Oticon Medical
Neuro Zti:
MR Conditional at 1.5 and 3.0 T

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ABSTRACT

Magnetic resonance imaging (MRI) is a widely used technique in clinical settings that provides professionals with valuable diagnostic and prognostic information about patients' health. MRI is used for the body as well as the brain, with brain scans accounting for 20-25% of all MRI scans performed worldwide[1]. For cochlear implant (CI) patients, this figure increases to 49%[2]. Understandably, cochlear implant users do not always feel comfortable about undergoing this examination. The new version of the Oticon Medical Neuro Zti implant has been designed to ensure a safe and comfortable MRI scan with the entire implant in place (including the magnet). It can withstand the strong static magnetic field of the MRI scanner at 1.5 and 3.0 Tesla (T) under specific scanning conditions. Thus, patients avoid surgery to remove the magnet and can maintain their hearing before and after their scan. This whitepaper describes why it is important to tackle this subject and shows how Oticon Medical addresses this patient concern with a secure device that allows medical check-ups, including MRI scans, to be carried out as safely as possible.

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1. Background

1.1 About MRI and statistics

Magnetic resonance imaging is a medical imaging technique used to observe the detailed anatomy of the body and diagnose diverse pathologies with a high level of accuracy. MRI scanners use strong static magnetic fields, magnetic field gradients and a radiofrequency (RF) field to generate images of the organs in the body. MRI is widely used in hospitals and clinics for medical diagnosis, following the stages of a disease without exposing the body to the ionising radiation compared to other imaging techniques (e.g. CT Scan).

To perform an examination, the patient is positioned within an MRI scanner where a strong static magnetic field is generated (which is called the B0) allowing hydrogen nuclei "spin" – normally present in the tissue – to be polarised. To acquire the signal, a sequence composed of radiofrequency field and magnetic field gradient pulses is run with very specific parameters (durations, delays and amplitudes). The pulsed RF field transmits energy to the spin, whereas the gradient magnetic fields are applied for spatial encoding.

MRI requires a static magnetic field that is both strong and homogeneous in the region of interest (ROI). The field strength of the magnet is measured in Tesla (T) – and while most of the available systems operate at 1.5 T, commercial clinical systems are available between 0.2 and 7.0 T.

50,000 scanners are estimated to be in use worldwide, with nearly 40 million MRI scans performed annually in the United States alone[3]. No official numbers exist on how many of the different types of MRI machines are available in different countries. In Europe, it is estimated that 1.5 T machines represent around 80% of the currently available machines and 3.0 T around 10-15%. This is expected to increase to 20% around 2025, while low-field machines (0.2 – 1.0 T) are progressively being replaced by 1.5 or 3.0 T scanners.

1.2 MRI examination and CI users

Because of the possible interaction between the strong magnetic field of MRI scanners and metallic objects, people with medical implants or other non-removable ferromagnetic objects inside their body may be unable to safely undergo an MRI examination. When an implant is composed of a magnetic material, it will interact with the static magnetic field resulting in torque, force or degradation of magnetic properties. Then, when gradients are switched ON and OFF to perform the examination, implant conductive materials are exposed to varying magnetic fields, which can generate heating, electrical currents or even vibration. An RF field, on the other hand, may also result in heating and induced currents.

In the same way as the general population, cochlear implant users may need magnetic resonance imaging during their lives, since this technology is indicated for diagnosis of a large range of pathologies (Dubrulle et al.[4]). For some of them, repeated MRI examinations are needed to follow the progression of the disease (e.g. neurofibromatosis type 2, multiple sclerosis).

Cochlear implant solutions consist of a speech processor, an external antenna and an active implant located on the surface of the skull behind the ear. This implant comprises of a magnet, hermetically sealed electronics and an electrode array inserted into the cochlea. MRI imaging after cochlear implantation was initially contraindicated. For this reason, the internal magnet had to be removed before performing MRI imaging and replaced again after the examination. This strategy reduces associated artifacts and discomfort from potential magnet dislocation. However, it creates the need for two minor surgical procedures (magnet removal and replacement), increases the risk of infection and leads to a period of non-use of the CI, and thereby no hearing ability while the incision site is healing.

