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Assessment of MRI issues for the Argus II Retinal Prosthesis☆

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Abstract

Objective: The objective was to evaluate magnetic resonance imaging (MRI) issues (magnetic field interactions, heating, artifacts and functional alterations) at 1.5 T and 3 T for the Argus II Retinal Prosthesis (Second Sight Medical Products, Sylmar, CA, USA).
Materials and Methods: Standardized protocols were used to assess magnetic field interactions (translational attraction and torque; 3 T, worst case), MRI-related heating (1.5 and 3 T), artifacts (3 T; worst case) and functional changes (1.5 and 3 T) associated with MRI.
Results: The magnetic field interactions were acceptable. MRI-related heating, which was studied at a relatively high, MR system-reported whole body averaged specific absorption rates, will not pose a hazard to the patient under the conditions used for testing. While artifacts were "moderate" in relation to the dimensions of the Argus II Retinal Prosthesis, optimization of MRI parameters can reduce the size of the artifacts. Exposures to MRI conditions at 1.5 and 3 T did not damage or alter the functional aspects of the Argus II Retinal Prosthesis.
Conclusions: In consideration of the test results, a patient with the Argus II Retinal Prosthesis may undergo MRI at 1.5 T or 3 T when specific guidelines and MRI conditions are followed, including those advised by the manufacturer.

Keywords: Retinal prosthesis; Magnetic resonance imaging; Safety; MRI, implants; MRI, artifacts

1. Introduction

Retinal prostheses have demonstrated the ability to restore partial vision in blind individuals through electrical stimulation of the retina [1–6]. Several clinical trials have established the ability to detect light vs. dark, and more recent studies have shown improved mobility and letter reading [4–6]. This represents a significant advancement in the treatment of vision loss.

Currently, most electronically activated implants used to treat neurological and other disorders are unacceptable or contraindicated for patients referred for magnetic resonance imaging (MRI) procedures, unless comprehensive evaluations are conducted to identify specific conditions that ensure patient safety [7–17]. This is due to concerns related to MRI-based issues that may pose risks or other problems to patients with these implants including magnetic field interactions, MRI-related heating, disturbances in the functional aspects of the devices and imaging artifacts that can impact the diagnostic use of MRI [7–17].

A new retinal prosthesis, called the Argus II Retinal Prosthesis System (Second Sight Medical Products, Sylmar, CA, USA), was developed to provide electrical stimulation of the retina to induce visual perception in blind individuals. This implant has a surgically implanted intraocular electrode array placed on the ganglion side of the retina (i.e., epiretinal) that is connected to an extraocular electronic stimulator with a receiver radiofrequency (RF) coil. These intraocular components are wirelessly connected to external equipment that includes glasses with a camera and transmitter RF coil, and a belt-worn video processing unit (VPU) with battery which is connected to the glasses through a cable [3–6].

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After receiving a retinal implant, it is likely that an individual may need to undergo an MRI procedure for purposes of diagnostic evaluation with this important imaging modality. Therefore, to ensure the safe use of this device in a patient referred for an MRI examination, this investigation evaluated the factors that may impact this implant in 1.5-T and 3-T MRI environments (i.e., worst case for a clinical MR system), including magnetic field interactions (translational attraction and torque), MRI-related heating, artifacts and functional changes associated with different MRI conditions. The primary goal was to identify specific guidelines and conditions that would permit the safe use of MRI in patients with the Argus II Retinal Prosthesis System. Of note is that the glasses with the camera and transmitter RF coil, and the belt-worn VPU with battery are not intended to be present during an MRI procedure.

2. Materials and methods

2.1. Argus II Retinal Prosthesis

The Argus II Retinal Prosthesis (Second Sight Medical Products, Sylmar, CA, USA) underwent evaluation in 1.5-T and 3-T MRI environments. This implant is designed to provide visual function to individuals with severe to profound vision loss due to outer retinal degeneration. It consists of implanted and external components. The Argus II Retinal Prosthesis is an epiretinal prosthesis that includes a receiving coil, electronics case and an electrode array that are surgically implanted in and around the eye (Fig. 1). The array is attached to the retina over the macula with a retinal tack. The external equipment includes glasses, a VPU with rechargeable battery and a cable connecting the VPU to the glasses. The glasses include a miniature video camera, which captures video images, and a coil that sends data and stimulation commands to the implant. The VPU converts the video images into stimulation commands and is body-worn. The Argus II System operates by converting video images into electrical energy that activates retinal cells, delivering the signal through the optic nerve to the brain where it is perceived as light. Notably, the external components of the Argus II Retinal Prosthesis (glasses and VPU) were not evaluated for MRI issues and, thus, are not allowed in the MRI environment and not intended to be in place during an MRI examination.

