Lack of Interaction Between Magnetic Resonance Imaging and the Copper-T380A IUD

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To determine if the CuT380A (ParaGard®) IUD is affected by magnetic resonance imaging (MRI), in vitro studies using a CuT380A IUD (ParaGard®), a copper bearing IUD, and a Signa 1.5T HR system were used to evaluate whether the dynamic magnetic forces generated by the MRI resulted in movement, torque, or heat when the IUD was exposed to the magnetic field generated by the MRI.

There was no deflection, turning motion (torque), or temperature change when the IUD was exposed to a magnetic field.

There appears to be no reason to exclude women with IUDs of the type examined from an MRI system or its environs. © 1997 Elsevier Science Inc. All rights reserved.

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Introduction

During the mid-1980s, intrauterine contraceptive devices (IUDs) were virtually eliminated from usage in the US, primarily because of fear of litigation. The inert intrauterine devices, i.e., Lippes Loop® and Safety Coil®, were both discontinued, and the Cu-7®, a copper-bearing device, was withdrawn from the market, leaving only the Progestasert® available for use.

In 1988, the copper-T380A (Ortho-McNeil Pharmaceutical Corp., Raritan, NJ) intracutaneous copper contraceptive device became available in the US. This intrauterine device has been used worldwide in over 30 million women and is highly effective, being the most effective intrauterine contraceptive device developed to date. It has a duration of use for up to 10 years.

In contrast to other developed countries, only about 1% of US women contraceptors select this method of contraception. However, the use of ParaGard is increasing, as it has in other industrialized countries. In European countries such as France and Germany, 10-20% of the women contraceptors use intrauterine devices as their contraceptive method of choice.

Although copper is not ferromagnetic, the question of the effect of magnetic resonance imaging of the pelvis in women using copper-bearing IUDs has been raised. Previously, this question was addressed with the Cu-7 and the inert Lippes Loop. A study by Mark and Hricak indicated that neither the Cu-7 nor the Lippes Loop moved under the influence of a magnetic field, nor did they heat during the spin echo sequences usually employed for pelvic imaging.

The ParaGard-T380A, like the Cu-7, is also reported to be unaffected by magnetic fields up to 1.5 Tesla by Shellock et al. However, since the introduction of the ParaGard T380A in 1988, there were four reports to the manufacturer of pelvic pain or heat in women wearing the IUD while having magnetic resonance imaging of the pelvic area.

These reports, and because of the configuration of the ParaGard-T380A, in particular the increased amount of copper and the location of the copper differing from that of the Cu-7, prompted a re-evaluation and re-examination of the effect of MRI scans on the ParaGard-T380A.

The reports that prompted this study follow.

Case #1

A 40-year-old patient who had a ParaGard-T380A in place for approximately three years without complications underwent a series of MRIs following an accident. No complications were reported with MRIs of the skull and cervical spine. Three days later, the patient had MRIs of the thoracic and lumbar spine. The patient's menstrual period was due the next day and cramping had been present earlier in the day. Al-
though there were no problems during the MRI of the thoracic spine, during the lumbar spine MRI, the patient reported vibrations in the table directly beneath her buttocks and pain in her pelvic area. The test was stopped and the pain faded. When the noise cycle restarted, the vibration and pain returned. The test was stopped and the patient stated that she shivered for about 30 min. The patient's menstrual period and accompanying cramps started 5 hr later.

**Case #2**

A patient who had a ParaGard-T380A in place for approximately four years without complications reported that two months previously, she started a new job working around four MRI machines. Since that time, she had been having pelvic discomfort and vaginal bleeding every two weeks. The patient had an annual exam one month prior to the report and the IUD was in place with no discharge or pelvic tenderness.

**Case #3**

A patient with a ParaGard-T380A in place had an MRI performed for a "disk problem." The procedure lasted approximately 1 hr. The patient reported that during the procedure, she felt the IUD heating up, although it was not painful. The patient stated that she was "aware" of the device. The patient reported that she became more aware of the device after having the MRI than prior to the procedure.

**Case #4**

A patient with a ParaGard-T380A in place had an MRI performed. The MRI was stopped because the patient experienced cramping and bleeding. The IUD was removed.

Because of these case reports, a study was performed to examine the effects of MRI scanning on the ParaGard-T380A.

**Materials and Methods**

All experiments were done on a Signa 1.5T MR system (GE Medical System Division, Milwaukee, WI).

The ParaGard-T380A is a T-shaped device made of polyethylene with approximately 176 mg of copper wire wound on the vertical stem, and a copper band or collar with approximately 66.5 mg of copper on each of the transverse arms (Figure 1); this provides approximately 380 mm of exposed surface area of copper. The ParaGard-T380A also contains barium sulfate to make it radio-opaque. When placed in the endometrial cavity, the device is placed near the fundus so that the copper bands on the horizontal arms are close to the os of the Fallopian tubes.