Following extensive work to measure torque, demagnetisation, displacement force and induced heating, both in vitro and in vivo, MRI was authorised for use with cochlear implants in 1995 under strict conditions, initially for 0.2 T MRI and then progressively up to the current strength of 3.0 T (Deneuve et al.[5]). CI manufacturers specify MRI scan conditions that must be followed

to prevent any harm to the patient or to the device, although complications may occur even when guidelines are followed. The most reported complication of MRI in CI was pain. Other potential complications included magnet displacement, magnet weakening (due to depolarisation, polarity reversal) and implant heating (Kim et al.[6], Srinivasan et al.[7]). Artifacts caused by the CI remain an issue but may be reduced using specific scanning sequences (Todt et al.[8]).

For patients with previous generations of implants from some manufacturers, there were recommendations to apply a pressure head bandage during the MRI examination to prevent magnet displacement (Tam et al.[9]). To optimise the pressure created by a bandage on the magnet, some experts suggest applying a rigid object directly above the implant magnet (Leinung et al.[10]). This still did not prevent the problems of magnet displacement or pain. (Kim et al.[6])

In summary, patients with a CI can be scanned only if specific conditions warranting their security are respected. All cochlear implants are labelled as MRI -conditional devices (Shew et al.[11]) and most of the newest cochlear implant generations are MRI conditional, even up to 3.0 T.

1.3 MRI examination at 1.5 T vs 3.0 T

Across the United States, European countries and most of the world, 1.5 T horizontal bore MRI remains the standard technology for MRI scanners. A 1.5 T machine is faster than lower strength MRIs and is ideal for examination of the abdomen and chest. Since the image quality depends on the static magnetic field strength, doubling the signal strength allows a 3.0 T MRI scanner to provide extremely clear and vivid images. At 3.0 T, the signal-to-noise ratio (SNR) is improved, and the image has a higher resolution. Additionally, the exams can often be done faster, thereby decreasing overall scan time. These factors are of great benefit to the patient in terms of diagnosis and comfort (Harmonay, Vikki [12]).

3.0 T MRI is ideal when details are especially crucial for diagnosis. However, in general an examination with a 3.0 T scanner can very often be replaced by an examination at 1.5 T. Therefore, the prevalence of 3.0 T examinations for CI users is still very low, but it is a fast-growing trend.

To respond to this trend, cochlear implant manufacturers are now offering solutions that allow a safe MRI examination with the magnet in place, even in stronger magnetic fields.

2. Oticon Medical positioning regarding MRI

2.1 Unique design of the Neuro Zti implant

The design of the Neuro Zti implant has been optimised with the help of leading experts to ensure comfort and safety for the patient. The implant features a unique fixation system that uses two titanium screws to hold the device firmly in place without the need for drilling a bone bed. Clinical studies have shown that this unique screw fixation system efficiently prevents implant displacement with no cases of implant migration (Guevara et al.[13], Schramm et al.[14]).

The second aspect of the design that ensures comfort and safety is an anchoring system that creates a ridge in the Neuro Zti implant, enabling a "snap-fit" that anchors the implant magnet casing and holds it firmly in place (Figure 1).

These unique features dramatically reduce the risk of magnet dislodgement or implant migration during exposure to the MRI scanner's magnetic field.

2.2 MRI compliance with the new Neuro Zti magnet

The Neuro Zti implant is now equipped with a new and unique magnet so that patients can safely undergo 1.5 and 3.0 T MRI scans without the need for magnet removal surgery (Figure 2). All MRI safety tests have been performed (displacement force, demagnetisation, torque magnet dislocation, gradient heating, vibration, gradient malfunction/rectification, RF heating and RF malfunction/rectification), some of them have been highlighted below. The results confirm that patients with the Neuro Zti implant and the 3T magnet can safely undergo MRI examinations under scanning conditions.