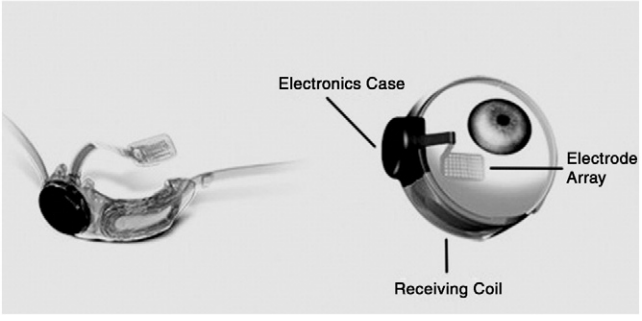

Fig. 1. The Argus II Retinal Prosthesis that underwent MRI testing. Note the electronics case, electrode array and receiving coil.

The dimensions of the implanted portion of the Argus II Retinal Prosthesis that underwent MRI evaluation are as follows: electronics case: height, 3.2 mm; diameter, 10.29 mm; receiving coil: height, 16.33 mm; width, 9.7 mm; wire diameter, 0.127 mm (coil wire diameter is 0.005”=0.127 mm); electrode array cable: length, 53.1 mm; width at cable area, 1.9 mm.

2.2. Magnetic field interactions

The Argus II Retinal Prosthesis was evaluated for translational attraction and torque using previously described, standardized test procedures in association with a 3-T MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI, USA; active-shielded, horizontal field scanner) [16,17]. The static magnetic field strength of 3 T was selected for this assessment because it represents the highest available magnetic field currently in widespread clinical use. Notably, the findings for magnetic field interactions testing apply to MR systems operating at 3 T or less [15].

2.2.1. Translational attraction

For the assessment of translational attraction, a test was conducted known as the “deflection angle test” [16,17]. The Argus II Retinal Prosthesis was attached to a special test fixture to measure the deflection angle in the MR system. The test fixture consisted of a sturdy structure capable of holding the device in position without movement and contained a protractor with 1°-graduated markings, rigidly mounted to the structure. The 0° indicator on the protractor was oriented vertically. The Argus II Retinal Prosthesis was suspended from a thin, lightweight string (weight, less than 1% of the device) that was attached at the 0° indicator position on the protractor. The test apparatus was positioned in the 3-T MR system at the point of the highest spatial gradient magnetic field. For the 3-T scanner used in this investigation, the highest spatial gradient magnetic field is 720 gauss/cm [16–19]. Sources of forced air movement within the MR system bore were turned off during the measurements. The maximum deflection angle from the vertical direction to the nearest 1° was measured three times, and an average value was calculated [16,17,19].

2.2.2. Qualitative assessment of torque

The next evaluation of magnetic field interactions was conducted to qualitatively determine the presence of magnetic field-induced torque for the Argus II Retinal Prosthesis using a previously described qualitative assessment technique [16,17]. This involved the use of a flat plastic device with a millimeter grid. The Argus II Retinal Prosthesis was placed on the test apparatus in an orientation that was 45° relative to the static magnetic field of the 3-T

MR system [16,17]. The test apparatus was then positioned in the center of the scanner, where the effect of torque is the greatest, and the implant was observed for possible alignment or rotation relative to the 3-T static magnetic field. The Argus II Retinal Prosthesis was then moved 45° relative to its previous position and observed for alignment or rotation. This process was repeated to encompass a full 360° rotation of positions for this implant.

The following qualitative scale was applied to the results [16,17]: 0, no torque; +1, mild or low torque, the device slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the device aligned gradually to the magnetic field; +3, strong torque, the device showed rapid and forceful alignment to the magnetic field; +4, very strong torque, the device showed very rapid and very forceful alignment to the magnetic field.

2.3. MRI-related heating

An assessment of MRI- related heating was performed at 1.5 T/64 MHz and 3 T/128 MHz on the Argus II Retinal Prosthesis since these static magnetic field strengths and frequencies are commonly used in the clinical setting.

