



Designation: F 2213 – 02⁴

Standard Test Method for Measurement of Magnetically Induced Torque on ~~Passive~~ Implants Medical Devices in the Magnetic Resonance Environment¹

This standard is issued under the fixed designation F 2213; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers the measurement of the magnetically induced torque produced by the static magnetic field in the magnetic resonance environment on ~~passive implants (implants that function without the supply of electrical power)~~ medical devices and the comparison of that torque to the equivalent torque applied by the gravitational force to the implant.

1.2 This test method does not address other possible safety issues which include but are not limited to issues of magnetically induced force due to spatial gradients in the static magnetic field, RF heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the MR system.

1.3 The torque considered here is the magneto-static torque due to the interaction of the MRI static magnetic field with the magnetization in the implant. The dynamic torque due to interaction of the static field with eddy currents induced in a rotating device is not addressed in this test method. Currents in lead wires may induce a torque as well.

1.4 The sensitivity of the torque measurement apparatus must be greater than $1/10$ the “gravity torque,” the product of the device’s maximum linear dimension and its weight.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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2. Referenced Documents

2.1 ASTM Standards:²

A 340 Terminology of Symbols and Definitions Relating to Magnetic Testing

F 1542 Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips

F 2052 Test Method for Measurement of Magnetically Induced Displacement Force on ~~Passive Implants~~ Medical Devices in the Magnetic Resonance Environment

F 2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants

F 2182 Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

2.2 IEC Standard:

60601-2-33 Ed. 2.0 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis, 2002³

3. Terminology

3.1 *Definitions*—For the purposes of this test method, the definitions in 3.1.1-3.1.18 shall apply:

3.1.1 *diamagnetic material*—a material whose relative permeability is less than unity.

3.1.2 *ferromagnetic material*—a material whose magnetic moments are ordered and parallel producing magnetization in one direction.

3.1.3 *magnetic induction or magnetic flux density (B in T)*—that magnetic vector quantity which at any point in a magnetic field is measured either by the mechanical force experienced by an element of electric current at the point, or by the electromotive force induced in an elementary loop during any change in flux linkages with the loop at the point. The magnetic induction is frequently referred to as the magnetic field. B_0 is the static field in an MR system. Plain type indicates a scalar (for example, B) and bold type indicates a vector (for example, \mathbf{B}).

3.1.4 *magnetic field strength (H in A/m)*—strength of the applied magnetic field.

3.1.5 *magnetic resonance (MR)*—resonant absorption of electromagnetic energy by an ensemble of atomic particle situated in a magnetic field.

3.1.6 *magnetic resonance diagnostic device*—a device intended for general diagnostic use to present images which reflect the spatial distribution or magnetic resonance spectra, or both, which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images or spectra, or both, may also be produced.

3.1.7 *magnetic resonance (MR) environment*—area within the 5 gauss (G) line of an MR system.

3.1.8 *magnetic resonance equipment*—medical electrical equipment which is intended for *in-vivo* magnetic resonance examination of a patient. The MR equipment comprises all parts in hardware and software from the supply mains to the display monitor. The MR equipment is a Programmable Electrical Medical System (PEMS).

3.1.9 *magnetic resonance examination (MR Examination)*—process of acquiring data by magnetic resonance from a patient.

3.1.10 *magnetic resonance imaging (MRI)*—imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei.

3.1.11 *magnetic resonance system (MR System)*—ensemble of MR equipment, accessories including means for display, control, energy supplies, and the MR environment.

3.1.12 *magnetically induced displacement force*—force produced when a magnetic object is exposed to the spatial gradient of a magnetic field. This force will tend to cause the object to translate in the gradient field.

3.1.13 *magnetically induced torque*—torque produced when a magnetic object is exposed to a magnetic field. This torque will tend to cause the object to align itself along the magnetic field in an equilibrium direction that induces no torque.

3.1.14 *magnetization (M in T)*—magnetic moment per unit volume.

3.1.15 *medical device*—an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component, part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or is intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

3.1.16 *paramagnetic material*—a material having a relative permeability which is slightly greater than unity, and which is practically independent of the magnetizing force.

3.1.17 *passive implant*—an implant that serves its function without the supply of electrical power.

