An MRI-Conditional Implantable Magnet Design with Self-Realigning Orientation

Bo Zhang (张波)[1], Ahmet Hirka[2], and Yakov Kanevskiy[1]

[1]Dexter Magnetic Technologies, Elk Grove Village, IL 60047, USA
[2]Dexter Magnetic Technologies, 79108 Freiburg im Breisgau, Germany

Patients with "MR Unsafe" rating magnetic implants are required to undergo implant removal surgery before they can take an MRI scan. Only implants labeled as "MR Conditional" can stay in the patient's body for MRI scan under specific conditions. In this article, the authors propose an MRI-conditional implantable magnet design with orientation that can be self-realigned or with an external homing magnet. This design can be readily adopted to a wide range of magnetic implant medical devices on the market, upgrading them from "MR Unsafe" to "MR Conditional" rating. Prototypes are tested to verify the design. Magnetic orientation realignment effectiveness is evaluated.

***Index Terms*—Implanted magnet, magnetic resonance imaging, self-realigning, spherical magnet.**

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I. Introduction

Magnetic resonance Imaging (MRI) is a medical imaging procedure for making images of the internal structures of the body. The strong magnetic field of an MRI scanner can affect medical implants that contain metal or magnets. When this happens, the implant may move or twist inside the patient's body, causing discomfort, pain, or injury [1]-[3]. Patients with "MR Conditional" cochlear implants can go through 1.5T or even 3T MRI under specific conditions without the need of surgically removing the implant magnet. Some of such cochlear implants utilize magnets with limited rotational movement; for example, diametrically oriented disk magnet encapsulated within a Titanium can and able to rotate 360° in the plane orthogonal to the magnet axis [4]. The in-plane rotation capability creates a less restrictive environment to the implant magnet; as a result, so long as the patient going through the MR scan does not tilt his/her head sideways by more than 30°, very few complain about discomfort. However, when the implant magnet's reaction to the MRI field is restricted, not only does it affect the patient's safety and comfort, but it also poses a threat to demagnetize or reverse the polarity of the implant magnet and cause device complications [5]-[8].

The aforementioned magnet design with in-plane rotation capability would not be practical for breast tissue expanders (BTE). BTEs are used in the breast reconstruction procedure in patients having undergone mastectomy. Most BTEs on the market have magnetic infusion ports and are labeled "MR Unsafe". These products feature an implanted magnet with orientation pointing forward (or backward) with respect to the patient's body; the purpose of which is to guide the surgeon to the saline infusion port. During an MR scan, the MRI high magnetic field would turn the magnet about 90°, deforming the BTE, causing pain or discomfort to the patient, or tearing the BTE. Therefore, patients with these implants are typically disapproved from MR scans, or otherwise the BTE would have to be surgically removed before an MRI procedure [9]-[10]. Nonconventional BTEs have started to emerge; for example, those with radiofrequency identification (RFID) infusion ports that do not contain magnets [11]. They are labeled as "MR Conditional". However, these novel BTEs require technologically sophisticated peripherals for the saline infusion process to work and are more costly to the patients and the healthcare system.

The BTE case could be solved with a design innovation of the implanted magnet. Other than a permanent magnet with fixed orientation, this article introduces a magnet design with the magnetic orientation rotatable in true three dimensions. Therefore, neither the patient nor the implanted magnet should be affected during an MRI. After the patient completes the MRI procedure, the anchor polepiece should realign the magnetic orientation to the original direction, either by the spontaneous magnetic reaction between the magnet and the anchor polepiece, or with the help of an external homing magnet. The homing magnet is only necessary if the differentiation of the North pole to the South pole is mission critical. Furthermore, the application of this novel design can be expanded to other implanted magnet sensor or coupling force or torque applications that require the magnet's orientation to be restored after an MRI scan.

