent ICP measurement trials, named as trial (2) obtained by another DICP device [DICP (2)] and trial (3) obtained by an AICP device [AICP (1)] [14], using the same rotational injury model in different pigs are shown in Fig. 12, as compared to trial (1) in Fig. 11. (Note that the indices do not necessarily reflect the chronological order of the trials. DICP (2) was a preliminary DICP device with a larger packaging.) The measurements are synchronized based on the time of injury (t = 0) to show the ICP data for 1.5 h before and after the injury. These data demonstrate that similar TBI-induced ICP trends were observed across the different trials with different devices and animals. Moreover, different peak ICP levels were observed at the different injury levels. However, for trial (2), an extreme ICP (max ICP well beyond 120 mm · Hg, peak at 165 mmHg) spike was measured acutely, which we believe to be quite unrealistic and due to a systematic error caused by the direct contact between the sensor and the brain tissue during and after (for the duration of spike) the head rotation. This issue was resolved for trial (1) by recessing the placement of the sensor with respect to the nozzle tip, as described previously.

# C. Gross Pathology

Gross pathological examinations were performed to assess the severity level of the injuries as well as to understand the underlying mechanisms that could produce the high post-injury ICP readings observed. Severe cortical subdural hematoma, as well as extensive bleeding on the brain stem and spinal cord was



Fig. 13. Brain gross pathology. (a) Coronal section (arrows showing blood accumulation within the third ventricle, as well as within a cortical sulcus). (b) Coronal section (arrow showing blood accumulation within the fourth ventricle).

present at the time of tissue harvest. Further, gross pathology indicated the presence of blood in ventricles (Fig. 13).

## V. DISCUSSION AND CONCLUSION

Several factors should be noted for proper interpretation of our findings, in particular for the ICP readings over the first several hours post-implant. Our results show that the capacitive pressure sensor demonstrates some degree of sensitivity to humidity changes. In addition, it is suspected that temperature sensitivity and the presence of an air pocket inside the nozzle, between the sensor and the CSF, would also cause instability of the device for the first few hours. It may also take a few hours (4-5 h) for a dry device to establish stable readings after implantation. It should be noted that DICP (2) had a similar period of instability to DICP (1). However, AICP (1) needed much shorter time to stabilize, potentially attributed to the different sensor measurement method used for the AICP device. We believe that the stabilization period of the device after surgery can be reduced, and drift can be improved by further modification of the device integration and its coating. In addition, considerations during implantation such as dropping small amount of saline in the nozzle to prevent an air pocket from forming could make the device more stable.

Following the TBI, the standard Camino probe was used to validate the measurements attained by our ICP devices. Over multiple trials, Camino measurements were within 10% of simultaneous measurements recorded from the DICP, with differences potentially attributed to different placements (intraparenchyma versus subdural). Also, the overall ICP trends recorded with the DICP devices were similar to that obtained using the AICP device [14]. Our fully implanted wireless ICP monitoring system expands the time-frame over which the ICP data can be measured following the induced TBI in animal models. For instance, tethered devices such as the Camino catheter cannot be present in the animal at the time of applying the head-rotational TBI without risking severe focal tissue damage and extreme forces on the catheter. To avoid risk of post-injury complications, a tethered device would need to be placed in the brain only after vital signs (e.g., breathing) have stabilized after the injury. Not only does this delay limit the ability to acquire data pertaining to acute injury-induced ICP changes, but the act of breaching the cranium to insert a tethered probe releases at least some of the pressure to be measured. Overall, the post-TBI ICP changes measured with our DICP matches closely with previous published reports using this swine model, where ICP changes were measured using the Camino catheter for multiple injury levels [29].

Our studies suggest that to make each measurement more reliable, we should perform a calibration for each individual device separately. Our current plan is subjecting 3–5 pigs to nonimpact head rotational accelerations to test our devices. In the future, when a larger number of animals are tested, a statistical test will be applied to study ICP trends after rotational injury.

ICP fluctuations are observed by live animal activities such as head movement. Some fluctuations may also be attributed to the random variation of the internal clock of the microcontroller. For noise reduction, coaxial cables are used in the nozzle to connect the microcontroller ports to the sensor. In the future long-term post-injury monitoring, the moving average can be applied to the data to smoothen out the short-term fluctuations and better highlight the long-term trend of the ICP data. For the current study, we only have 3-h post-injury data, and no moving average is used to obtain a better resolution and details of ICP changes in such a short period.

