Magnetic Resonance Imaging & VeriChip™ RFID Human Implant at 1.5 Tesla

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***Abstract*—Magnetic resonance imaging (MRI) effects on certain metallic implanted medical devices were researched. A great deal of research has been done on MRI compatibility of medical devices and most active devices are contraindicated for use in an MR environment. MRI compatibility test (1.5 T) on the VeriChip™ RFID human implant device were performed. It was found that the VeriChip™ device would not create adverse medical effects for an implanted patient. However, it was found that the device may be inactivated as a result of MR testing. It is concluded that the VeriChip™ RFID human implant device is MR safe but not MR compatible.**

***Index Terms*— MRI Compatibility, Safety, Implantable Devices, Medical Devices, VeriChip**

I. Introduction

All current Magnetic Resonance Imaging (MRI) devices are labeled by the Food and Drug Administration (FDA) to contraindicate patients with metallic implanted devices. This is a strong contraindication for good reason in that patients with these devices may have very adverse effect from an MRI scan up to and including death.

To evaluate the risks of metallic biomedical devices, a common set of testing protocols is used. These are device movement, device heating, imaging artifacts, and device operation. Metallic devices researched included: cardiac pacemakers, cardiac defibrillators, a cardiac recording system, brain neurostimulators, bladder neurostimulators, an infusion system, drug infusion pumps, ocular magnetic devices, cochlear implants, programmable valves, dental implant devices, and radio frequency identification devices.

Information on each device came from a set of biomedical research papers, studies, and reports. Ethical complications, medical risks, and medical benefits were taken into consideration. Non-ferromagnetic and weakly ferromagnetic materials such as Phynox, Elgiloy, austenitic stainless steel, titanium alloy, and commercial pure titanium were investigated. MRI safety and compatibility testing on the VeriChip™ radio frequency identification device was completed. The results were compared to several other biomedical implants to conclude if the device would be MRI safe and/or compatible weighing benefits and risks. MRI safety with metallic implants is extremely important as the patient may be put in a very dangerous situation if the device is not safe. The FDA has a MDR database of patients who have gone through MRI scans and lists two MRI-related deaths in MDR-351516 (02Dec92) and MDR-175218 (02Dec92). Although not all metallic objects can harm or kill a patient, it is very important to weight the risks and benefits for any implanted metallic biomedical device.

II. Methodology & Theory

1) *Introduction to Device Movement in MRI*

There are two types of movement that can occur from MR fields on biomedical devices. They are deflection, or translational movement, and torque, or rotational movement. When the spatial magnetic field exists, translational movement is seen. When the field gradient is small and magnetic field large, rotational movement effects are seen.

Deflection Force measurements are described by New et al. A metal device is hung near the magnetic portal and adjusted so that the angle of deflection greatest vertically. This angle was measured with a protractor. The equation is:

$$F = m \cdot g \cdot \tan(\theta)$$

where m is the mass of the biomedical device, g is the gravitational force on earth (9.8 m/s/s), and θ is the measured deflection angle from the vertical axis.

Torque Force measurements are described by New et al. A metal device is hung at the magnetic center and a lead weight is hung from that at an angle of rotation of 45º. The equation is:

$$N = (M + m) \cdot L \cdot g \cdot \sin(\theta)$$

where M is the lead weight mass, L is the distance from the pivot to center of mass and θ is the measured angle of rotation (45º adjusted).

2) *Introduction to Device Heating in MRI*

Device heating is caused by induced electromotive forces in conductive implants due to gradient magnetic fields in an MR environment. If sufficient voltage is generated and the device is close enough to a conductor, it may experience arching affects, which create heat. Heating measurements are always taken in the worst-case orientation of the device. The MR device is adjusted to near maximum RF exposure recommended by the FDA.

3) *Introduction to Imaging Artifacts*

Images captured by the MR device can be distorted by the local magnetic field. This alters the position versus frequency equation that is essential to the device operation. Many factors can cause image artifacts including device material, device position, and MR field strength. Types of image artifacts include distortion, noise, and signal loss. Imaging artifact measurements are done by imaging a phantom that imitates an in-vivo human environment. Images are then done with the device and the two images compared.

4) *Introduction to Device Operation*

Device operation refers to the ability for an active or passive biomedical device to continue proper operation. For active devices, this may include not deactivating and not activating improperly. For passive devices, this may include no memory alterations and ability to operate after the MR scan. For both active and passive devices, this includes correct operation during the MR scan. A device is considered MR safe if it does not cause direct harm to the patient during a scan. If the device is safe and retains its function during and after an MR scan, it is considered MR compatible.

III. Results & Discussion

Several metallic biomedical implants in general MRI situations were examined. Each device was weighed for benefits and risks using each of the compatibility criteria described in the introduction and was much like the work of Frank Shellock. These results were compared with the following VeriChip™ MRI safety and compatibility results to develop our conclusion.

