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Assessment of MRI issues at 1.5 T for the Temperature Logger Implant

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ABSTRACT

Purpose: The Temperature Logger Implant is a newly developed device that is capable of providing data for animal studies on thermoregulatory function, hibernation, hypothermia, and general health. During research, it may be necessary to conduct a magnetic resonance imaging (MRI) examination on an animal with this device implanted to assess anatomical changes or other conditions. Notably, this new device was specially designed to be unaffected by the electromagnetic fields used for MRI. Therefore, to verify that there would be no problems related to MRI, the purpose of this investigation was to evaluate MRI-related issues for the Temperature Logger Implant.

Methods: Tests were performed on the Temperature Logger Implant using well-accepted techniques to evaluate magnetic field interactions (translational attraction and torque, 1.5 T), MRI-related heating (whole body averaged specific absorption rate, 2.9 W/kg), artifacts (T1-weighted, spin echo and gradient echo pulse sequences), and functional changes related to exposure to eight different imaging conditions.

Results: Magnetic field interactions were relatively low (deflection angle 4°, no torque) and heating was minor (highest temperature rise, $\geq$ 1.1 °C) indicating that these factors will not pose a hazard to an animal. The largest artifact (gradient echo pulse sequence) extended 10 mm from the size and shape of the Temperature Logger Implant. Exposure to the eight different conditions at 1.5 T/ 64 MHz did not alter or damage the operational aspects of the device.

Conclusions: The findings demonstrated that MRI can be performed safely on an animal with this new Temperature Logger Implant and, thus, this device is deemed “MR Conditional” (i.e., using current labeling terminology), according to the conditions used in this investigation.

1. Introduction

The study of body temperature regulation in human subjects and other mammals is integral such as safety pharmacology and biodefence and is beneficial for investigations of thermoregulatory function, hibernation, and hypothermia (Kaaijk et al., 2013; Shellock and Rubin, 1984; Snapp and Heller, 1981; Barnes, 1989; Ortmann and Heldmaier, 2000; Tøien et. al, 2011; Tøien and Mercer, 1995). Determining the body temperature of freely-moving animals using tethered measurement techniques is typically inferior to using implanted devices, especially when unperturbed recordings are needed on a long-term basis. Importantly, implanted devices that can either transmit temperature data in real time or store values for future retrieval are less stressful to animals (Jinka and Duffy, 2013; Kaaijk et al., 2013) and less likely to be compromised or destroyed.

Given the increased use of magnetic resonance imaging (MRI), as a viable method to study anatomical changes and physiological alterations in laboratory and freely-moving animals, an implanted temperature recording device would be practicable. Recently, a Temperature Logger Implant was specially developed at the Institute of Arctic Biology, University of Alaska Fairbanks (UAF), for use in hibernating bears as well as other medium to large sized animals in consideration of the various issues that could negatively impact the safety and other aspects of the device with respect to the electromagnetic fields used for MRI (Shellock, 2018). Because MRI technology uses a powerful static magnetic field, rapidly switching time-varying gradient magnetic fields, and radiofrequency (RF) fields, substantial hazards may impact metallic implants (Shellock, 2018). Therefore, the purpose of this investigation was to evaluate magnetic field interactions (translational attraction and torque), MRI-related heating, artifacts, and possible functional changes

Abbreviations: PCB, Printed Circuit Board; EEPROM, Electrically Erasable Programmable Read-Only Memory; MEMS, Microelectromechanical Systems (MEMS); ASTM, American Society of Testing and Materials; SAR, Specific Absorption Rate; GRE, Gradient Echo Pulse Sequence; UAF, University of Alaska Fairbanks

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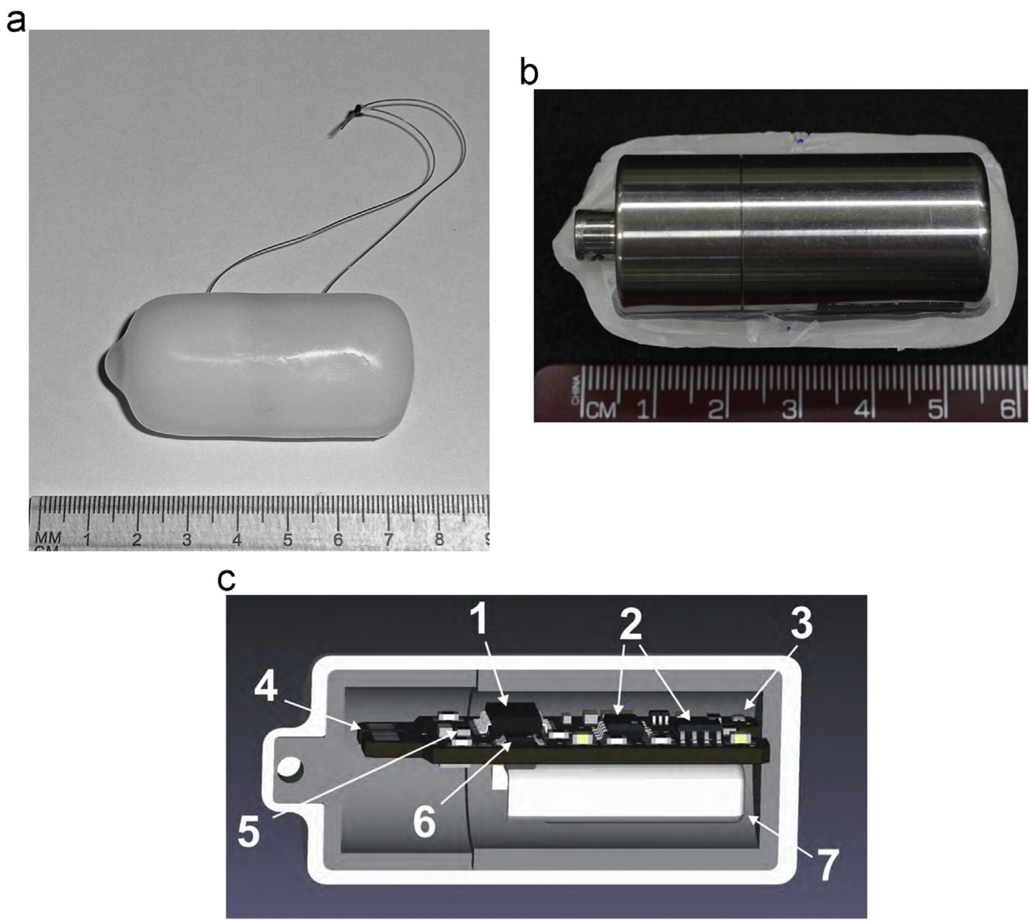