II. Problem Definition and New Design Concept

A. *Would-Be Scenario of BTEs in MRI Field*

A permanent magnet rigidly embedded in an implanted medical device is subjected to high magnetic force and/or torque in the MR scanner field. The magnetic force $\boldsymbol{f}$ and torque $\boldsymbol{\tau}$ exerted on a magnet with magnetic moment $\boldsymbol{m}$ by a uniform magnetic field $\boldsymbol{B}$ are given by (1) and (2), respectively.

$$\boldsymbol{f} = (\boldsymbol{m}\nabla) \cdot \boldsymbol{B} \tag{1}$$

$$\boldsymbol{\tau} = \boldsymbol{m} \times \boldsymbol{B} = \mu_0 \boldsymbol{m} \times \boldsymbol{H}, \tag{2}$$

where $\boldsymbol{H}$ is magnetic field strength.

In the case of the commercially available BTEs, a disk Nd-Fe-B magnet with axial orientation is incorporated in a metallic housing, which is then molded in silicone, located just behind the infusion port. The surgeon uses an external port locating magnet to interact with the implanted magnet to identify and

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mark the infusion port location, where a needle would be injected through the port and deliver saline to the BTE, as shown in Fig. 1(a). The attractive magnetic force between the implant magnet and the port locating magnet can be analytically or numerically calculated. For instance, if the implant magnet is a Nd-Fe-B magnet of N42 grade, and Φ15mm X 3mm in size; the port locating magnet is also a Nd-Fe-B magnet of N42 grade, and Φ5mm X 8mm in size, then the attractive force at 20mm distance between the magnets is 0.1 N. This is the magnitude of force that is sufficient to align the two magnets without causing the patient much pinching sensation.

During an MRI, the patient would lay flat on the MR scanner platform. The orientation axis of the implanted magnet would be at an acute angle with the main magnetic field of the MR scanner, as in Fig. 1(b). The strong magnetic field of the MR scanner twists the implanted magnet in the human body sagittal plane clockwise or counterclockwise (depending on the magnet polarity), therefore causes discomfort, pain or even injury to the patient. The magnet in the BTE can generate up to 0.8Nm torque in 1.5T MRI, or 1.6Nm torque in 3T MRI. The magnet could also be partially demagnetized (it happens when a portion of the magnetic domains are flipped directions by the MR field) or even have its polarity reversed (it happens when all the magnetic domains are flipped) by the MR field to lose function and bring complications to the infusion procedure later. It becomes clear that a disk magnet rigidly secured in the medical implant is not suitable for MRI procedures. It is the reason why such BTE implants are labeled as “MR Unsafe”.

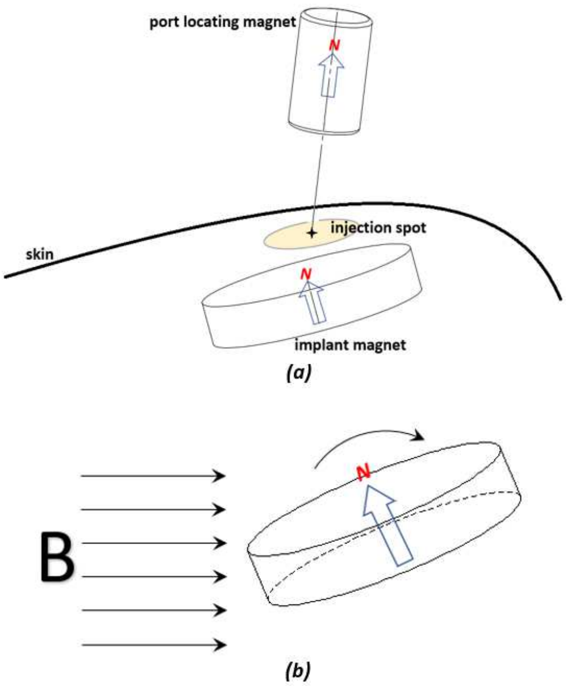

Fig. 1. Implanted BTE magnet reacting to magnetic field. (a) Implant magnet interacting with port locating magnet to facilitate identification of infusion port location; (b) Twisting magnetic torque exerted on implant magnet during MR scan.

