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MRI Facility Safety — Understanding the Risks of Powerful Attraction

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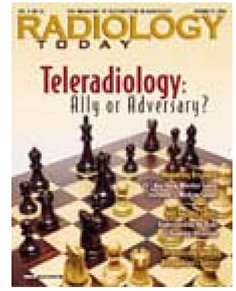

Diagnostic imaging professionals who work with MR equipment understand and accept that its enormous power also carries potential risk. What they may not realize, however, is that terrible accidents—like one in Valhalla, N.Y., in 2001 that killed a 6-year-old boy—are not simply flukes attributable to a facility's momentary negligence. By its very nature, MRI poses three significant threats to operator and patient safety:

• so-called missile effects;

• biostimulation device interference; and

• cryogenic gas venting.

The good news is that even long-established MRI sites can usually be retrofitted for safety improvements at a reasonable cost. "Safer doesn't have to mean more expensive," says medical facilities architectural designer Tobias Gilk. "In fact, we would argue the opposite." His employer, Missouri-based Junk Architects, PC, specializes in MRI suite design. Gilk served as project manager for the first MRI installation renovation to conform to the standards laid down in the American College of Radiology's (ACR) original 2001 White Paper on MR Safety.

Metal Drawn to the Magnet

Missile effects is the term generally used to describe the way MR's high-powered magnet pulls some metallic objects into its field. The Valhalla case—where an emergency oxygen tank was drawn with such velocity and force that it killed the young boy in the bore—is the most horrific incident to be picked up by the popular press, but similar, nonfatal occurrences happen fairly regularly around the country.

Routine patient screening before scanning is intended to prevent such problems, but when imaging centers power down their systems, they regularly report finding paper clips, pens, keys, staples, and an array of other magnetized items in the bore. While technologists usually worry most about these small objects distorting scanning, it's also important to realize that an MRI magnet can pull a stray hairpin across the room at 40 miles per hour.[1] In fact, Gilk cites a case where "an MRI patient needed to have a bobby pin surgically removed from their nasal cavity when the pin was drawn towards the center of the bore [while] the patient was lying head-in in the scanner."

As if that instance is not serious enough, hemostats, scissors, wheelchairs, patient gurneys, intravenous poles, and defibrillators have all been turned into projectiles capable of severe harm. When nonmedical people enter the magnet room, things can get even worse. In one instance, a police officer's gun discharged as it was sucked out of his grip; in another, a firefighter was trapped and nearly suffocated as he was drawn into the bore when the breathing apparatus strapped to his back became magnetized in the MRI room. Only slightly less dangerous—because the people involved managed to escape injury—are several documented incidents involving mop buckets, vacuum cleaners, toolboxes, and other everyday items.[2]

Force Fields

The phenomenon by which metal becomes spontaneously magnetized is ferromagnetism, which affects iron, nickel, cobalt, and many other familiar metals and alloys. Although most implants today are made with titanium or other nonferromagnetic metals, it's common knowledge that MRI systems can affect older angio and cerebral clips, bone pins, dental work, and even some tattoo dyes. That's the key reason patients are screened. What's less recognized is how MRI scanners may interfere with devices such as pacemakers, pulse oximeters, automated defibrillators, cardiac monitors, insulin pumps, cochlear implants, and vagus and other neurological stimulators.

Many people believe MRI radio frequency (RF) shielding acts like the lead shielding in a CT room, keeping the hazard trapped in the scanning room, "but that's not the case," says Gilk. "MRI interacts with its own space, and the spaces around it, in a way that's entirely different." Where a CT installation's lead shielding is designed to keep radiation inside, MRI shielding keeps stray radiowaves out. "The focus is on protecting the magnet from interference, not the other way around," says Gilk.

