Assessment of Vascular Stent Heating with Repetitive Transcranial Magnetic Stimulation

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Objective: A high proportion of patients with stroke do not qualify for repetitive transcranial magnetic stimulation (rTMS) clinical studies due to the presence of metallic stents. The ultimate concern is that any metal could become heated due to eddy currents. However, to date, no clinical safety data are available regarding the risk of metallic stents heating with rTMS. *Methods:* We tested the safety of common rTMS protocols (1 Hz and 10 Hz) with stents used commonly in stroke, nitinol and elgiloy. In our method, stents were tested in gelled saline at 2 different locations: at the center and at the lobe of the coil. In addition, at each location, stent heating was evaluated in 3 different orientations: parallel to the long axis of coil, parallel to the short axis of the coil, and perpendicular to the plane of the coil. *Results:* We found that stents did not heat to more than 1°C with either 1 Hz rTMS or 10 Hz rTMS in any configuration or orientation. Heating in general was greater at the lobe when the stent was oriented perpendicularly. *Conclusions:* Our study represents a new method for ex vivo quantification of stent heating. We have found that heating of stents was well below the Food and Drug Administration standards of 2°C. Thus, our study paves the way for in vivo testing of rTMS (≤10 Hz) in the presence of implanted magnetic resonance imaging-compatible stents in animal studies. When planning human safety studies though, geometry, orientation, and location relative to the coil would be important to consider as well. **Key Words:** Stent—rTMS—temperature—stroke—magnetic field—implant.

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Introduction

Transcranial magnetic stimulation (TMS) is a popular neurophysiological technique to stimulate the brain. TMS applies rapidly changing magnetic fields from over the scalp and skull to induce brief currents in underlying cortices.[1] Currents can modify excitability of targeted and interconnected cortices. When TMS is applied as repeated pulses at preset frequencies, also known as repetitive TMS (rTMS), currents help modify excitability for long periods of time. High frequencies like 3 Hz (or greater) can raise excitability, whereas low frequencies like 1 Hz can suppress excitability. Chronic changes in excitability help promote recovery in several neurologic diseases.[2]

In particular, rTMS has received significant attention in the area of stroke recovery.[3,4] This is because high frequency rTMS can facilitate excitability of weak cortices in the stroke hemisphere, whereas low frequency rTMS can suppress overactivity of cortices in the intact hemisphere. Unfortunately, a high proportion of patients with stroke do not qualify for rTMS due to the presence of metallic implants, such as clips or stents. The ultimate concern is that metallic implants can become heated due to strong, alternating magnetic fields applied during TMS (termed eddy currents; 1.5-2T). Heating of more than 6°C above body temperature can result in significant tissue or brain damage.[2]

Implants like stents are disproportionately exclusionary for stroke more than other neurologic diseases. This is because more than 13% of the 795,000 strokes that occur annually in the United States require intracranial stenting for re-vascularization and endovascular recanalization.[5] This proportion does not even include the significant proportion of patients who receive carotid stents to prevent index or recurring strokes. Even though several types of stents have been tested and approved for safe use in 3T magnetic resonance imaging, no clinical safety data are available regarding the risk of heating with rTMS.[6,7]

Therefore, here, we outlined and conducted an ex vivo experiment to test the safety of rTMS with stents used commonly in stroke.[8,9] We delivered rTMS based on parameters applied commonly, viz., frequencies of 10 Hz and 1 Hz.[2,10] We compared heating of stents to heating of a gold electrode, which is used commonly to simulate instances of acute heating in ex vivo studies (Rotenberg et al, 2007), and a control setup to account for convective heating and artifacts. We anticipated that none of the rTMS paradigms would heat stents to levels considered unsafe by the Food and Drug Administration (FDA) standards.[11,12] Overall, by demonstrating safety of stents with rTMS, we sought to build upon studies that have demonstrated safety of implants like titanium plates or aneurysm clips with rTMS.[13-15] These original studies have helped offer more patients with epilepsy an opportunity to undergo noninvasive, well-tolerated therapies like rTMS. In the same vein, more patients with stroke would have an opportunity to experience greater therapeutic benefit if stents were found to be safe for use with rTMS. Even though rTMS in stroke is still an investigational therapy, the potential significance of our study would be to allow more patients to participate in research and clinical trials or studies.

Methods

Test Materials

We measured heating of 2 types of stents used commonly for carotid and middle cerebral artery stenting in stroke: an open-cell nitinol stent (nickel titanium alloy) (Cordis SMART Stent, Dublin, OH) with 10-mm diameter and 20-mm length and an elgiloy (cobalt-chromium alloy) wall-stent (Schneider Worlwide, Bülach, Switzerland) with 7-mm diameter and 20-mm length. Like in other ex vivo safety studies, we compared heating of stents to that of gold disc electrodes[13] (Grass Technologies, Warwick, RI). Gold heats acutely with rTMS and hence serves as a positive control. Additionally, we compared heating of stents to heating of our setup without any test material to account for convective heating and artifacts.

Experimental Setup

Test materials were placed directly below a figure-of-8 rTMS coil that was water-cooled (MagPro R30, Magventure, Farum, Denmark). A water-cooled coil ensures that heating of nearby metallic objects can be attributed to eddy currents than to conducted or radiated heat.[13] The coil was placed at a distance of 1.5 cm from the test materials (Fig 1). This distance was meant to simulate a typical scalp-to-cortex application[16] (Fig 1), and is evidenced to be close enough to elicit maximal heating in other cobalt-chromium-nickel implants.[15] Temperature was recorded with a K-type thermocouple and data logger (Fig 1) at a sampling rate of 1 Hz and a resolution of .1°C (Extech HD200, Waltham, MA). Temperature was recorded at ambient room temperature. Test materials were submerged in gelled saline (maintained at ambient room temperature) that possesses electrical and thermal properties similar to human tissue. Even though ex vivo experiments are unable to replicate properties of tissue and fluid between the coil and the test material, gelled saline is the most commonly used medium to replicate in vivo physiological environment.[17,18] Other ex vivo studies have used similar fluid-filled media to simulate the physiological environment.[13]

Testing Conditions

We tested 2 different rTMS protocols. We applied 1 Hz rTMS (1 pulse per second, 1200 pulses) and 10 Hz rTMS (40 trains, 50 pulses each, 25-second inter-train interval).