2.3.1. Phantom and experimental setup

MRI-related heating was assessed for the Argus II Retinal Prosthesis using a plastic, head/torso phantom filled to a depth of 10 cm with semisolid, gelled saline (i.e., 0.8 g/L NaCl plus 5.85 g/L polyacrylic acid in distilled water) that was prepared to simulate human tissue, according to previously describe protocols [7–10,12,13,16,17]. A plastic frame was placed on the bottom of the phantom along with a small plastic post to maintain the position of the Argus II Retinal Prosthesis in order to simulate an anatomical scenario with regard to MRI-related heating (i.e., placed on the edge of the head/torso phantom, in the “head” portion of the phantom). Because this phantom and experimental setup lacks “blood flow” or perfusion, it simulates an extreme condition used to assess MRI-related heating for an implant or device.

2.3.2. Temperature recording system and placement of thermometry probes

Temperature measurements were obtained using a fluoroptic thermometry system (Model 3100, LumaSense Technologies, Santa Clara, CA, USA). The fluoroptic thermometry probes (0.5 mm in diameter) were positioned on the Argus II Retinal Prosthesis to record representative temperatures, as follows: probe #1, receiver coil, bottom; probe #2, electrode array; probe #3, electronics case; probe #4, receiver coil, body. The thermometry probes were visually inspected immediately before and immediately after each MRI heating experiment to ensure that they were properly positioned, as stated above.

2.3.3. MRI conditions: 1.5 T/64 MHz

MRI was performed at 1.5 T (1.5 T/64 MHz, Symphony, Siemens Medical Solutions, Erlangen, Germany) using the transmit RF body coil. MRI parameters were selected to generate a relatively high level of RF energy, producing an MR system-reported whole body averaged specific absorption rate (SAR) of 3.5 W/kg for 15 min of scanning. The land-marking position (i.e., the center position or anatomic region for the MR imaging procedure) and section locations were selected to encompass the entire area of the Argus II Retinal Prosthesis.

2.3.4. MRI conditions: 3 T/128 MHz

MRI was performed at 3 T (3 T/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI, USA) using the transmit RF body coil. MRI parameters were selected to generate a relatively high level of RF energy, producing an MR system-reported whole body averaged SAR of 3.5 W/kg for 15 min of scanning. The land-marking position (i.e., the center position or anatomic region for the MR imaging procedure) and section locations were selected to encompass the entire area of the Argus II Retinal Prosthesis.

2.3.5. Experimental protocol

The Argus II Retinal Prosthesis was positioned in the plastic head/torso phantom, as previously described. The fluoroptic thermometry system was calibrated, and the fluoroptic thermometry probes were applied to the implant. The head/torso phantom was filled with the gelled saline and allowed to equilibrate to the environmental temperature for more than 24 h in each MRI environment (i.e., 1.5 and 3 T). The MR system fan was not on during the MRI-related heating assessment in each case. The room and MR system bore temperatures were at constant levels throughout the experimental sessions. After recording baseline temperatures (5 min), MRI was performed for 15 min with temperatures recorded at 10-s intervals. The MRI-related heating tests were performed on separate days at 1.5 T and 3 T. The highest temperature changes recorded by the fluoroptic thermometry probes are reported for the Argus II Retinal Prosthesis for each MRI condition.

2.4. Artifacts

MRI artifacts were evaluated at 3 T for the Argus II Retinal Prosthesis by obtaining MR images with implant attached to a plastic frame and then placing it in a gadolinium-doped, saline-filled plastic phantom [9,13,16,17]. MRI was performed using a 3-T MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI, USA), a transmit/receive RF head coil and the following parameters:

1. T1-weighted, spin echo pulse sequence; repetition time, 500 ms; echo time, 20 ms; matrix size, 256×256; section thickness, 10 mm; field of view, 24 cm; number of excitations, 2; bandwidth; 16 kHz.
2. Gradient echo (GRE) pulse sequence; repetition time, 100 ms; echo time, 15 ms; flip angle, 30°; matrix size,

256×256; section thickness, 10 mm; field of view, 24 cm; number of excitations, 2; bandwidth, 16 kHz.