3.1.18 *tesla, (T)*—the SI unit of magnetic induction equal to 10^4 gauss (G).

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards*; Vol 03.04, volume information, refer to the standard's Document Summary page on the ASTM website.

Annual Book of ASTM Standards, Vol 13.01.

³ Available from the International Electrotechnical Commission (IEC), 3 rue de Varembe, Case postale 131, CH-1211, Geneva 20, Switzerland.

4. Summary of Test Method

4.1 The static field in a magnetic resonance system produces a torque on an implant a device that acts to align the long axis of the object with the magnetic field. The torque is evaluated using a torsional pendulum method. An implant A device is placed on a holder suspended by a torsional spring. The apparatus is placed in the center of the magnetic resonance equipment magnet where the magnetic field is uniform. The torque is determined from the measurement of the deflection angle of the holder from its equilibrium position. The frame holding the spring and holder assembly is rotated and the torque as a function of angle of the implant is determined. The maximal magnetic torque is compared to the worst case gravity torque, defined as the product of the maximum linear dimension of the device length and the device weight.

5. Significance and Use

5.1 This test method is one of those required to determine if the presence of a passive implant medical device may cause injury to the person with the implant during a magnetic resonance examination and in the magnetic resonance environment. Other safety issues which should be addressed include magnetically induced force (see Test Method F 2052) and RF heating (see Test Method F 2182).

5.2 If the maximal torque is less than the product of the longest dimension of the implant medical device and its weight, then the magnetically induced deflection torque is less than the worst case torque on the implant device due to gravity. For this condition, it is assumed that any risk imposed by the application of the magnetically induced torque is no greater than any risk imposed by normal daily activity in the Earth's gravitational field. This is conservative; it is possible that greater torques would not pose a hazard to the patient.

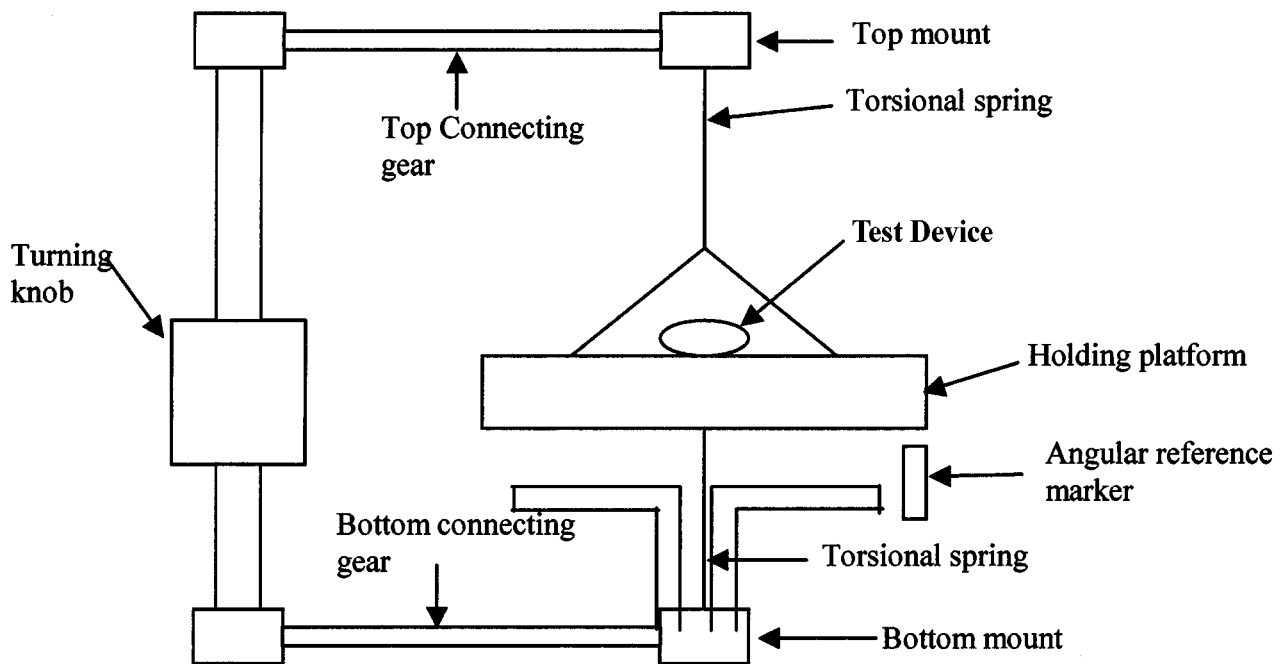
5.3 This test method alone is not sufficient for determining if an implant is safe in the MR environment.