Figure 2: Neuro Zti with the new magnet

2.2.1 New 3T magnet

The new magnet (Figure 3) is manufactured by one of the world's leading producers of special magnetic alloys with a unique composition of rare-earth elements. These rare-earth elements have different magnetic properties and are also widely used in the aerospace industry. Thanks to its properties and a patented manufacturing process, this unique magnet has a high resistance to demagnetisation during 3.0 T MRI scans (see the demagnetisation test below).

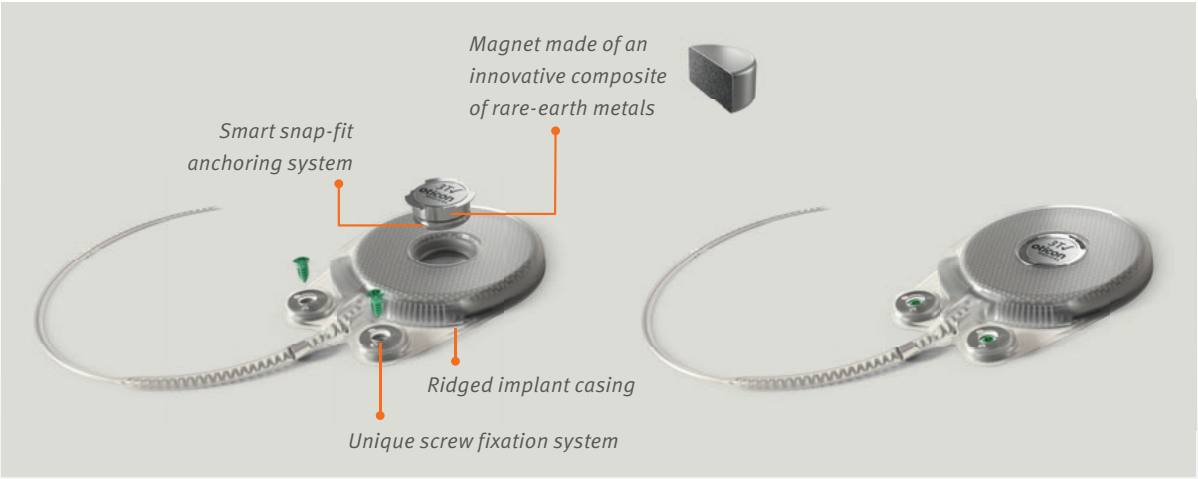

Figure 1: Neuro Zti with the new magnet and unique fixation screws

Figure 3 : Neuro Zti 3T new magnet (left) mounted inside a titanium casing (middle and right)

2.2.2 Static magnetic field safety

Demagnetisation

Depending on the strength and orientation of an applied external static magnetic field, the magnet of a cochlear implant system may partially or entirely lose its magnetic strength (demagnetisation). This has clinical consequences as the patient would have to return to the clinic for re-fitting of the sound processor as a new, stronger antenna magnet would be required. This also has consequences for the radiologist who will perform the MR scan. The orientation of the applied magnetic field is related to the patient's head in the scanner. CI manufacturers have given very restrictive instructions to radiologist with respect to how to position a CI recipient's head in a scanner. The resistance to demagnetisation is given by the intrinsic coercivity parameter (Hci), which is the amount of magnetic force required to completely demagnetise a magnetic material. This parameter depends not only on the magnet alloy composition, but also on the manufacturing process.

To evaluate the demagnetisation risk, a set of magnets were exposed to a 3.0 T static magnetic field inside an MRI scanner in different orientations. Magnetisation was measured before and after 10 exposures and until 2 days after exposures[15] to ensure the results' stability in time. Then, the magnetisation decrease or increase percentage was calculated. The average demagnetisation or gain of magnetisation was evaluated for different angles (from 30° to 150°) between the permanent magnet magnetisation (m) and the static magnetic field (B0), as represented in Figure 4.

