Original Report

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New Metallic Implant Used for Permanent Contraception in Women: Evaluation of MR Safety

OBJECTIVE. This ex vivo investigation evaluated the safety of using MR imaging with a new metallic implant designed to provide permanent birth control.

CONCLUSION. The findings indicated that it should be safe for patients with this metallic contraceptive implant to undergo MR imaging with systems using static magnetic fields of 1.5 T or less.

The presence of a metallic device in a patient undergoing MR imaging may cause an injury from the movement or excessive heating of the object [1–6]. In addition, the metallic implant may create substantial artifacts that can impair the diagnostic accuracy of MR imaging [1–8]. To determine whether a metallic implant presents any of these problems, ex vivo testing is conducted using standardized techniques to determine magnetic field interactions, heating, and artifacts [3–5].

Recently, a new metallic implant has been developed for permanent contraception in women. This implant, the ESSURE device (Conceptus, San Carlos, CA), is a dynamically expanding microcoil that is placed in the proximal section of the fallopian tube using a nonincisional technique. Subsequently, the device elicits an intended benign tissue response, causing tissue ingrowth into the device and thereby anchoring it firmly in the fallopian tube. This benign tissue response is local, fibrotic, and occlusive. Accordingly, the presence of this implant is meant to alter the function and architecture of the fallopian tube, resulting in permanent contraception.

Because the ESSURE device is made of metal, safety concerns arise regarding the use of MR imaging in women with the device. Therefore, this investigation was conducted to evaluate magnetic field interactions and heating using ex vivo testing techniques at 1.5 T. In addition, artifacts related to this metallic implant were characterized.

Materials and Methods

ESSURE System and Device

The ESSURE system is composed of the ESSURE device (the metallic implant portion) and a disposable delivery system and introducer (Figs. 1 and 2). The ESSURE device comes attached to a delivery wire housed in a release catheter, which is then placed inside a catheter for hysteroscopic deployment into the fallopian tube.

Safety tests for MR imaging were conducted on the metallic implant that remains in the fallopian tube (Fig. 1). It is composed of 316L stainless steel, platinum, iridium, nickel–titanium alloy, silver solder, and polyethylene terephthalate fibers (Fig. 1). Currently, this device is classified as an investigational device in the United States but is used and marketed in other countries.

Assessment of Magnetic Field Interactions

Tests for magnetic field interactions were performed on one randomly selected sample of the ESSURE device using a previously described procedure known as the deflection angle test [3]. This test was conducted using a shielded 1.5-T MR imaging system (General Electric Medical Systems, Milwaukee, WI). A 20-cm length of thin thread was attached to the ESSURE device and then to a plastic protractor so that the angle of deflection from the vertical plane could be measured. The accuracy of

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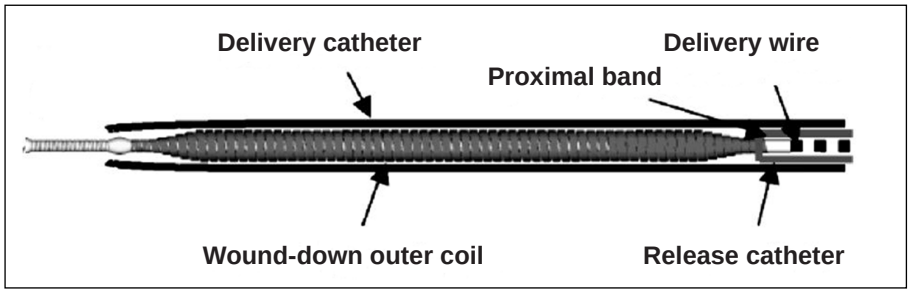

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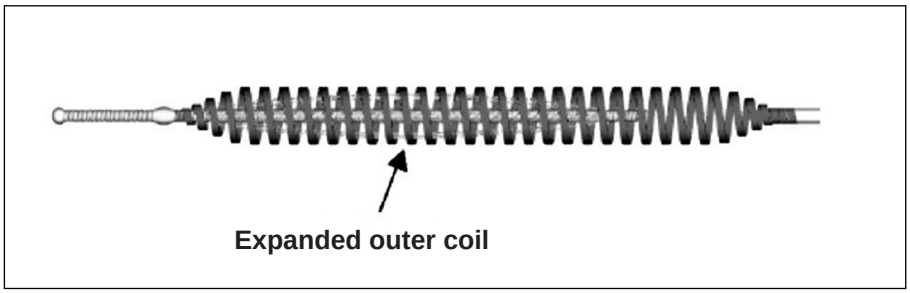

