MR Safety

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INTRODUCTION

To date we have seen virtually no long-term adverse biological effects of extended exposure to MRI as a whole. However, if we examine separate components of the magnetic resonance imaging process we observe several effects of magnetic, gradient and radio frequency fields. Most are inconsequential and reversible, however, there are certain patient and operator risks, which should be discussed. The need to evaluate MR for potential risks and hazards is clear and, in order to validly discuss long-term biological effects of MRI, we should consider all of the components of the imaging process. Those elements include not only the main magnetic field also known as the static magnetic field, but also time varying magnetic fields caused by magnetic field gradients, and radiofrequency fields created by RF transmitter and receiver coils.

THE MAIN MAGNETIC FIELD

The main magnetic field is also known as the static magnetic field. This field is responsible for the alignment of nuclei for magnetic resonance imaging. In solenoidal electromagnets the field is generally horizontal whereas in permanent magnets the field is generally vertical (figures 1 and 2).

FIGURE 1: Horizontal Field

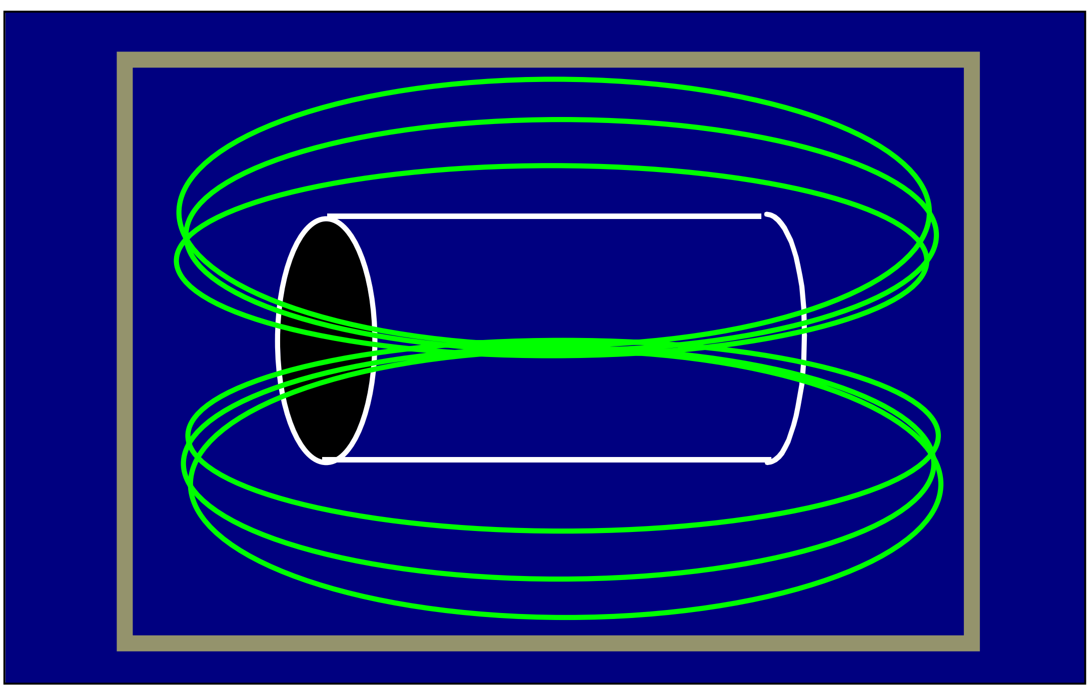
FIGURE 2: Vertical Field

Biological Effects of the Static Magnetic Field

The primary concern with the static (main) magnetic field is the possibility of potential biological effects. In nature, the magnetic field associated with the earth does have significant effect on lower life forms. The orientation of magneto-static bacteria and the migratory patterns of birds are influenced by the .6 gauss magnetic field,which surrounds the earth. In MR, Small electrical potentials have been observed in large blood vessels, which flow perpendicular to the static magnetic field, however even at 10 T no adverse effects have been noted on the ECG's of squirrel monkeys. The majority of studies show no effects on cell growth and morphology at field strengths below 2 T. Furthermore, no evidence of adverse effects have been noted in persons working with linear accelerators who are exposed to large static magnetic fields. The current FDA limit for a clinical MR system is 4 Tesla.