The imaging planes were oriented to encompass the long axis and short axis of the Argus II Retinal Prosthesis. The frequency encoding direction was parallel to the plane of imaging in each case (i.e., long-axis vs. short-axis orientation of the implant). The image locations obtained through the Argus II Retinal Prosthesis represented the largest or worst-case artifacts (i.e., based on reviewing multiple section locations in each imaging plane for this device), and these images were selected for evaluation [9,13,16,17]. Planimetry software was used to measure (accuracy and resolution ±10%) the cross-sectional area of the largest artifact size for each pulse sequence and for each orientation of the section location [9,13,16,17]. The image display parameters (i.e., window and level settings, magnification, etc.) were carefully selected and used in a consistent manner to provide valid measurements of sizes for the artifacts [9,13,16,17]. This methodology has been used in many previous reports involving the characterization of artifacts for metallic implants [9,13,16,17]. Furthermore, the static magnetic field strength of 3 T was selected for this assessment because it represents the highest available magnetic field currently in widespread clinical use. The findings for artifact testing apply to MR systems operating at 3 T or less [15].

2.5. Evaluation of the effects of MRI at 1.5 T/3 T on function

To determine if the Argus II Retinal Prosthesis sustains damage or a change in function, experiments were performed to assess the effects of 1.5-T/64-MHz and 3-T/128-MHz MRI conditions on these implants, as previously described [9,13]. The different MRI conditions and orientations for the samples were used to cover a range of possible scenarios with regard to having a patient with this implant inside of a 1.5-T or 3-T MR system. Eight different MRI conditions at 1.5 T and 3 T were selected to be representative of typical techniques used for clinical MRI examinations [9,13].

Nine different samples of the Argus II Retinal Prosthesis were used for each MRI exposure protocol. Prior to the exposures and after the exposures, each Argus II Retinal Prosthesis underwent characterization of the functional and operational aspects of the implant. Thus, electrical tests were performed on these implants that were developed to carefully characterize the functionality and critical specifications of the Argus II Retinal Prosthesis. This means that the overall electrical "pass or fail" decision on the Argus II Retinal Prosthesis was determined by this test protocol relative to the MRI exposures. The nine different samples of the Argus II Retinal Prosthesis were attached to a fluid-filled, cylinder-shaped phantom using porous paper tape in different positions (three different locations and three different orientations) as shown in Table 1. The cylinder-shaped phantom with the samples was then placed in a large plastic box-shaped phantom (40-cm length, 30-cm width, 22-cm height) filled with approximately 5 L of water (i.e., to entirely cover the Argus II Retinal Prostheses). The water provided a conductive medium to surround the implants undergoing the MRI exposures and to "load" the transmit/receive RF body coil of the respective MR system [13].

Table 1
Orientations used for the samples exposed to MRI conditions at 1.5 T and 3 T (nine different samples of the Argus II Retinal Prosthesis were used for each static magnetic field strength and frequency)

Sample	Orientation
#1	Sagittal, parallel
#2	Sagittal, 45°
#3	Sagittal, perpendicular
#4	Coronal, parallel
#5	Coronal, 45°
#6	Coronal, perpendicular
#7	Axial, parallel
#8	Axial, 45°
#9	Axial, perpendicular

2.6. MRI protocols

MRI was conducted on the cylinder-shaped phantom with the nine different Argus II Retinal Prostheses after it was placed inside of the water-filled box-shaped phantom using a transmit/receive RF body coil and 1.5-T/64-MHz (Magnetom, Software Numaris/4, Version Syngo MR 2002B DHHS Siemens Medical Solutions, Malvern, PA, USA) and 3-T/128-MHz (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI, USA) MR systems. The Argus II Retinal Prostheses were exposed to eight different pulse sequences (Table 2) for approximately 1 min per pulse sequence. The land-marking position (i.e., the center position or anatomic region for the MR imaging procedure) and section locations were selected to encompass all Argus II Retinal Prostheses to ensure thorough and complete exposure to the selected MRI conditions at 1.5 T/64 MHz and 3 T/128 MHz.

3. Results

3.1. Magnetic field interactions

The results for the assessment of magnetic field interactions at 3 T for the Argus II Retinal Prosthesis indicated that the mean deflection angle was 12° and the torque was 0 (no torque).

3.2. MRI-related heating

At 1.5 T/64 MHz, the highest temperature change was +0.6°C in association with MRI performed for 15 min at an MR system-reported whole body averaged SAR of 3.5 W/kg. At 3 T/128 MHz, the highest temperature change was +2.1°C in association with MRI performed for 15 min at an MR system-reported whole body averaged SAR of 2.9 W/kg.