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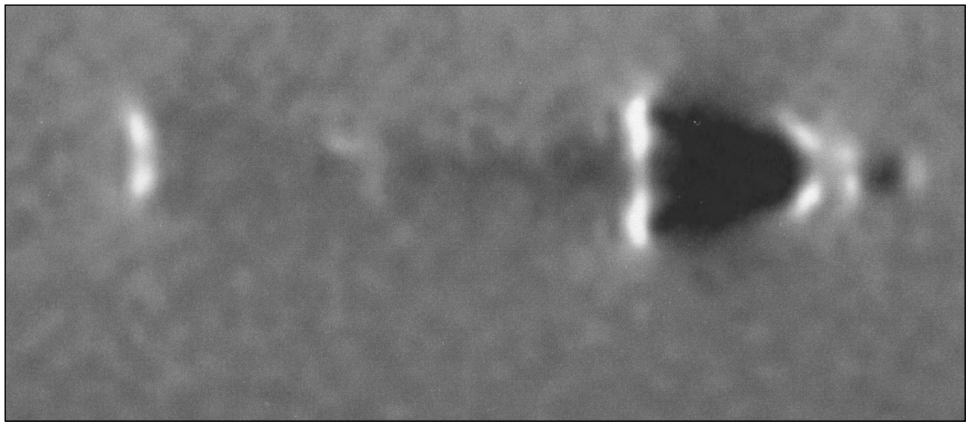
Fig. 1.—Schematic of metal implant (ESSURE contraceptive device; Conceptus, San Carlos, CA) used for permanent contraception in women.
A, Illustration shows device attached to delivery system in low-profile, wound-down configuration.
B, Illustration shows configuration with outer coils expanded.



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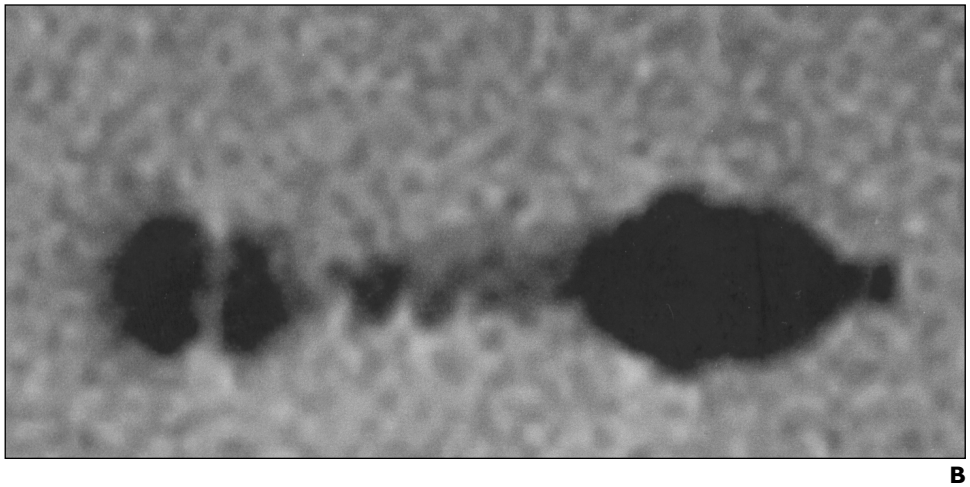

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Fig. 2.—MR imaging artifacts related to ESSURE device (Conceptus, San Carlos, CA).
A, MR image of device in gel-filled phantom reveals artifact arising in T1-weighted spin-echo pulse sequence (TR/TE, 500/ 20). Imaging plane was oriented to encompass long axis of implant.
B, MR image of device in gel-filled phantom reveals artifact arising in gradient-echo pulse sequence (100/15; flip angle, 30°). Imaging plane was oriented to encompass long axis of implant.

this measuring device is within ± 0.5° [3]. The deflection angle was measured at the position in the MR imaging system previously determined to be the maximal spatial gradient of the magnetic field [3].