5.4 The sensitivity of the torque measurement apparatus must be greater than 1/10 the "gravity torque," the product of device weight and the largest linear dimension.

5.5 The torque considered here is the magneto-static torque due to the interaction of the MRI static magnetic field with the magnetization in the implant. The dynamic torque due to interaction of the static field with eddy currents induced in a rotating device is not addressed in this test method. Currents in lead wires may induce a torque as well.

6. Apparatus

6.1 The test fixture is depicted in Fig. 1. It consists of a sturdy structure supporting a holding platform supported by a torsional spring. Materials should be non-ferromagnetic. The device may be taped or otherwise attached to the holding platform. The supporting structure will have fixed to it a protractor with 1° graduated markings and the holding platform will have a marker so that the angle between the basket and the support structure can be measured. The supporting structure is rotated with the turning knob. The equilibrium angle between the supporting structure and the holding platform outside the magnetic field represents the zero torque angle. The torque inside the magnet is equal to the product of the deflection angle and spring constant. The torsional



NOTE—The angular reference marker is used to locate the angular marks on protractors connected to the bottom mount and the holding platform.

FIG. 1 Diagram of the Torque Apparatus

spring diameter should be chosen so that the maximal deflection angle is less than 25°. A photograph of a torque apparatus is shown in Fig. 2.

7. Test Specimens

7.1 For purposes of device qualification, the device evaluated according to this test method should be representative of manufactured ~~implant~~ devices that ~~are in the~~ have been processed to a finished-sterilized condition. (for example, sterilized).

7.2 For purposes of device qualification, any alteration from the implant finished condition should ~~not be altered in any manner~~ prior to testing, reported. For instance, if sections are cut from the device for testing, this should be reported.

8. Procedure

8.1 Fig. 1 depicts the test fixture, which is placed in the middle of the magnet where the magnetic field is uniform. The test device is placed on the holding platform with one of its principal axes in the vertical direction. The entire apparatus is placed in the center of the magnet in the region of uniform magnetic field. Rotate the fixed base and measure the deflection of the device with respect to the base at 10° increments for angles between 0° and 360°. Note that at angular values where the angular derivative of the torque changes sign, there will be an abrupt change in deflection angle as the device swings to the next equilibrium position. Try to measure the deflection angle as close as possible to this swing so that the maximal torque will be determined.

8.2 Repeat the process in 8.1 twice, once for each of the other two principal axes of the device in the vertical direction.

8.3 Lead wires should be arranged in a manner that is representative of the *in vivo* configuration. If feasible, the wires should carry the currents that are applied *in vivo*.

9. Calculation

9.1 The torque is $\tau = k\Delta\theta$ where $\Delta\theta$ is the deflection angle of the basket from its equilibrium position relative to the fixed base outside the magnet and k is the spring constant.

