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Evaluation of Magnetic Resonance Imaging Issues for Implantable Microfabricated Magnetic Actuators

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Abstract

The mechanical robustness of microfabricated torsional magnetic actuators in withstanding the strong static fields (7 T) and time-varying field gradients (17 T/m) produced by an MR system was studied in this investigation. The static and dynamic mechanical characteristics of 30 devices were quantitatively measured before and after exposure to both strong uniform and non-uniform magnetic fields. The results showed no statistically significant change in both the static and dynamic mechanical performance, which mitigate concerns about the mechanical stability of these devices in association with MR systems under the conditions used for this assessment. The MR-induced heating was also measured in a 3-T/128-MHz MR system. The results showed a minimal increase (1.6 °C) in temperature due to the presence of the magnetic microactuator array. Finally, the size of the MR-image artifacts created by the magnetic microdevices were quantified. The signal loss caused by the devices was approximately four times greater than the size of the device.

Keywords

Magnetic microactuator; magnetic resonance safety; implantable MEMS; RF heating; image artifact

1 Introduction

Recent advances in micro- and nano-fabrication technology have enabled the development and use of miniaturized implantable devices for various medical applications. For example, there now exists various minimally invasive implantable sensors to monitor levels of pressure [1,2], glucose [3,4], lactate [4], oxygen [5], strain [6] and other clinically relevant

parameters. Similarly, implantable microscale actuators are currently being developed for various *in vivo* applications, such as drug delivery [7–11], material removal (e.g., ablation or biopsy) [12], structural support (e.g., scaffolds or stents) [13] and obstruction clearance [14]. The field of brain-machine interfaces have been developed for a variety of microfabricated neural implants that record from and stimulate the central nervous system to treat many clinical conditions.

Simultaneously, the demand for advanced imaging technologies, such as magnetic resonance (MR) imaging (MRI) in medical diagnostics, have also increased rapidly. Each of the implantable devices mentioned above contain materials that may not be acceptable with the strong static, time-varying, and radio-frequency (RF) electromagnetic fields used by MR systems. The strong magnetic fields and field gradients may cause unintended interaction between the tissue and the device, which may pose danger to patients with the implants. As such, the issue of safety in implantable microdevices in the MRI environment has become a matter of utmost importance in ensuring patient safety.

The feasibility of using microfabricated magnetic actuators to improve the functionality of medical catheters used in hydrocephalus management have previously been reported [15,16,14]. Hydrocephalus is a serious neurological disorder that is often characterized by an abnormal accumulation of cerebrospinal fluid (CSF) in the ventricles of the central nervous system. Patients with hydrocephalus are typically treated with chronically implanted shunt systems to divert excess CSF from the brain to the abdomen. Unfortunately, these shunt systems are plagued with a high rate of failure (e.g., 40% of implanted shunt systems fail within the first year), which is largely due to cellular obstructions in their ventricular end [17]. This has catapulted shunt replacement and revision surgeries as the most common operations in most neurological centers and as the most common surgeries at the pediatric centers around the country [17].

Using magnetic microactuators, the cell-clearing capabilities that may combat cellular obstruction at the ventricular-catheter pores have been well-documented [14]. The ultimate goal of this research is to improve the existing hydrocephalus treatment option by increasing the lifetime of ventricular catheters, which are sites of cellular obstructions, using integrated magnetic microactuators. The cell-clearing capability notwithstanding, any magnetic microactuators chronically implanted into the brain must be evaluated for safety with MR systems. In case these patients need MRI diagnosis in the future, it is imperative that the integrated magnetic microactuators remain intact when subjected to strong magnetic torque, force, and RF heating to prevent injuries to patients and damage to other devices.

There are several possible mechanisms by which an MR system can adversely affect implanted devices. In fact, there already exist standards for determining potential MRI issues of conventional medical devices. The American Society for Testing and Materials International (ASTM) has developed standards to test four different metrics to determine the MR safety of medical devices. These include: the magnetic field interactions (translational attraction and torque) [18,19], RF-induced heating [20], and image artifact [21].

The effects of potential MR-induced heating and image artifacts can be evaluated using the standard ASTM methods since a larger array of devices can be tested at once. Testing an array of devices, which includes a relatively large volume of the silicon substrate, may result in greater heating and larger artifact size, when compared to an individual device. Nevertheless, the potential heating caused by the magnetic microactuators array is expected to be minimal given the microscopic volume of conductive and magnetic material present, and the relatively low conductivity of the silicon substrate.

