

A Catalog of Magnetic Resonance Imaging Compatibility of Penile Prostheses

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ABSTRACT

Introduction. Erectile dysfunction has been successfully treated with penile prosthesis implantation for over 50 years. Ferromagnetic implants or devices may create a potentially hazardous or painful situation during magnetic resonance imaging (MRI). A modern catalog of the MRI compatibility of penile prostheses is not available.

Aim. Evaluate the safety profile of implanted, penile prostheses during MRI.

Main Outcome Measure. Review available in vitro safety data and reported patient complications experienced during MRI with a penile prosthesis in place.

Methods. A search of PubMed™ for articles documenting a penile prosthesis present during MRI was performed. Radiology texts and product information from manufacturers producing a penile prosthesis were reviewed. Direct discussion with product manufacturers was also performed to obtain additional safety and compatibility information.

Results. Nine clinical articles noted the presence of a penile prosthesis at the time of magnetic resonance imaging. No articles documented a complication from MRI of a man with a penile prosthesis. A single patient with an unnamed malleable prosthesis was noted to have twisting of the device during MRI which did not result in discomfort or malfunction of the device. In vitro studies support the safety of most prostheses during MRI.

Conclusion. The available data suggests there is little risk for most patients with a penile prosthesis who undergo MRI. Notable exceptions include Dacomed's Omniphase and Duraphase device and the MRI-conditional Spectra device manufactured by AMS. Current manufacturers of penile implants provide wallet cards and medical letters to support safety when undergoing an MRI. Prior prosthesis implantation should not preclude patients from having an MRI. **Lowe G, Smith RP, and Costabile RA. A catalog of magnetic resonance imaging compatibility of penile prostheses. J Sex Med 2012;9:1482–1487.**

Key Words. Erectile Dysfunction; Penile Prosthesis; Magnetic Resonance Imaging; Safety; Penile Implant

Introduction

Erectile dysfunction has been successfully treated with penile prosthesis implantation for over 50 years [1]. In 1980, the Jonas prosthesis utilized embedded silver wires in a silicone sheath to improve malleability of the penis [2]. More recently, both American Medical Systems (AMS, Minneapolis, MN, USA) and Coloplast (Minneapolis, MN, USA) have manufactured a malleable penile prosthesis with either a stainless steel or silver wire core including the Spectra™ articulated prosthesis. Currently, implantation of inflat-

able penile prostheses (IPP) are 10 times more commonly performed [3] than malleable implants. Inflatable penile prostheses have also undergone many improvements since their introduction in 1973. These refinements have created a prosthesis which is now less likely to become infected or sustain mechanical failure.

Magnetic resonance imaging (MRI) technology is commonly used in medical practice. MRI induces a magnetic field and a radiofrequency field during image acquisition. The static magnetic field is generally regarded as safe for short periods of time, with the few documented injuries related to

the inadvertent presence of ferromagnetic materials [4]. Gradient magnetic fields are created during MRI and can create nerve or muscle activity that the patient may experience as pain. Radiofrequency fields are often transformed into heat within the patient's tissue. Physical, physiologic, and environmental factors determine the effects of this temperature change. The effect of each field type is dependent on the specific study protocol utilized and the signal characteristics of the particular magnet.

MRI uses radiofrequency radiation under controlled magnetic fields in order to produce images. The proportional relationship between resonant frequency and magnetic strength allow images to be obtained. For image acquisition, nuclei with an odd number of protons or neutrons are placed in a uniform magnetic field causing the protons to align. The net magnetization can be increased with a stronger magnetic field and provide a higher signal. The higher magnetic resonance signal leads to improved imaging by increasing the signal-to-noise ratio. MRI is now utilized in all regions of the body. Most installed systems are 1.5 to 3 Tesla; however, experimental systems exceed 10 Tesla [5]. MRI requires specific safety considerations based on the magnetic field. Ferromagnetic objects near the magnet experience a force of attraction. This is variable based on magnetic field strength, proximity, object mass, and its composition. Fatalities have resulted from ferromagnetic objects in this strong magnetic field as these objects can reach speeds up to 67 meters per second. MRI magnets are strong enough to pull a large floor polisher into the system [6]. Unfortunately, the lack of specific safety information regarding the compatibility of a specific implant may lead a patient to forego an important MRI due to these safety concerns.

