

# What Women Want

It's true – we've uncovered the mystery.  
When it comes to uterine fibroids, women  
want an option that is non-invasive.  
Enter MR-guided focused ultrasound.





When it comes to options in healthcare, we've come a long way. In just the last few years, there have been more advancements in clinical care than ever before – not to mention showing real promise for detection and treatment for some of the most nebulous conditions, such as Alzheimer's, Parkinson's, and prostate cancer.

And even though there's more information to physicians and patients than ever before, there is one condition that leaves women to suffer in silence. It's painful, it's embarrassing – and until recently, many women felt and have been told their only real option was a complete hysterectomy. The condition? Uterine fibroids.

### Understanding treatment options

"There is an extreme lack of education and awareness about the full range of choices women have," says Joy Polefrone, PhD, director of patient support organizations for the Focused Ultrasound Surgery Foundation ([www.fusfoundation.org](http://www.fusfoundation.org)). "Most women are told their only choice is a full hysterectomy and rarely is MR-guided focused ultrasound (MRgFUS) included." This is a huge disservice, Dr. Polefrone says, due to the fact that MRgFUS is the only non-invasive option that is available to women today.

For women who aren't comfortable with the removal of their reproductive organs, the 6-week recovery time, or simply don't want to undergo surgery, MRgFUS can be a viable solution. Unlike hysterectomy, myomectomy, or uterine artery embolization, MRgFUS does not require a lengthy recuperation that prevents women from resuming normal schedules, such as work or caring for her children.

So what's the problem? Quite simply, it's a double-edged sword, says Denise Nebgen, MD, PhD, clinical assistant professor of obstetrics and gynecology, Weill Cornell University at The Methodist Hospital (Houston).

"Options for uterine fibroids are based on the clinician's knowledge of existing treatments, and many are unaware of it as an option," Dr. Nebgen explains. "There is selective reimbursement, which impacts the volume of procedures. The lower volume of procedures means there is not enough research yet on the technique. With more research data, we can lobby for national reimbursement and potentially increase physician awareness."

Other women's health issues, such as breast cancer, are becoming acceptable topics of conversation. Uterine fibroids, however, are just not discussed among women despite the fact that uterine fibroids are surprisingly common. More than 70% of women between the ages of 25 and 52 are diagnosed with them at some point. It's also a condition that affects ethnic women. African-American women are three-times more likely to have symptomatic fibroids than Caucasian women.

### Cut it out

While it's surprising that only 25 to 30% of women with uterine fibroids seek treatment, Dr. Polefrone also notes that one-third of hysterectomies are performed due to uterine fibroids. Even though Dr. Nebgen concedes that a hysterectomy is the most-common treatment and the only technique that guarantees a fibroid will not grow back, she maintains it is not an option for everyone.

"Focused ultrasound, is the only treatment option that can give women the ability to return to work the next day," says Dr. Nebgen. Both hysterectomy and myomectomy (see chart on next page) are very invasive with the potential



*Dr. Denise Nebgen*

Denise R. Nebgen, MD, PhD, DDS, is a clinical assistant professor of obstetrics and gynecology, Weill Cornell and Baylor College of Medicine (Houston), an attending ob/gyn at The Methodist Hospital and in private practice with University OB/Gyn of Texas. She received her doctorate in Molecular Biology and Biochemistry at Northwestern University Graduate School (Chicago) and her medical degree from the University's medical school. Dr. Nebgen completed her residency in ob/gyn at Baylor College of Medicine. She has lectured extensively, participated in numerous clinical trials and frequently published in peer review journals. Currently, she is a member of several medical societies, including the AMA and ACOG.