Unlike the tests for MRI-related heating or image artifacts, the effects of magnetic field interactions should not be evaluated as an array because the relatively low volume of magnetic material compared to non-magnetic bulk will improperly demonstrate the effects of magnetic forces on an individual device. Testing an individual device using the ASTM method is also inappropriate because these devices are designed to be driven using magnetic forces. The primary concern is to ensure that the strong magnetic torque and force present in an MR environment will not compromise the mechanical integrity of the microscale magnetic devices. In order to demonstrate that these devices can withstand the exposure to strong magnetic fields, a more appropriate mechanical testing methods for these magnetic microactuators needed to be devised.

There are considerable literature on utilizing the static and time-varying magnetic fields of MR systems to drive microscale implantable magnetic devices [9, 22,23]. However, there is a lack of research on quantitatively evaluation on the potential MRI issues (i.e., structural, thermal, etc.) related to a implantable, magnetically-driven, fixed microactuator devices. Evaluating the change in resonant frequencies of microdevices is a well-known approach to assess the mechanical integrity of a device [24]. By comparing the resonant frequencies of these magnetic microactuators before and after MRI exposure, it is possible to demonstrate the mechanical robustness of these devices.

In this report, the quantitative impact of MR system on torsional magnetic actuators and the impact on these microdevices on the performance of MR systems are evaluated. The structural robustness of these microscale devices are demonstrated by withstanding the strong static magnetic fields and field gradients of a 7-T animal MR system, which was chosen due to its worst-case field strength and field gradients. Using a well-established method, the amount of heat generated during a 3-T human MR are recorded [25–27,20]. Finally, the size of the image artifact caused by the presence of these devices in 3-T MR images are quantified [21].

2 Device Design and Theory

2.1 Design and Operation of Torsional Magnetic Microactuators

The microactuator consists of a silicon nitride structural plate anchored on its sides by two torsion beams (Figure 1a). A ferromagnetic element is electroplated on top of the circular structural plate in order to apply magnetostatic torque to the device. The torsional magnetic actuators used for this report were designed to have the same beam geometry: 198 μm in length, 20 μm in width, and 1 μm in thickness. Although the length and thickness of the magnetic element were also constant across all devices (400 μm and 7 μm , respectively), the magnet width varied (Table 1).

In the presence of a magnetic field, the torque generated by the ferromagnetic element causes the structural plate to rotate about the long axis of the torsional beams (Figure 1b). The degree to which the structural plate rotates is described by the following equation

$$\theta = \frac{v \cdot (\vec{M} \times \vec{H})}{k_\phi} = \frac{v \cdot M \cdot H}{k_\phi} \cdot \sin(\gamma - \phi), \quad (1)$$

with angular rotation θ , magnet volume v , magnetization vector $\vec{M}$ and scalar magnitude M , magnetic field vector $\vec{H}$ and scalar magnitude H , the angular torsion-beam stiffness k_ϕ , and the angle between the magnetic field and the magnet ($\gamma - \phi$) [28,29].

The dynamic response of the torsional actuators is also well described in literature [30,31]. The primary resonant frequency mode can be described as

$$\omega = \sqrt{\frac{k_\phi}{M_{\text{eff}}}}, \quad (2)$$

with the effective mass of the structural plate M_{eff} . Although MR system generate ac magnetic fields, their frequency is typically much higher (>100 MHz) than the mechanical resonant frequency of the microactuators (~ 1 KHz).

In a dc magnetic field, the uniformity of the magnetic field plays an important role in inducing movement. Two different movement types can occur in a static magnetic field: rotation and displacement. The rotation occurs when magnetostatic torque is generated in a uniform magnetic field and the displacement occurs when translational force is induced by the non-uniform magnetic field.

Moreover, the orientation of the device in relation to the magnetic field is also critical in device movement. That is, the torque and the displacement could occur along each axis of the device depending on the orientation by which the device is entering the magnetic field (Figure 2). Maximum movement and the corresponding stress, however, will typically occur along the beam dimension with least stiffness (i.e., along x and z axis for torsion and translation, respectively).

2.2 Torque-Induced Shear Stress

As can be seen in Eq. 1, the maximum torque that can be generated by the magnetic element occurs when the magnetization direction γ and the applied magnetic field direction ϕ are perpendicular ($\gamma - \phi = 90^\circ$). Since the torsional beam can rotate in either direction, the deflection does not exceed 90° (Figure 3a).