10. Report

10.1 The report shall include the following for each specimen tested:

~~10.1.1 Implant~~

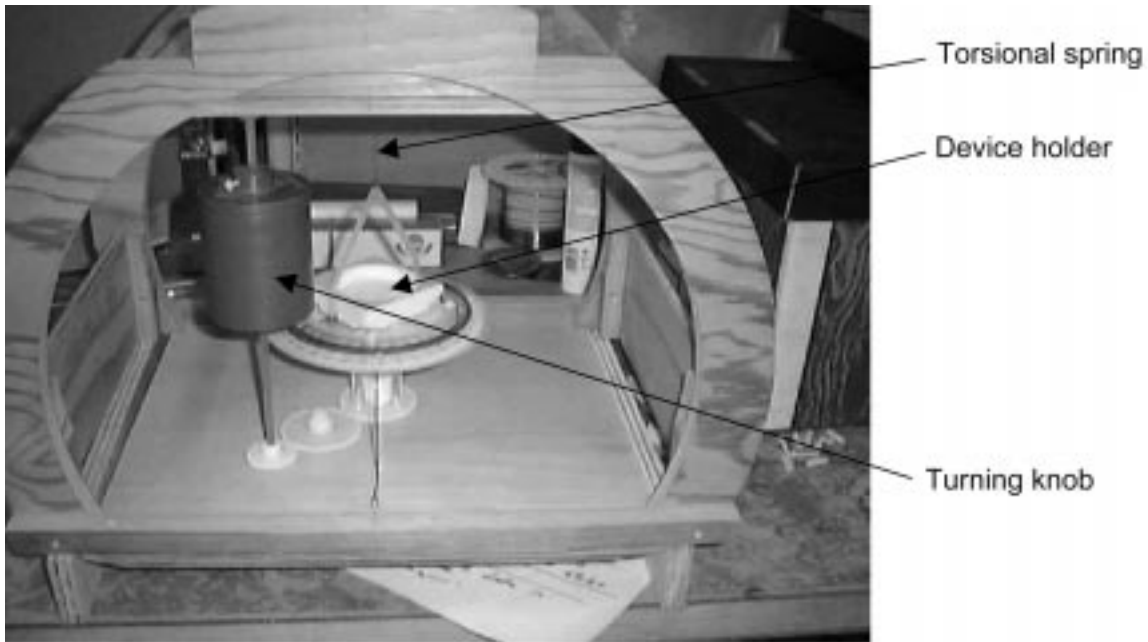
10.1.1 Device product description including dimensioned drawing(s) or a photograph with dimensional scale.

10.1.2 A diagram or photograph showing the three configurations of the ~~implant device~~ during the test.

~~10.1.3 Implant~~

10.1.3 Device product identification (for example, batch, lot number, type number, revision, serial number, date of manufacture).

~~10.1.4 Number~~



NOTE—The turning knob is used to to rotate the mounts supporting the torsional pendulum.

FIG. 2 Photograph of an Apparatus for Measurement of Magnetic Torque

10.1.4 Materials of construction (ASTM designation or other).

10.1.5 Number of specimens tested with explanation for the sample size used.

10.1.56 Weight of the ~~dev~~implant~~ce~~.

10.1.67 Dimensioned diagram or photograph describing the ~~dev~~implant~~ce~~.

10.1.78 Description of the type of magnet and the value of the static field B_0 .

10.1.89 Cartesian coordinate (x,y,z) location of the center of mass of the device during the test using a right handed coordinate system with origin at isocenter of the magnet. Include a diagram showing the MR system and the coordinate axes.

10.1.910 Diagram or photograph of the test apparatus, including the value of the spring constant.

10.1.101 Plots of torque in units of N-m versus angular position of a device axis with respect to the direction of the static field. There will be three plots in total, one for each principal axis of the device oriented in the vertical direction.

10.1.12 Calculations of torque that would be exerted on current loops in the device (see Appendix X4).

10.1.13 Include a description and photograph of alterations that were done to the device.

11. Precision and Bias

11.1 The precision and bias of this test method has not been established.

12. Keywords

12.1 force, magnetic; implant; metals (for surgical implants); MRI (magnetic resonance imaging); MR safety; torque, magnetic

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE FOR DEVELOPMENT OF THE TEST METHOD

X1.1 The primary reason for this test method is to determine the magnetically induced deflection torque on ~~passive implants~~ medical devices that may be subjected to magnetic resonance imaging or may be subjected to the MR environment. Note that this test method only addresses the magnetically induced torque and that the results of this test ~~method~~ alone are not sufficient to determine whether a particular ~~implant~~ medical device is safe in the MR environment. As described below, the torque is produced when the magnetization in the device is not oriented along the static field. The static field also produces a force on ~~an implant~~ a device that tends to attract a ferromagnetic object toward the center of the magnet. For a device to be safe in the MR environment, the magnetically induced deflection force and torque should be less than forces and torques to which the implant would be subjected if it were not in a large magnetic field; for example, a force less than the weight of the device and a torque less than that produced by normal daily activities (which might include rapidly accelerating vehicles or amusement park rides). Other possible safety issues include but are not limited to RF heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the MR system. Although a commercial 1.5 T MR system currently produces the conditions that would most commonly be encountered by a medical device, 3 T MR systems have been cleared for market and are becoming more common in clinical situations. It is important to note that a medical device to be that is safe or compatible in the MR environment, it must a 1.5 T scanner may not be shown to produce negligible levels so in a 3 T system. Also, there can be major differences in the characteristics of RF induced heating open and cylindrical MR systems. For instance, the static field spatial gradients may be significantly higher in open systems.