Magnetic field–related torque was then qualitatively determined for the ESSURE device using a technique that has been previously described in the literature [3]. The implant was oriented on the test device 45° relative to the static magnetic field of the system. The test apparatus with the implant was then positioned in the center of the imaging system. The ESSURE device was directly observed for any movement with respect to rotation relative to the 1.5-T static magnetic field. The device was then moved 45° relative to its previous position and again observed for alignment or rotation. This process was repeated to encompass a full 360° rotation of positions for the implant [3]. A previously reported [3] qualitative scale of torque was applied to the results: 0, no torque; 1, mild torque (the device changed orientation slightly 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).

Evaluation of Heating

A previously described experimental protocol [3, 4] was used to evaluate MR imaging–related heating of the ESSURE device. Heating of the implant during MR imaging was determined by performing an extreme radiofrequency power exposure experiment, with the device placed inside a specially constructed phantom filled with a semisolid gel that simulates the convective heating qualities of human tissue [3–5]. The shape of the phantom approximated the geometry and mass of a human torso [3]. The ESSURE device was mounted on a thin plastic frame to permit placement that would simulate its intended in vivo use.

MR imaging was performed using a 1.5-T, 64-MHz MR imaging system with a transmit–receive body coil and a pulse sequence that produced a whole-body-averaged specific absorption rate of 1.3 W/kg and a spatial peak specific absorption rate of 2.7 W/kg. This relatively high level of radiofrequency energy was selected in consideration of the clinical use of MR imaging [3].

Temperature recordings were obtained using an MR-compatible fluoroptic thermometry system (Luxtron 3100; Luxtron, Santa Clara, CA). The system probes were attached to the ESSURE device to record representative temperatures: Probe 1 was placed 0.5 mm from the proximal end of the device, and probe 2 was placed 0.5 mm from the center of the device. In addition, a third probe was placed in the gel-filled phantom at a position approximately 30 cm away from the device to record a reference temperature.

The gel-filled phantom with the implant and thermometry probes attached was placed in the MR scanner and allowed to equilibrate to environmental conditions for more than 1 hr. Baseline temperatures were recorded at 20-sec intervals for 5 min. MR imaging was then performed for 20 min, with temperatures recorded at 20-sec intervals.

Evaluation of Artifacts

To characterize artifacts related to the ESSURE device, we placed it inside a gel-filled phantom (a 20-cm-long cylinder with a diameter of 25 cm) and then performed MR imaging with a 1.5-T system and a transmit–receive body coil. The parameters for the T1-weighted, spin-echo pulse sequence were TR/TE, 500/20; matrix size, 256 × 256; section thickness, 5 mm; field of view, 16 cm; number of excitations, 2; and bandwidth, 16 kHz. The parameters for the gradient-echo pulse sequence were 100/15; flip angle, 30°; matrix size, 256 × 256; section thickness, 5 mm; field of view, 16 cm; number of excitations, 2; and bandwidth, 16 kHz. Imaging planes were oriented to encompass both the long and short axes of the ESSURE device.

The MR system planimetric software (SD for accuracy and resolution, ± 10%) was used to obtain a cross-sectional area measurement of the artifact for the ESSURE device with regard to the dimensions for each pulse sequence and for each image orientation [3]. All image display parameters (e.g., magnification and window and level settings) were carefully selected and used in a consistent manner to facilitate valid measurements of artifact size.

Results

According to the findings for magnetic field interactions, the ESSURE device displayed no magnetic field interactions (i.e., deflection angle, 0°; torque, 0) during exposure to the 1.5-T MR imaging system. Findings for the heating test showed the highest temperature changes were less than or equal to 0.6˚C. The highest temperature change recorded by the reference thermometry probe was 0.4˚C.

Artifact test results for the ESSURE device are summarized in Table 1. In general, the artifacts for this implant were visualized as localized signal voids relative to the device's size and shape. Images obtained with the gradient-echo pulse sequence showed artifacts with larger cross-sectional areas compared with those obtained using the T1-weighted spin-echo pulse sequence (Fig. 2).