The tests confirm that the new and unique properties of the Neuro Zti magnet exhibit a stable high resistance to demagnetisation when exposed to a 3.0 T static magnetic field, with only 2.9% lost, considered as negligible in the worst-case position (with an angle of 150°), resulting in a maintained performance of the retention force with the external part, even after multiple 3.0 T MRI exams.

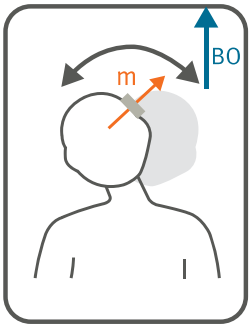

Figure 4: Angle between the permanent magnet magnetisation (m) and the static magnetic field (B0), from 30° to 150° corresponding to the different head positions

Torque

In the presence of a strong external static magnetic field, a magnetic moment is created within a ferromagnetic material so that it will rotate to be aligned with the B0 field. That is why the primary risk of the magnetic moment is the torque of the whole implant, which may result in tissue damage. Based on the ASTM F2213-17[16] standard, the torque is characterised using a torsional spring system as shown below in Figure 5. Torque has been measured as a function of the angle between B0 and the axial magnetisation of the magnet, resulting in a maximum value of 266 ± 19 mN.m^{-1}.

The retention strength of the Neuro Zti casing on the human skull was calculated considering the worst case torque with a value of 15 kPa. In addition, the extrapolated lowest strength of the human skin when perpendicular to Langer's lines (skin tension lines) is about 4.4 MPa, which corresponds to the skin strength of an elderly person (Yang et al.[17]). Furthermore, Edwards et al.[18] calculated the maximum skin deformation before failure to be greater than 60%. The theoretical potential deformation generated by torque on the Neuro Zti implant was calculated to be 0.025%, which is negligible compared to the maximum skin deformation of 60% described in the literature.

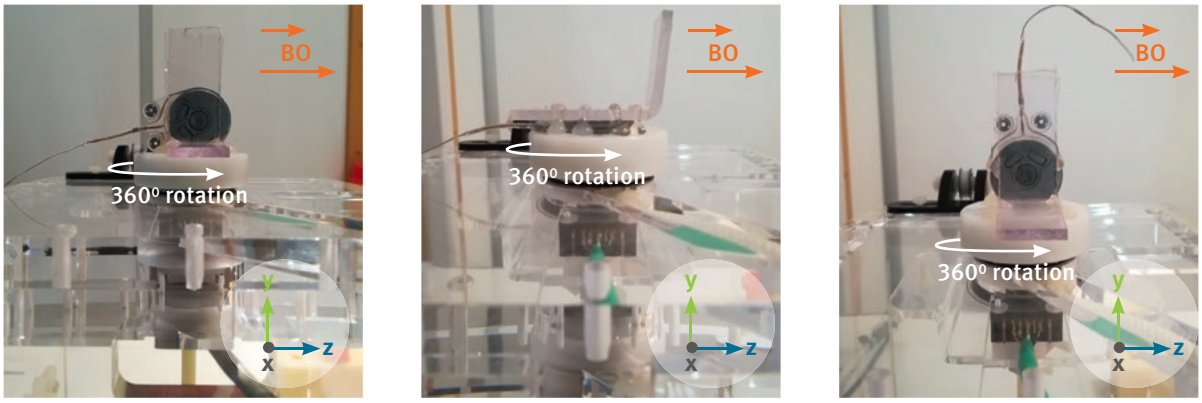

Figure 5: Torque test setup with Neuro Zti implant positioned in the three directions (source: Healtis).

