

# **Understanding and Using Magnetic Resonance Guided Focused Ultrasound Surgery (MRgFUS) for Treating Fibroids**

## **Slide 1: Understanding and Using Magnetic Resonance Guided Focused Ultrasound Surgery (MRgFUS) for Treating Fibroids**

I am Dr. Richard Chudacoff and I will be talking about the understanding of and using magnetic resonance-guided focused ultrasound surgery for treating fibroids. MR-guided focused ultrasound treatment for fibroids is now an option for all gynecologists.

## **Slide 2: Magnetic Resonance Guided Focused Ultrasound Surgery (MRgFUS)**

In 1926, the first study was conducted that showed that focused ultrasound could have a biologic effect on tissue. Over the past eight decades, research has been conducted to evaluate the potential use and safety of this technology. In the 1950s, focused ultrasound was evaluated primarily for Parkinson's disease and other brain-related disorders. The technique provides an approach for destroying diseased brain tissue, obviating the need for invasive surgery in treating these diseases. The biggest set-back was that the investigators did not have a good way of visualizing what was being treated. Clinical trials currently are underway in the treatment of breast, prostate, brain, liver and bone cancer, but the first approval for focused ultrasound treatment was granted by the FDA in October 2004. This was for ExAblate® 2000, for the treatment of uterine fibroids. ExAblate® 2000 is non-invasive, it is an outpatient procedure using high-intensity focused ultrasound waves to thermally ablate or destroy tissue and the magnetic resonance imaging is used to guide, monitor and control treatment.

## **Slide 3: MRgFUS Defined**

The MR is similar to how a camera is used during video laparoscopy. Scanning every three seconds, the MR allows us to determine the precise area of sonication and the energy dose into the desired treatment area. Thus, the MR guides the focused ultrasound energy using real time thermal imaging.

## **Slide 4: How MRgFUS Works**

As gynecologists familiar with the imaging applications of ultrasound, we are well aware that ultrasound energy can pass through skin, muscle, fat and other soft tissue. Low intensity ultrasound is used for diagnostic imaging and has no biologic effect on cells or tissue. High intensity ultrasound focused on a small target area raises the temperature of the tissue enough to destroy it – thermal ablation. This denatures proteins, causing irreversible cell damage. The resulting coagulative necrosis is relatively painless, much in contrast with the ischemic necrosis of uterine artery embolization. The tight focus of the ultrasound energy allows delivery of the intended dose to a precise location.

## **Slide 5: Focusing Sound Waves Inside the Body**

As kids, we used to focus sunlight through magnifying glasses to heat leaves and other objects.

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The focus of the energy would be great enough to burn a small area, yet putting a finger in the unfocused beam path would not cause an increase in temperature. High frequency ultrasound waves pass through the tissue in the same manner as a magnifying glass, to heat up an intended region of treatment without injury to tissue in the non-focused beam path.

### **Slide 6: Sound Waves**

In this manner, we can concentrate a precise and predetermined treatment dose to the targeted tissue without collateral injury.

### **Slide 7: Sonication**

The single exposure of focused ultrasound energy is called a sonication. Each sonication spot is between the size of a large grain of rice and a jelly bean. Multiple sonications are necessary to ablate the targeted fibroid tissue; for example, about 50 sonications are needed to ablate a 7 cm fibroid in a procedure that would take about 90 minutes.

### **Slide 8: Function of MRI**

Initial MR images are used to screen suitable patients, both for the number and characteristics of the myoma, as well as other potential obstacles that need consideration before and during treatment. MR images are of high enough resolution to distinguish fibroid boundaries and structures such as sacral nerves to ensure safe treatment. MR also differentiates leiomyomas from adenomyomas, adenomyosis and possible invasive disorders. Planning MR images on the day of treatment allows the team to position the patient in relation to the transducer, targeted tissue and obstacles such as bowel, bone and nerve roots. Real time thermal images are received during the treatment, which assures the gynecologist that sufficient ultrasound energy is delivered to cause thermal ablation within the desired tissue. This real time data is then used to adjust the next sonication. Most amazing is the real time immediacy of treatment outcome.

### **Slide 9: Planning Images on MRI**

The therapy is planned in three dimensions. Treatment is also monitored in three dimensions to ensure the entire volume of tissue achieves adequate thermal dose.

### **Slide 10: MRI Provides Real-Time Temperature Data**

The MR operates during every sonication. The MR thermometry provides real time feedback during treatment, showing regions that have met thermal dose requirements. This allows the physician to observe temperature changes inside the body in real time during treatment. Based on these observed temperature changes, the physician can adjust treatment parameters accordingly to ensure safe and effective thermal ablation. As the treatment is performed, the MR thermal mapping system displays the relative tissue temperature as a color map superimposed on an anatomic MR image.

### **Slide 11: Methods of Heating Tissue**

Focused ultrasound is the means of introducing energy into the intended treatment area. It is the energy that destroys the tissue, similar to microwave, conduction, convection, laser or radio frequency waves.