Table 2
Parameters used to expose the Argus II Retinal Prosthesis to 1.5-T/64-MHz and 3-T/128-MHz MRI conditions

	#1	#2	#3	#4	#5	#6	#7	#8
1.5-T MRI conditions								
Pulse Sequence	T1-SE	T2-SE	T1-FSE	T2-FSE	GRE, 3D	FGRE, 3D	GRE, MTC	EPI
TR (ms)	700	3000	700	5000	20	3.7	628	3400
TE (ms)	10	100	12	113	3	1.1	10	103
Flip angle	N/A	N/A	N/A	N/A	25	8	5	N/A
Field of view	30 cm	30 cm	30 cm	30 cm	30 cm	30 cm	30 cm	30 cm
Section thickness	10 mm	10 mm	10 mm	10 mm	3 mm	3 mm	10 mm	1 mm
Imaging plane	Axial	Axial	Axial	Axial	Volume	Volume	Axial	Axial
3-T MRI conditions								
Pulse sequence	T1-SE	T2-SE	T1-FSE	T2-FSE	GRE, 3D	FGRE, 3D	GRE, MTC	EPI
TR (ms)	700	3000	700	5000	20	3.7	628	3400
TE (ms)	10	100	12	113	2.7	1.2	10	103
Flip angle	N/A	N/A	N/A	N/A	25	8	5	N/A
Field of view	30 cm	30 cm	30 cm	30 cm	30 cm	30 cm	30 cm	30 cm
Section thickness	10 mm	10 mm	10 mm	10 mm	3 mm	3 mm	10 mm	1 mm
Imaging plane	Axial	Axial	Axial	Axial	Volume	Volume	Axial	Axial

T1-SE, T1-weighted spin echo; T2-SE, T2-weighted spin echo; T1-FSE, T1-weighted fast spin echo; T2-FSE, T2-weighted fast spin echo; 3D, three-dimensional; FGRE, fast gradient echo; MTC, magnetization transfer contrast; EPI, echo planar imaging; N/A, not applicable; SE, spin echo; TR, repetition time; TE, echo time.

3.3. Artifacts

Artifact test results are summarized in Table 3. For the Argus II Retinal Prosthesis, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were "moderate" (based on a qualitative scale of small, moderate and large) in size in relation to the size and shape of this implant. The GRE pulse sequence produced larger artifacts than the T1-weighted, spin echo pulse sequence. Fig. 2 shows examples of artifacts for the gradient pulse sequence in long-axis and short-axis orientations relative to the Argus II Retinal Prosthesis.

3.4. Effects of MRI conditions on function

After exposure to MRI conditions at 1.5-T/64-MHz and 3-T/128-MHz MR exposures, each Argus II Retinal Prosthesis was able to "power up." There were no significant changes in the power characteristics of these implants. Notably, the nominal power level characterization remained the same for each Argus II Retinal Prosthesis. The second finding is that all tests for these implants with "pass/fail" criteria that will cause a complete device failure *passed* in the baseline testing session and also *passed* after the MRI exposures. Thus, based on the electrical testing data, there was no damage or alteration in the functional aspect of the Argus II Retinal Prostheses associated with exposures to the 1.5-T/64-MHz and 3-T/128-MHz MRI conditions.

Table 3
Summary of MRI artifacts at 3 T for the Argus II Retinal Prosthesis

Pulse sequence	T1-SE	T1-SE	GRE	GRE
Signal void size	979 mm^2	959 mm^2	2242 mm^2	3381 mm^2
Imaging plane	Long axis	Short axis	Long axis	Short axis

4. Discussion

4.1. Magnetic field interactions

For the assessment of translational attraction, the average deflection angle was 12° at 3 T for the Argus II Retinal Prosthesis. This information should be considered according to the information provided by the American Society for Testing and Materials International [19], as follows: "If the implant deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field." Therefore, this implant passed the aforementioned acceptance criterion with respect to a 3-T MR system. The qualitatively measured torque was 0 (no torque). Thus, the Argus II Retinal Prosthesis will not create a hazard to a patient in a 3-T MRI environment with respect to rotational alignment to the static magnetic field.