The retention strength of the Neuro Zti implant on the skull is 15 kPa, which is less than 1/100 ($< 10^{-2}$) of the weakest skin strength of 4.4 MPa. Therefore, we can consider that the torque generated by an external static 3.0 T magnetic field does not present any safety risk for the patient, the implant remaining secure and steady during the exam. With the Neuro Zti properly implanted, the torque on the device cannot damage the skin.

Flipping out

Since the the Neuro Zti magnet can be removed, there might be a potential risk of magnet dislodgement or "flipping out". Multiple tests to assess this risk and guarantee patient safety have been conducted. As a worst-case scenario and prior to the MRI test, magnets were extracted several times from their respective implant's housing using the extraction force testbench. Then, the Neuro Zti implants were placed inside a tool filled with saline water with the magnets free to move. The tool was positioned on a 3.0 T MRI table and moved to the isocenter (centre of the MRI tunnel). Visual inspection was conducted at the end of the exposure and no flipping out or dislodgement had occurred during 3.0 T exposure.

Displacement Force

In the presence of a spatial gradient along a magnet, a displacement force is created. To characterise the displacement force induced on the Neuro Zti implant, a test was conducted based on the ASTM F2052 – 15[19], by measuring the deflection angle of the device freely suspended when exposed to the spatial gradient field. The maximum displacement force calculated is about 2 N in 3.0 T MRI scanners.

Two Neuro Zti features are critical for mitigation of the risk of magnet displacement:

- The cross-section resistance of the implant (shown in red in Figure 6) before the implant breaks is 242 N. Therefore, the maximal displacement force of 2 N inside a 3.0 T MRI scanner is negligible compared to the maximum strength of the Neuro Zti implant of 242 N (~1/100).

- The implant's fixation screws can resist an externally applied force and ensure the implant remains stable. The required axial pull-out force of the Neuro Zti implant of 70 N (both screws) and 35 N (one screw) is significantly stronger than the maximal displacement force caused by a 3.0 T scanner (2 N).

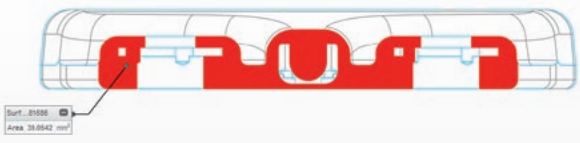

Figure 6: Cross section of Neuro Zti implant showing the higher mechanical resistance areas in red

The solid design of the Neuro Zti implant, in combination with the unique screw fixation system, ensures the implant remains in a stable and secure position even if it is exposed to the displacement forces exerted by the

strong magnetic fields of a 3.0 T MRI scanner (2 N). Thus, the risk of implant displacement is reduced to very low levels.

2.2.3 Radiofrequency field safety

One major risk related to the RF field is heating. The wires of the electrode array act as an antenna picking up RF energy with part of it being dissipated into the tissue as heat through the electrodes. The RF heating study conducted with Oticon Medical EVO and CLA electrodes followed the ISO/TS 10974:2018[20] standard. This relies on the transfer function method, which links the temperature rise at the electrodes to a known tangential electric field (amplitude and phase) along the electrode array wires[21]. Thousands of in-vivo simulated tangential electric fields were extracted by varying different parameters such as realistic clinical electrode arrays routings (Figure 7 left), human anatomies, birdcages and imaging landmarks (different Specific Absorption Rate or SAR exposure).

The temperature rise values, corresponding to a 60 minute exposure, were evaluated by applying all the combinations of tangential electric fields to the transfer function. Further validations were conducted on the 3D model of the Zti implant using in-vivo full-wave electromagnetic and thermal simulations. Simulated electrode array temperature rise results are shown in Figure 7 right.

Worst case temperature rises results as a function of the distance (d) between the top of the head and the MRI scanner isocenter are shown in Figure 8. When applying SAR limitations of 0.6 W/kg (SAR_{wb} whole body average) and 1 W/kg (SAR^{h} head average) for a distance less than 30 cm between the top of the head and the isocenter, the maximum heating induced by the RF field was well within the maximum threshold of 4 °C. In addition, no SAR limitation is needed under the normal operating mode if the distance between the head and isocenter is greater than 30 cm, which translates into a whole-body average SAR levels of 2 W/kg (Figure 8).