Analyses of the gross pathology revealed evidence of extensive TBI-induced bleeds and corresponding blood accumulation on and within the brain tissue. Such overt disruption of the vasculature most likely caused the immediate post-injury ICP changes, whereas persistently elevated ICP was likely influenced by both cytotoxic and vasogenic edema. An added benefit of using a fully implanted wireless device is the ability to monitor chronic ICP changes across the full spectrum of injury severities. In the current study, the pig could not survive from such injury conditions. Therefore, there was no long-term post-injury study, and only about 3 h of post-injury data were measured. Our future studies will evaluate the ability of the DICP device to measure ICP over days to weeks following TBI in swine model.

Mimicking cerebral edema from nontraumatic conditions such as hydrocephalus could be accomplished by infusing saline into the animal's brain for inducing intracranial hypertension, which was previously demonstrated in [12]. The mechanism of ICP changes due to nontraumatic conditions is similar to that of hydrostatic tests applied to the DICP devices, which have shown the capability of such sensors to monitor pressure variation.

Another important issue for an implantable device for longterm study is battery life. Based on current mode of system and transmission, the average current consumption is about 18.3  $\mu$ A and the coin battery we used was 220-mA·h battery (CR2032). Assuming a stable voltage (2.5 V) can be sustained with discharging half of the battery capability, based on current consumption of the DICP, the device would provide a stable signal for approximately 250 days, which is five times longer than that of the AICP [12]. Moreover, in the future, a rechargeable battery will be utilized in the device, potentially enabling RF recharging or optical recharging of the battery.

In summary, using a novel wireless device, we have demonstrated dynamic ICP increases as an immediate consequence of nonimpact closed-head rotational injury, mimicking moderate-to-severe TBI, in swine. Additionally, robust and automatic recording capability of the DICP device was further aided by the improved antenna performance, as investigated here. This implantable device will be utilized as a tool to diagnose and track ICP changes following TBI for a range of severities with diminished risk of infection.

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**Xu Meng** (S'08) received the B.E. degree in electronics and telecommunications and M.S. degree in biomedical engineering from the Beijing Institute of Technology, Beijing, China, in 2006 and 2008, respectively, and is currently working toward the Ph.D. degree in biomedical engineering at Drexel University, Philadelphia, PA.

His research interests are the clinical application of microwave and RF in medical implants and telemedicine.

Mr. Meng is a student member of the IEEE Microwave Theory and Techniques Society (IEEE MTT-S), Engineering in Medicine and Biology Society (IEEE EMBS), Consumer Electronics Society (IEEE CES), and American Association for the Advancement of Science (AAAS). He was a recipient of a Calhoun Fellowship presented by the School of Biomedical Engineering, Drexel University (September 2008–December 2012), the Provost Fellowship Drexel University (September 2008–September 2010), National Science Foundation (NSF) Fellowship (2010), and the IEEE MTT-S Graduate Fellowship for Medical Application (2011).



Kevin D. Browne was born in Camden, NJ, in 1969. He received the B.A. degree in biology from Rutgers University, New Brunswick, NJ, in 1992.

He is currently a Research Specialist with the Department of Neurosurgery and the Center for Brain Injury and Repair, University of Pennsylvania, Philadelphia. He has authored several papers related to head injury. His current research concerns the outcome of repetitive concussions and the influence of primary blast overpressure on brain pathology.



**Shi-Min Huang** (S'12) is currently working toward the dual B.S./M.S. degree in electrical engineering at Drexel University, Philadelphia, PA.

In Summer of 2011, he was selected as a STAR Scholar and was with Drexel University. He is currently involved in the study of blast-induced TBI.

Mr. Huang is a member of Pennoni Honors College, Drexel University (September 2010–June 2015). He was a recipient of the Drexel University Dean's Scholarship (September 2010–June 2015).



**Constance Mietus** received the B.A. degree in biology and psychology from the University of Pennsylvania, Philadelphia, in 2009.

She is currently a Research Specialist with the Department of Neurosurgery, Center for Brain Injury and Repair, Perelman School of Medicine, University of Pennsylvania. She is pursuing a career in medicine. Her research interests include the biomechanically induced mechanisms of cell injury and death following TBI.



**D. Kacy Cullen** received the B.S. degree in mechanical engineering, M.S. degree in mechanical engineering, and Ph.D. degree in biomedical engineering from the Georgia Institute of Technology, Atlanta, in 2000, 2002, and 2005, respectively.