X1.1.1 The terms MR safe and MR compatible are defined below.

X1.1.1.2 MR Safe—The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions

X1.1.1.3 MR Compatible— The device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

X1.2 There are other possible methods for evaluation of the magnetic torque on an implant in the magnetic resonance environment. In one alternative technique, (Shellock et al., 2000), the magnetic torque is counteracted by tension in strings attached to a turntable holding the device. The torque is determined from the measured tension in the strings.

X2. TORQUE VERSUS ANGLE FOR A FERROMAGNETIC IMPLANT

X2.1 Definitions of Symbols:

- M_s = saturation magnetization in Tesla (T)
- τ_y = torque about the vertical axis due to magnetic field
- N_n = demagnetizing factor perpendicular to the plane of the device
- N_t = demagnetizing factor in the plane of the device
- μ_0 = permeability of free space = $4 \pi \times 10^{-7}$ H/m
- H_0 = MRI system static field expressed in A/m
- B_0 = MRI system magnetic flux density expressed in Tesla (T); $B_0 = \mu_0 H_0$
- \hat{n} = unit vector perpendicular to the plane of the device
- θ = angle of \hat{n} with respect to MRI x-axis in the horizontal plane
- α = angle of magnetization M_s with respect to \hat{n}
- W_T = magneto-static energy per unit volume

X2.2 The static field in an MR-imager system will induce a torque in a soft magnetic material because of the magnetic shape anisotropy. Fig. X2.1 depicts a soft magnetic object in the uniform static field H_0 . The following is assumed:

- (1) The shape of the object is sufficiently regular that the magneto-static energy is well described with three demagnetizing factors in the Cartesian co-ordinate system.
- (2) The object is oriented symmetrically in the field so that the magnetization is entirely in the xz plane and thus the only torque component is about the vertical y -axis.
- (3) The static field B_0 is sufficiently large that all the magnetization in the sample is in the same direction.

X2.3 The relevant magnetic energies are those due to the external and demagnetizing fields. Using SI units, the total magnet static energy per unit volume is written as:

$$W_T = \frac{-M_s^2}{2\mu_0} (N_n - N_t) \sin^2\alpha - M_s H_0 \sin(\theta + \alpha) \quad (X2.1)$$

At equilibrium it is required that $\partial W_T / \partial \alpha = 0$. Thus,

$$W_T = \frac{-M_s^2}{2\mu_0} (N_n - N_t) \sin 2\alpha - M_s H_0 \cos(\theta + \alpha) = 0 \quad (X2.2)$$

Make the definition:

$$\beta = \frac{M_s}{2\mu_0 H_0} (N_n - N_t) \quad (X2.3)$$

The energy equation, Eq X2.2, can then be written as:

$$\cos(\theta + \alpha) + \beta \sin 2\alpha = 0 \quad (X2.4)$$

The torque about the y -axis is:

$$\tau_y = M_s H_0 \cos(\theta + \alpha) \times \text{volume} \quad (X2.5)$$

where:

volume = the device volume.

The maximal amplitude of the torque is:

$$\tau_{max} = \frac{M_s^2}{2\mu_0} (N_n - N_t) \times \text{volume} \quad (X2.6)$$