One of the critical aspects of an MRI safety program entails effective and thorough patient screening. This is generally performed by a health-care professional through a checklist of questions, including a section containing implants, devices, and objects that may place a patient at risk or impair imaging (Supporting Information Appendix S1). Ferromagnetic implants may create a potentially hazardous or uncomfortable situation through heating, torque, and translational attraction. Therefore it is important to understand the nature of a particular implant or device as well as the specific associated risks in a strong magnetic field.

We have fielded many requests from radiologists regarding the MRI compatibility of a particu-

lar penile prosthesis immediately prior to a planned procedure. The radiologists have requested we provide assurance that the patient would not be at risk given his prior implant. While this request has been principally for patient safety, there is a significant concern regarding possible medico-legal implications of MRI with implants in place. It is important to review the current knowledge regarding MRI safety of penile prostheses and develop a modern catalog of implants and MRI compatibility to assist imaging providers as well as urologists who treat these men. The MRI compatibility of various penile prostheses is not routinely made available to patients who are infrequently counseled regarding this potential risk.

Methods

A search of PubMed™ was performed to reveal articles documenting the use of MRI in patients with a penile prosthesis. Each of the references and related articles for these manuscripts were explored for further unique data on MRI compatibility of a penile prosthesis. Results pertaining to in vivo and in vitro data were collected. Reference manuals for MRI safe devices and implants were searched for information regarding penile prostheses. In addition, contact was made with AMS and Coloplast to determine the current MRI compatibility of available products as well as previously manufactured and implanted devices that remain. The results were then compiled to create an up-to-date review regarding MRI compatibility of penile prostheses.

Results

The PubMed search revealed 16 articles with keywords "penile prosthesis" and "magnetic resonance imaging". A review of each of these articles revealed only nine clinical articles noting the presence of a penile prosthesis at the time of MRI (Table 1). No reports of an MRI associated complication secondary to the properties of a penile prosthesis were able to be identified. One patient was noted to have twisting of the penile prosthesis but experienced no pain or discomfort [13].

Moncada et al. [11] documented the largest group of patients (N = 65) to undergo penile MRI with a penile prosthesis in place. This study utilized a 1.5 Tesla magnet and reviewed several different penile prostheses. Fourteen of these patients were studied for sustained penile pain after placement of the prosthesis and the remain-

Table 1 MRI compatibility reports in the literature

Study author	Prosthesis	MRI signal strength	# patients	Reason for MRI	Adverse Events
Agrawal et al. [7]	Inflatable	NR	1	Ejaculatory pain	None
Brook et al. [8]	NR	NR	1	Pelvic mass on ultrasound	None
Derouet et al. [9]	AMS 700 CX AMS 700 Ultrex	NR	2	Prosthesis infection	None
Hricak et al. [10]	Malleable (6) Inflatable (1)	0.35T & 1.5T	7	Not described	None
Kirkham et al. [13]	Malleable (2) Inflatable (2)	NR	4	Not described	None
Levin et al. [12]	AMS Dynaflex	1.5T	1	Pelvic pain	None
Moncada et al. [11]	AMS Dynaflex Mentor Mark II AMS Ultrex Plus Mentor Alpha I	1.5T	65	Penile pain	None
Shellock [4]	AMS Malleable 600 AMS 700 CX Flexi-Flate Flexi-Rod Flexi-Rod II Jonas Mentor Flexible Mentor Inflatable <i>Omniphase</i> <i>Duraphase</i>	1.5T	0	In vitro deflection forces—only the Omniphase and Duraphase showed a strong ferromagnetic deflection	None
Thiel et al. [14]	NR	1.5 T	6	multiple	None
Yildirim et al. [15]	Mentor Alpha I	NR	1	Prolonged erection	None

NR = not reported

ing 51 patients served as the normal population. Twelve of the fourteen penile pain patients were found to have buckling of one of the prosthesis cylinders as the etiology of their pre-MRI diagnosed pain, compared to only one patient in the no pain group (OR = 300, 95% CI 25–3,590.9). No complications of the MRI evaluation were noted.