Although SAR limitation is applied to patient with the 3.0 T Neuro Zti implant (SAR_{wb} = 0.6 W/kg and SAR_{h} = 1 W/kg), image quality can still be maintained for clinical diagnosis. In fact, Martinez et al[22] have demonstrated with in-vivo measurements that low average head SAR levels down to 0.12 ± 0.02 W/kg, or 0.09 ±0.01 W/kg do not compromise image quality but will only increase exam duration.

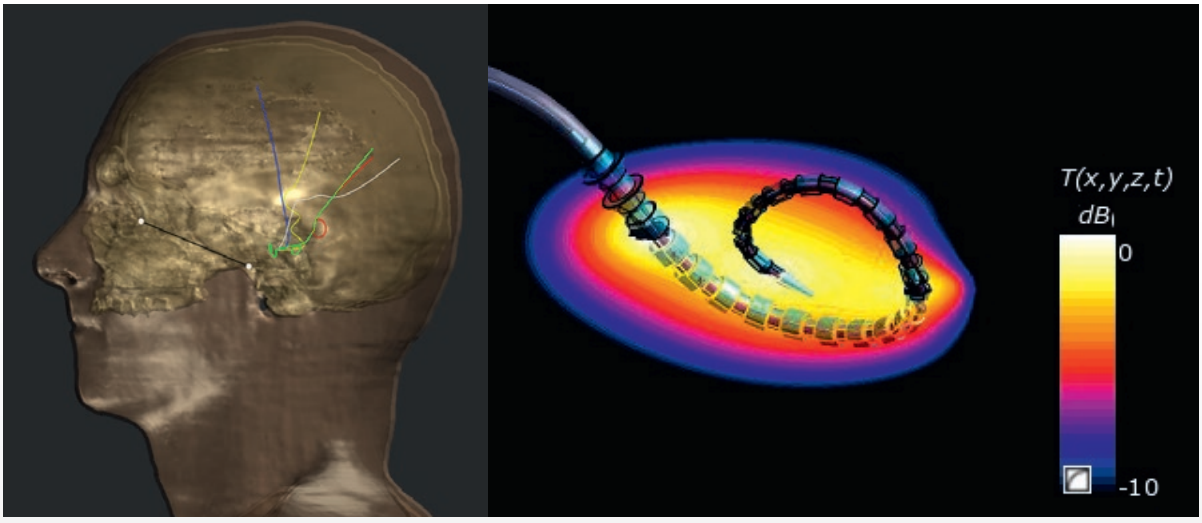

Figure 7: Left: In-vivo tangential electric field extraction along 10 realistic electrodes array paths. Right: Thermal simulation results using Multiphysics Sim4Life simulation platform (ZMT Zurich MedTech AG). In-vivo normalised temperature rise distribution in dB scale at 128 MHz for Neuro Zti electrode array at the plane of maximum value (0dB).