TABLE 1 Mean Size of MR Imaging Artifact for ESSURE Device[a]

Pulse Sequence	Plane Orientation	Signal Void (mm^2)
T1-weighted spin-echo	Long axis	424
	Short axis	108
Gradient-echo	Long axis	518
	Short axis	186

[a]ESSURE contraceptive device (Conceptus, San Carlos, CA).

Discussion

Magnetic Field Interactions

The results of the ex vivo deflection angle and torque tests indicated no magnetic field interactions for the ESSURE device, which is not surprising considering the materials used to make this implant. Previous publications have reported that 316L stainless steel, platinum, iridium, nickel–titanium alloy, and silver display no magnetic field interactions when exposed to static magnetic fields of as much as 2.35 T [1–3, 6–8]. Therefore, no risk of movement or dislodgment of this metallic implant exists for patients who undergo MR imaging procedures performed at 1.5 T or less.

MR Imaging–Related Heating

The experiment performed to determine MR imaging–related heating for the ESSURE device showed that no substantial temperature increases for this implant were associated with procedures involving relatively high radiofrequency energy. The highest temperature changes (≤0.6˚C) were well within physiologically acceptable levels and would not present any hazard to human tissue [6, 9–11]. Therefore, this implant will not present any thermogenic risk to a patient undergoing MR imaging under the conditions used in this study (whole-body-averaged specific absorption rate, 1.3 W/kg for 20 min).

Previous investigations have used ex vivo testing techniques to evaluate MR imaging–related heating for passive implants of various sizes, shapes, and metallic compositions [3–5, 12]. In general, these data indicated that only minor temperature elevations occurred in association with MR imaging in patients with relatively small implants (i.e., similar to the ESSURE device) [3–5, 12].

Artifacts

The ex vivo assessment of artifacts related to the ESSURE device showed that the occurrence of artifacts was comparatively low. In part, this finding was due to the relatively low magnetic susceptibility values of the metallic materials used to make this implant [7, 8]. MR images obtained with the gradient-echo pulse sequence were subject to larger artifacts than those obtained with the T1-weighted spin-echo pulse sequence. Nevertheless, artifacts should not be a problem in imaging patients with the ESSURE

device, unless the area of interest to be imaged is in exactly the same position as the implant.

Other Contraceptive Devices

Other contraceptive devices have been tested for MR imaging safety, including intrauterine devices (IUDs) and contraceptive diaphragms [1, 2, 8, 10, 11]. IUDs may be made entirely of nonmetallic materials, such as plastic, or a combination of nonmetallic and metallic materials. Typically, copper is the metal used in IUDs. For example, the Copper T (ParaGard, Ortho-McNeil Pharmaceuticals, Sommerville, NJ) has a fine copper coil wound around a portion of the IUD. The results of testing conducted to determine the MR safety aspects of IUDs with metal components indicated that these objects are safe for patients imaged with MR systems operating at 1.5 T or less. The metallic component of an IUD may cause artifacts; however, such artifacts are relatively minor because of the low magnetic susceptibility of copper and relatively small size of the IUD [7, 10, 11].

Most contraceptive diaphragms have metallic rings that maintain the device's position during use. Notably, some of these metallic rings are made from ferromagnetic materials. MR safety testing conducted at 1.5 T has shown that these contraceptive diaphragms are strongly attracted by the static magnetic field of the MR imaging system. However, MR imaging has been performed safely in patients with these contraceptive devices, without patient complaints of sensations of movement or heating (Shellock FG, unpublished observations, 1996). MR imaging artifacts caused by contraceptive diaphragms with ferromagnetic rings are quite substantial because of the size of the devices and the magnetic susceptibility of the materials used to make them [1]. Nevertheless, the presence of a diaphragm is not considered a contraindication for a patient undergoing MR imaging at 1.5 T or less [1, 2, 8].

In summary, the results of the MR imaging safety tests indicated the ESSURE device will not present an additional hazard or risk to a patient undergoing MR imaging with a system operating with a static magnetic field of 1.5 T or less. Therefore, this metallic implant is considered MR-safe in the context of the specific conditions used for testing.

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