Fringe Fields

The secondary concern of the effects of the main magnetic field is the hazards of siting of MR imagers. The static magnetic field has no respect for the confines of conventional walls, floors or ceilings. The stray magnetic field, outside the bore of the magnet, is known as the fringe field. Although most magnetic resonance imagers today are magnetic field shielded, so as to confine the fringe field to an acceptable location either within the scan room or in the case of a mobile MR system to within the confines of the truck itself, we must still be aware of the field when the final siting decision is made. Even the field strength felt high above the floor below the imager must be considered when siting, to prevent the untimely demise of a painter with a pacemaker who inadvertently climbed a ladder to paint the ceiling (figure 3).



Passive shielding can be achieved with iron in the walls of the scan room. Active shielding uses additional coils within the magnet housing to confine the fringe field.

Static Fields Below 2T

Although no biological effects have been observed in human subjects at field strengths below 2T, reversible abnormalities have been noted on electrocardiograms (ECG's). An increase in the amplitude of the T-wave is noted on the ECG due to the Magnetic Hydrodynamic Effect or the Magnetic Hemodynamic Effect. This effect is produced when a conductive fluid, in this case blood, moves across a magnetic field. This effect is proportional to the strength of the magnetic field and tends to present problems for cardiac gating techniques in high field scanners. Gating problems occur when the system recognizes and tries to trigger from, the T-wave rather than the R-wave. Image quality suffers as a result of insufficient cardiac gating. However, no serious cardiovascular effects have been observed in patients, and it is totally reversible by removing the patient from the magnet (figure 4).