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## **Slide 12: Threshold Temperature for Necrosis (Cell Death)**

The thermal dose threshold for tissue necrosis is well known. With MR-guided focused ultrasound, we try to treat temperatures to 57 degrees Celsius by adjusting the energy dose delivered by each sonication.

## **Slide 13: Characteristics of MRgFUS-Treated Fibroids**

By adjusting the beam path, we can precisely ablate our intended regions of treatment. As the photograph on the left shows, areas that received adequate thermal dose not only correspond to areas of non-perfused volume, but also correlate to thermally damaged tissue on the pathology specimen. The histologic section on the right shows a sharp demarcation of treated and non-treated tissue reflecting the precision of this non-invasive surgical modality.

## **Slide 14: The System Table**

The ExAblate table is a modified GE MR table. The transducer sits in a specifically modified cradle. The patient then lies on the table, a gel pad and water bath lie between the patient and the transducer facilitating the ultrasound waves.

## **Slide 15: MRI Provides Anatomic Guidance**

The MR provides anatomic guidance allowing us to determine the tissue we want to treat, as well as areas of interest that we might want to bypass, such as surgical clips, scars, sciatic nerve and bowel.

## **Slide 16: Targeting of Tumors and Visualization**

MR's high-quality, cross-sectional anatomic resolution enables exact targeting of tumors and visualization in three dimensions. T2-weighted MR scans show the pelvic anatomy in excellent detail by slice. This sagittal image shows the spine, uterus and uterine fibroids. This slice of a different depth shows the endometrium in green and the other anatomical structures.

The axial orientation shows the uterus, uterine fibroid, bowel, sacral nerves and pelvis. In this slice, at a different depth, you see the uterus, uterine fibroid, endometrium and pelvis. The coronal view shows these organs from a third orientation.

The next slice shows the same anatomy at a different depth. The visualization enables the physician to clearly identify the anatomy and treatment target for safe and effective treatment.

## **Slide 17: Roles of Ob/Gyn and Radiologist**

Prior to bringing the patient in for treatment, the radiologist and the gynecologist will read the MRI films. The MRI is evaluated to determine if the patient is a candidate for MR-guided focused ultrasound. However, the radiologist will rule out adjacent pathology. Thus, the gynecologist will not be required to pick up pathology not related to treatment. During the treatment phase, the gynecologist will then ensure the beam paths are safe and the gynecologist then executes the focused ultrasound treatment. After the treatment, the gynecologist will look at the perfusion studies to determine non-perfused volume. The radiologist will read the follow-up films performed two to three months after treatment. Again, at this time, the radiologist will scan for adjacent pathology. Thus, both physicians determine patient eligibility and play a part in treatment.

## **Slide 18: Skills and Background Needed to Perform MRgFUS**

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Most gynecologists have the necessary skills and background needed to be trained in MR-guided focused ultrasound surgery. Knowledge of different types of pelvic masses, location and variability of myomas, the ability to differentiate between leiomyomas, adenomyomas and other uterine pathology and basic computer skills in use of graphic interfaces, combined with the training provided by Insightec and MR-guided focused ultrasound surgery training-physicians, the learning curve is neither steep nor long. Usually, in less than the required ten supervised treatments, the gynecologist will feel confident in performing these procedures.

### **Slide 19: During the Procedure**

During the procedure, there is constant interaction between the patient, nursing attendants and the treatment team. The patient usually receives a very mild conscious sedation, more for the comfort of lying on the MR table in a prone position for 90 minutes and up to 3 hours. Patient feedback and treatment sensations optimize treatment parameters decrease risk of side effects of treatment.

### **Slide 20: Patient Sensation During Treatment**

Patient may feel warmth on the skin during a sonication. They also may feel a sensation similar to cramping in the pelvic region that lasts 3 to 5 seconds during the sonication. These sensations should stop after the sonication stops. Patients may also feel some discomfort lying in a prone position on an MR table. This is a non-sonication-related event. The patient should not feel pain radiating down the leg, pain in the back of the thigh, pain in their legs or buttocks that lasts after the sonication stops, nor should they feel pain or extreme heat on the skin's surface.

### **Slide 21: Post MRgFUS**

After treatment, the patient is given a dose of gadolinium to determine the areas of non-perfusion which correlate to the regions of treatment that received an adequate thermal dose.

### **Slide 22: At the End of Treatment, We See What's Treated**

Here we see an almost perfect match of non-perfusion to the areas that reached adequate thermal dose.

### **Slide 23: Patient Recovery and Follow-up**

Patients may experience some degree of abdominal pain, cramping and/or nausea shortly after the procedure. Patients will require 1 to 2 hours of rest at the treatment site after treatment and someone to drive them home secondary to the conscious sedation. Usually, an over-the-counter pain medication, such as a non-steroidal anti-inflammatory agent, is all that is required. Some patients may experience cramping similar to menstrual period cramping or have shoulder or low-back pain that lasts a few days after treatment from lying in the treatment position.

### **Slide 24: Conclusion**

In conclusion, MR-guided focused ultrasound with the ExAblate® 2000 is not difficult to learn and the obstetrician-gynecologist can quickly become adept at using it safely and effectively.

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