



MR-guided Focused Ultrasound for Uterine Fibroids

Magnetic Resonance-guided Focused Ultrasound (MRgFUS) uses ultrasonic pulses to heat up and destroy fibroid tumors — abnormal benign growths in a woman's uterus. Also known as focused ultrasound surgery, it uses MR guidance to accurately target the fibroids and spare healthy tissue.



Tell your doctor about any health problems, recent surgeries or allergies and whether there's a possibility you are pregnant. The magnetic field is not harmful, but it may cause some medical devices to malfunction. Most orthopedic implants pose no risk, but you should always tell the technologist if you have any devices or metal in your body. Guidelines about eating and drinking before your exam vary between facilities. Unless you are told otherwise, take your regular medications as usual. Leave jewelry at home and wear loose, comfortable clothing. You may be asked to wear a gown. If you have claustrophobia or anxiety, you may want to ask your doctor for a mild sedative prior to the exam.

What is Focused Ultrasound of Uterine Fibroids?

Magnetic Resonance-guided Focused Ultrasound (MRgFUS) is a noninvasive, incisionless technique used to treat abnormal benign growths in a woman's uterus called fibroid tumors or fibroids. Uterine fibroids are very common, occurring in approximately one in four women, and often have no symptoms. However, in some cases, they can impair quality of life by causing such symptoms as:

- heavy menstrual bleeding
- prolonged menstrual periods
- pelvic pain and pressure
- frequent urination

MRgFUS works by delivering a series of targeted ultrasonic pulses, or sonications, to heat up and destroy the fibroids. The procedure, also known as focused ultrasound surgery or focused ultrasound ablation, is

performed under MR guidance to ensure accurate targeting of the fibroids while avoiding harm to adjacent, healthy tissue.

Magnetic resonance imaging (MRI) is a noninvasive test used to diagnose medical conditions.

MRI uses a powerful magnetic field, radio waves and a computer to produce detailed pictures of internal body structures. MRI does not use radiation (x-rays).

Detailed MR images allow doctors to examine the body and detect disease. The images can be reviewed on a computer monitor. They may also be sent electronically, printed or copied to a CD, or uploaded to a digital cloud server.

What are some common uses of the procedure?

MRgFUS is an incision-free option that offers a significant alternative to more invasive treatments such as hysterectomy, myomectomy and uterine fibroid embolization (also known as uterine artery embolization), all of which require hospitalization. Hysterectomy – a common treatment for fibroids – removes the uterus and prevents a woman from ever getting pregnant. MRgFUS helps preserve the uterus (and thus a woman's ability to potentially become pregnant) and is performed on an outpatient basis.

How should I prepare?

An MRI scan will be performed prior to treatment to determine if you are a good candidate for MRgFUS. Pre- and peri-menopausal women with fibroids of a manageable size that are not surrounded by bowel or bone are usually considered eligible. The MRI scan will also be used to help plan your treatment.

Guidelines about eating and drinking before an MRI scan vary with the specific exam and also with the imaging facility. Unless you are told otherwise, you may follow your regular daily routine and take food and medications as usual. The radiologist, technologist or nurse may ask if you have asthma or allergies of any kind, such as an allergy to iodine or contrast material, drugs, food, or the environment. The contrast material most commonly used for an MRI exam contains a metal called gadolinium. Gadolinium can be used in patients with iodine contrast allergy, but may require pre-medication. It is far less common for a patient to have an allergy to a gadolinium-based contrast agent used for MRI than the iodine-containing contrast for CT. However, even if it is known that the patient has an allergy to the gadolinium contrast, it may still be possible to use it after appropriate pre-medication. Patient consent will be requested in this instance.

MRgFUS will require an injection of contrast material into the bloodstream after the procedure to ensure that all of the fibroid has been treated.

You should also let the radiologist know if you have any serious health problems, or if you have had any recent surgeries. Some conditions, such as severe kidney disease, may prevent you from being given gadolinium contrast for an MRI. If you have a history of kidney disease or liver transplant, it will be necessary to perform a blood test to determine whether the kidneys are functioning adequately.

Jewelry and other accessories should be left at home if possible. Prior to the exam, you will be required to change into a gown supplied by the MRI clinic. All jewelry, including external body piercings, must be removed prior to the MRI scan for safety and to ensure better image quality.