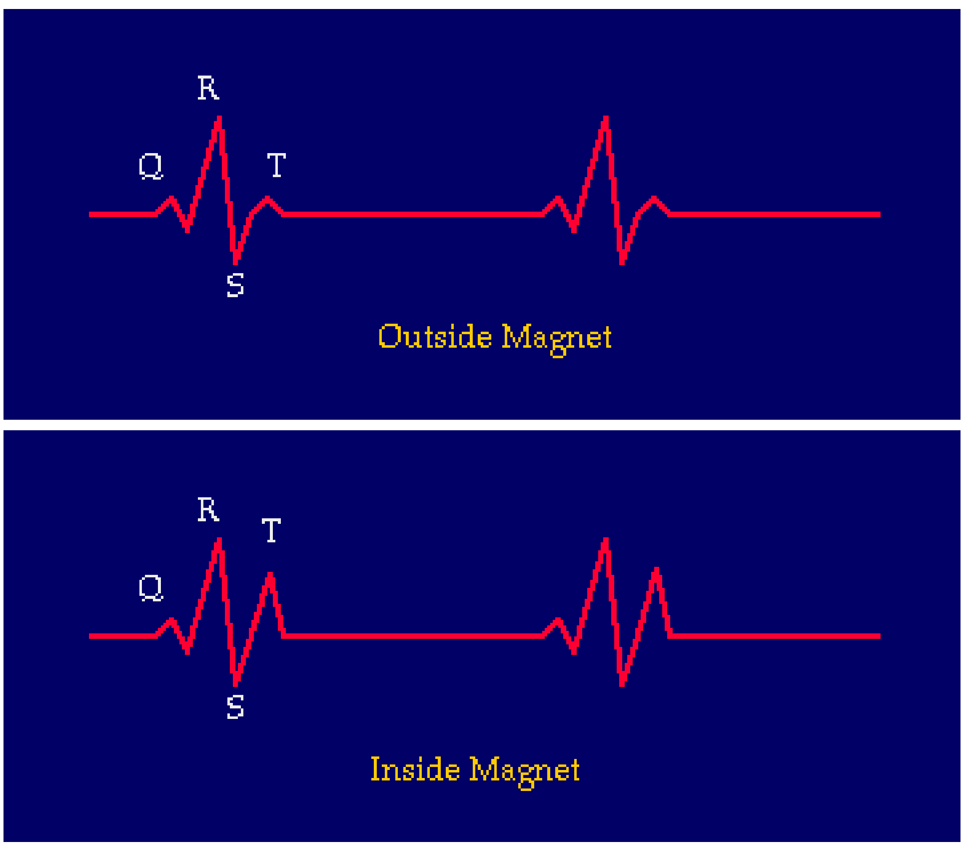


Figure 4

Pregnant Patients

The Safety Committee of the Society for Magnetic Resonance Imaging published Policies, Guidelines, and Recommendations for MR Imaging Safety and Patient Management in 1991. Those guidelines stated, "MR imaging may be used in pregnant women if other nonionizing forms of diagnostic imaging are inadequate or if the examination provides important information that would otherwise require exposure to ionizing radiation (e.g., fluoroscopy, CT, ect.). It is recommended that pregnant patients be informed that, to date, there has been no indication that the use of clinical MR imaging during pregnancy has produced deleterious effects. However, as noted by the FDA, the safety of MR imaging during pregnancy has not been proved."

Pregnant Employees

MR imaging facilities have established individual guidelines for pregnant employees in the magnetic resonance environment. The majority of facilities have adopted the policy that pregnant employees can safely enter the scan room of superconductors in which the magnetic field is on, but stay out while the scanner is running during which time the RF and gradient fields are employed. Some facilities have a policy that requires the employee stay out of the magnetic field entirely during the first trimester of pregnancy.

A survey conducted by Dr. Emanuel Kanal showed no increased incidence of spontaneous abortions among MR technologists and nurses. (It should be noted that the incidence of spontaneous abortions is roughly 30% of all pregnancies.) Following that survey, Dr. Kanal's facility changed their in-house policy from one in which technologists were kept out of the magnetic field during pregnancy, to a policy which allows pregnant technologists in the room to set up the patient but not to remain during image acquisition. It has been suggested that informed workers make their own decision. This recommendation was influenced by a U.S. legal decision concerning the rights of pregnant workers in hazardous environments.

Projectiles

Ferromagentic metal objects can become airborne and act as rockets known as projectiles in the presence of the strong static magnetic field (figure 5). Small ferromagnetic objects such as paper clips and hair pins will have a terminal velocity of 40 mph when pulled into a 1.5 tesla magnet.

Even surgical tools such as hemostats, scissors and clamps, while made of a material known a "surgical stainless steel", are highly attracted to the main magnetic field. Conventional oxygen tanks are also highly ferrous and are attracted to the static magnetic field. They should never be brought into the scan room, however there are non-ferrous O2 tanks which are MR compatible. Sand bags have also become suspect since many are filled, not with sand, but will steel shot, which is highly ferrous. It is recommended that all objects be tested with a hand-held bar magnet for attractive potential before entering the MR scan room. Also it is advised that all nursing, housekeeping, fire department, emergency and MR personnel be educated to the potential risks and hazards of the static magnetic field. Signs should be posted to deter possible entry into the scan room with ferromagnetic objects. Metal detectors are available, but can, in most cases offer a false sense of security. It is recommended the general public be kept outside fields of 5 - 15 Gauss.

IMPLANTS AND PROSTHESIS

As we look at metallic implants and their safety profile in the MR environment we see three serious effects which include; torque, heating and artifacts. Therefore, before we consider imaging patients with MR we must be aware of surgical procedures that the patient has undergone prior to the MR examination.

Torque and Heating

Some metallic implants have shown considerable torque when placed in the presence of a magnetic field. The force or torque exerted on small and large metallic implants can cause serious effects, as unanchored implants can potentially move unpredictably within the body. The type of metal used in such implants is one factor, which determines the force exerted on them in magnetic fields. While non-ferrous metallic implants may show little or no deflection to the field, they could cause significant heating due to their inability to dissipate heat caused by radiofrequency absorption.

Artifacts from Metallic Implants

Although artifacts cannot be considered as a biological effect of the MR process, misinterpretation of MR images can yield devastating consequences. It should be noted that the type of metal, as well as size of the metallic implant, determines the size of the artifact noted on the MR image. The field strength of the MR system and well as the pulse sequence (i.e. gradient echo or Fast Spin Echo) will also effect the size of the artifact. Therefore, if a metal-type artifact is noted on the MR image and no metal is present within the patient, this could indicate the presence of blood products suggestive of a hemorrhagic lesion.

