Safety of 3 Tesla Magnetic Resonance Imaging on iStent Implants: An Ex-Vivo Study

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Précis: Our study shows that iStent implant does not cause significant image artifacts, heating, or displacement during magnetic resonance imaging (MRI) scan. This device can be safely used in patients undergoing MRI scans using 3 Tesla (3T) machines.

Purpose: The iStent is a medical grade titanium implant commonly implanted in the anterior chamber angle of glaucomatous eyes in order to reduce intraocular pressure and medication burden. As many people now have these devices implanted in their eyes, the issue of their compatibility with MRI in terms of safety and interference with interpretation of these studies commonly arises. The purpose of this study is to evaluate the safety of 3T MRI scans in eyes that have undergone iStent implantation and to assess the interference of the implant to the scan interpretation.

Materials and Methods: An ex vivo model of sheep eye with an iStent and proximately placed heat detector probe was used to study changes in the temperature during MRI 3T scan. The study included 2 fresh eyes with preserved extraocular muscles and orbital fat tissue placed in the orbital cavity of a human skull. Each eye with orbital content was scanned with a 3T MRI machine.

Results: No displacement of the implant was observed during MRI scanning. The heat detector showed mild temperature elevation during the first minutes of the scan from 14.6 to 16.5°C. The iStent was best visualized in T2 turbo spin echo sequences and showed no significant artifacts.

Conclusion: iStent implants did not move during the MRI scan, showed minimal interaction with the magnetic field in terms of heating and image distortion. These interactions were not strong enough to present a substantial risk to patients with this implant undergoing an MRI scan.

Key Words: artifact in scan, glaucoma, istent, MRI, MIGS

Glaucoma is a leading cause of severe visual impairment and irreversible blindness.1 In recent years, minimally invasive glaucoma surgery (MIGS) is gaining considerable popularity. It is low risk, cost-effective over the long term, has good visual outcomes and effectively reduces intraocular pressure (IOP).2 One of the most commonly used MIGS is the iStent, a 1 mm, heparin-coated, medical grade titanium implant, which is approved by the Food and Drug Administration.3,4 It creates a direct pathway between the anterior chamber and Schlemm’s canal by bypassing the trabecular meshwork, thus decreasing IOP.5 More than 1 drainage device can be simultaneously implanted in the same eye to increase the reduction in IOP.5,8 Although titanium is a paramagnetic material, some clinicians have questioned whether titanium implants are safe for use in conjunction with magnetic resonance imaging (MRI) and if they cause artifacts in the scans.

MRI is an important diagnostic tool for a variety of conditions. It has excellent soft-tissue contrast and is considered to be safer than other imaging modalities, as it does not expose the body to radiation.9 MRI machines with magnetic fields of 3 Tesla (3T) have been widely adopted worldwide and have significantly improved diagnostic ability by increased signal to noise ratio and increased spatial and temporal resolution.10 Ultra-high magnetic field MRI machines of up to 10T have been recently introduced and are currently being used as research tools. They are expected to be integrated into clinical practice in the foreseeable future.11,12 The interaction of the magnetic field with metal limits the use of MRI in cases with some implants, such as those used in orthopedics and dentistry. The number of patients with implantable devices, including in the eyes, is increasing. Studies have shown that severe artifacts appear in MRI scans of patients with cardiac and orthopedic titanium implants, which significantly influence the image quality.13,14 Therefore, it is necessary to evaluate the performance and clinical value of these systems in patients with implanted ophthalmic devices.15,16

This study evaluated safety parameters (temperature changes, device displacement, and dislocation) during 3T MRI scans in eyes with implanted iStent device. In addition, we assessed the presence of artifacts that interfered with image interpretation.

MATERIALS AND METHODS

The study included 2 fresh sheep eyes with preserved extraocular muscles and orbital fat tissue placed in the orbital cavity of a human skull. Eyes of the young Awassi breed were used in this study. Animals were not older than 12 months. Sheep eyes were obtained shortly after slaughter, kept in iced coolers, and used within 12 hours. Before performing the MRI scan, the eyes were kept at room temperature for at least 1 hour to allow them to equilibrate to room temperature. Experimental samples were prepared as follows: eyes with preserved extraocular muscles and orbital fat tissue were placed in the orbital cavity of a human skull. A paracentesis was performed, and the eye was filled with ophthalmic visco-surgical solution (Biolon; Bio-technology General Ltd., Be’er Tuва, Israel). A first-generation iStent microbypass implant (GTS100R model with a preloaded right-handed injector; Glaukos, San Clemente, CA) DOI: 10.1097/IJG.0000000000001801
made of medical grade titanium obtained for research purposes was then implanted into the anterior chamber angle under an operating microscope, without a direct view of the angle as shown in Figure 1 because of difficulties of proper angle visualization with a gonio lens in the sheep eye. The viscoelastic material was not removed from the anterior chamber before the scan to preserve the volume of the chamber. Siemens phantom plastic bottles (model 08624186) which contains 1900 mL solution (per 1000 g H2O dist.: 3.75 NiSO4×66H2O, 5 g NaCl) were used to simulate greater weight of the scanned model, allowing to set the highest specific absorption rate during the scan. Thin-section, multiplanar brain and orbital imaging was performed using Siemens 3T MRI machine (MAGNETOM Vida, Siemens Healthineers 2018) with a static magnetic field of 3T. The Tesla M3—MIPM temperature monitoring system with an infrared probe and fiber optic cable (TeslaM3-Mammendorfer Institut fur physik und Medizin GmbH, Germany) placed over the implanted drainage device was used to perform continuous measurements during the scan. The average specific absorption rate of at least 2.33 W/kg was used in each scan. Maximum gradient strength was 4500 g/cm (45 T/m) with average scan time of 12 minutes. Both eyes were scanned similarly before and after iStent implantation. The scan before implantation of the drainage device was used as a control.