In view of the findings for magnetic field interactions for this implant, there are no safety issues for patients undergoing MRI examinations on MR systems operating at 3 T *or less*. Furthermore, a patient with the Argus II Retinal Prosthesis would be allowed to undergo an MRI procedure immediately following implantation because of the relatively minor magnetic field interactions that are present.

4.2. MRI-related heating

The highest temperature changes recorded for the Argus II Retinal Prosthesis during MRI procedures performed at relatively high 1.5-T and 3-T MR system-reported whole body averaged SAR values (3.5 W/kg and

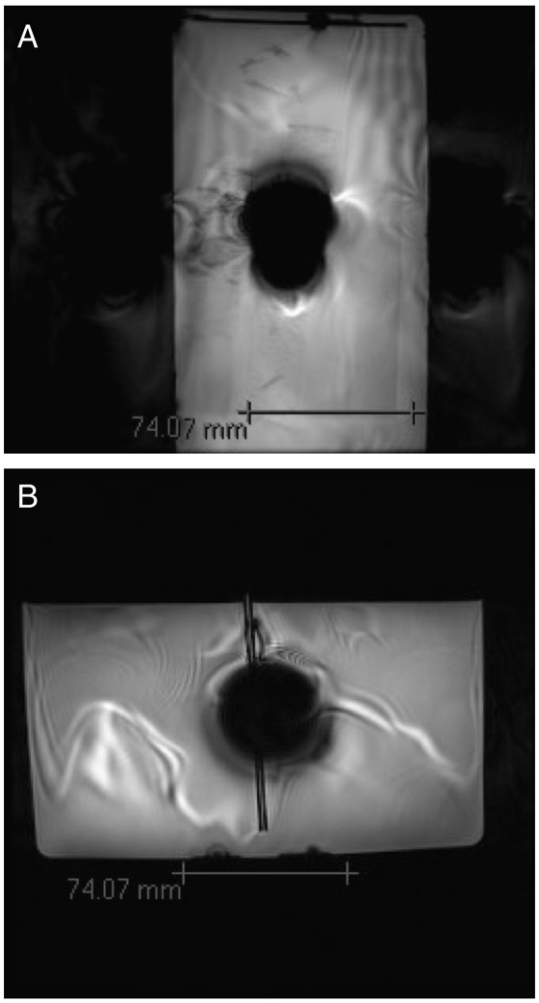

Fig. 2. MR images showing artifacts at 3 T for the Argus II Retinal Prosthesis (GRE pulse sequence). (A) Section location oriented to the long axis of the implant. (B) Section location oriented to the short axis of the implant.

2.9 W/kg, respectively) were 0.6°C (at 1.5 T) and 2.1°C (at 3 T). These temperature elevations will not pose a hazard to a patient with this implant under the MRI conditions used for the evaluation of heating. Of further note is that, during the heating assessment, a "static" medium (i.e., no perfusion) was used, such that a certain acceptable margin of safety may be presumed with regard to possible MRI-related heating issues for the Argus II Retinal Prosthesis.

Substantial implant heating may be generated during MRI, but this only occurs with implants made from conducting materials of certain lengths and/or in shapes of closed loops with relatively large diameters [7,11,14,15]. Notably, for the Argus II Retinal Prosthesis, all metallic and electrically conducting components are relatively small and short in length (Fig. 1). Therefore, the findings (i.e., no excessive temperature rises) for MRI-related heating for this implant under MRI conditions used at 1.5 T/64 MHz and 3 T/128 MHz were not unexpected.

4.3. Artifacts

Artifacts associated with the Argus II Retinal Prosthesis were "moderate" in relation to the size and shape of this implant. The extent of the artifact seen on MR images depends on the specific implant, the magnetic susceptibility of the materials used to make the implant and the imaging parameters that are applied [14,15]. If the anatomic area of interest is close to the Argus II Retinal Prosthesis, the diagnostic use of MRI could be impaired or compromised. However, it is possible to utilize MRI parameters that minimize the size of the artifact, as long as this is performed carefully to achieve adequate signal-to-noise and contrast-to-noise ratio during the diagnostic imaging procedure. To reduce artifacts associated with the Argus II Retinal Prosthesis, as well as other implants that contain metal, the following may be considered: use a fast spin echo pulse sequence, increase the readout bandwidth and decrease the voxel size.