Potential static mechanical forces exerted by the magnetic field were investigated by measuring the deviation of a ParaGard-T380A IUD that was suspended by a thin string at the portal of the magnet. This location was chosen because the magnetic force is greatest at the portal.

Potential dynamic magnetic forces, due to induced currents in the copper loops, were investigated during a standard imaging sequence by visually and optically determining the presence of angular torques on the IUD suspended by a string in the magnet's center. The standard imaging sequence incorporates rapidly switching magnetic gradient pulses that could potentially generate induced currents in a conductive loop (i.e., the copper coil). The cross-sectional area of the copper coil is small; therefore, we would expect the currents to be small, yet to exist. Such an induced current would generate a magnetic field along the axis of the conductive loop, and this magnetic field would interact with the other magnetic fields (primarily the

Figure 1. Copper-T380A IUD.
large static field) to create a torque that would twist the IUD. An image sequence with a low repetition rate (approximately 3 sec) was chosen so direct visual inspection could be used. In addition, the reflection of laser light impinging on the arms of the IUD was also observed to enhance sensitivity to the turning motion. To further maximize sensitivity, imaging parameters that resulted in a small field of view (16 cm) and thin slices (3 mm) were chosen to create maximum gradient fields.

Potential heat generation during an MRI study was examined by embedding the IUD in an agarose gel, scanning the gel and IUD in the MRI system with the same parameters used in clinical examinations, and measuring signal intensity changes in the gel. Previous studies have demonstrated that the MRI relaxation parameters ($T_1$ and $T_2$) are proportional to temperature and measurement of MRI signal intensity, a function of these relaxation parameters provides a direct measure of temperature changes.

The agarose gel simulates the physical and thermal properties of human tissue, and embedding the IUD in the gel simulates the worst-case situation that could be found in vivo. In vivo tissue would have blood flow that would aid cooling and reduce induced thermal effects. No external probes were used that might introduce focal variable (e.g., heat sinks or current generation). Use of the same MRI system and pulse sequences suspected of heating the IUD allows direct dynamic evaluation of possible thermal changes that might occur during the imaging process.

The agarose gel system was calibrated prior to the IUD measurements using methods developed by one of the authors (TJ Russer, unpublished). Agarose gel was prepared as 1% solution in distilled water using Seaplaque® (FMC Corporation, Rockland, ME). A warm agarose solution was poured into a plastic box (approximately 10 x 10 x 5 cm on a side). The base had a regular 11 x 11 array of depressions at the bottom and the lid had a corresponding array of 0.175-cm-diameter holes spaced 0.4 cm apart. This arrangement accommodated 12.5-cm-long glass capillaries of inner diameter 0.12 cm mounted vertically in the box. The capillaries were closed at the bottom and open at the top to permit thermocouples to be inserted. A 0.48-cm-diameter hole in the center of the lid and base accommodated a glass tube through which heated water could be pumped. The capillary and larger glass tubes were positioned and warm gel was poured into the container. The agarose gel, with the capillaries and glass tube in place, was allowed to set overnight at room temperature.

The agarose gel phantom was positioned in the center of a standard quadrature “head” coil within the MRI system. Heated, temperature-controlled water was pumped through the tube to create a radially symmetric temperature profile. Type T (copper-containing) thermocouples were placed in the capillaries at four points along a radius from the central tube. A Gradient Echo pulse sequence was used (TR/TE = 15/5.6, 20 flip angle, 10 mm slice thickness, 256 x 256 matrix, and a 12-cm field of view) to image and measure temperature in the phantom. In previous studies, this sequence was optimal for detecting small temperature changes [TJ Russer, unpublished]. With this sequence, three slices parallel to the base of the phantom were acquired in 9 sec. The scans were made at eight different temperature settings (i.e., the temperature of the water flowing through the center tube) from 22°C to 65°C, with the temperature measured immediately before the imaging sequence. Region of interest cursors positioned on the image on the system console, at locations corresponding to the thermocouples, were used to measure signal intensity (Figure 2).

The IUD test jig was prepared by half-filling a cylindrical box (6 cm diameter) with the agarose gel, allowing the gel to firm, placing the IUD device on the gel, and then filling the entire box with gel. The jig was allowed to set overnight at room temperature. An identical cylindrical gel phantom box was prepared as a control measure for the signal intensity.

Using the MRI parameters given above, the jig was scanned repeatedly for periods lasting up to 1 hr in both the head and body coils. Care was taken to ensure the IUD was centered on one of the image slices.

