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Tongue implant for assistive technologies: Test of migration, tissue reactivity and impact on tongue function

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ABSTRACT

Objective: The Tongue Drive System (TDS) is a new wearable assistive technology (AT), developed to translate voluntary tongue movements to user-defined computer commands by tracking the position of a titanium-encased magnetic tracer (Ti-Mag) implanted into the tongue. TDS application, however, is constrained by limited information on biological consequence and safety of device implantation into the tongue body. Here we implant a stainless-steel pellet in the rat tongue and assay pellet migration, tongue lick function, and tongue histology to test the safety and biocompatibility of unanchored tongue implants.
Design: Water consumption, weight and lick behavior were measured before and for >24 days after implantation of a stainless-steel spherical pellet (0.5 mm) into the anterior tongue body of twelve adult male rats. X-rays were obtained weekly to assess pellet migration. Pellet location and tissue reaction to implantation were determined by post-mortem dissection and histology of the anterior tongue.
Results: By dissection pellets were distributed across the transverse plane of the tongue. Measures of water consumption, weight, and lick behavior were unchanged by implantation except for a decrease in consumption immediately post-implantation in some animals. By X-ray, there was no migration of the implant, a finding supported by pellet encapsulation demonstrated histologically. Measures of lick behavior were minimally impacted by implantation.
Conclusion: A smooth spherical stainless-steel implant in the anterior tongue of the rat does not migrate, is encapsulated and does not substantially impact lick behavior. These findings support the implantation of small tracers in the anterior tongue in humans for operating wearable assistive technologies.

1. Introduction

Some 12,000 individuals in the United States suffer spinal cord injury (SCI) each year; of these, individuals with incomplete (39.5%) and complete (16.9%) tetraplegia have limited options for and high costs of assistive devices (National Spinal Cord Injury Statistical Center, Spinal Cord Injury Facts and Figures, 2011). Despite advances in neuroprostheses and brain-computer interfaces, individuals with high-level SCI (i.e. C4 and above) and other neurological diseases which lead to tetraplegia, such as amyotrophic lateral sclerosis and brainstem stroke, have limited options for control of their environments. Currently such control relies upon interaction via a voluntary motor system unaffected or less affected by the SCI, typically either muscles of the face or neck. However, these systems provide limited signal diversity and bandwidth for computer command and cannot be used over extended periods.

Tongue motor innervation by cranial nerve XII is spared, even in individuals with high-level SCI. With its many degrees of freedom, facility for production of precise voluntary movements and non-fatiguing muscle profile, the tongue would thus appear to be a natural interface between cognition and computer for these individuals. Heretofore, the unique inherent abilities of the tongue as an interface has not been fully developed due to limitations in translating voluntary tongue movements in a precise, reproducible, unobtrusive, practical and safe manner. These limitations arise from the inaccessibility of the tongue inside the oral cavity and the requirement that interfaces do not impair preservative

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functions of the tongue in respiration, oral transport and swallowing, as well as speech.

The Tongue Drive System (TDS) was specifically designed with these considerations in mind. A key innovation of the TDS is the wireless and contactless translation of tongue movements via a small titanium-encased permanent-type magnet (Ti-Mag) affixed to the anterior tongue (Huo & Ghovanloo, 2010; Kim et al., 2012; Laumann et al., 2015). The TDS consists of an array of 3-axial magnetic field sensors, mounted near the user's cheeks on a headset to track the position of the tiny magnetic tracer, the size of a lentil (4.8 mm length, 1.5 mm thickness). Any tongue movement results in changes in the magnetic field inside and around the user's mouth. The electronics on the headset wirelessly transmit the measured magnetic field variations from all sensors to a nearby PC or smartphone, which runs a sensor signal processing (SSP) algorithm that attenuates the earth's magnetic field (EMF) components from the incoming signals, followed by a magnetic signal classification method that can currently indicate 7 distinct positions of the magnetic tracer within the 3-D oral space in real-time. These tongue gestures are then translated to specific user-defined commands, and sent to target devices, e.g., a wheelchair (Huo & Ghovanloo, 2008; Kim et al., 2012).

The effectiveness of the TDS has been demonstrated in both SCI and healthy individuals in pilot studies with magnets attached by temporary adhesion to dorsal tongue epithelium or by tongue piercing (Huo & Ghovanloo, 2010; Kim et al., 2013). However, these approaches are impractical for long term use due to lingual and dental complications, the requirement of persistent hygienic maintenance and resistance by older patients to tongue piercing. An optimal solution is to implant the Ti-Mag tracer in the tongue body obviating the need for implant maintenance (as with tongue piercing) and minimizing the risk of swallowing the magnetic tracer or damaging teeth and gums.