B. Spherical Magnet on Steel Plate

This work introduces an MRI-conditional BTE design that incorporates a spherical magnet. To understand how the design works, it is best to start with a free-standing spherical magnet placed on a magnetic surface, *e.g.*, a steel base plate, as shown in Fig. 2(a). The arrow indicates the magnetic North-pole direction. Without external influences, the magnet-plate system will find its equilibrium when the magnetic orientation is in the upright direction; we define the angle $\boldsymbol{\theta}$ to be 0° for the equilibrium state. When the magnet is turned away from its equilibrium position, the plate exerts a magnetic torque, $\boldsymbol{\tau}$, on the magnet. An analysis reveals the relationship between $\boldsymbol{\theta}$ and $\boldsymbol{\tau}$ to be sinusoidal,

$$\tau = -T_p sin2\theta, \tag{3}$$

where T_p is the torque amplitude, as shown by Fig. 2(b). The spherical magnet is subjected to maximum torque when it is perturbed to sway ±45° from upright direction (represented by point $\boldsymbol{o}$). If the magnet is turned to ±90° positions (points $\boldsymbol{u}$ and $\boldsymbol{v}$), the torque $\boldsymbol{\tau}$ would be zero, the same as at point $\boldsymbol{o}$, but it is noted that $\boldsymbol{u}$ and $\boldsymbol{v}$ are unstable equilibriums in contrast to point $\boldsymbol{o}$ which is a stable equilibrium. Therefore, the torque $\boldsymbol{\tau}$ has a re-aligning effect on the magnet to return it to the upright direction. In real world, the steel plate surface is not ideally smooth, so the rolling friction force would prevent the spherical magnet from returning to the true upright position, but the effect is usually insignificant. The phenomenon also applies to a diametrically oriented cylindrical magnet-steel plate system.

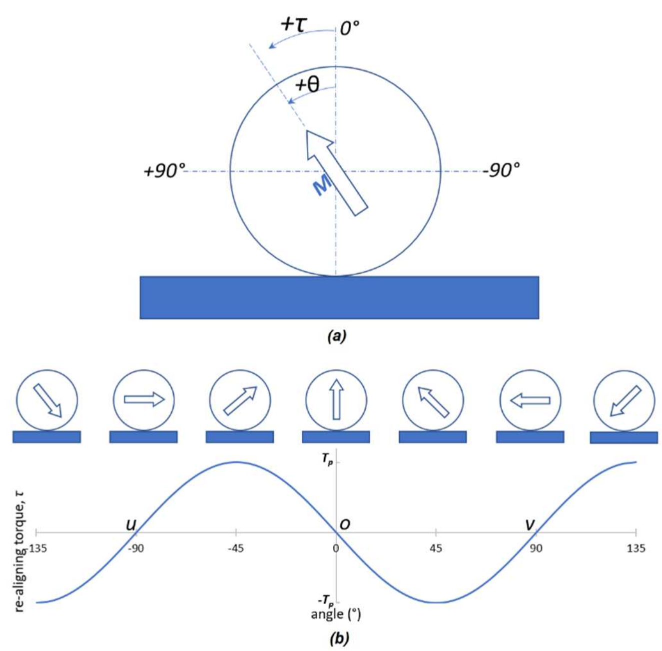

Fig. 2. Self-realignment of spherical magnet on magnetic base plate. (a) Definition of positive direction of perturbation angle and magnetic torque; (b) Relationship between re-aligning torque and perturbation angle.

C. Housed Spherical Magnet with Anchor Polepiece

The above design concept can be readily adopted to the BTE medical implant by the incorporation of a nonmagnetic housing to encapsulate the spherical magnet and a magnetic anchor polepiece, as seen in Fig. 3(a) and 3(b). The nonmagnetic housing has a dome-shaped top and a flat bottom, laser welded together; the material can be titanium alloy or stainless steel.

The anchor polepiece is made of ferrous metal (*e.g.*, steel or magnetic stainless steel); its shape can be a solid disk as in Fig. 3(a) or a ring as in Fig. 3(b); its purpose anchoring the magnet's orientation in the upright direction to facilitate the infusion port locating as well as minimize magnet movement and abnormal sensations.