Figure 2. Signal intensity versus temperature.
Region of interest cursors were placed on the image at various points around the IUD and signal intensity was measured on the successive images (Figure 3).

Results
The results of the thermal calibration experiments are shown graphically in Figure 2. Signal intensity is a linear, monotonic function of temperature and has an accuracy of approximately ±1°C. As seen in Figure 4, no significant temperature changes were seen.

Prior to scanning, the suspended IUD was allowed to stabilize until no motion could be seen or detected. No subsequent motion was detected once scanning was initiated. There was no static deflection of the IUD, additionally, no turning motion or torque of the IUD that correlated to the application of gradient pulses was observed. These observations are consistent with the fact that the device contains no magnetic or magnetizable components.

Discussion
An MRI system creates images via the interaction of tissue with large but static magnetic fields, smaller but rapidly varying (gradient) magnetic fields, and pulses of radio-frequency energy. Any of these fields and waves can potentially cause harm to a patient, especially if they have an implanted or embedded metallic or magnetic foreign object.

Large magnetic fields (1.5 Tesla—30,000 times the strength of the earth’s magnetic field), as in the experiments reported here, can exert tremendous forces on magnetic or magnetizable objects. While most devices placed in the body (e.g., dental braces and fillings, prosthetic hips, surgical clips) do not interact with the magnetic field, some do and are absolutely contraindicated (e.g., some aneurysmal brain clips, and older prosthetic heart valves), and scans of patients with these devices have led to patient harm and, in at least one instance, death.

Only ferromagnetic or magnetizable (i.e., paramagnetic) material will experience a static force in an MRI system. In practice, this usually means ferrous materials. Other materials, metallic or not, will not experience any magnetic force. In particular, the materials used in the ParaGard, i.e., copper, barium sulfate, and plastic, are not magnetic and should not experience any force in the magnet. This was indeed the case.

The radio-frequency waves used to excite the spins have considerable peak powers, ranging up to tens of kilowatts in most systems. The only known interaction between such radio waves and tissue or the kinds of materials found in the ParaGard-T380A is thermal, direct heat generation due to induced currents or losses in dielectrics. Therefore, it is not the peak power that is important but rather the average power. In all MRI imaging systems, the radio waves have a very low duty cycle (pulses of several microseconds duration repeated in 10- to 1000-millisecond intervals), and so the average power projected into patients is usually on the order of tens of watts. All MRI systems commercially available in this country, under the direction of the FDA, arc limited to generate no more than several hundred watts in the patient, a value that is on the order of the 100 or so watts generated by the patient’s own basal metabolism. (The protocol for power limitation involves limitation on the Saturation Absorption Rate, but the effect is to limit deposition to less than 200 watts.) It would be unlikely, although not impossible, that heat could be
generated in IUDs, but the present experiments, done with the highest duty cycle possible in this type of system, demonstrate that no measurable heat (or temperature rise) is generated.

The rapidly switched (gradient) magnetic fields that are used to determine location in the body (i.e., where the signal produced by the excited spins is coming from) can induce currents and voltages in tissue and in the materials of such implanted structures as IUDs. Tens of gauss are switched on and off, from one direction to another, in times on the order of milliseconds or less. Such rapid and intense field changes can directly generate voltages in any substance and currents in conductive materials. The currents produced in the metal elements of the copper-bearing IUDs, or in the material surrounding them, could themselves generate heat; but as demonstrated, the amount of heat, if any, is not significant, since no measurable temperature rise was seen.

The induced currents also create torques through interaction with the large static magnetic field, but as demonstrated, the torque (and by inference the induced current), if any, is not sufficient to be demonstrable with this IUD.

The present study confirms and extends the observations of Mark and Hricak. In their study of two different types of IUDs, neither the copper-bearing Cu-7 nor the inert Lippes Loop moved in the magnetic field, nor did they generate any detectable heat. The authors concluded that screening patients for the presence of an IUD before MRI seems unnecessary, and removal of an IUD solely for the purpose of MRI is not justified. The present results with the copper-T380A suggest that the recommendations of Mark and Hricak also are applicable to MRI of ParaGard users.

It is unlikely that the symptoms experienced by the patients reported in the case reports during their MRIs were related to the effects of the magnetic fields or temperature changes on or at the IUDs.

In summary, the present study examined the possibility that the strong magnetic and radio-frequency waves used in MRI systems could interact with copper-bearing IUDs in women undergoing an examination. We particularly explored the possibility that there may be thermal and mechanical effects and found no evidence that these are generated in an in vitro system. We believe that there is no reason to exclude women with the ParaGard-T380A from an MRI system or its environs.

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References
5. ParaGard-T380A; prescribing information.