Plate steel is the only physical material that can contain an MRI system's magnetic field. "The lines of force penetrate brick, wood, concrete, cement—which means that not only people outside the MRI suite but even people and machines outside the building can be affected," Gilk explains. "Any steel in the building construction reshapes the magnetic fields in the MRI, and MRI magnetizes the steel in the building. So the levels of complexity are several orders of magnitude greater than a CT, even though they may not look all that different on the floor plan."

Current designs using plate shielding, however, usually are not equipped to deal with the newest crop of 3 Tesla (3T) commercially available systems—and even higher-powered research magnets. Compare, for example, the typical few millimeters of steel plate with the 14-inch–thick, 500-ton shielding New York University recently installed around its new 7T whole-body scanning system. Gilk likens the result of inadequate shielding to swimming in a lake during a thunderstorm: "Steel is to magnetic force as water is to electricity—it offers a more efficient conductor."

Active Shielding

Many, if not most, of the MR systems used in the United States today have little if any steel shielding. Instead, most incorporate active shielding, which uses secondary magnets on the MR magnet to compress its field and reduce the footprint. However, says Gilk, these don't always work as intended. "The potential exists for the active shield magnets on certain systems to fail independently of the primary magnet. When this occurs, the magnetic field grows to two to three times its previous size. So the hazards you think are limited to the magnet room, or only in the MRI suite, may very well expand all around you."

Without proper shielding, patients outside the MRI suite can be seriously affected in ways that may not be immediately apparent. "The magnet can shift a device, alter function, or disrupt its operation even if it doesn't stop it," notes Gilk. "For device-dependent patients, that interruption can be fatal. There have been instances of medical device settings being changed momentarily that had longer-lasting impact."

In the same way, MRI magnets have been known to affect gamma cameras, nuclear medicine hot labs, PET/CT scanners, and other equipment—even those sited at what seems a reasonable distance. “The extraordinary sensitivity of today’s [imaging] systems—the same feature that makes them so valuable—makes them vulnerable to such disruptions. You don’t want to expose them to anything significantly above normal,” he says. “Basically, any magnetic force stronger than the one that makes a compass point north can disrupt or degrade some types of this equipment.”

In one worst-case instance, Gilk recalls, a major institution removed its MRI system and installed a PET/CT system in the same room. Although the hospital had purchased a top-of-the-line model, “they were never able to get the clinical-quality images that they expected out of this incredibly expensive new equipment.” Despite repeated vendor testing and adjustments, after more than one year of disappointing results and added expense, they finally realized that the thin steel shielding left from the MRI had become permanently magnetized, emitting a very low-level but nonetheless detrimental influence.

Worse, the vendor who sold the MRI, bought it back, and dismantled it was the same vendor who sold and installed the PET/CT system. “So a single vendor was involved in the entire chain of events, and even the vendor didn’t know where to look for the source of the problem,” notes Gilk.

Venting Cryogen Gases

Like the magnetic field, MRI’s other hazard is invisible. It’s also odorless and tasteless, meaning that a leak in the cryogen piping can easily go undetected until it’s too late. Again, while such events are extremely rare, they have occurred—and most existing MRI facilities are unprepared to handle them.

Today’s superconducting MRI systems are designed to vent liquid helium via an integral duct system that releases the gas outside the building both automatically and on command. When a system “quenches,” however, all the cryogens discharge at once. Although most quenches are triggered either manually or as a result of technical or environmental problems, one or two systems quench each year without any discernable cause, says Gilk. “These situations are generally not a question of the magnet’s function.”

Sometimes during quenches the cryogen blasts into the magnet room, where it can pose a series of threats to patients and staff. As the gas expands, pressure within the room increases dramatically. “Inside the typical magnet are as much as 1,000 liters of liquid helium. As it warms up, 1 liter of liquid helium has an expansion ratio of 760 to one,” Gilk points out. “If all the liquid helium were let loose into a magnet room the size of one shown in the average vendor template, it would expand to about five times the volume of air already there.” That would pin an inward-swinging door shut against the frame. Because magnet room doors are so large, a 1/2 pound per square inch would exert approximately 1 ton of pressure on the door, making escape virtually impossible until the pressure can be equalized.