The resulting shear stress on the torsion beams due to induced torque can be estimated using well-established formulas [32]. Rotating the torsion beam to the maximum deflection angle of 90° about their x axis will induce 801 MPa of shear stress (Figure 2, 3b). The literature indicates that the fracture-strength of a low-stress silicon-nitride layer deposited by low-pressure chemical-vapor deposition (LPCVD) is approximately 6 GPa [33,34], which is far greater than the amount of shear stress that the beams would experience in an MR system. Thus, a minimum effect on the torsion-beam mechanics of devices inserted into the strong magnetic field of an MR system can be expected.

2.3 Displacement-Induced Tensile Stress

The magnetic field near an MR system is typically non-uniform. A gradient in the magnetic field will induce a translational force F_{trans} on a ferromagnetic element, which can be expressed by

$$F_{\text{trans}} = v \cdot (\vec{M} \cdot \nabla) \vec{B} \quad (3)$$

with magnetic flux gradient ∇B .

Since each MR system has a unique magnetic field profile, it is difficult to estimate the non-uniformity of the stray magnetic field. For this report, a site-planning document provided for a high-field-strength (7 T) MRI magnet (70/30USR, Bruker Biospin, Billerica, MA) was

used to estimate the maximum magnetic flux density gradient (17 T/m). As seen in Eq. 3, the translational force F_{trans} is linearly proportional to the magnet volume v . Given the dimensions of the magnetic microactuators, the largest force that the device will experience is approximately 14 μN . As previously mentioned, the largest movement due to the magnetically induced translation will occur along the z axis. Using a Roark's formula [32], the maximum tensile stress due to the translation along the z axis (out-of-plane) can be approximated to be 208 MPa, which is still far less than the fracture strength of the LPCVD silicon nitride (~ 6 GPa).

3 Experimental Methods

3.1 MR-induced Torque and Translation

The microfabrication steps as well as the static and dynamic mechanical characterization procedures for the torsional magnetic microactuators are described in [14]. Using a laser-based deflection setup (Figure 4), the static deflections and the dynamic responses of the torsional magnetic microactuators were measured before and after exposing the devices to a 7 T animal MR system (70/30USR, Bruker Biospin, Billerica, MA).

The MRI exposure procedure was designed such that maximum torque and translation force are imparted on the magnetic microactuators. The location of the greatest uniform magnetic field is found within the MRI magnet bore, whereas the highest magnetic field gradient is found at the entrance of the MRI bore. Prior to exposure to the MR system, the silicon chip containing the array of devices was glued inside a cubic plastic container (16.4 cm^3) to ensure that no magnet fragment could get lost inside the MR system.

To test the effect of magnetic torque on the device, the plastic container was placed inside the MRI bore for 20 min (duration of a typical MRI scan) along each of the three axes of the device. Following exposure, the devices were removed from the MR system and were visually inspected using a small permanent magnet. For the translational force, the plastic container with the device array was placed on the loading arm of the MR system and guided into the MRI bore. The movement into and out of the bore was repeated five times for each of the three axes of the devices. Following exposure, the devices were visually inspected prior to post-exposure testing.

3.2 MR-induced Heating

The magnetic microactuator array tested for the MR-induced heating is shown in Figure 5. The silicon array was evaluated using a 3-T clinical MRI system (Excite, HDx, 14X.M5, General Electrical HealthCare, Milwaukee, WI) according to a well-established protocol [25–27]. The magnetic microactuator array was placed inside a plastic ASTM head/torso phantom filled with 10-cm-depth of gelled mixtures of 1.32 g/L of sodium chloride, 10 g/L of polyacrylic acid and distilled water [20].

Temperature measurements were obtained by using a fluoroptic thermometry system (Model 3100; Luxtron, Santa Clara, California). The fluoroptic thermometry probes (SFF-2, Luxtron, Santa Clara, California) were positioned on three places on the magnetic microactuator arrays to record representative temperatures (Figure 6). In addition, a thermometry probe was placed in the phantom away from the device to record a reference temperature during the heating experiment. Background temperatures were also recorded without the devices in the phantom from the same locations.

MR imaging parameters were applied to generate a relatively high level of RF energy at 3 T as follows: fast spin echo pulse sequence; axial plane; repetition time, 425-msec; echo time, 14-msec; echo train length, 4; flip angle, 90 degrees; bandwidth, 16 kHz; field of view, 40-

cm; imaging matrix, 256×256; section thickness, 10-mm; number of section locations, 20; phase direction, anterior to posterior; transmitter gain setting, 180; imaging time, 15-min; patient body weight used, 50-kg. These imaging parameters produced an MR imaging system-reported value of 2.9 W/kg for the whole-body averaged specific absorption rate (SAR). The land-marking position (i.e., the center position or anatomic region for the MR imaging procedure) and section locations were selected to encompass the entire area of the magnetic microactuator array. The room temperature and bore temperature of the scanner were monitored throughout the experiment and did not change by more than 1 °C per one hour.

