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Magnetic resonance imaging safety of Nucleus® 24 cochlear implants at 3.0 T

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Abstract. With infants as young as 12 months receiving cochlear implants that are designed to last more than 70 years, magnetic resonance imaging (MRI) safety at magnetic field strengths >1.5 T is an important consideration, as not only is the likelihood that most people will require an MRI procedure in their lifetime increasing but also the likelihood that this procedure will be at field strengths >1.5 T. Results with Nucleus® 24 indicate that MRI safety at 3.0 T is possible with the implant magnet removed. The effects of torque and demagnetization of the implant magnet at 3.0 T have been shown to be excessive, and currently safety can only be ensured with the implant magnet removed. © 2004 Elsevier B.V. All rights reserved.

Keywords: Cochlear implant; Magnetic resonance imaging; MRI safety

1. Introduction

An estimated 21.9 million magnetic resonance imaging (MRI) procedures were performed in the US in 2002, with an estimated total of 141.8 million procedures performed between 1991 and 2002 [1,2] making MRI one of the fastest growing diagnostic imaging modalities.

Enhanced image quality and decreased scan times, the reasons 1.5 T MRI scanners outperform lower field strength scanners, are now the reasons 3.0 T MRI outperforms 1.5 T technology. Greater image resolution and shorter scan times has also lead to an expansion in the number of clinical applications of 3.0 T MRI, which is contributing to increased demand for 3.0 T systems.

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2. Materials and methods

All tests were performed using Nucleus® 24 implants in both a Siemens Magnetom Trio and GE Signa Horizon HLX 3.0 T MRI machine.

Cochlear implants interact with the magnetic and radio frequency (RF) fields generated by the MRI scanner producing the following effects:

- Force on the implant: due to the static magnetic field;
- Torque on the implant: due to the static magnetic field;
- Unintended stimulation: due to the RF field;
- Degradation of implant function; due to both the static magnetic field and RF field;
- Heating: due to the RF field;
- Image artifacts: due to the implant;
- Implant magnet demagnetization: due to the static magnetic field.

Nucleus® 24 implants have a removable implant magnet, with all tests, except for demagnetization and torque, performed with the implant magnet removed.

Test protocols were based on MRI safety testing standards [3–7] and previous testing of Nucleus® implants at 1.5 T [8].

3. Results at 3.0 T

3.1. Implant force

The average force on the Nucleus® 24 with magnet removed was 0.02 N. This is significantly less than the force on the implant due to gravity alone (0.09 N).

3.2. Implant torque

The average torque on the Nucleus® 24 with magnet removed was 0.0005 N m, also significantly less than the torque on the implant due to gravity alone (0.003 N m).

3.3. Unintended stimulation

A specialised head phantom was developed to measure the voltage differential between the extra and intra-cochlear electrodes during a high RF scan. A baseline was first obtained using a modified Nucleus® 24 implant without capacitors fitted thus preventing any current flow between electrodes. The test was then repeated using a functional Nucleus® 24 implant. The outputs were identical, as were the outputs with the electrode positions reversed, indicating no stimulation between electrodes.

3.4. Implant function

Implant function was tested before and after multiple MRI procedures, with no change in implant function measured.

3.5. Implant heating

Only the temperatures at the electrode tip increased as the result of the continuous 15-min high-powered MRI scan at 3.0 T. The temperature rose to 1.3 °F (0.7 °C) at the tip of the electrode only.

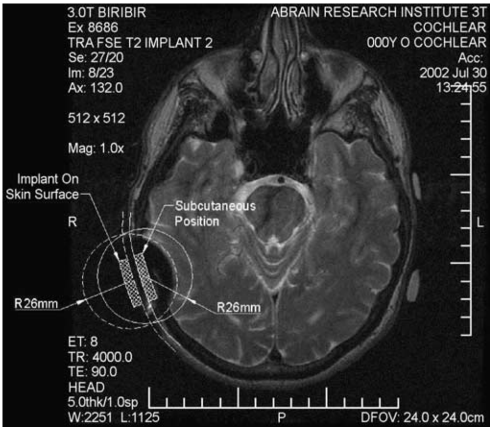

Fig. 1. Nucleus® 24 image artifact (without magnet).

3.6. Image artifacts

A Nucleus® 24, without implant magnet, firmly attached to the side of the head of a volunteer produced a maximum artifact radius of 1.4 in. (36 mm). This artifact was equivalent to that produced using a phantom model, and found to be identical with respect to the implant position outside or inside the head phantom.

Fig. 1 shows the maximum axial artifact section with the implant firmly attached to the side of the head, and also as would be expected in an implanted case. Image artifacts with the implant magnet attached are typically three times larger, or approximately 4 in. (100 mm) in radius, obscuring much of the brain.

3.7. Implant magnet demagnetization

Ten implant magnets were exposed to the 3.0 T static magnetic field at various orientations. The maximum demagnetization occurred when the magnetic fields were opposed (180°), with an average 90.1% level of demagnetization.

4. Discussion

With the acceptance of both cochlear implantation and MRI growing rapidly, cochlear implant recipient will likely undergo an MRI procedure at some time in their life, and this procedure may very likely be at field strengths greater than 1.5 T.

In a review of the US MRI scanner and coil markets [9], it was identified that the enhanced image quality and decreased scan times delivered by 3.0 T MRI scanners is generating substantial demand as hospitals and imaging clinics move toward adopting higher field strength systems, shifting from 1.5 to 3.0 T systems. And with the full realization of new applications, 3.0 T systems are likely to become the clinical standard.

Results of MRI safety testing with Nucleus® 24 implants at 3.0 T with implant magnet removed indicate that all interaction, such as implant force, implant torque, unintended stimulation, implant function and implant heating are within safe limits.

The force and torque measured with the magnet removed are both insignificant (0.02 N and 0.0005 N m). Both however would increase significantly if the implant magnet were left in place. For example, the torque on the implant magnet was calculated as 0.36 N m at 3.0 T. This is equivalent to attaching a 1.8 gal (7 l) container of water to the edge of the implant magnet.

Implant function was shown to be unaffected at 3.0 T, with no unintentional stimulation produced and a temperature rise of 1.3 °F (0.7 °C), being significantly less than the recognised standard for tissue temperature heating of 3.6 °F (2 °C).

Image artifacts due to the implant are relevant only for brain images, which in 2001 accounted for over one third of all MRI procedures [1]. In these cases imaging with the magnet removed significantly reduces the artifact size providing much greater detail, allowing for more accurate diagnosis.

The implant magnet was demagnetized by 90.1% at 3.0 T, which would result in an inability to locate and attach the external transmitter coil. Preliminary testing of Nucleus® 24 implant magnets at 1.5 T resulted in very little demagnetization (<10%) compared to other studies that have reported maximum demagnetization of 38% [10] and 78.5% [11] at 1.5 T. The head will always be positioned at or pass through the bore of the MRI scanner where field gradients are strongest (even for lower extremity scans). Therefore, only removal of the implant magnet at 3.0 T guarantees that full functionality of the implant magnet is retained.

5. Conclusion

Nucleus® 24 implants have been shown to be MRI safe at 3.0 T with the implant magnet removed. A review of MRI technology trends indicates that the field strengths will continue to rise and that 3.0 T is likely to replace 1.5 T as the clinical standard for MRI. MRI with the implant magnet in place may be possible at lower field strengths; however, the artifacts produced limit the diagnostic relevance of the images produced. At 3.0 T, the level of demagnetization, and the physical torque on the magnet remains unsafe, and currently the only option available to allow safe MRI at 3.0 T is the removal of the implant magnet.

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