C-C-C-Cold!

At roughly 450° F below zero, liquid helium also creates a severe hypothermic risk; people can suffer serious burns. Because the cryogenic helium gas will liquefy oxygen out of the air, both asphyxia and fire are real threats. “Add a spark of static electricity, and you’ve got a virtually inextinguishable fire,” says Gilk.

Unlike missile accidents, where some culpability can be assessed to human error, quenching can be the result of completely uncontrollable circumstances. Power failure, vibrational shock, and temperature swings, such as those occuring during earthquakes and severe storms, can affect an MRI unit if its setting is not well protected. Immediately following Hurricane Katrina, for example, Gilk's firm sent a memo to MRI operators in the affected states reminding them to "treat the magnet as if it could quench at any time." Given the magnitude of Katrina's devastation and the general lack of preparedness among facilities, he considers some MRI incidents almost inevitable. "We know last year's hurricanes caused at least one magnet in Florida to quench, not from storm damage but from power failure," he says.

Attracting New Attention

Despite recognized risks, records of MRI accidents and safety failures remains largely anecdotal. Typically, unless a person is injured or equipment is damaged, the incident won't be reported at all—because there is no requirement to do so at either the federal or state level. The FDA's Medwatch database, which doesn't categorize MRI-related incidents separately from other accidents involving medical devices, lists fewer than 100 incidents per year. Most of those were posted by vendors to document scanner problems.

"The FDA has drawn a funny line in the sand," says Gilk. The agency regulates device design, but not device siting. "If the MRI machine itself emits a greater dose of RF energy than it's designed to, and if the patient absorbed that excess RF energy, that's a device failure," which clearly comes within the agency's purview. "But if the magnetic field is within normal operating parameters, [an accident or near-accident] doesn't need to be reported."

Many experts agree with Gilk that MRI mishaps "happen with alarming frequency." Some experts estimate that close calls in the MRI suite occur on the order of approximately one per month. Even the anecdotal evidence, says Gilk, "suggests that big accidents, the kind that require bringing the magnet down, happen about once every five years for each MRI system."

One of the most frequently quoted studies on MRI safety hazards was published in 2000 by radiologists at the University of Texas. Reviewing some 138,000 scans covering 15 years revealed that incidents where patients or workers were injured or narrowly escaped injury have risen sharply since 1987. The authors concluded that as MRI becomes more widely available and is used more often on a broader range of patients, the potential for accidents increases. The Texas study only covers incidents reported up to five years ago; according to most available information, MRI-related incidents continue to increase.[3]

Depending on the Vendors

To date, MRI original equipment manufacturers "have had a somewhat unique position because of the lack of [operational] regulation," Gilk says. The technology has evolved so swiftly and spread so rapidly that both the government and medical communities have come to rely on scanner vendors as the prime—and sometimes only—source of information. "Fifteen years ago, when MRI was 'the new kid on the block' and everything came from the vendors," Gilk says, "people got complacent and accepted the idea that that's the way MR information is distributed, henceforth and forever after."

One result is that currently most of the market leaders offer MRI site layout templates, often in engineering a computer-aided design format that enables a facility's architects to "cut and paste" plans into their own location blueprints. The attitude that "the vendor must know more about this than I do" prevails—and is one of the largest hurdles to improving MRI site design safety, says Gilk. "MRI buyers don't fully read or always understand the fine print in the vendor-developed plans, which essentially says that the siting design and template serves one function: to provide a space that meets the minimum technical operational and service requirements for that given device. The templates have nothing to do with maximizing imaging quality, or with suite safety. And they only reluctantly address safety within the magnet room itself."

