Case report

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MRI after successful eyeWatch™ implantation

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Abstract

The eyeWatch™ is a new glaucoma drainage device that includes an adjustable mechanism that can vary the resistance to aqueous humor outflow during the postoperative period to reduce the burden of postoperative intraocular pressure (IOP) management. The mechanism contains a magnetic rotor that can be adjusted using an external magnetic control unit. Adjustments of the position of the rotor are performed mostly in the initial postoperative follow-up period in order to reach the target IOP. However, for some patients, it might be necessary to perform MRI for the sake of medical investigations. As the MRI is creating a strong magnetic field, this magnetic field is likely to interact with the adjustable rotor of the eyeWatch™, resulting in modification of the IOP. We report the case of an 82-old female patient successfully operated with the implantation of an eyeWatch™. The patient underwent a cerebral MRI for persistent headache. Shortly after the MRI procedure, the patient was checked at the eye clinic to assess the position of the rotor and to measure the IOP. The eyeWatch™ was readjusted to the former position set before undergoing the MRI. No complications were reported in the follow-up after MRI. This case demonstrates that MRI examinations can be safely performed after glaucoma surgery using an eyeWatch™ without compromising on the quality of the imaging or the stability of the IOP. This is a complication-free procedure that only requires checking the new position of the rotor and re-adjusting the implant, if necessary, to achieve the target IOP.

Keywords

Glaucoma, glaucoma surgery, glaucoma drainage device, eyeWatch, MRI, GDD

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Introduction

A novel adjustable glaucoma drainage device eyeWatch™ (eW) (Rheon Medical, Lausanne, Switzerland) was developed and implanted on patients suffering from advanced glaucoma. The eyeWatch™ was designed to better control IOP in the early postoperative phase using an adjustable resistance to control aqueous outflow from the anterior chamber to the end plate.[1,2] The principle of function of this device lies in the use of an adjustable rotor that can be controlled non-invasively using the magnet of an external control unit (eyeWatch Pen). The magnetic field of the control unit is interacting with the magnetic field generated by the magnet embedded within the core of the rotor. By precisely orienting the axis of the magnet from the control unit, it is possible to change the orientation of the rotor. These changes in orientation enable the mechanism to be set in different positions to gradually open or close the lumen of the tube inside the eW. A variable and adjustable opening of the lumen results in an adjustable resistance to the outflow of aqueous humor, that permits a fine tuning of the aqueous outflow, allowing a control of the postoperative IOP.[3]

Magnetic resonance imaging (MRI) is an instrument used for imaging the internal structures of the human body. It is

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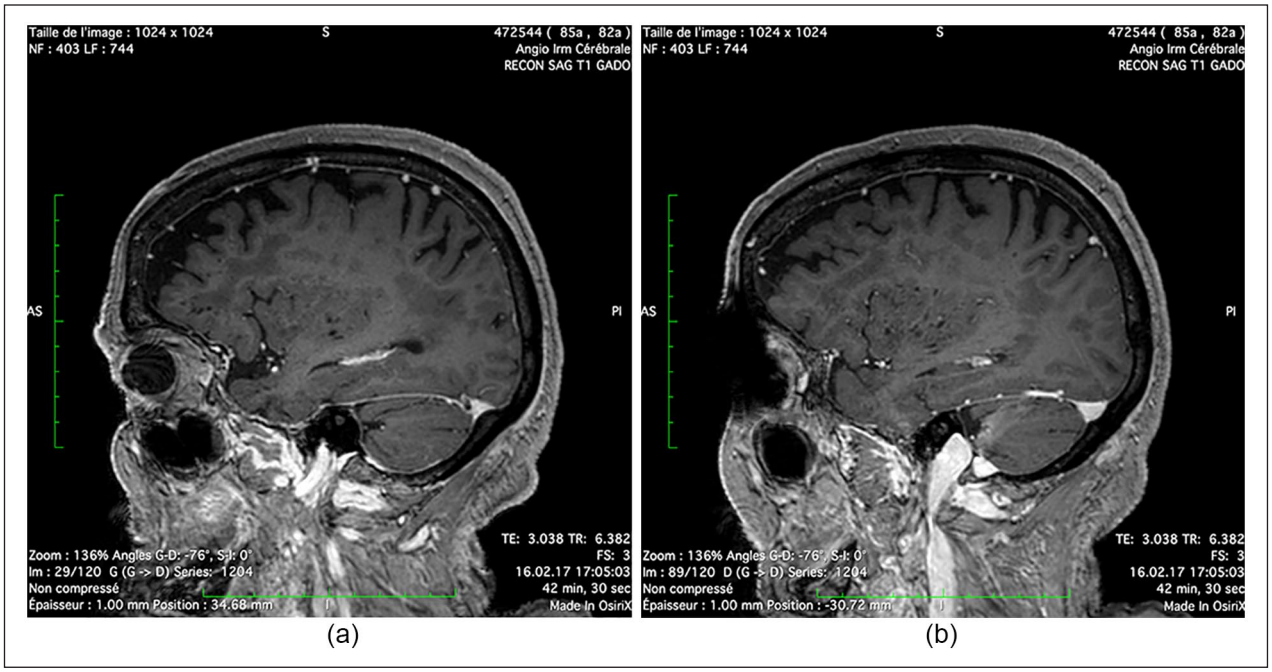