Device Movement. Deflection and torque force was measured in different VeriChip™ devices. The VeriChip™ device has a BioBond™ cap-sheath, which creates a strong bond between the device and body tissues. The MRI forces were examined in a worst-case scenario orientation and compared to the force (tinsel strength) needed to tear the device away from connective tissue within a patient's body. It was found that the deflection plus torque forces in worst case-scenario are an order of magnitude lower than what would be needed to tear the device from connective tissue. It can be said that the likelihood of the VeriChip™ device tearing free from tissue and migrating is very slim at 1.5 Tesla or less. However, because there is some movement the patient may feel a tugging sensation. Because the force of movement is very small, there will likely be no pain associated with this pulling. It is suggested that the implant be in the upper arm or away from important vessels or organs. However, in the case that the VeriChip™ were implanted near a large vessel or organ, the patient should undergo substantial pre-testing as the device may move and affect the nearby vessel or organ.

Device Heating. The VeriChip™ devices were subjected to over 30 minutes of testing in all orientations. The RF pulses were set to near allowable maximum per FDA standards. It was found that there was no noticeable (0.1°C change) heating of the VeriChip™ device.

Image Distortion. Images of the device within a phantom taken in common orientations and examined for visual noise. There was noticeable loss of signal near the antenna portion of the device. However, the device did not distort more than 10% beyond its barrier. Due to the size of the device (12mm), it can be said that the distortion caused by the VeriChip™ would not effect the accuracy of MR image reading and diagnosis. It is very unlikely that important information, especially if the device were implanted in the upper arm, would be covered up by the VeriChip™ implant. It can be concluded based on movement, heating, and image distortion that the VeriChip™ RFID implant is MR safe.

Device Operation. RFID scanning of the VeriChip™ devices using an Applied Digital scanner confirmed that they devices worked prior to testing. After testing device movement, heating, and image distortion, one VeriChip™ device had failed to scan. It can be concluded that the VeriChip™ RFID implant is not MR compatible. However, as a single failed device may be due to statistical error, further examination of device operation would be necessary. The VeriChip™ device is safe inside a patient during MRI testing as far as device movement, heating, and image distortion. However, the device may fail due to the MRI exam.

IV. Ethical Consideration

Because of the complexity involved in assessing risks versus benefits for patients, some ethical considerations have been examined. Many ethical implications of the VeriChip™ and how MRI may affect these implications have been considered. For those who are considering a VeriChip™ security implant, the letter written by the FDA regarding possible incompatibility has been mentioned. However, it has been found that the device will not cause adverse medical effects on the patient as far as device movement, heating, and image distortion. Yet, it was also found that the device might fail during MRI testing. A patient who may get an implant should weight the benefit of the device with the risks of getting an MRI. If the patient is more likely to undergo an MRI scan, they should be strongly encouraged to consider their implantation decision or at the very least understand that the device may fail due to an MRI scan.

The problem arise in that the VeriChip™ device is suppose to last 20 years. Not many people have a good idea of how many MRI scans they may need in the next 20 years. So, a patient who would actually need this type of device should only do so for health benefit & privacy reasons; taking into consideration the MRI incompatibility of the device. For example, a patient may need to store drug allergy or other important medical information using the device but only want medical personnel to know of their condition. Patients who do not need this device for privacy or security reasons should probably understand the health benefit is outweighed by the risks involved in MRI as the device may be inactivated which would not allow it to

convey the patient's identification information. A medical alert bracelet, for example, can convey this information but does so in a more public manner. Yet again, if the patient were in a position where there security is vastly important then they would need to consider the MRI effects. As one can see, there are many MRI-related considerations that should be taken into account before someone considers a VeriChip™ implant.

A generalization could be made in that most people do not hold positions dealing with sensitive security or financial information. So, most people in general would not have the risks of an MRI scan with the VeriChip™ implant outweighing the security benefit of the device. It can be said that most people do not have medical ailments that would call for a VeriChip™ implant to relay this type of information. Under this generalization one could see that a government law requiring these devices be implanted in everyone would not be useful and likely would be unethical. Not only from the risks versus benefits standpoint, but also from a personal rights to privacy standpoint. This fear of a government law has created much ethical debate, especially with the Christians who believe in the "Mark of the Beast" revelation stating, "And he shall make all, both little and great, rich and poor, freemen and bondmen, to have a character in their right hand or on their foreheads: And that no man might buy or sell, but he that hath the character, or the name of the beast, or the number of his name." It is well worth noting that certain implantable biomedical devices hold strong ethical considerations behind the decision to have them implanted, whether they are MRI contraindicated or not.

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