Dynamic study of wireless intracranial pressure monitoring of rotational head injury in swine model

X. Meng, K. Browne, S.M. Huang, D.K. Cullen, M.R. Tofighi and A. Rosen

For what is believed to be for the first time, the dynamic study of wireless intracranial pressure measurements in a swine model of traumatic brain injury is described. This achieves an extremely important milestone, since the measurements demonstrate the system's robustness, and the feasibility of acquiring wireless readings of the intracranial pressure resulting from non-impact rotational head injury in swine. The fully implanted device uses a capacitive pressure sensor modulating an RF oscillator, coupled to a planar inverted-F antenna. The results match well those obtained from a standard fibre-optic based (tethered) commercial intracranial pressure monitor, as well as published literature data, and may enable a future trend in the use of implantable wireless systems for research or clinical diagnoses.

Introduction: Increased intracranial pressure (ICP) is an important component of secondary brain injury following traumatic brain injury (TBI). Indeed, the prevention and control of increased ICP is one of the fundamental therapeutic goals following TBI across a range of severities. Standard commercially available ICP measuring equipment uses a tethered fibre-optic probe that penetrates the brain, which can remain implanted in TBI patients or animals for only a short period of time. Therefore, a small fully embedded wireless ICP device, implanted during a straightforward procedure, drastically simplifies subsequent clinical management of brain injury patients. In particular, by offering a means for semi-invasive and long-term pressure measurement, this technology may guide subsequent neurosurgical decisions and reduce the risk of infection in a neurointensive care setting.

In a previous study [1], a device (featuring subdural placement of a biomedical microelectromechanical system (MEMS) capacitive sensor) operating at 2.4 GHz was developed. The device was implanted in a canine model for a static test, and hypo- and hyperventilation were used to effect variations in ICP. A MEMS sensor was preferred over a piezoresistive one [2] for its temperature stability and power consumption considerations. The *in vitro* and *in vivo* results demonstrated the feasibility of microwave pressure monitoring through scalp, long-term device integrity, and repeatability of pressure measurements

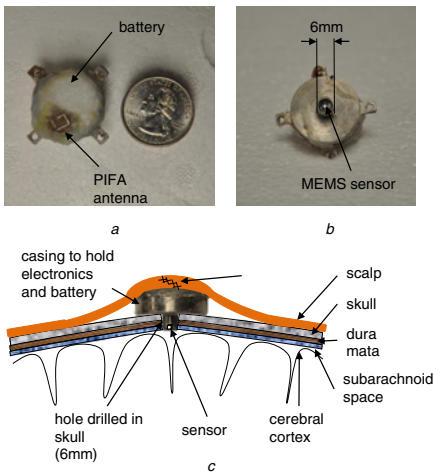

Fig. 1 *Complete wireless ICP device*

a Top view
b Bottom view also showing 6 mm-diameter nozzle
c Device placement in head

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This Letter presents the first time test results of the device's utilisation to study TBI-induced ICP changes (dynamic measurements) in a large animal (i.e. a pig). Moreover, the device has been engineered to improve performance in this application, including a modification previously described [2] to allow for the electronics and battery to be maintained in a larger diameter housing placed over the skull (Fig. 1) rather than in the 12 mm-diameter housing placed previously inside the skull [1, 2]. The skull burr hole for the newer device needing to accommodate only a 6 mm-diameter nozzle thus requires a minimally invasive and considerably simpler surgical procedure. To demonstrate the device's dynamic performance, a swine model was chosen and closed-head rotational acceleration injury was induced.

Device and method: For this completely implantable wireless ICP device, the ICP variation changes the oscillation frequency of an RC oscillator (~700 kHz) modulating a 2.4GHz RF oscillator coupled to a planar inverted-F antenna (PIFA) [1]. The device (Fig. 1) is housed in a titanium case and the sensor connects to the board via a coaxial cable in the nozzle. The sensor makes contact with the cerebrospinal fluid (CSF), which circulates in the subdural or subarachnoid space (Fig. 1*c*).

The animal study was carried out in accordance with the policies set out 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'. On Day 1, the sensor was implanted as detailed in Fig. 1. On the following day, non-impact brain trauma was induced via rotational acceleration as described in [3]. The animal's head was attached to a Hyge pneumatic actuator via a padded snout clamp. A custom linkage converted linear motion into angular motion of the Hyge device, triggered by a release of pressurised nitrogen, into angular motion (rotational acceleration) of the head. The Hyge device was set to deliver a rotational velocity of 138 rad/s in the sagittal plane over 12 ms. This level of injury was sufficient to cause a measurable increase in ICP. Heart rate, respiration, oxygenation, and temperature (36.9°C) were measured continuously before and after the injury. Pre- and post-injury ICP measurements were obtained to evaluate the dynamic performance of the device.