In another study, Kirkham and colleagues found no specific patient complaints from men with a penile prosthesis during or following an MRI; however, a malleable penile prosthesis was noted to be rotationally unstable and twisted during imaging [13]. The patient was undergoing MRI evaluation of a malleable prosthesis for preexisting buckling of the device. The components remained in separate corpora and no evidence of erosion was noted. The specific device was not indicated. The rotation and twisting was not associated with patient pain or functional changes to the prosthesis. Hricak et al. [10] detailed a series of six malleable and one inflatable prosthesis tested at 1.5 Tesla or less with no noted complications. The remaining studies were case reports of patients undergoing MRI while having a penile prosthesis in place. Unfortunately, the type of prosthesis or strength of magnet was not uniformly reported in these studies.

The most complete reference was Shellock's *Reference Manual for Magnetic Resonance Safety, Implants, and Devices* [4]. In this manual all penile

prosthesis components and implants were deemed safe for 1.5 to 3 Tesla magnetic field except the Duraphase and Omniphase malleable penile implants. These two products were noted to have ferromagnetic properties which could lead to movement or dislodgement of the implant. The Duraphase and Omniphase were felt to have the potential to cause patient discomfort during MRI but unlikely to severely injure a patient. The only referenced study for this conclusion was an abstract presented by the author's group on in vitro analysis.

A review of the AMS and Coloplast websites was performed to obtain information on MRI compatibility of their currently available penile prostheses. No information could be obtained regarding MRI compatibility of the Coloplast Titan OTR from the site. The company did have a medical letter documenting MRI compatibility for the Genesis, Alpha I, Excel, Mark II, Acu-Form, and Titan prostheses (Supporting Information Appendix S2). The current wallet cards provided to patients from Coloplast do list the MRI magnet characteristics to ensure MRI compatibility. The AMS Ambicor prosthesis did not have any web information regarding MRI compatibility. The AMS Spectra was noted to be MRI compatible on the AMS website [16] as was the AMS 700 series prosthesis [17]. AMS specifies, regarding the Spectra prosthesis, that it was determined to be

MR-conditional according to the terminology specified by the American Society for Testing and Materials (ASTM). This designation was assigned after non-clinical testing demonstrated that the Spectra produced a temperature rise of 1.6 Celsius during an MRI performed for 15 minutes in a 3-Tesla system. MRI quality may additionally be compromised if the area of interest is in close proximity to the device. If imaging is performed, additional measures may be required by the radiation technologist to compensate for the presence of the device. The company states that a patient with this device can be scanned safely immediately after placement under the following conditions: a static magnetic field of 3.0 Tesla or less and the highest spatial gradient magnetic field of 720-Gauss/cm or less.

On the current wallet cards provided by AMS for patients after implantation there is a statement of MRI compatibility. In addition, AMS provides a medical letter documenting the safety data compiled in regards to 700 series, Ultrex, LGX, Ambicor, Dynaflex, Hydroflex, Dura II, 600 series malleable, and Spectra prostheses (Supporting Information Appendix S3). Both companies detail a static field of 3 Tesla or less with spatial gradient field of 720 gauss/cm or less as safe conditions. During testing, Coloplast documented a temperature rise of 0.5°C, and AMS noted a maximal rise of 1.6°C, as detailed in the medical letters.

Discussion

MRI safety and compatibility of implants is a concern to both patients and physicians. Frequently, the patient requires an MRI for a condition unrelated to the penile prosthesis. Most patients are unaware of the components within their device and frequently do not know the type of prosthesis implanted. Physician counseling regarding the MRI compatibility of implanted devices is infrequent. Physicians are rightfully hesitant to provide reassurance with limited data available in the literature and concern over litigation. Ultimately the patient and physician are placed into a situation of utilizing alternative imaging modalities or proceeding with insufficient knowledge.