*Dr. Joy Polefrone*

Joy Polefrone, PhD, is the director of Patient Support Organizations at the Focused Ultrasound Surgery (FUS) Foundation, as well as the executive director of Fibroid Relief ([www.fibroidrelief.org](http://www.fibroidrelief.org)), a patient support organization for women with uterine fibroids. Having taught yoga since 2001, Dr. Polefrone has a strong background in wellness education and complementary medicine that compliments her scientific training from the University of Virginia in Cancer Immunology. In addition to her work in patient support, Dr. Polefrone works collaboratively with the Research and Education Team at the FUS Foundation.





Procedure	Description	Advantages	Disadvantages	Return to normal activity	Hospital days	Procedure time	Efficacy
<b>Hysterectomy</b>	<p><i>Laparoscopic assisted and supracervical</i> are two types of hysterectomy. <i>Laparoscopic assisted</i> hysterectomy involves the surgical removal of the uterus via an abdominal incision using an optical instrument called a laproscope, which is inserted through the small incision and permits visualization of the uterus. A <i>supracervical</i> hysterectomy is done through the vagina. The body of the uterus is removed, but the cervix remains intact.</p> <p>Choice between the two procedures depends on the uterine size, a woman's medical history, and the surgeon.</p>	Fibroids will not recur because the uterus is removed.	Reproductive potential is lost. Side-effects may include urination and defecation disorders, earlier menopause, and osteoporosis. Many women receive hormone replacement therapy (HRT) after a hysterectomy. Women on HRT for 5 or more years have increased risk of stroke, heart disease, breast cancer, and blood clots.	28 to 56 days	2 to 5 days	1.5 to 3.0 hours	Hysterectomy is the only sure way to cure uterine fibroids. Recovery from an abdominal hysterectomy requires 1 to 2 months, but fibroids will never recur.
<b>Myomectomy</b>	One or more fibroids are removed with open abdominal surgery. Surgery can also be performed via a small abdominal incision using an optical instrument called a laparoscope which permits visual examination of the fibroids. An endoscope which is a device with a light attached can also be used to view the uterine cavity.	Only the fibroids are excised. No reproductive organs are surgically removed.	Symptoms may recur if new fibroids develop.	4 to 44 days	1 to 3 days	1 to 3 hours	Myomectomy successfully controls symptoms in about 80% of cases. Complete success is less likely in patients with many fibroids. Retreatment required in 2-37% of cases.
<b>Uterine Artery Embolization</b>	The uterine artery which supplies blood to the uterus can become blocked with small particles to decrease fibroid blood supply. Uterine artery embolization is a new procedure aimed at preventing the need for major surgery. The method stops the blood supply that make fibroids grow.	Symptoms are relieved with a shorter hospital stay than required for hysterectomy or myomectomy. The incision is small and no organs are removed.	Risks include radiation, menopause, serious infection, bleeding, and blockage of blood supply to other organs.	7 to 10 days	1 day	45 minutes to 2 hours	UAE relieves heavy bleeding in 90% of women, and relieves pain in 85%. Fibroids may take 2 to 3 months to shrink enough to improve symptoms. Retreatment required in 1.2-16% of cases.
<b>Focused Ultrasound Surgery</b>	Focused ultrasound waves heat and destroy fibroid tissue. MRI images are used to guide treatment and feedback.	Outpatient procedure involves no incisions, radiation, or anesthesia. Return quickly to normal life.	Fibroids may recur with time. As a relatively new treatment (FDA-approved in October, 2004), it is not a widely known alternative.	1 day	Outpatient procedure – no hospital stay	3 hours	92% of patients in clinical trials have significant symptom improvement. Retreatment required in 14% of cases.
<b>Hormone Therapy</b>	Gonadotropin releasing hormone agonists (GnRH) inhibit estrogen secretion, and produce a temporary menopause. Treatments can be used to control heavy menstrual bleeding and to shrink fibroids.	Shrinking fibroids before myomectomy or hysterectomy may permit vaginal instead of abdominal hysterectomy. GnRH agonists also decrease blood loss – both menstrual and surgical.	Depending on the medication, treatment may cause menopausal symptoms, and increased risk of osteoporosis. Symptoms may return rapidly if treatment stops.	N/A	No hospital stay	N/A	Gonadotropin releasing hormone agonists (GnRH) decrease estrogen levels, fibroid mass, and pressure symptoms. If medication stops, fibroids rapidly regrow. Oral contraceptives reduce heavy menstrual bleeding associated with fibroids, but do not stop fibroid growth.
<b>Watchful Waiting</b>	No treatment. Fibroids continue to be monitored.	Fibroid symptoms may decrease with the onset of menopause.	Fibroids may continue to grow and symptoms may worsen.	N/A	No hospital stay	N/A	N/A