In most cases, an MRI exam is safe for patients with metal implants. However, people with the following implants cannot be scanned and should not enter the MRI scanning area:

- most types of cochlear (ear) implants
- some types of clips used for brain aneurysms
- some types of metal coils placed within blood vessels
- many electronic devices such as cardiac defibrillators, pacemakers and neurostimulators

You should tell the technologist if you have medical or electronic devices in your body so that the safety of these devices may be assessed. These objects may interfere with the exam or potentially pose a risk to you, depending on their nature and the strength of the MRI magnet. Many implanted devices will have a pamphlet or card explaining the MRI risks for that particular device. If you have the pamphlet or card, it is useful to bring that to the attention of the technologist or scheduler before the exam. Some implanted devices require a short period of time after placement (usually six weeks) before being safe for MRI examinations. Examples include but are not limited to:

- artificial heart valves
- implanted drug infusion ports
- artificial limbs or metallic joint prostheses
- implanted nerve stimulators
- metal pins, screws, plates, stents or surgical staples

In general, metal objects used in orthopedic surgery pose no risk during MRI. However, a recently placed artificial joint may require the use of another imaging procedure. If there is any question of their presence, an x-ray may be taken to detect and identify any metal objects.

Patients who might have metal objects in certain parts of their bodies may also require an x-ray prior to an MRI. You should notify the technologist or radiologist of any shrapnel, bullets, or other pieces of metal which may be present in your body due to prior accidents. Foreign bodies near and especially lodged in the eyes are particularly important. Dyes used in tattoos may contain iron and could heat up during MRI, but this is a very rare problem. Tooth fillings and braces are usually not affected by the magnetic field, but they may distort images of the facial area or brain, so the radiologist should be aware of them.

See the MRI Safety page for more information.

What does the equipment look like?

The traditional MRI unit is a large cylinder-shaped tube surrounded by a circular magnet with a moveable

examination table that slides into the center of the magnet. MRgFUS is performed in a specialized unit that has a high-energy, focused ultrasound transducer set in the examination table which contacts the woman's lower abdomen. The transducer is a cup-shaped device attached to a moveable arm that is operated remotely by a radiologist situated in an adjacent room.

The computer workstation that processes the imaging information and allows the radiologist to operate the MRgFUS is located in a separate room from the scanner.

How does the procedure work?

With MRgFUS, the radiologist can focus ultrasonic energy on a single point inside the body without damaging the tissue around it. The process is similar to focusing sunlight with a lens to burn a hole in a leaf. Each sonication will destroy a small area of the fibroid, and the process is repeated until the entire fibroid has been treated.

Unlike x-ray and computed tomography (CT) exams, MRI does not use radiation. Instead, radio waves re-align hydrogen atoms that naturally exist within the body. This does not cause any chemical changes in the tissues. As the hydrogen atoms return to their usual alignment, they emit different amounts of energy depending on the type of body tissue they are in. The scanner captures this energy and creates a picture using this information.

In most MRI units, the magnetic field is produced by passing an electric current through wire coils. Other coils are located in the machine and, in some cases, are placed around the part of the body being imaged. These coils send and receive radio waves, producing signals that are detected by the machine. The electric current does not come in contact with the patient.

A computer processes the signals and creates a series of images, each of which shows a thin slice of the body. These images can be studied from different angles by the radiologist.

MRI is able to tell the difference between diseased tissue and normal tissue better than x-ray, CT and ultrasound.

How is the procedure performed?

MRgFUS is performed as an outpatient procedure in an MRI scanning room. The entire process typically takes several hours. Because light sedation is used, you will need someone to drive you to the facility and take you home afterward. In preparation for the procedure, you'll need to shave your lower abdomen between your pubic bone and bellybutton.

You will change into a gown before treatment. An intravenous line will be placed in one of your veins to inject contrast material and to give you medication for relaxation and pain.

You'll also have a Foley catheter inserted into your bladder to drain it during treatment, as filling of the bladder will displace the uterus and change the positioning of the fibroids. Ultrasound gel may be used to fill the rectum, which moves the uterus and the fibroids away from bowel or bone before sonication.

Additionally, you will be asked to wear compression stockings to prevent deep vein thrombosis (blood clots).

A pregnancy test is routinely performed before the procedure to avoid unintentionally harming a developing fetus.

Women should always inform their physician or technologist if there is any possibility that they are pregnant. However, MRI has been used for scanning patients since the 1980s with no reports of any ill effects on pregnant women or their unborn babies. Still, because MRgFUS includes an injection of a gadolinium based IV medication as well as medication to help reduce pain and discomfort during the procedure, pregnant women should not undergo MRgFUS.

Before treatment, you will be given a light sedative to help you relax.

Once in the MRI room, you will lie face down on the padded examination table with your arms extended forward and your head resting on a pillow. Your pelvis will rest on a gel pad to establish direct contact with the skin. A coil will be placed over your pelvis to aid imagin

Once the ultrasound transducer is positioned directly under the fibroid, the table is moved into the core of the MRI scanner. Your head, arms and shoulders will remain outside of the machine.