Figure 1. Sagittal reconstruction of T1-weighted gadolinium enhanced sequences of MRI scan centered on the left (a) and right (b) orbit of an 82-year old patient.

being extensively used nowadays as a powerful diagnostic tool for a wide range of pathologies. In that respect, we cannot rule out that some patients might need, to some extent, MRI investigations for pathologies that are not necessarily related to ophthalmology. Due to the intrinsic working mechanism of the eW, that is, the use of a small magnet encased in the core of the rotor, questions might arise about the compatibility of MRI with the implementation of eW devices. There are two sides of the problematic, on the one hand, we have to analyze the role played by the small metallic and magnetic parts embedded in the eW when undergoing MRI sessions with a patient bearing an eW implant. Indeed, the metallic and magnetic parts might significantly interfere with the quality of the images delivered by the MRI machine and alter the results of this imaging. On the other hand, we have to consider the effects of the very strong magnetic field applied during MRI sessions on the structure of the eW. Safety and efficiency issues are to be taken into consideration. What would be the effects of the MRI magnetic field on the stability of the device, that is, will the implant be at risk of being dislocated from too strong pulling forces? As the orientation of the rotor in the eW is controlled by an external magnetic field, what will be the new position of the rotor after completion of the MRI sessions? How far the rotor will have moved from its original position set before the performance of the MRI procedure?

In order to answer these questions, we are reporting the clinical results of a MRI procedure and the post-procedure performed regarding the assessment of the eW function and the IOP shortly after MRI was done.

Case description

An 82-year old Caucasian female patient presented with a pseudoexfoliation glaucoma that was poorly responding to antiglaucoma medication. Under maximally tolerated medication IOP was stabilized at around 20 mmHg, and the Snellen best-corrected visual acuity (BCVA) was 0.4. The patient underwent a non-penetrating deep sclerectomy (NPDS) in 2003 that was no longer efficient to adequately control IOP to prevent further optic nerve damages. In order to achieve a lower IOP the patient underwent a second glaucoma surgery with implantation of an eyeWatch™ in combination with a GDD on September 2016.[1]

Magnetic resonance imaging

The patient was complaining from persistent headache that motivated performing MRI for better diagnosing the causes of the discomfort. A 3 Tesla MRI was performed on February 2017 using a Philips Achieva 3.0 T TX (Philips, Amsterdam, NL). The overall duration of the procedure was 42 min and the acquisition was centered around the head. The images were processed using OsiriX Lite v.11.0.3 (Pixmeo, Bernex, Switzerland). Briefly an T1-weighted, T2-weighted, T1-weighted and T2-weighted enhanced with gadolinium, axial, sagittal and coronal, MRI scan was obtained. Series of images were analyzed using OsiriX Lite for the purpose of clinical diagnosis and image quality assessment.

Images of MRI obtained during this session are presented on Figures 1 and 2. There were no major artifacts detrimental

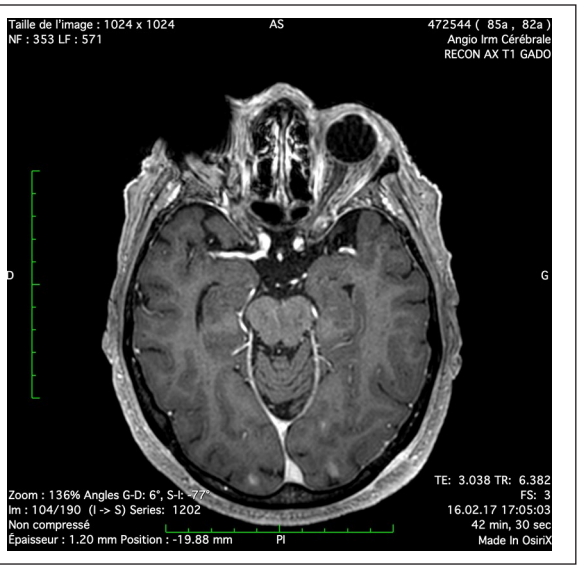

Figure 2. Axial reconstruction of T1-weighted gadolinium enhanced sequences of MRI scan centered on the orbits of an 82-year old patient.

for the proper visualization of the brain structures on the MRI scans and these images were fully usable for the purpose of excluding cerebral pathologies. The sagittal section centered on the left orbit was normal (Figure 1(a)). The sagittal section centered on the right orbit demonstrated specific alterations that prevented representing the intraorbital structures. For instance, the roof of the orbit and the frontal bone were not visible on a distance of 15 to 20 mm around the eW (Figure 1(b)). Similarly, on the axial section, centered at the level of the orbits, the artifact was masking the anterior portion of the right orbit and ocular globe. Portion of the posterior orbit and optic nerve can nevertheless be seen (Figure 2). When it comes to safety, the patient did not complain about discomfort or pain during the completion of the MRI session. There were no changes in the vision reported during or after the MRI procedure.