Fig. 1. a. The Temperature Logger Implant that underwent MRI testing. The suture (0-Prolene) is used to tether the device in the animal, in situ (the scale is in centimeters). **b.** Photograph of the Temperature Logger Implant with half of the El-wax coating cut away to show the cylindrical titanium alloy capsule with a layer of heat shrink below the wax. Capsule measures: 21.55 mm (O.D.) x 48.5 mm (L) without a protrusion at one end, total length, 54.2 mm. The thickness of the heat shrink and Elvax layer adds 3–5 mm to dimensions in each direction. **c.** Simplified three-dimensional rendering of the Temperature Logger Implant showing a cross section of the device (threaded section of the gray titanium alloy capsule not shown). The printed circuit board (PCB) measures 15 mm (W) × 42.4 mm (L), with a 16-bit microcontroller (1), two EEPROMS (2), magnetic sensor switch (3), card edge connector (4), MEMS oscillator (5) and a temperature sensor (6). The Lithium-Polymer rechargeable battery (7) shown below the PCB measures 7 mm (H) × 17 mm (W) × 25.5 mm (L). There is an insulated copper foil located on top of the circuit board for additional shielding (not shown). The outer electrical insulation and sealing (white color) consists of four layers of wax coating (Elvax blend) on top of one layer of heat shrink.

for this new implant in association with the use of a 1.5 T/64 MHz MR system.

2. Materials and methods

2.1. Temperature Logger Implant

In this investigation, the Temperature Logger Implant, officially known as the Alaska Temperature Logger Implant (large version), developed by the second author (Dr. Tøien), at the Institute of Arctic Biology, UAF, was subjected to tests to determine if the electromagnetic fields used with MRI technology could create issues for this device. The design of the Temperature Logger Implant was such that it prioritized issues that may be encountered relative to the use of MRI safety with consideration given to minimizing ferromagnetic content, protecting against data loss, while having an acceptable size and satisfactory sampling rates and battery time. Physically, the logger is contained in a commercially available, O-ring-sealed non-magnetic titanium alloy (Ti-6Ai-4V) capsule, 21.55 mm (O.D.) x 48.5-mm (L), total length 54.2 mm including a short protrusion at one end (Fig. 1). The metallic capsule provides a means of mechanical protection and shielding of the Temperature Logger Implant (Fig. 2).

The metallic capsule was sealed and insulated on the outside by dipping it in four layers of wax (a mix of 80% paraffin wax and 20% Elvax 240W, Dupont, originally supplied by Minimitter Co.) which was applied on top of heat shrink to facilitate the removal of wax when downloading data (Fig. 1). With the 3–5 mm wax coating the dimensions of the Temperature Logger implant is approximately 30 mm (D) × 61 mm (L). A suture (0-Prolene) with a single anchoring point in the mid-section facing away from the internal temperature sensor is added to the Temperature Logger Implant after the second layer of wax. The particular type of wax that was selected for use for the Temperature Logger Implant was chosen because of the prior excellent experience with the biocompatibility of similar wax coated loggers and transmitters when implanted in their target animals (i.e., typically implanted in the abdominal cavity of American black bears, Ursus americanus), (Tøien et. al, 2015). The amount of bulk and mass added by the wax is of no concern to these large animals; similar sized devices have previously been implanted in the abdominal cavity of black bears without complications (Tøien et al., 2011). Notably, non-insulated titanium encased devices have previously been reported to be externalized in five out of six black bears (Laske et al., 2005). Alternatives to the wax coating may be considered in the future; in previous studies on black bears, implanted commercial transmitters with a silicone-polyurethane encapsulation did not cause any complications (Tøien et al., 2011, 2015).

To minimize ferromagnetic properties, a 250 mAh rechargeable, non-magnetic Lithium-Polymer battery was used (Model PGEB-NM651825, PowerStream) in the Temperature Logger Implant. This non-magnetic battery does not have protection circuitry that would consume additional power. The battery fits tightly inside the capsule with the wrapped up protective foil of each edge of the battery slightly compressed, making further anchoring inside the capsule unnecessary.

The printed circuit board (PCB) of the Temperature Logger implant, was glued to the battery with a drop of epoxy (Fig. 1). The PCB contains a card edge connector for charging the battery and to allow communication with the on-board 16-bit microcontroller. The board further contains two electrically erasable programmable read-only memory (EEPROM) units for data storage, a temperature sensor, a microelectromechanical systems (MEMS) resonator for timekeeping, a Spintronic (or spin transport electronics)-based magnetic sensor switch to optionally turn off sampling in the presence of a magnetic field, non-