MRgFUS involves repeated sonications under imaging guidance. The MR images enable the radiologist to see the precise location of the uterine fibroids and the locations of nearby structures to be avoided, such as the bowel. While MRI monitors the targeted fibroid and surrounding structures, the ultrasound transducer focuses sound waves at a small area of the fibroid, raising its temperature high enough to destroy the fibroid cells without damaging other tissues.

Each sonication lasts about 15 to 25 seconds, during which time the radiologist monitors the progress and reviews temperature-sensitive images. Since each sonication treats a very small area, the process must be repeated until the entire fibroid is treated. The procedure usually requires 50 or more sonications and can take several hours to complete, depending on the size and number of fibroids treated.

Once the sonications are completed, you will receive an injection of contrast material so that the radiologist can study the MR images to make sure that the fibroid has been destroyed.

What will I experience during and after the procedure

You will be awake but lightly sedated throughout the procedure.

You will be alone in the scanner room but the radiologist and medical staff will be monitoring you through a glass window in the adjoining control room and with a two-way communication system, including a microphone and speaker. Staff will also come into the scanning room to check on you periodically.

The radiologist will inform you when the MR images are being acquired and when you are receiving sonications.

During treatment, it is normal to feel a warming sensation in the pelvic region. You also may experience

pain similar to that of a menstrual cramp. You can immediately stop the procedure at any time by using the handheld safety button provided to you. In addition, you'll be asked about your comfort level throughout the treatment so that your medication can be adjusted or other necessary changes can be made.

After the procedure is complete, you will rest for a few hours in the clinic while the sedative wears off. You'll then be able to return home. You should be able to resume your normal daily activities within a day or two after treatment.

You may experience some abdominal or pelvic pain in the days following the procedure. In most cases, this can be treated with over-the-counter medications such as ibuprofen (Advil, Motrin IB, others) or acetaminophen (Tylenol, others).

Occasionally MRgFUS may cause redness on your abdominal skin, skin burns, bleeding and/or bruising immediately after treatment. These effects usually resolve within a week or two.

Irregular menstrual bleeding may occur for a few weeks after the procedure.

Over months and even years, your body will gradually and naturally absorb the treated tissue.

Most women's fibroid-related symptoms significantly improve within the first six months after MRgFUS. Patients should continue to have symptom relief after three years of follow-up.

Who interprets the results and how do I get them?

MRgFUS is performed in a specialized clinic by an interventional radiologist or a specially trained diagnostic radiologist. The radiologist will send a signed report to your primary care or referring radiologist, who will share the results with you. You will have a follow-up MRI exam about six months after the procedure, or earlier if needed to assess the size of the fibroid.

What are the benefits vs. risks?

Benefits

- MRgFUS may provide rapid improvement of symptoms associated with uterine fibroids without invasive surgery.
- MRgFUS offers a brief recovery time and may allow a quick return to normal activities after the procedure.
- MRgFUS has a low risk of complications.
- MRgFUS may restore fertility in certain cases. A number of women have had successful pregnancies after treatment for uterine fibroids. However, the long-term effects of MRgFUS on a woman's ability to become pregnant and carry a baby to term are still being studied. Because MRgFUS hasn't been in use as long as other fibroid treatments, there is less long-term data

available on its safety and effectiveness and its effects on fertility and pregnancy.

- MRI is a noninvasive imaging technique that does not involve exposure to radiation.
- The MRI gadolinium contrast material is less likely to cause an allergic reaction than the iodine-based contrast materials used for x-rays and CT scanning.

Risks

- The MRI exam poses almost no risk to the average patient when appropriate safety guidelines are followed.
- If sedation is used, there is a risk of using too much. However, your vital signs will be monitored to minimize this risk.
- The strong magnetic field is not harmful. However, it may cause implanted medical devices to malfunction or cause distortion of the images.
- Nephrogenic systemic fibrosis is a recognized, but rare, complication related to injection of gadolinium contrast. It usually occurs in patients with serious kidney disease. Your doctor will carefully assess your kidney function before considering a contrast injection.
- There is a very slight risk of an allergic reaction if contrast material is used. Such reactions are usually mild and controlled by medication. If you have an allergic reaction, a doctor will be available for immediate assistance.
- MRgFUS may cause burns to the skin on your lower abdomen with possible scar formation.
- The procedure carries a possible, but rare, risk of bowel injury.
- MRgFUS may result in temporary or permanent nerve damage and cause numbness, muscle weakness, or sensory loss.
- Blood clots may occur as a result of the procedure.

What are the limitations of Focused Ultrasound of Uterine Fibroids?

MRgFUS may not be a good choice for some patients, including:

- women with multiple abdominal scars
- women with many fibroids or very large fibroids

As with many other fibroid treatments, MRgFUS may not be able to treat some fibroids. You may require further treatment if your symptoms return.

Not all insurance companies cover MRgFUS. Check with your provider for more information.

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