3.3 Image Artifact

MR image artifacts were assessed for the magnetic microactuator array by performing MR imaging at 3T (Excite, HDx, Software 14X.M5, General Electric HealthCare, Milwaukee, WI) and a send-receive RF coil using a gadolinium-doped saline fluid-filled plastic phantom according to a well-established protocol [25–27, 21]. The silicon-based array containing two intact 800- μ m-wide magnetic microactuators was attached to a plastic frame to facilitate MR imaging within this phantom. The following pulse parameters were used: (1) T1-weighted spin-echo pulse sequence; repetition time, 500 msec; echo time, 20 msec; matrix size, 256×256; section thickness, 10-mm; field of view, 24-cm; number of excitation, 2; bandwidth, 16 kHz, (2) gradient echo (GRE) pulse sequence; repetition time, 100 msec; echo time, 15 msec; flip angle, 30 degrees; matrix size, 256×256; section thickness, 10-mm; field of view, 24-cm; number of excitations, 2; bandwidth, 16 kHz. The GRE pulse sequence typically has a greater degree of artifact associated with it when MR imaging is performed on a metallic device. Thus, the use of the GRE pulse sequence represents a type of extreme MR imaging condition.

The imaging planes were oriented to encompass the long axis and short axis of the magnetic microactuator. The frequency encoding direction was parallel to the plane of imaging. The images were selected to represent the worst-case artifact for the devices. Artifact is defined as a 30% difference in signal intensity between a baseline image acquired with and without the tested device.

4 Results

A total of 30 devices with varying magnet volumes was tested (Table 1) to quantify potential effects of strong magnetic fields from a MR system on the structural integrity of tested devices. Visual inspection following each exposure revealed no broken beams for any of the tested devices.

4.1 Static Response

The static response of the devices with an increasing magnetic field from 0 to 5 kA/m, which resulted in a maximum deflection angle ranging from 15° to 30° was tested. Within this magnetic-field-strength range, the angular deflection increased linearly with the applied field (Figure 3a). A Kruskal-Wallis test showed no statistically significant change in static response due to exposure to the MRI magnetic field ($p = 0.395$) when comparing the slope of the angular deflection of each device before and after exposure to a 7-T MR system (Figure 7).

4.2 Dynamic Response

Figure 8 shows the resonance characteristic of each device before and after MRI exposure. A before-and-after comparison of the first resonance mode also showed statistically insignificant change following exposure to an MR system ($p = 0.838$). These results indicate

that, as expected, these torsional magnetic microactuators are capable of withstanding the magnetostatic torque and translational force induced by a very strong magnetic field produced by a 7-T MR system.

Some shunt systems prohibit patients from getting images using a stronger MR system (>3 T) due to concerns of potential complications with the programmable shunt valves [35–38]. Fortunately, a typical MR system used for human patients has a magnetic flux density of 1.5 T to 3 T. Compared to the 7-T scanner used to test the devices, the relatively weaker magnetic field strength of the clinically relevant MR systems should induce much smaller magnetostatic torque and force and thus results in an even smaller impact on the mechanical integrity of the devices.

4.3 MR-Induced Heating

As can be seen in Table 2, the largest temperature change generated by the magnetic microactuator due to a relatively high level of radio-frequency energy at 3T was 1.6 °C. The background probe without the device recorded a temperature change of 1.5 °C, indicating a minimal effect of localized heating of these devices at these conditions.

4.4 Image Artifact

Table 3 lists the results of image artifact evaluation. Overall, the gradient echo pulse sequence produced larger artifacts than the T1-weighted, spin echo pulse sequence. The largest artifact produced by the magnetic microactuator array containing two 800- μ m-wide magnetic microactuators was approximately four times greater than the size of the actual array (Figures 5,9). Thus, it is possible that these microactuators may hinder imaging of similarly-sized neural structures of interest depending on the eventual location of the implanted device. Although other imaging techniques such as computer tomography may be used to supplement the MR imaging, these results suggest that the final arrangement of the microactuators in a ventricular catheter as well as the actual location of the implant may need to be better investigated to ensure the magnetic microactuators have minimum impact on the MR imaging.