Each scan included standard sequences used for routine orbital examinations: T1 Turbo Spin Echo (T1 TSE) in the axial plane, T2 TSE in the axial plane, T2 TSE with fat suppression in the axial plane, and T2 TSE with fat suppression in the coronal plane. In order to test a translational motion of the implant, we assessed the distance from the most medial part of the implant from the nasal septum and parallel to the interzygomatic line. While reviewing the scans we compared the premeasurements with the postscan findings.

RESULTS

The thermometer registered no change in temperature during the 3T MRI scan in the control scan without the iStent. In eyes with the iStent implanted, a 1.9°C rise, which peaked ~3 minutes after the beginning of the scan was detected. The heating was observed predominantly at the beginning of the scan.

No migration or deflection of the implant was observed during MRI scanning. The iStent was best visualized in the T2 TSE with fat suppression sequence scans and showed no significant artifacts (Fig. 2). The stent was not visualized in the T1 sequence.
DISCUSSION

MRI is a widely used imaging modality, and its use is increasing. During the MRI scan, the intensity of the magnetic field is varied causing hydrogen atoms to align in the same direction before returning to their original state. This creates the energy signals measured by a conductive field coil placed around the imaged object. All materials have different levels of magnetism, from ferromagnetic substances like iron, cobalt, and nickel, that are highly magnetized, to paramagnetic substances such as titanium, aluminum, and crown glass that are weakly magnetized by an external magnetic field. Patients with implanted devices are at risk of it migrating or heating during MRI. In addition, artificial distortion can influence the diagnostic quality of the scan. Factors influencing the risk of performing MRI scans in patients with implants include degree of ferromagnetism, location and orientation of the implant, parameters of the device, and strength and gradient of the magnetic field. Several studies demonstrated a low risk of such complications as implant deflection, artifacts formation related to MRI examination in patients with nonocular titanium implants. Also, a few studies demonstrated the safety and compatibility of an MRI scan among patients with the stainless steel EX-PRESS miniature glaucoma shunt (Optonol Ltd, Neve Ilan, Israel). However, to the best of our knowledge, except for the manufacturer statements presented on the official Glaукos website about safe use of magnetic field of up to 7T, there is no report in the literature about MRI compatibility of the medical grade titanium iStent. Since the stronger MRI machine are not widely available in the clinical practice, studying the influence of 3T MRI scan on the iStent is highly important.

The current study evaluated three aspects of MRI scanning with the iStent: displacement, heating, and artifacts. We believe that the ex vivo model created for this study with surrounding orbital fat, muscles, and bone, accurately resembles a real-life scenario, and the results are thus applicable to human patients in everyday practice. To the best of our knowledge, this model was not previously described in experimental studies of ocular devices in terms of their interaction with the MRI exam.

Magnetic fields during MRI scans create electromotive forces in a conductive material that can cause heating of the implant and the surrounding tissue. Potentially, this forces in a conductive material that can cause heating of the implant and the surrounding tissue. To imitate a real-life situation, we used phantoms with saline, which allowed us to increase the detected mass of the scanned parts using a 3T scanner, and consequently to imitate an actual orbital scan as closely as possible. Dislodgement and shifting of paramagnetic such as titanium implants during MRI scanning has not been described. However, this phenomenon continues to be a concern because of the potential hazardous consequences of implant movement as described by Kelly et al in a patient undergoing an MRI scan with an unsuspected ocular metallic foreign body. Physicians should be aware of possible risks and serious complications that could happen in the case of metallic implant dislocation during a scan. In eyes with titanium iStent implants, we did not observe any dislocation or shifting of the device during the 3T MRI examination. Anatomical landmarks were used in this study to assess the implant position before and after the scan.

Artifacts during MRI scans occur frequently for various reasons. For example, motion and aliasing artifacts, and artifacts caused by chemical shift. Especially common are those seen in fluid-filled structures surrounded by fat, such as the globe in the orbit, foreign body artifacts, etc. Unwanted signals and noise spikes can be caused by a patient interacting with MRI hardware or by the scanner hardware itself. Previous studies showed that, despite their MRI compatibility, titanium prosthesis can still produce significant artifacts, severely influencing the interpretation of the magnetic resonance images (MRI) of the eye. As can be seen in Figure 2, no artifacts appeared in the model of the eye with an implanted iStent during standard orbital MRI scans. Also, it should be noted that the best visualization of an iStent was observed in T2 weighted scans.

As was shown in previous studies with nonferromagnetic, nonocular implants, our study using an ex vivo model confirmed the safety of using MRI in eyes with titanium implants. The iStent did not cause image artifacts that lead to misinterpretation of the scans. Also, no significant heating, displacement or dislocation of the iStent occurred. To the best of our knowledge, except for the manufacturer statements presented on the official Glaükos website, this is the first study to demonstrate MRI compatibility with the iStent.

This study has several limitations such as small sample size, examination of eye after only one iStent implantation, a nonhuman model. Displacement of the iStent did not occur under 3.0T conditions, but behavior of the implant under stronger MRI condition should be also evaluated, since significant amount of movement of the ex-press shunt in the 4.7T environment was described in the literature. Another limitation of the study is that scanning settings were exceeding the manufacturer’s recommendation for 3T MRI and normally are not used in the clinical practice. Assessment of implant motion using anatomical landmarks method did not reveal any macroscopic movement, while microscopic movement could still exist and should be evaluated in the future.

However, we feel that the results of this study, together with the quoted supporting literature support the free use of MRI scans in eyes with implanted iStents. Further research of MRI influence on other MIGS devices (eg, Hydrus microstent) should be considered.

REFERENCES

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