4.4. Effects of MRI on function

A malfunctioning or damaged Argus II Retinal Prosthesis related to exposure to the harsh electromagnetic fields used for MRI procedures can seriously impact the patient. Therefore, it is vital to identify possible functional disturbances for the Argus II Retinal Prosthesis in association with various MRI conditions. Fortunately, the findings of the tests designed to assess the effects of exposures to various 1.5-T/64-MHz and 3-T/128-MHz MRI conditions revealed that there was no damage or adverse effect on the implant's functionality. However, as an appropriate precaution, it is strongly recommended that the Argus II Retinal Prosthesis be tested by a qualified clinician or trained personnel from the manufacturer as soon as possible following the MRI examination to confirm that it is still functioning properly. Notably, this is a standard precautionary measure for electronically active implants relative to the use of MRI [14,15]. Importantly, it should be noted that the results of the functional assessment for this implant are specific to the methods and test conditions that were used.

4.5. Possible limitations

Testing conducted on the Argus II Retinal Prosthesis involved 1.5-T/64-MHz and 3-T/128-MHz MR systems *only*. Therefore, it is unknown if possible adverse interactions can occur related to scanners operating above or below these particular static magnetic field strengths and frequencies. Furthermore, the safety of performing an MRI examination in a patient with the Argus II Retinal Prosthesis with another additional metallic or other electronically activated device (e.g., cochlear implant, deep brain stimulation system, vagus nerve stimulation system) implanted in the head is also unknown, and therefore, those scenarios are considered contraindications for MRI procedures.

4.6. Conclusions and recommendations

In general, for each electronically activated neurostimulation system that has MRI labeling approved by a governmental agency, there are highly specific guidelines, procedures and conditions that must be followed to ensure patient safety relative to the use of MRI technology [14,15]. Based on the MRI test findings for the Argus II Retinal Prosthesis related to 1.5-T and 3-T MRI conditions, under the protocols used for this evaluation, there were no substantial concerns for this implant. Accordingly, using the most current MRI terminology for labeling, the following guidelines are recommended [20]:

Nonclinical testing demonstrated that the Argus II Retinal Prosthesis meets the *MR Conditional* classification. A patient with Argus II Retinal Prosthesis can be scanned safely anytime after implantation under the following specific conditions:

4.6.1. Static magnetic field

Static magnetic field of 1.5 T or 3 T *only*.

Highest spatial gradient magnetic field of 720 gauss/cm or less.

4.6.2. MRI-related heating, 1.5 T

In nonclinical testing, the Argus II Retinal Prosthesis produced the following temperature rise during MRI performed for 15 min of scanning (i.e., per pulse sequence) in the 1.5-T (1.5 T/64 MHz, Symphony, Siemens Medical Solutions, Erlangen, Germany) MR system: highest temperature change, +0.6°C. Therefore, the MRI-related heating for the Argus II Retinal Prosthesis at 1.5 T using a transmit/receive RF body coil at an MR system-reported whole body averaged SAR of 3.5 W/kg indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +0.6°C.

4.6.3. MRI-related heating, 3 T

In nonclinical testing, the Argus II Retinal Prosthesis produced the following temperature rise during MRI performed for 15 min of scanning (i.e., per pulse sequence) in a 3-T (3 T/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI, USA) MR system: highest temperature change, +2.1°C. Therefore, the MRI-related heating for the Argus II Implant at 3 T using a transmit/receive RF body coil at an MR system-reported whole body averaged SAR of 2.9 W/kg indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +2.1°C.

4.6.4. MRI artifacts

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Argus II Retinal Prosthesis. Therefore, optimization of MR imaging parameters to compensate for the presence of the implant may be necessary.

4.6.5. Device functionality

The results of nonclinical tests indicated that the exposure of the Argus II Retinal Prosthesis to various conditions using 1.5-T/64-MHz and 3.0-T/128-MHz systems will not damage the device or have adverse effects on the device's functionality. However, it is strongly recommended that the Argus II Retinal Prosthesis be tested by a qualified clinician or trained personnel from the manufacturer as soon as possible following the MRI examination MRI to confirm that it is still functioning properly.

Important note: Do not take the external equipment (VPU and glasses) of the Argus II System into the MR system room. The external equipment was not tested in the MRI environment and is not permitted to be worn by the patient or other individual in the MR system room. Severe harm to individuals in the MR system room or damage to this equipment may result.

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