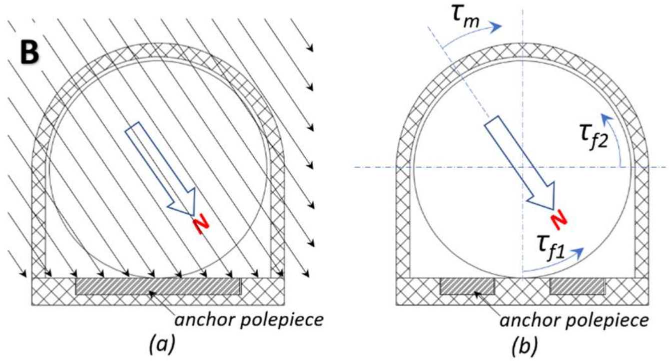

Fig. 3. Self-realignment of spherical magnet in nonmagnetic housing. (a) During MRI scan, spherical magnet aligns orientation with MR field; (b) After the MR field is turned off, spherical magnet self-realigns orientation to near upright direction.

In the presence of the strong MRI field, the spherical magnet can overcome the interaction by the anchor polepiece and align its North pole orientation with the MRI field direction as illustrated in Fig. 3(a), without turning the magnet housing. The patient should barely notice any discomfort. The risk of partial demagnetization or polarity reversal is therefore eliminated.

When the MR field is turned off, the interaction between the implant magnet and the anchor polepiece dominates again and the spherical magnet should self-realign, as shown in Fig. 3(b). Magnetic torque $\boldsymbol{\tau_m}$ tends to rotate the spherical magnet toward the upright direction. Because the restriction of the housing wall and bottom, the spherical magnet is subjected to sliding friction forces, which in turn exert friction torques $\boldsymbol{\tau_{f1}}$ and $\boldsymbol{\tau_{f2}}$ on the spherical magnet. It is noteworthy that the spherical magnet will not completely return to, but very close to, the upright position, due to the friction forces / torques. The angle differential is named the "axis deviation angle" in this work and dependent on the friction coefficients of the housing bottom and/or anchor polepiece materials. In practice, appropriate lubricants or specialty coatings can be applied to the anchor polepiece or housing walls to minimize friction.

For illustration purpose to facilitate a visual comprehension of the presented design, Fig. 4 superposes the rendering of the port locating magnet, magnet housing (needle stop), implant (spherical) magnet, and anchor polepiece, on the image of a partially inflated commercially available BTE.

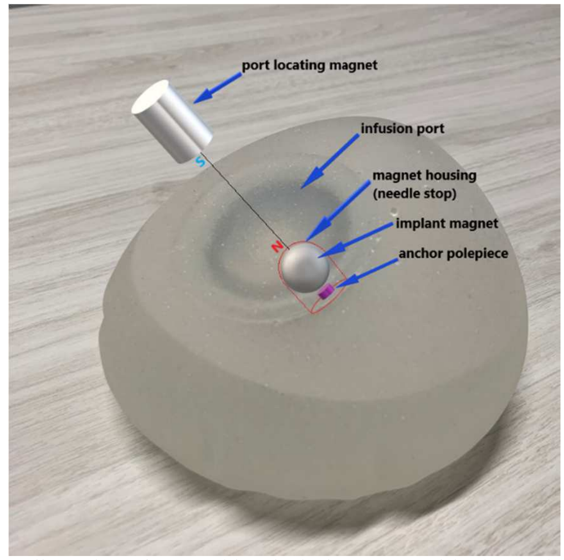

Fig. 4. Illustration of BTE with spherical magnet and its interaction with external port locating magnet

D. Homing Magnet

If the MR field direction differs the implant magnet's original North pole orientation by more than 90°, the implant magnet would come out of the MR scanner with orientation that is about 180° different than its original orientation. In that case, an external homing magnet would be needed to bring the implant magnet to its original orientation, as shown in Fig. 5. The homing magnet does not have to be a separate magnet. Depending on the magnetic strength of the infusion port locating magnet, it can be dually purposed to act as a homing magnet. A surgeon can be trained to easily use just the infusion port locating magnet to determine if the implant magnet is oppositely oriented, and if so, use the infusion port locating magnet to correct its orientation and locate the injection spot.