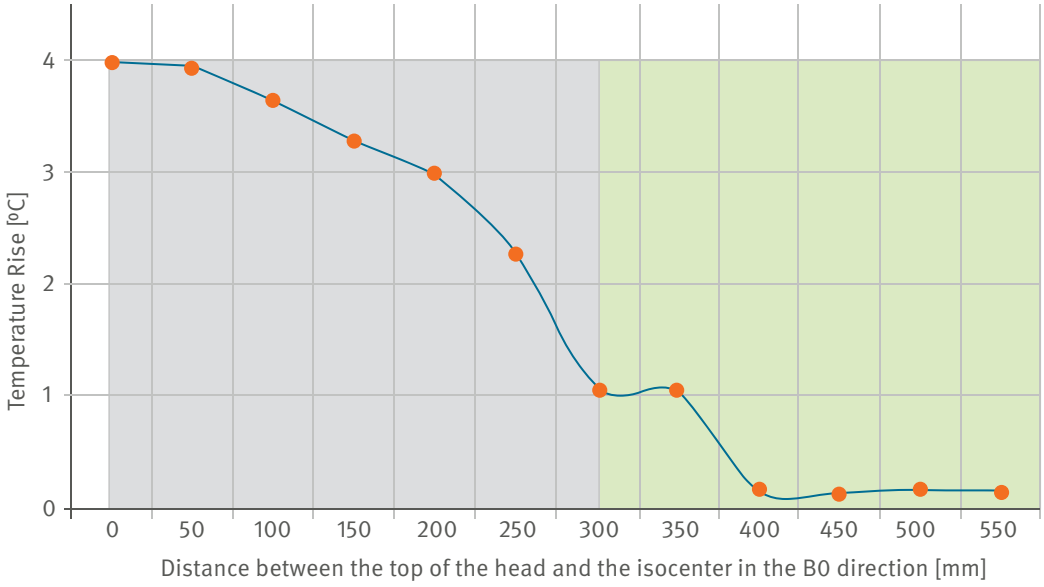

Figure 8: Maximum electrodes heating as a function of imaging landmark after a scan duration of 60 min

The Neuro Zti implant allows patients to safely undergo 3.0 T MRI examination up to 60 minutes, without running the risk of the MR scanner inducing excessive heat, which may cause tissue damage, by limiting the maximum SAR level to 0.6 W/kg (whole body average) and 1 W/kg (head average) if the distance between the top of the head and the isocenter is less then 30 cm. No SAR limitation is required if the distance between the head and the isocenter is greater than 30 cm, allowing for a whole-body average SAR levels of 2 W/kg. These SAR value limitations have no negative impact on the image quality of the MRI scan.

2.2.4 Artifacts assessment

Image artifacts are caused by the presence of implanted metallic or magnetic devices such as the implant magnet. This is a known issue for all cochlear implants, and other implantable devices such as pacemakers. Artifacts are created by eddy currents and magnetic susceptibility. Artificial hyperintense signal, fat suppression failure