Beyond the obvious issue of liability, says Gilk, "every MRI really has to fit a specific patient care need in its individual setting. An MR system in a children's hospital doesn't serve the same function as one in an outpatient imaging facility, which in turn doesn't serve the same function as one in an emergency department. Each facility has different patient populations, demands, acuity levels, and so on. The design of the suite should be tailored to each and every one individually. And that degree of hand-holding is probably not a game that any of the major MRI manufacturers want to get into."

He adds, "Nobody should regard vendor-provided information as suspect in any way. To do that is ignoring crucial information about what needs to be [in the MRI suite]—and what should not be there—for the equipment to operate correctly. But people who take [vendor templates] as the ending point rather than the starting point can be compromising the safety and operational and image quality of an incredibly sophisticated technology."

Sharing Responsibility

Medical architects must take a slice of the responsibility, too, he adds. "Architects have not done a great job of promulgating the information that designers really ought to know about MRI facilities." For example, he notes that the leading designers' text, Guidelines for Design and Construction of Hospital and Healthcare Facilities, which is published by the American Institute of Architects and Health and Human Services, does not include the ACR White Paper safety recommendations in its most recent revision.

That's important because JCAHO relies on the guidelines text as its chief reference for clinical area design standards within hospitals and other healthcare facilities. Says Gilk, "The ACR White Paper came out some years ago, and earlier this year the AIA closed its revision process for the 2006 edition, yet there are only about five sentences worth of MRI siting guidance [in the manuscript]. There's about four times as much information on the design of a laundry facility… It may be another three years, 2009, before architects are really given [an objective] resource for designing more effective, efficient, safer imaging facilities."

Setting Safer Standards

Fortunately, Gilk says, system vendors do such great jobs of designing the magnets themselves that lethal accidents are rare, but "vendors leave everything outside the MRI suite up to [the buyer]." Dealing with the issues in a uniform fashion was precisely the point of the ACR White Paper. Yet, the ACR guidelines aren't always implemented or even disseminated effectively.

The second installment of this series will examine what the guidelines actually detail, how they can be implemented, and where the momentum for continuous safety improvement may come from in the future.

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For More Information

In the wake of the Valhalla, N.Y., accident, many Web sites now address MRI safety issues, including Junk Architects, PC at www.mri-planning.com. Other sources include professional organizations, continuing medical education institutions, government agencies, vendors, and sites compiled by radiologists and medical physicists. Here are some of the most informative and interesting sites available:

http://199.96.2.32/AHRAArticles/AHRAArticles.dll/Show?ID=272

http://www.acr.org/s_acr/bin.asp?CID=3260&DID=12183&DOC=FILE.PDF

http://www.acr.org/s_acr/sec.asp?CID=

http://www.ajronline.org/cgi/content/full/177/1/27?

http://www.asahq.org/Newsletters/2002/6_02/litt.html

http://www.ecri.org/Include/Docs/hazard_MRI_080601.pdf

http://www.fda.gov/cdrh/ode/primerf6.html

http://www.fda.gov/cdrh/safety/mrisafety.html

http://www.gehealthcare.com/usen/mr/mrsafety/index.html

http://www.ismrm.org/mr_sites.htm

http://www.MagneticResonanceSafetyTesting.com

http://www.MRIsafety.com

http://www.patientsafety.gov/alerts/MRI.doc

http://www.patientsafety.gov/SafetyTopics/mrihazardsummary.html

http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=419408

http://www.radiology.upmc.edu/MRsafety/

http://www.refindia.net/rlinks/reviewedlinks/MRI_safety.htm

http://www.simplyphysics.com/flying_objects.html

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1. Carr M, Grey ML. Magnetic resonance imaging: Overview, risks, and safety measures. AJN. 2002;102(12):26-33.

2. Rogers LF. MR safety: Better safe than sorry. AJR. 2002;178:1311.

3. Chaljub G, Kramer LA, Johnson RT, et al. Projectile cylinder accidents resulting from the presence of ferromagnetic nitrous oxide or oxygen tanks in the MR suite. AJR. 2001;177:27-30.