Aneurysm Clips

The presence of some intracranial aneurysm clips is an absolute contra-indication to MR imaging. A recent study found that some clips which were labeled by the manufacturer as safe for MR imaging exhibited ferromagnetic properties such as rotation and even translation. Within the patient, clip motion may damage the vessel, resulting in hemorrhage, ischemia or death. Currently, it is recommended that patients with intracranial aneurysm clips be examined by MRI only if the clip is definitely known to be non-ferrous. It is recommended that written documentation be available as to the make and model of the clip to facilitate checking the MR compatibility. A up-to-date listing of implants and compatibility can be found at http://www.mrisafety.com.

Heart Valves

Twenty-five of 29 heart valve prosthesis were evaluated for magnetic susceptibility and showed considerable deflection to the magnetic field. The deflection, however was minimal compared to pulsatile cardiac motion. Most Starr-Edward valves at the present time are safe, however model Pre-6000 is an absolute contraindication for MR imaging. Therefore, patients with most valvular implants are considered safe for MR however, since there are valves whose integrity is compromised, careful screening for valve type is advised.

Dental Devices and Materials

Twelve of 16 dental implants showed measurable deflection to the magnetic field, however most are thought to be safe for MR imaging. Although most devices are not significantly effected by the magnetic field, susceptibility artifacts can adversely effect image quality in MR especially in gradient echo imaging. It should be noted, however, some dental devices are magnetically held in place and therefore can pose potential risks for MR imaging.

Penile Implants

Only one of 9 penile implants tested showed measurable deflection to the magnetic field. Even though the Dacomed Omniphase has shown measurable attraction to the magnetic field, it is unlikely that this could cause severe damage to the patient. However, it is likely that this would be uncomfortable and it may be advised to use an alternative imaging procedure for diagnosing these patients.

Otologic Implants

Three of 3 cochlear implants were attracted to the magnetic field, are magnetically or electronically activated and pose contraindications to MR imaging. Many patients with otologic implants have been issued a card warning them to avoid MR imaging.

Ocular Implants

Of 12 ocular implants tested two were deflected by a 1.5 T static magnetic field. The Fatio eyelid spring could cause discomfort and the retinal tack could injure the eye since they are made from stainless steel and are effected by the main magnetic field.

Intra-Ocular Ferrous Foreign Bodies
Another concern of metallic implants in and around the eye is the potential problems caused by intra-ocular ferrous foreign bodies. It is not uncommon for patients who have worked with sheet metal or who had been employed welding to have metal fragments or slivers located in and around the eye. Since the magnetic field exerts a force on ferromagnetic objects, a metal fragment in the eye could move or be displaced, and cause injury to the eye or surrounding tissue. It is true that small intra-ocular fragments could be missed on a standard radiograph. However, a recent study demonstrated that metal fragments as small as 0.1 X 0.1 X 0.1 mm were detected on standard radiographs. Also metal fragments from 0.1 X 0.1 X 0.1 mm to 0.3 X 0.1 X 0.1 mm were examined in the eyes of laboratory animals in a 2.0 T magnet. Only the 0.3 X 0.1 X 0.1 mm fragments moved (rotated) but did not cause any discernable clinical damage. Therefore, although CT is more accurate in detecting the presence of a small foreign bodies, plain film radiography is considered the accepted standard in screening for intra- ocular ferrous foreign bodies with sufficient size to cause ocular damage.

Bullets Pellets and Shrapnel
Although a majority of ammunition has proved to be made of nonferrous materials, ammunition made in foreign countries or produced by the military has shown traces of ferromagnetic alloys. Also, in an effort to reduce lead poisoning in ducks, the U.S. government has required the use of steel-shot instead of lead, which could produce a potential hazard in patients who have inadvertently been shot. Therefore, it is advised to take extreme caution in imaging patient with bullets or shrapnel and to be aware of the location of such metal within the body.

Orthopedic Implants, Materials and Devices
Each of 15 orthopedic implants tested showed no deflection within the main magnetic field. However, sufficient currents being induced in the metal by the magnetic and radiofrequency fields can heat a large metallic implant such as a hip prosthesis. It appears however, that such heating is relatively low. Therefore, a majority of orthopedic implants have been imaged with MR without incident.

Surgical Clips and Pins
Abdominal surgical clips are generally safe for MR imaging because they become anchored by fibrous tissue. Metallic implants also produce imaging artifacts in proportion to their size and can distort the image.