for blood loss, require several days as a hospital inpatient, and can take up to eight weeks for full recovery and resumption of normal activity, she adds.

Third party insurers, however, are beginning to see the light at the end of the tunnel. Recently, UnitedHealthcare began reimbursing MRgFUS in the state of Texas as a result of lobbying efforts by Sightline Health, Dr. Nebgen, and others. "While the procedure itself can be considered to be somewhat costly, the overall economic impact to the healthcare system is much less than the invasive alternatives," she says. MRgFUS can cost approximately \$5,000 to \$7,000, yet surgery, hospitalization and recuperation costs can run in the tens of thousands of dollars, not including lost income for the patient.

"So far, all the data we have shows MRgFUS to be an effective procedure," Dr. Nebgen explains. In fact, according to Insightec, 4,500 patients have been treated with the technology with a 92% success rate.

Currently, US guidelines of the procedure are limited to women who are considered to be "family complete." Other countries, however, have less restrictions upon its use with women who are looking to maintain fertility.

"But, for many women of child-bearing age, hysterectomy is not an option," says Dr. Polefrone. In fact, she is collecting data to determine whether MRgFUS impacts either a women's fertility or capability to carry a fetus to full-term. "The fertility data is compelling," she adds.

The goal for both Dr. Nebgen and Dr. Polefrone is to raise awareness so that all women have a full spectrum of options for the treatment of uterine fibroids. "We are not saying MRgFUS is right for everyone," says Dr. Polefrone, "but it deserves to be considered with the other options."



## From the patient – dealing with uterine fibroids

The compelling part of the MRgFUS story is learning how it impacts patients. Here are the stories of real patients and how they were impacted by fibroids.

### Wendy's story: Healthy lifestyle, a grapefruit-sized fibroid

Wendy Perkins describes herself as a naturalist, a vegetarian who grows much of her own food, a regular at the gym and the local green market, and she doesn't take medicine – not even an aspirin. So when she felt a walnut-sized lump near her uterus, she was surprised, but immediately made an appointment with her OB/GYN.

"The doctor told me I had a uterine fibroid," explains Wendy. "I had never heard of a fibroid so I thought it was good news until the doctor handed me a pamphlet on getting a hysterectomy." A hysterectomy? This goes against everything for which Wendy stands.

After researching uterine fibroids and discovering that many women can live with them and after menopause, the fibroids often shrink and no longer cause discomfort, Wendy decided to wait until she was post-menopausal.

The fibroid, however, continued to grow. When it reached the size of a grapefruit, it began to impact her quality of life. Not only were her periods very heavy, but the fibroid became visible on Wendy's 110-pound frame. "I became depressed and didn't want to go out anymore – and that was definitely not me," Perkins comments. As a result, she felt it was time to take action, and sought second opinions.

Physicians repeatedly told Wendy that hysterectomy was her only option. The seventh physician she saw gave her a prescription for Lupron – an injectable medication that temporarily takes the female hormone estrogen out of the patient's system in hopes the estrogen withdrawal will cause the fibroid to dry up and disappear. Lupron did shrink the fibroid, and when Wendy completed the prescription, her stomach was nearly flat again.

What Wendy didn't know, unfortunately, was that the fibroid prolonged her menopause. Ten months after ending Lupron, the fibroid had grown to the size of a six-month fetus, 26 cm.