Management of the eyeWatch™ after MRI

At the end of the MRI procedure the patient was referred the same day to the eye clinic where she was initially operated for assessing the actual position of the rotor of the eW. On last examination before MRI the position was 0 and the pressure was 11 mmHg. After MRI, the new reading of the rotor position was 3, indicating that the eW has moved and was now resting in an intermediate position. Consequently, the IOP has risen up to 15 mmHg. Using the magnet of the eyeWatch Pen, the rotor was then set back to position 0 to allow reaching a lower target IOP. A further measurement of the IOP 20 min after this adjustment indicated that the IOP was now reaching 10 mmHg. After completion of this setting, no further adjustment was deemed necessary.

Conclusion

This case is the first documented publication of a MRI performed after implantation of an eW. Clinical data and images are indicating that there are no specific risks associated with the strong magnetic field used during the acquisition of MRI scans. The implant has not moved or was not dislocated from the eye, for the pulling forces applied on the device were not very strong. As such, the patient was not likely to experiment any pain or discomfort from potential movements of the implant. The MRI images were fully usable for the purpose of visualizing intracranial structures despite the presence of the eW and the cofounding influence of the magnetic parts. Most of the right eye structures were shadowed by artifacts, only the orbital cone and optical nerve were visible (Figures 1(b) and 2).

A few glaucoma devices are made of metal or contain a ferromagnetic component. The Ex-PRESS (Alcon Laboratories, Fort Worth, TX, USA), the iStent (Glaukos, San Clemente, CA, USA) trabecular micro-bypass stent and the Hydrus Microstent (Ivantis Inc, Irvine, CA, USA) are examples of microdrainage devices out of metal currently used in glaucoma surgery.[4,5] All these three devices are claimed to be safe in a 3 Tesla magnetic resonance system. In addition, studies have shown that in presence of an Ex-PRESS filtration device, MRI artefact did not interfere with image interpretation and no complications related to MRI were encountered.[6]

However, the size of the eW is more important than the Ex-PRESS, the iStent or the Hydrus Microstent. Furthermore, the eW not only contains metallic parts, but the rotor itself is a small magnet. As such the influence of the eW on MRI scans is expected to be more important than that of the three implants mentioned before. Indeed, the size of the image artifact for the eW is greater (ca. 30 mm) and extends beyond the 15-mm reported by the manufacturer for the iStent models, for instance. This kind of artifacts prevents from visualizing the ocular globe which contains the eW. Nonetheless the clinical imaging of intracranial and brain structures was not markedly altered by the artifacts centered around the eW.

Performing MRI on an eye operated with an eW likely influences the position of the rotor as a result from the strong magnetic field on the device. As such, the position set before MRI might be modified at the completion of the MRI procedure. This will influence the IOP and could be detrimental for the prevention of further glaucoma damages. Therefore, it is mandatory to reassess the position of the rotor after MRI, measure the IOP, and readjust the position if the latter has changed from the one set before MRI.

To conclude, our data demonstrates that a MRI examination after implantation of an eW device is safe. Interpretation of MRI scans of the brain is globally unaffected by the artifacts caused by the eW, whereas some portions of the orbit

imaging around the implant may not be visible. An ophthalmological check after MRI scan should be performed on every patient bearing an eW. We are unaware of previous reports of this finding in the literature.

Declaration of conflicting interest

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Prof. N. Stergiopulos is the CEO and founder of Rheon Medical. Dr. A. Villamarin is employed by Rheon Medical. Prof. A. Mermoud and Dr. S. Roy have no conflicts of interests to disclose.

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References

1. Roy S, Villamarin A, Stergiopulos C, et al. Initial clinical results of the eyeWatch: a new adjustable glaucoma drainage device used in refractory glaucoma surgery. *J Glaucoma* 2019; 28(5): 452–458.
2. Roy S, Villamarin A, Stergiopulos C, et al. Comparison between the eyeWatch device and the ahmed valve in refractory glaucoma. *J Glaucoma* 2020; 29(5): 401–405.
3. Villamarin A, Roy S, Bigler S, et al. A new adjustable glaucoma drainage device. *Invest Ophthalmol Vis Sci* 2014; 55(3): 1848–1852.
4. Dahan E and Carmichael TR. Implantation of a miniature glaucoma device under a scleral flap. *J Glaucoma* 2005; 14(2): 98–102.
5. Camras LJ, Yuan F, Fan S, et al. A novel Schlemm's Canal scaffold increases outflow facility in a human anterior segment perfusion model. *Invest Ophthalmol Vis Sci* 2012; 53(10): 6115–6121.
6. Mabray MC, Uzelac A, Talbott JF, et al. Ex-PRESS glaucoma filter: an MRI compatible metallic orbital foreign body imaged at 1.5 and 3T. *Clin Radiol* 2015; 70(5): e28–e34.