Halo Vests and Other Similar Externally Applied Devices
When we plan imaging a patient wearing a halo vest we need to consider several risk factors which include; deflection and subsequent dislodging the halo, heating due to RF absorption, electrical current induction within the halo rings, electrical arcing and severe artifactual consequences which could render the imaging acquisition useless. There are commercially available nonferrous and nonconductive halo vests, which are MR compatible. Therefore, in light of the potential risks and hazards associated with halo vests, it may be advised to be certain the halo vest can be safely worn during the study

before proceeding with MR imaging. One should also carefully examine and even test the screws used in such halo vests to ensure they are not ferrous.

Electrically, Magnetically or Mechanically Activated or Electrically Conductive Implanted Devices

Certain implanted devices are contraindicated for MR imaging because they are either magnetically, electrically or mechanically activated. These implants include; cochlear implants, tissue expanders, ocular prosthesis, dental implants, neurostimulators, bone growth stimulators, implantable cardiac defibrillators, implantable drug infusion pumps as well as the more commonly known cardiac pacemakers. (Pacemakers will be discussed later in more detail.) The functionality of such implants will be impaired by the magnetic field within the imager, therefore patients with such implants should not be imaged with MR. Also, devices which dependant on magnetization to affix to the patient such as magnetic sphincters, magnetic stoma plugs and magnetic prosthetic devices could be demagnetized and should be removed prior to (or contraindicate) MR imaging.

Pacemakers

Cardiac pacemakers are an absolute contraindication for MRI. Even field strengths as low as 10 gauss may be sufficient to cause deflection, programming changes or to close the reed switch and convert a pacemaker to an asynchronous mode. Also, even in patients were the pacemaker has been removed remaining pacer wires could act as an antenna and by induced currents, cause cardiac fibrillation. Warning signs should be posted at the 5 gauss line to prevent the exposure of anyone with a pacemaker or other electronic implants.

GRADIENT MAGNETIC FIELDS

All MR imaging systems are equipped with a set of resistive wire windings known as gradient coils. Gradients provide position dependent variation in magnetic field strength and are pulsed on and off during and between RF excitation pulses. The purpose of these gradients is to spatially encode information contained in the emitted RF signal however, in doing so, they create a time-varying magnetic field (TVMF). Figure 6 is an example of the gradient coils creating a varying magnetic field in the Z direction. There are actually 3 sets of gradient coils capable of producing a TVMF in all three orthogonal directions (X, Y, and Z). For oblique imaging, gradient coils are used in combination (Figure 6)

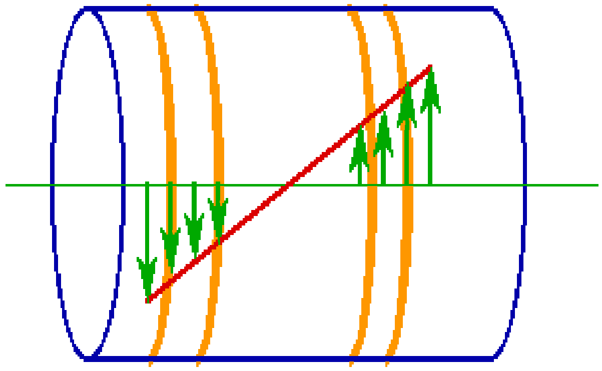


FIGURE 6

Time-Varying Magnetic Fields

There have been a large number of studies performed on the biological effects from TVMF since they exist around power transformers and high voltage lines in today’s environment. The health consequences are not related to the strength of the gradient field, but rather changes in the magnetic field that causes induced currents. In MR, the safety concern is with the nerves, blood vessels and muscles that act as conductors in the body. According to Faraday's law of induction, changing magnetic fields will induce electrical currents in any conducting medium. Induced currents are proportional to the material conductivity, the rate of change of the magnetic field and the radius of the inductive loop. In MR this effect is determined by factors such as pulse duration, wave shape, repetition pattern, and the distribution of the current in the body. The induced current is greater in peripheral tissues since the amplitude of the gradient is higher away from isocenter.