As a result, Wendy met with Suzanne D. Le Blang, MD, at University MRI (Boca Raton, FL), a radiologist who was performing MRgFUS. Wendy was identified as a perfect candidate for the four-hour procedure.

"It was fairly painless – especially compared to what I went through before with the fibroid," she explains. "From the moment it was ablated, the symptoms were gone. Within 15-20 minutes, I felt OK to go home. I even gardened later that day!"

Wendy had 400 cc of her 600 cc fibroid removed. The remnants softened and two to three weeks after the procedure, her stomach was flat again.



#### About the organization

Fibroid Relief, a patient support organization launched by the FUS Foundation, is dedicated to supporting women suffering from uterine fibroids who seek non-invasive treatment alternatives. The foundation is committed to raising awareness about the benefits of Focused Ultrasound, regardless of manufacturer, and will work tirelessly to promote patient access through education and advocacy activities. The organization believes all patients should have access to the most trusted and reliable health information, which empowers patients to make the best decisions to maintain and improve their health.

Fibroid Relief strives to put the power of choice in the hands of uterine fibroid sufferers. We aim to contribute to an increased dialogue between patients, physicians, and payers so patients can make the best individual treatment decisions without regard to reimbursement protocols and roadblocks.

#### Frances' story: Three fibroids, one uterus

For several years, Frances Thomas coped with pressure in her abdomen and heavy, painful menstrual periods. When her physician diagnosed her with uterine fibroids, she kept the information to herself and balked at the options she was given. "I had three fibroids, one the size of a golf ball, one the size of an apricot, and one the size of a grapefruit," says Frances. "Worse, my doctor told me I only had two options: hysterectomy or uterine embolization, and I refused to do either."

Fortunately for Frances, she shared her diagnosis with family and close friends. "Take it from me, you have to talk about it. Once I did, it was like a whirlwind, every door opened up to me and I found out my sister and a close friend were suffering from uterine fibroids."

Similar to Wendy, Frances researched the condition to seek other treatment options. She started with acupuncture, which she found to be healing, and also did herbal therapy. These treatments, however, only provided relief from the symptoms, not addressing the condition. It was then that she discovered MRgFUS. "I wanted to be 80 to 90% symptom free, and that is what MR-guided focused ultrasound did for me," she explains.

Frances describes the procedure as life changing. "You can tell such a difference, my abdomen went down as soon as I had the procedure," she explains. "I was back to work within three days, I was working out in three to four days, so that was wonderful. I'm back to a sense of just being normal, being a full woman, and I don't have any concerns, which is just great," she concludes. ■



#### The ExAblate

Currently, the only FDA-cleared system for MRgFUS is the ExAblate from InSightec, Ltd. To identify the treatment volume, the ExAblate uses conventional diagnostic MR images taken at the beginning of treatment. The physician delineates the tumor and defines safe treatment pass-zones that will avoid energy passage through sensitive tissue. The physician selects an application-specific treatment protocol that determines the main attributes of the planned treatment. The system then computes a treatment plan, composed of 20 to 100 sonication points that cover the specified target. During treatment,

the system's robotic system positions the transducer below the target point and delivers the planned energy.

A key feature of ExAblate is its ability to provide real-time monitoring of energy deposition. During energy delivery, ExAblate directs the MR to continuously acquire thermal images that include the point being treated and the surrounding anatomy. These images, once processed, provide the essential feedback of where the energy is delivered and the temperature reached. This quantitative feedback allows the physician to monitor and adjust treatment parameters.

The workstation displays thermal images and computes and displays the treated regions. Spots are treated in sequence. The process of adjusting parameters and sonicating under real-time MR imaging continues until the planned volume of treatment is fully treated. Viewing images of the region immediately following treatment enables the physician to evaluate the treatment outcome.

According to sources at InSightec, over 4,500 women have been treated with ExAblate with close to 92% experiencing symptom relief.