Results: To calibrate the device prior to the animal study, hydrostatic tests [1] were carried out at different pressures at a fixed temperature (34.5°C) and at different temperatures at a fixed pressure (5 mm•Hg), in the presence of the Camino catheter (Camino 1104B, Integra Life Sciences) as the reference. The measured performance of the wireless ICP device, i.e. temperature sensitivity (frequency change against temperature change) and pressure sensitivity (frequency change against pressure change) were 0.491 kHz/°C and −0.332 kHz/mm•Hg, respectively.

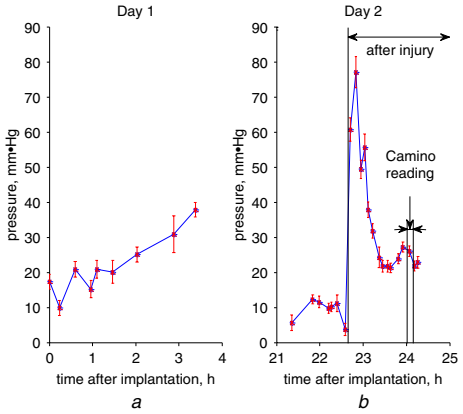

Fig. 2 *ICP measurements for two days*

a Day 1: conducted after implantation
b Day 2: pre-injury baseline and post-injury response
Error bar represents overall standard deviation of error, i.e. square root of sum of standard deviations (errors) squared contributed by individual items, namely calibration process, Camino reading, and repeated ICP readings at each time point during measurements

Fig. 2*a* depicts the ICP data monitored for a period of 3 hours and 24 minutes after the implantation on Day 1. The results represent a gradual increase in pressure up to 37.8 mm•Hg, which we believe to be due to the surgery. Fig. 2*b* illustrates the ICP data monitored during Day 2, including pre-injury baseline and the post-injury data. Day 2 was started with an average pre-injury baseline of 9.5 ± 3.4 mm•Hg (mean ± standard deviation). The first post-injury data was recorded two minutes after the head rotational injury induced at 22 hours and 40 minutes after the implantation. The pressure reading was 60.7 mm•Hg. The peak pressure value was 77.1 mm•Hg, reached

eight minutes after the injury. However, by 42 minutes following the injury, the ICP returned to 24.3 mm•Hg. To confirm our measurements, the gold-standard Camino ICP monitor was introduced into the parenchyma 74 minutes after the injury, and placed contralateral and anterior to our wireless ICP device. The standard ICP monitor measured 22 mm•Hg, while concurrently our wireless ICP device measured 26.1 $\pm$ 1.5 mm•Hg. Immediately after removal of the Camino, the wireless ICP reading was 21.8 $\pm$ 1.4 mm•Hg.

Discussion: We have developed and validated a novel fully implantable wireless device to measure ICP changes in a large animal model of TBI. 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 swine (peak angular acceleration of 52 101 rad/s^2). Within minutes following this severe closed-head TBI, our device measured an ICP increase in excess of 60 mm•Hg, above the baseline. These results were consistent with previous published reports using this swine model (obtained by the Camino catheter for a similar injury level) showing an ICP increase of as high as 50 mm•Hg above the baseline during five minutes following the injury [3]. In addition, we show a drop in ICP after eight minutes following the injury and a return to a relatively stable level after 40 minutes, which also agrees with reported trends [3]. The post-injury ICP values stabilised at a higher than normal level (within a range of 21.2 to 27.2 mm•Hg) which would likely have persisted for a protracted time period owing to ongoing secondary sequelae. The variation in results between the tethered Camino probe and those obtained with our wireless ICP device were minimal, but may be partially attributed to different placements (intraparenchyma against subdural) of these devices. In future applications, this miniature, implantable wireless device may be utilised as a research or clinical tool to diagnose and track ICP changes acutely or in a delayed fashion following brain injury.

Conclusion: We believe that the results obtained have successfully demonstrated the ability and robustness of the wireless ICP device in measuring intracranial pressure as a consequence of rotational head injury mimicking a moderate-to-severe TBI in a large animal model.

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One or more of the Figures in this Letter are available in colour online.

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