The amplitude or maximum slope of the gradient magnetic fields in given in units of mT/m or G/cm. A maximum amplitude of 10mT/m is equivalent to 1G/cm. Most systems manufactured until early 1996 had maximum gradient amplitudes of 8mT/m to 10mT/m. Newer system, particularly high field systems, now have maximum gradient amplitudes of up to 25mT/m. Safety concerns do not necessarily center around the higher amplitudes, but rather how fast the gradient fields reach that amplitude. The time for gradient fields to reach maximum amplitude is known as "Rise Time" and is given in units of microseconds (s). The faster the rise times, the greater the likelihood of peripheral nerve stimulation. Combining the maximum amplitude with the rise time gives rise to measurements expressed in dB/dt. As of December, 1996, the FDA limits on gradient are as shown in the table in Figure 7.

Maximum dB/dt 6 Tesla/second or less
For Axial Gradients
dB/dt < 20 T/s for T > 120 s;
or dB/dt < 2,400/t (s) T/s for 12 s < T < 120 s;
or dB/dt < 200 T/s for T < 12 s
Figure 7

Biological effects vary with current amplitude from reversible alterations in vision, to irreversible effects of cardiac fibrillation, alterations on the biochemistry of cells and in some cases, inspired fracture union. Studies also show stimulation of bone healing by inducing an electrical field and then altering the magnetic field to the direction of the desired area of interest. Effects experienced in MR, rang from mild cutaneous sensations, involuntary muscle contractions to cardiac arrhythmias. Visual effects occur when retinal phosphenes are stimulated by induction from TVMF and light flashes or "star's in one's eyes" are the end result. These studies were performed on human and animal subjects and were performed at field strengths up to 3T.

Acoustic Noise

As we activate and deactivate current through the gradient coils during image acquisition, we create a significant amount of acoustic noise. Temporary hearing loss has been reported using conventional sequences. Gradient noise may also interfere with patient communication. An acceptable and inexpensive means for the prevention of hearing loss is the regular use of disposable earplugs. A more expensive alternative would be "anti-noise" or destructive noise apparatus, which, not only reduces noise, but also permits better communication between the operator and the patient. As gradient amplitudes increase and rise times decrease, acoustic noise becomes greater.

RADIOFREQUENCY FIELDS

Exposure of the patient to radio frequency occurs during MR examinations, as the hydrogen nuclei being imaged are subjected to an oscillating magnetic field. The source of this radiation is the radiofrequency coils that surround the patient inside the magnet bore.

Radiofrequency Irradiation

As the energy level of frequencies used in clinical MR imaging is relatively low when compared to x-rays, visible light and microwaves, the predominant biological effect of RF irradiation absorption is the potential heating of tissue. Although non-thermal effects have been reported, to date they have not been confirmed. As an excitation pulse is applied, some nuclei absorb the RF energy and enter the high energy state. As they relax, nuclei give off this absorbed energy to the lattice. In frequencies below 100 MHz, 90% of absorbed energy results from tissue currents (eddy currents in tissues) induced by the magnetic component of the radiofrequency field. As we increase frequency we increase absorbed energy, therefore, heating of tissue is largely frequency dependant. For this reason, in MR systems operating below 1.0 Tesla, RF heating becomes less of a concern.

Specific Absorption Rate (SAR)
MR imaging systems cannot measure RF exposure, therefore, it is necessary to measure RF absorption which is manifested as tissue heating. The health related issue of RF heating is the patient's ability to dissipate excess heat. Energy dissipation can be described in terms of Specific Absorption Rate (SAR). SAR is expressed in Watts/Kg, a quantity that depends on induced electric field, pulse duty cycle, tissue density, conductivity and the object radius. Knowing the patients weight and the pulse sequence parameters allows for proper monitoring of SAR. Therefore, care must be taken in recording the patient's proper weight to ensure the SAR does not exceed the permitted levels. SAR can be used to calculate an expected increase in body temperature, in an average examination we could expect the body temperature to rise from approximately 0 to 2' C.

In the United States, the FDA sets guidelines for SAR shown in the following table.

FDA SAR GUIDELINES
0.4 W/Kg whole body average
8 W/Kg peak in any 1 gram of tissue
3.2 W/Kg - head

In Canada, the recommended SAR level is 2 W/Kg.