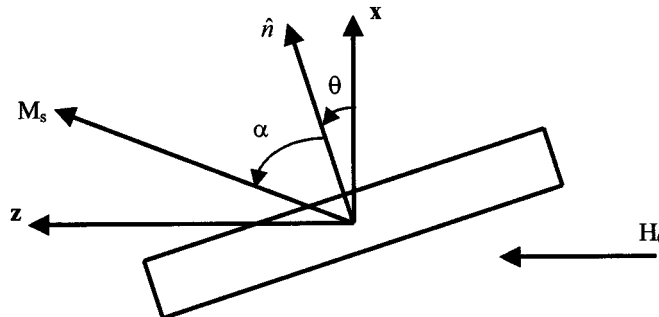


FIG. X2.1 Geometry for Evaluation of the Torque on a Soft Ferromagnetic Object

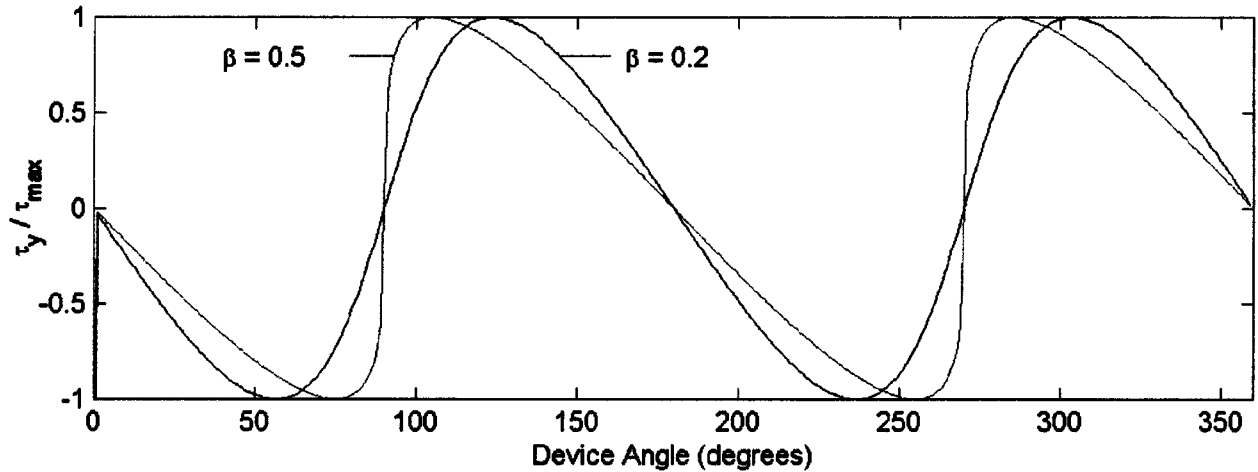


FIG. X2.2 Calculated Angular Dependence of the Torque Normalized to the Maximal Value versus Device Angle for Two Values of β , defined in Eq X2.3

Assuming that the device is magnetically homogeneous and magnetically saturated, the magnetic force is essentially equal to:

$$F_m = \frac{M_s}{\mu_0} |\nabla B| \times \text{volume} \quad (X2.7)$$

From the knowledge of the field gradient ∇B and the measured magnetic force F_m , the saturation magnetization can be determined from Eq X2.7. An upper bound on the torque can then be estimated with Eq X2.6. In general, implants exhibiting minimal force will also exhibit minimal torque.

NOTE X2.1—The maximum torque under the stated assumptions is insensitive to the value of the static field, though the angular dependence will depend somewhat on the strength of H_0 .—

X3. FORCE ON A WIRE WITH CURRENT

X3.1 A wire carrying a current (such as the lead wire of a stimulator) will experience a force known as the Lorentz force. For a straight section of wire carrying a current I , the force per unit length F_l is given by:

$$F_l = I \hat{\rho} \times \hat{A}_0 \quad (X3.1)$$

where:

$\hat{\rho} \equiv$ a unit vector along the length of the wire.

X3.2 The force is thus in a direction perpendicular to the directions of the wire and the magnetic field. For example, for $B_0 = 1.5$ T and $I = 1$ A, the force per unit length is 1 T.

X4. TORQUE ON A CIRCULAR CURRENT LOOP

X4.1 A current loop in a magnetic field will experience a torque. For a loop of area A , n turns and carrying a current I , the torque is given by:

$$\tau = \mu_0 n A I \hat{n} \times B_0 \quad (X4.1)$$

where:

$\hat{n} \equiv$ a unit vector perpendicular to the loop.

X4.2 For example, for $B_0 = 1.5$ T, $I = 1$ A, and $nA = 1$ A, the torque will be 1.3×10^{-6} N-m. In practice the Lorentz torque should only be significant for devices carrying large currents, such a defibrillator leads and power electronic components.

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