5 Discussions and Conclusions

The presented results demonstrate that the microfabricated torsional magnetic actuators are capable of withstanding the impact of the magnetic field produced by a 7-T MRI magnet. The magnetostatic torque and force are linearly proportional to the magnet volume (Eqs. 1 and 3), while the mechanical stiffness is dependent on the beam geometry [32]. These results suggest that by using these parameters, it is possible to effectively engineer a given level of mechanical MRI safety into these magnetic microactuators.

The results also show that the impact of MR-induced heating caused by the device may be minimum. The experiment with a silicon-based 12×12 mm array containing 30 magnetic microactuators showed minimum temperature increase in the worst case scenario. It remains to be seen whether an array containing more devices will cause additional localized heating. Therefore, additional heating experiments may be necessary once the MEMS-integrated ventricular catheter (Figure 1) is produced.

Finally, the dimensions of the MR image artifact caused by the presence of the magnetic microactuator array were reported. The results show that a considerable area of a scan may be hindered by this device array. However, the true impact of the image distortion may be unknown until actual implantation of the MEMS-enabled ventricular catheter *in vivo*. That is, depending on the location and the final arrangement of the devices, the image artifact may only be present in an area of little clinical importance. Regardless, it is given that

further assessment of the image artifact will be necessary to determine the optimum number and arrangement of devices to minimize the distortion size. In summary, the results provide a promising outlook for the realization of mechanically robust, thermally innocuous, and visually manageable MEMS-integrated ventricular catheters that may be used safely in a clinical setting without complications due to the use of an MR system.

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Fig. 1.

A set of 3D schematic diagrams of the torsional magnetic microactuators: (a) mechanically released but unactuated, (b) actuated device by an applied magnetic field, (c) integrated into a ventricular catheter.

Fig. 2. COMSOL simulation of torsion and translation along each axis. Note that the maximum stress occurs for movement along the x axis for torsion and the z axis for translation.

Fig. 3.

The static response of torsional magnetic microactuators and corresponding beam shear stress. (a) Maximum angular deflection in an increasing magnetic field. Note that no device rotates more than 90° and that the response is nearly linear when applied magnetic field strength <5 kA/m. (b) Amount of shear stress as a function of angular rotation. Note that at 90°, the shear stress is much less than the fracture strength.

Fig. 4. A 3D illustration of the laser-deflection setup. As the magnetic microactuator rotates at a given applied magnetic field, the position sensitive device captures the displacement of the laser-beam position.

Fig. 5. Photograph of the silicon-based magnetic microactuator array tested for the MR-induced heating and artifact. Array dimension $\approx 12 \times 12 \text{ mm}^2$.

Fig. 6. Photographs illustrating the location of the fluoro-optic thermometry sensors. Note that the Probe #1 is in closest proximity to the microactuators. Electroplated nickel is present throughout the surface of the array.

Fig. 7.

Comparison of the angular deflection slope for the tested devices before and after MRI exposure. Left: comparison of the aggregated angular deflection slope of every tested devices. Right: the angular deflection slope of each device type. Note that there is no error bar for Device ID: 14-2 ($n = 1$). The slope of each device was measured using an increasing magnetic field, ranging from 0 to 5 kA/m. The results are expressed as average $\pm$ s. d. $n = 31$.

Fig. 8.

Comparison of the first-mode resonance for the tested devices before and after MRI exposure. Left: comparison of the aggregated resonant frequency of all tested devices. Right: the resonant frequency each device type. Note that there is no error bar for Device ID: 14-2 ($n = 1$). The results are expressed as average $\pm$ s. d. $n = 31$.

Fig. 9. Gradient echo pulse sequence images of the magnetic microactuator arrays. The dark area in the middle of images are artifacts caused by the array. (a) Section location oriented to the long axis of the device array. (b) Section location oriented to the short axis of the device array.

Table 1

Number of devices tested and magnet width

Device ID	13-2	13-3	13-4	13-5	14-2	14-3	14-4	14-5
<i>n</i>	4	6	6	4	1	2	3	5
Width (μm)	364	304	220	112	376	336	280	208

Table 2

MR-induced heating of magnetic microactuators due to 3-Tesla MR imaging.

Thermometry Probe	Highest Temperature Change [°C]
Probe #1	+1.6°C
Probe #2	+1.6°C
Probe #3	+1.5°C
Probe #4 (Reference)	+0.7°C
Background Probe	+1.5°C
Background Reference Probe	+0.7°C

Table 3

Image artifact due to magnetic microactuators at 3-Tesla MR imaging.

	T1-SE	T1-SE	GRE	GRE
Signal void size [mm ²]	288	78	552	324
TR [msec]	500	500	100	100
TE [msec]	20	20	10	10
Imaging plane	Long axis	Short axis	Long axis	Short axis