Studies have shown that patient exposure up to three times the recommended levels produced no serious adverse effects despite the elevations of skin and body temperatures. As body temperature increases, we also expect to see an increase in blood pressure and heart rate. A study performed showed no significant increase in these vital signs. Even though these effects seem insignificant, patients having compromised thermo-regulatory systems may not be candidates for MR. Also those areas of the body with the inability to dissipate heat such as, the orbits and the testicles have been evaluated independently and in standard pulse sequences have shown no significant increase in temperature Corneal temperatures were shown to increase from 0' to 1.8' C. However as faster imaging sequences arise, these areas may need to be re-evaluated. Fast Spin Echo sequences are more of a concern relating to increases in SAR, especially the more advanced versions with higher echo train lengths (ETL or Turbo Factor).

RF ANTENNA EFFECTS

Radiofrequency fields can be responsible for significant burn hazards due to electrical currents that are produced in conductive loops. Equipment used in MRI such as ECG leads and surface coils should be used with extreme caution. When utilizing surface coils, the operator must be careful to prevent any electrically conductive material (i.e. cable of surface coil) form a "conductive loop" with itself or with the patient. Tissue or clothing could potentially be ignited by uninsulated cables. Coupling of a transmitting coil to a receive coil may also cause severe thermal injury. Routine checks of surface coils by the site's engineer should be performed to ensure proper function. It was recommended by the New York Academy of Science at a conference in which they presented "Biological Effects and Safety Aspects of NMR", that wires used in MR imaging systems should be electrically and thermally insulated. Although rare, considering the number of MR studies performed, second and third degree burns have occurred
.

CLAUSTROPHOBIA

Although claustrophobia, like other psychological effects seem less than critical in light of other biological effects of MRI, it is a condition that warrants mention. RF heating, gradient noise and the confines of the imager itself add to the possibility of claustrophobic reactions. Although the majority of these effects are transient, there have two reported cases of patients who were not reported to be claustrophobic prior to the MR examination, that had great difficulty in completing the examination, and developed persistent claustrophobia. These patients required long term psychiatric treatment. Therefore, it is important to have controllable air movement within the bore of the magnet to maintain a comfort zone for patients. This, along with good patient contact and education, could help reduce claustrophobic reactions, which clearly is a safety concern in MRI.

CRYOGEN SAFETY

Currently, all superconducting magnets use liquid helium to maintain the magnet coils at a temperature enabling superconductivity. The helium and magnet coils are maintained in a vacuum. The temperature of liquid helium is approximately -269 degrees C or 4.17 degrees K. Liquid helium will boil at 4.22 degrees K. Any disruption to the temperature or loss of the vacuum will cause the liquid helium within the magnet to "boil off" causing an immediate and sudden loss of the magnetic field. This event is referred to as a "quench". When this occurs, the helium will expand at a rate of approximately 760 to 1. This means that for every liter of liquid helium, 760 liters of gas would be produced. This marked expansion in volume causes the gas to rush out of the magnet and, under normal conditions, be vented outside the scan room and building. There have been several instances where this has not occurred resulting in the helium being vented into the scan room itself. Should this occur, it may very well be impossible for the operator to open the scan room door. This is due to the marked increase in air pressure inside the scan room since many systems may hold over 700 liquid liters of helium (760:1 expansion).

In the event of a quench, the patient should be removed from the scan room as quickly as possible. Although not immediate, asphyxiation can occur from breathing helium. Additionally, because of the extremely cold temperature of helium gas, frostbite is also a concern. In the event of a large change in room pressure, ruptured eardrums are also a possibility. Every site should have a written policy establishing what to do in the event of a quench.

SAFETY EDUCATION

Patient and personnel screening is, to date, the most effective way in which to avoid potential health hazards to patients in MRI. Patients and MR employees with questionable ferromagnetic foreign objects either in or on their bodies, should be rigorously examined so as to avoid any serious health risks and accidents. Careful questioning and education of patients and all personnel can achieve maintaining this controlled environment. In addition, routine preventative maintenance checks by the service engineer, and continuing education is also important. Therefore, careful planning and diligent upkeep of an MR facility can provide a safe environment for both patients and employees.

The link below will take you to an MRI web site maintained by Dr. Frank Shellock. This site includes current books, which can be ordered via the web site, as well as a current list of implants and devices tested for MR compatibility.

MRI Safety Web Site: http://www.mrisafety.com

If you have an internet connection, clicking on the above link will open the MRI Safety Web page.