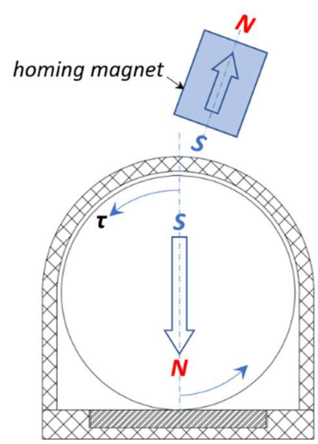

Fig. 5. Homing magnet realigns oppositely oriented implant magnet

Just as the implant spherical magnet cannot perfectly realign itself to the upright position, the homing magnet can bring the implant magnet very close to but not the exact upright direction in a mathematical sense. Though in reality, the difference is insignificant and results in an injection spot locating error by mere millimeters. The surgeon should still be able to guide the needle to penetrate through the infusion port.

III. PROTOTYPE CONSTRUCTION AND TEST PROCEDURE

A prototype is constructed using a Φ8mm Nd-Fe-B spherical magnet, clear acrylic housing, and a Φ3.5mm steel anchor polepiece, as shown in Fig. 6. The MRI field is simulated by external magnets of various stack lengths. Refer to Table I for a complete component list. The spherical magnet is observed to respond sensitively to external field.

Fig. 6. Prototype of MRI-conditional implant magnet and reaction to homing magnet

When the external "MRI field" is removed, the spherical magnet attempts to return to its original orientation but stops short because of the friction between the housing and the magnet. A stack of six pieces of the external magnet, simulating a homing magnet or an infusion port locating magnet, is used to restore the spherical magnet's orientation. The spherical magnet's magnetization angle is then measured on Matesy M-axis, which is a commercial magnetic measuring system to characterize permanent magnets of the magnetic moment and magnetization angle specifications.

TABLE I
PROTOTYPE COMPONENT LIST

Components	Size	Material	Magnetic orientation
Spherical magnet	Φ8mm, sphere	Nd-Fe-B, N42	Easy axis
External magnet	Φ8mm X 3.2mm, disk, multiple	Nd-Fe-B, N50	Axial
Anchor polepiece	Φ3.5mm X 0.5mm	Carbon steel	N/A
Housing	Φ20mm X 14mm	Acrylic, clear	N/A

IV. EXPERIMENTAL RESULTS

The spherical magnet's magnetization orientation is ideally in the upright direction. The difference between the actual tested magnetization direction and the ideal upright direction is called the axis deviation angle. 216 tests are conducted on M-axis, and the measured axis deviation angles are recorded, as shown in Fig. 7. The cosine of the axis deviation angle contributes to the interactive force between the implant magnet and the infusion port locating magnet and is also plotted in Fig. 7. It becomes evident the external magnet can bring the spherical magnet orientation to within 8° from the upright direction, and the retained interacting force factor is within 99%, in most of the attempts.

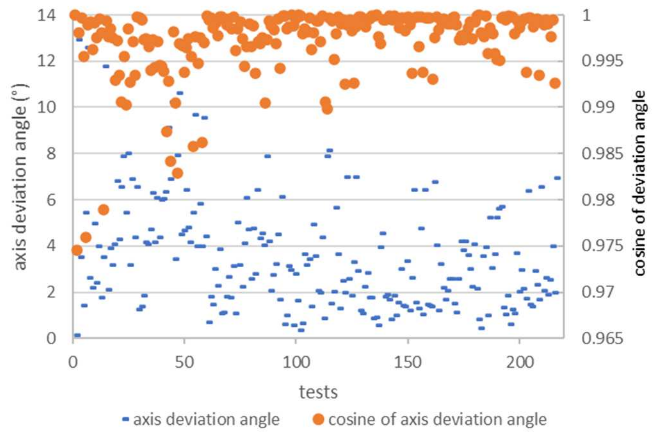

Fig. 7. Magnet axis deviation angle measurements and cosine of axis deviation angles

V. CONCLUSIONS

A novel implantable magnet design is presented, valuable to applications where the patient needs to go through MRI scan and where the implant magnet's orientation needs to be restored after the MRI scan. Prototypes are constructed to test the concept. Satisfactory results are observed. The prototypes are currently under evaluation. The technology can be readily expanded to magnetic sensor or magnetic force coupling implantable magnet applications.

Future work includes experimenting with anchor polepiece design optimization and friction minimization to home the implant magnet and introduce the MRI-conditional commercial BTE product to the market.

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