From 2005 to 2006, he was a Postdoctoral Researcher with the Laboratory for Neuroengineering, Georgia Institute of Technology . From 2007 to 2009, he was a Postdoctoral Fellow with the Center for Brain Injury and Repair, University of Pennsylvania, Philadelphia, PA. Since 2009, he

has been an Assistant Professor of Neurosurgery with the Perelman School of Medicine, University of Pennsylvania. He has authored or coauthored over 30 papers. He serves on the Editorial Board of *Critical Reviews in Biomedical Engineering*. His research program operates at the intersection of neurotrauma and neural engineering by applying biomedical engineering principles to better understand the causative mechanisms of neural injury such as TBI, as well as to develop cutting-edge neural tissue engineering-based treatments to promote regeneration and restore function.

Dr. Cullen is a member of the Biomedical Engineering Society, the American Society of Mechanical Engineers, the National Neurotrauma Society, and the Society for Neuroscience.



Mohammad-Reza Tofighi (S'98–M'00–SM'05) received the B.S.E.E. degree from the Sharif University of Technology, Tehran, Iran, in 1989, the M.S.E.E. degree from the Iran University of Science and Technology, Tehran, Iran, in 1993, and the Ph.D. degree in electrical engineering from Drexel University, Philadelphia, PA, in 2001.

In April 2001, he became a Post-Doctoral Research Associate, and then a Research Assistant Professor with Drexel University, where he was involved in research on the development of microwave

and millimeter-wave test fixtures for measurement of the complex permittivity of biological materials and microwave oscillators phase and frequency-locking techniques. Since August 2004, he has been with Capital College, Pennsylvania State University, Middletown, where he is currently an Associate Professor of electrical engineering and teaches a variety of undergraduate and graduate courses on RF and microwaves, communication systems, and electromagnetics. During Spring and summer 2012, he was a Visiting Research Professor with Drexel University. He has authored or coauthored several IEEE journal and conference proceedings papers. He authored "Measurement Techniques for Electromagnetic Characterization of Biological Materials" of the *Handbook of Engineering Electromagnetics* (Marcel Dekker, 2004). His main research interest is medical applications of RF and microwaves. In particular, he conducts research on wireless implants, biomedical antennas, and complex permitivity measurement of tissues.

Dr. Tofighi is the current chair of the IEEE MTT-10, Technical Committee (TC) on biological effects and medical applications of RF and microwave. He has served in IEEE Microwave Theory and Techniques Society (IEEE MTT-S) sponsored conferences, including the IEEE MTT-S International Microwave Symposium (IMS), Radio and Wireless Symposium (RWS), and BioWireleSS Conference as a Technical Program Committee (TPC) member and subcommittee chair/vice-chair for several years.



**Arye Rosen** (M'77–SM'80–F'92) received the Masters degree in engineering from The Johns Hopkins University, Baltimore, MD, the M.Sc. degree in physiology from Jefferson Medical College, Philadelphia, PA, and the Ph.D. degree in electrical engineering from Drexel University, Philadelphia, PA.

He has been involved in research and development of microwave/millimeter-wave devices and circuits, microwave optical interaction, high-power semiconductor lasers, and the utilization of energies for application in therapeutic medicine for the past 40 years.

He is currently Academy Professor of Biomedical and Electrical Engineering with the School of Biomedical Engineering, Science and Health Systems and Associate Vice Provost for Strategic Initiatives, Drexel University, Philadelphia, PA. He is also Associate in Medicine with Jefferson Medical College, where since 1970, he has been engaged in research with the Division of Cardiology. He has authored over 200 technical papers. He co-edited *High-Power Optically Activated Solid-State Switches* (Artech House, 1993) and *New Frontiers in Medical Device Technology* (Wiley, 1995). He coauthored *RF/Microwave Interaction with Biological Tissues* (Wiley 2006). He has authored six book chapters in the field of engineering and medicine.

Dr. Rosen is an elected member of the National Academy of Engineering since 2002. He is an elected member of Committee on Science and the Arts, The Franklin Institute (2003). He is a member of the John Scott Award Advisory Committee, City of Philadelphia Board of Directors of City Trusts (2004). He was an IEEE Distinguished Microwave Lecturer (1997–2000), during which time he has presented his work and the work of others in the U.S., Japan, Europe, and the Middle East. He was the recipient of numerous awards, including the IEEE Third Millennium Medal (2000) and an IEEE Microwave Application Award (2000). He was also the recipient of a 1989 IEEE Region One Award and a 1997 Drexel University College of Engineering, Electrical and Computer Engineering Department, Distinguished Alumni Award.