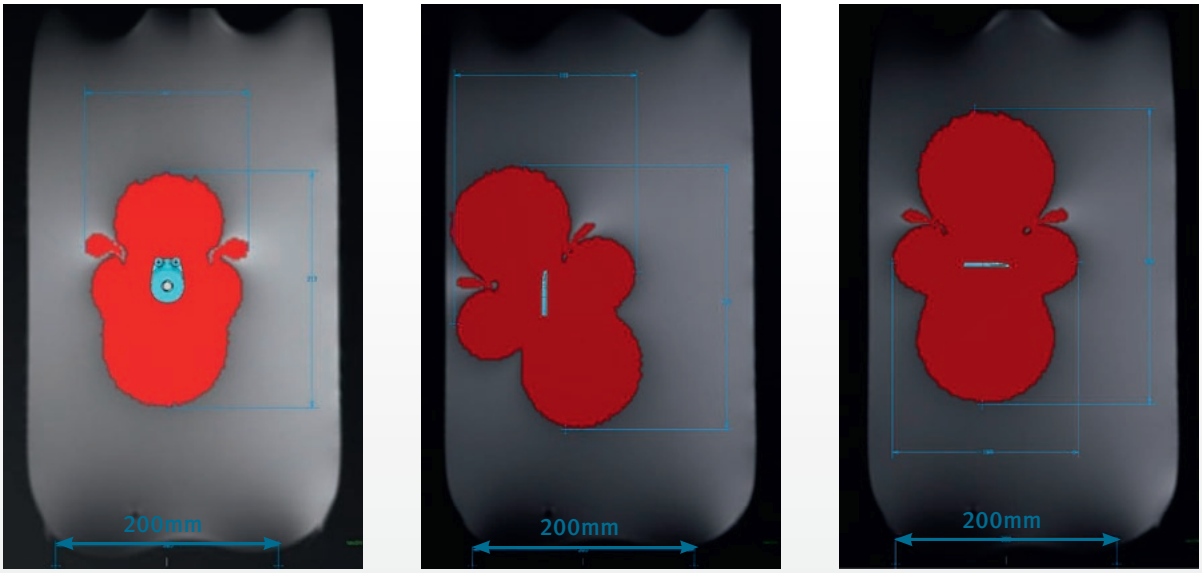

Figure 9: Maximum sagittal artifact acquired with a spin echo sequence as a function of Neuro Zti implant orientation inside a homogeneous phantom. From left to right: sagittal plane, coronal plane and axial plane. (source: Healtis)

and geometric distortion may impair the diagnostic accuracy, which often results in signal loss. To characterise the artifact induced by the Neuro Zti implant within the field of view (FOV) during an MRI examination, typical MRI sequences such as Spin Echo (SE) and Gradient Echo (GE) were used. The test was performed in-vitro, based on the standard ASTM F2119[23]. Sagittal plane acquisitions were performed for each frequency encoding direction (Anterior to Posterior (AP), Superior to Inferior (SI)) with different implant orientations as shown in Figure 9.

The worst case artifact with a spin-echo sequence for the Neuro Zti with the new 3.0 T MR conditional magnet is 141 mm with magnet in place, and 56 mm with the magnet removed.

Although the Neuro Zti implant artifact is not considered as a risk for the patient, artifact size must be considered by the radiologist prior to the MRI examination, as it might cover the region of interest used for the diagnosis.

2.3 Neuro Zti easy magnet removal process

If, for any reason, the Neuro Zti magnet needs to be removed – most likely for a head scan where the implant without the magnet creates a smaller artifact around the implanted region that might be of interest for the radiologist – this can be done quickly and easily (Figure 10).

Magnet removal can be carried out under local anaesthetic with only a small skin incision. With the dedicated Oticon Medical surgical tool, the magnet is simply removed in a few steps without lifting the implant. The magnet can be replaced without damaging the body of the implant and causing unnecessary stress for the patient. This straightforward process can be repeated if additional MRI exams are needed. (Wagner et al. [24])

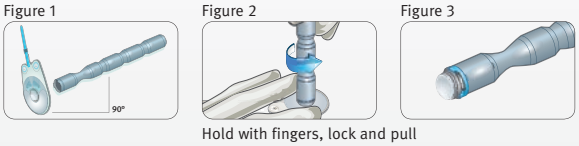

Figure 10: The Neuro Zti magnet removal process

Conclusion

The Neuro Zti implant with the new 3.0 T magnet represents the latest cochlear implant design that enables patients to undergo high-strength 3.0 T MRI examinations without the inconvenience and potential pain of an additional surgical procedure to remove the implant magnet, or potential adverse effects such as magnet dislodgement. The Neuro Zti is the only cochlear implant that addresses the challenges created by the exposure to a 3.0 T static magnetic field through an innovative magnet composition of rare-earth materials associated to a highly specialised manufacturing process, while allowing the radiologist to remove the magnet if needed for a diagnostic purpose. Thanks to its unique implant anchoring system, Neuro Zti users do not require any head bandaging when undergoing 3.0 T MRI examinations and they can be examined for up to 60 minutes, without any concerns for their safety.

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Notes

Because sound matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the power of sound to people at every stage of life. As part of the Demant group, a global leader in hearing healthcare with more than 16,500 people in over 30 countries and users benefitting from our products and solutions in more than 130 countries, we have access to one of the world's strongest research and development teams, the latest technological advances and insights into hearing care.

Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology. We work collaboratively with patients, physicians and hearing care professionals to ensure that every solution we create is designed with users' needs in mind. We have a strong passion to provide innovative solutions and support that enhance quality of life and help people live full lives – now and in the future.
Because we know how much sound matters.

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