Despite these advantages, features unique to tongue biology might negatively impact the safety and reactivity of implantation of a free-standing device in the anterior tongue. Complex changes in tongue stress-strain patterns during oromotor behaviors (e.g., Felton et al., 2008) as well as routine tonic and forceful tongue muscle activation in preservative behaviors (i.e., respiration, swallowing) may impact the formation of a sequestering implant capsule. Tongue muscles are highly capillarized (Granberg, Lindell, Eriksson, Pedrosa-Domellof, & Stal, 2010) and the presence of large ventral lingual arteries and branches raises the possibility of embolization if a small device is not appropriately integrated into surrounding tissue.

To assess safety and reactivity of implantation of a small, unanchored device in the anterior tongue we assayed implant migration, tongue lick function and tongue histology following injection of a 0.5 mm stainless-steel pellet into the rat tongue. Our findings reveal only minimal and temporary impact of implantation on tongue biology.

2. Materials and methods

2.1. Husbandry and measurement of rat licking

All procedures were conducted in accordance with Georgia Institute of Technology Institutional Animal Care and Use Committee. Animals were housed singly to enable individual collection of water consumption and lick data. Water (500 cc bottle) and food was offered *ad libitum*. Animals were weighed at least weekly from at least 4 days before to at least 24 days after implantation. Water consumption (weight change of water in bottle in grams) was determined on most days but sometimes was expressed as the average of 2–4 days of consumption. Actual or average daily water consumption was related to measures of lick behavior assessed during the period of consumption. We sought to measure licking under normal conditions to create a baseline and assess the possible impact of implantation on drinking behavior; therefore we collected lick data continuously and did not constrain access to the nipple. Lick measures were collected for at least 6 days prior to implant using capacitive and resistive custom systems designed at Georgia Tech. Briefly, the capacitive lick meter was designed to measure changes in capacitance between the stainless-steel nipple of the water bottle and instrument ground. The only electrode of the capacitive lick meter was wrapped around the neck of the stainless-steel nipple without changing its shape or characteristics. When the rat tongue touched the nipple, the animal's body changed the capacitance between nipple and ground, which was detected using an AT42QT1011 touch sensor integrated circuit (Atmel, San Jose, California; see Fig. 1). The resistive lick meter required two electrodes and monitored changes in the impedance between these two electrodes during licking. One electrode was attached to the stainless-steel nipple and the other, which served as the ground electrode, was a metal grid spread over the floor of homecage. When the animal tongue touched the nipple, a low resistive path was created between the two electrodes changing the impedance detected by the circuit. The outputs of both types of lick meters were sampled by a MSP430 microcontroller (Texas Instruments) and delivered to a personal computer via Universal Serial Bus (USB) every 11.2 ms (~90 Hz).

2.2. Implant procedure

Twelve adult male Sprague-Dawley rats (291–412 g, assigned identification GT1-G12) were induced with isoflurane in a

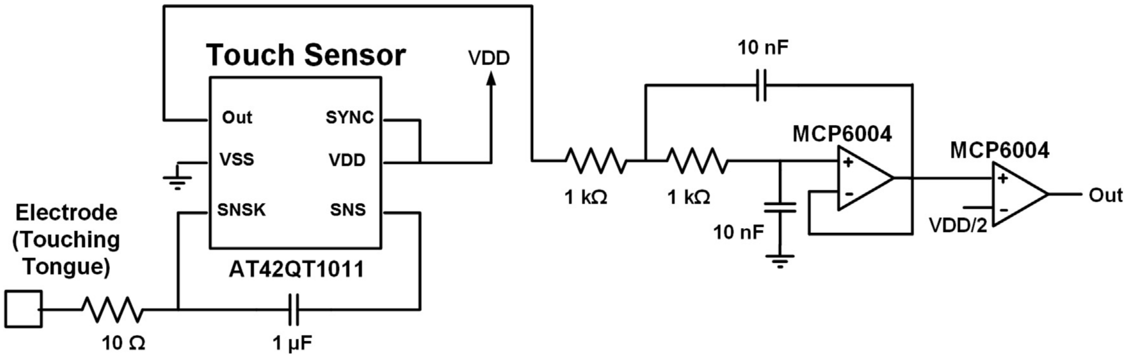

Fig. 1. The schematic of the lick meter interface, the main component of which is a single-key QTouch© touch sensor chip (AT42QT1001, Atmel, San Jose, CA). This chip comes in a small SOT23 package and its touch sensitivity can be adjusted with an external capacitor (1 μF in this case).