In vitro testing of implants is commissioned to particular companies such as Magnetic Resonance Safety Testing Services. The testing is performed according to procedures developed by the American Society for Testing and Materials (ASTM) and the International committee on Magnetic

Resonance Safety. These procedures measure: displacement force (ASTM F2052) by placing the object in a magnetic field while suspended on a string, radio frequency induced heating (ASTM F2182) by measuring temperature through placement of the implant in the field compared to field temperature without the implant present, and device torque (ASTM F2213) through comparison of magnetic field torque on the device compared with gravitational force on the device. The ASTM does note that each of these procedures is not sufficient to determine if an implant is safe in the MRI environment.

A total of 88 patients undergoing MRI with a penile prosthesis in place have been reported. There were no patient complications reported from these procedures and only one report of implant rotation which did not result in patient discomfort or failure of the device. Since there have been approximately 11,000 to 27,000 implants performed yearly since 1970, clearly many more MRI's have been performed on these men without reported adverse events. Unfortunately, the literature is limited by inadequate information on the type of prosthesis or the strength of the magnetic utilized. In four reports, field strength of 1.5 Tesla was used. In vitro studies have shown the tested prostheses to be safe except the Duraphase and Omniphase [4]. Coloplast and AMS have used the in vitro data to determine conditions for safe MRI practices in patients with a penile prosthesis. From this, each has developed a letter documenting MRI compatibility. Additionally both provide the patients with a wallet card and it is important to ensure the patient receives this card at the time of the implantation.

It is essential for physicians to report instances of a patient who experiences a complication to improve our understanding of the actual risk. As there have been no significant adverse event reported during or after an MRI in a man with a penile prosthesis, our review concludes that for the majority of prosthetic devices, it is safe for a man with a penile prosthesis to undergo an MRI (Table 2).

Limitations of this study relate to the information available. In vitro MRI safety studies have been provided by the manufacturers of the product while independent in vitro or in vivo studies have not been performed to verify the reported data. Many articles are limited in detail regarding the type of prosthesis implanted or the strength of the magnetic field during MRI. The only documented abnormal experience noted is penile twisting with

Table 2 Safety of common penile prostheses

In vitro or in vivo penile prosthesis data documented in the literature—safe products:

AMS 600 series including malleable 600, 600 M, 650
 AMS 700 series including CX, CXR, LGX, Ultrex, Ultrex Plus
 AMS Ambicor
 AMS Dura II
 AMS Dynaflex
 AMS Hydroflex
 Coloplast Acu-Form
 Coloplast (formerly Mentor Corp.) Alpha I
 Coloplast Excel
 Coloplast Genesis
 Coloplast (formerly Mentor Corp.) Mark II
 Coloplast Titan and Titan OTR
 Dacomed Jonas
 Osmond
 Surgitek Flexi-Flate
 Surgitek Flexi-Rod
 Surgitek Flex-Rod II
 Uniflex 1000

In vitro penile prosthesis data to suggest possible risk:

Dacomed Duraphase
 Dacomed Omniphase

a malleable prosthesis in place [11]. To date, no serious reports of patient complications from MRI with a penile prosthesis exist. Medical need should determine the risk associated with a patient who has the Duraphase or Omniphase prosthesis.

Conclusion

MRI is a common imaging modality currently utilized for many patients with varying disease processes. Penile prosthesis implantation has regained popularity and therefore is more commonly being noted at the time of MRI screening. In vitro studies support the safety of most penile prostheses during MRI. Notable exceptions include Dacomed's Omniphase and Duraphase device and the MRI-conditional Spectra device manufactured by AMS. The current literature suggests that there is little risk for most patients who undergo MRI with a penile prosthesis in place. AMS and Coloplast provide wallet information cards and medical letter to support patient safety while undergoing MRI. Physicians should report any adverse events associated with MRI in men with a penile prosthesis. Based on the available data, prior prosthesis implantation should not preclude patients from undergoing an MRI.

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Statement of Authorship

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(a) Final Approval of the Completed Article

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1.

Appendix S2.

Appendix S3.

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