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Ideas in Hospital-Based Imaging

MRgFUS Master Plan

Houston's SightLine Health pursues a reimbursement change, hoping that payors will recognize the benefits of this uterine fibroid treatment

By Renee DiIulio

MR-guided focused ultrasound (MRgFUS) is not new—the ExAblate 2000 system from InSightec, Dallas, was given FDA approval in fall 2004. But with just over 2 years on the market, the system isn't old either. As is the case with many infant technologies, payors have not yet begun to reimburse the procedure for uterine fibroids. This factor has limited MRgFUS's use, despite such advantages as noninvasiveness, minimal side effects, and cost-efficiency. But the reimbursement climate may soon change.

SightLine Health LLC, Houston, which offers the service, has begun discussions with three major medical insurance companies to initiate reimbursement, according to T.J. Farnsworth, SightLine president and CEO. "MRgFUS can be expensive but is more cost-effective when compared to surgical methods," he says. "Payors are realizing that the procedure can be completed in 3 hours with no anesthesia versus a 2- or 3-day hospital stay and 2 weeks of bed rest and pain medication."

He notes that the methodology already has two CPT3 tracking codes: one for simple procedures (0071T) and a second for complex (0072T). "Our fee schedule is in the $17,000 to $25,000 range for complex procedures," Farnsworth explains, noting that patients typically pay $10,000 to $17,000 cash, depending on procedure length and complexity as well as fibroid size.

The cost has limited the number of women who decide to undergo MRgFUS. "The procedure is not cheap, which has been a major hurdle. But we knew this going into it and are trying to overcome it now," Farnsworth says, referring to the reimbursement discussions.

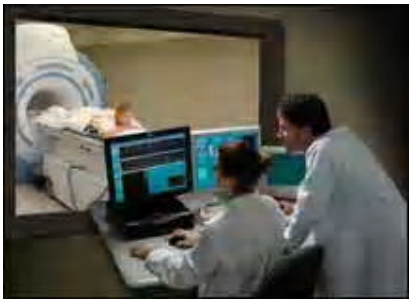
Farnsworth's argument is bolstered by positive research data. He estimates that more than 2,500 women have opted for the procedure throughout the United States since its introduction. "We've found about a 5% recurrence rate in commercial applications of MRgFUS," he says, comparing it to about 17% for uterine arterial embolization. Myomectomy patients show even higher recurrence rates.

Hybrid Technology

The hybrid system incorporates MR and ultrasound. Real-time MR provides guidance and temperature mapping; ultrasound is the ablation tool. Currently, ExAblate 2000 is the only device approved by the FDA for this use.

"The system uses a lens to focus the hundreds of transducers in the array to a specific pinpoint, which can be as small as a grain of rice or as large as a jelly bean. The sound waves heat the tissue to necrosis," says Farnsworth, who likens the process to that of a child burning leaves with a magnifying glass.

The precision avoids the destruction of collateral tissue that occurs with radiation.



A patient undergoes MRgFUS at SightLine Health in Houston.

The beam is guided by real-time MR imaging, which identifies tumors and verifies dead tissue. "We are able to measure temperature changes in real time to confirm the tissue has been destroyed," Farnsworth says.

The ExAblate system has been approved for use only with 1.5T and 3T MR systems from GE Healthcare, Waukesha, Wis.

Though the procedure can take up to 4 hours for very complex cases, it does not require anesthesia, and patients generally are able to return to work within a day. There is no consistent use of medications, radiation, or hormones. There also are no associated surgical risks, such as infection, blood loss, and adverse reaction to anesthesia. Farnsworth notes that it can be challenging to remain still in the MR machine for 3 hours, but patients are typically given mild sedatives, not painkillers, to relax.

The procedure, however, is not for everyone. "MRgFUS is typically recommended for patients with six or fewer larger symptomatic fibroids," he says. It would not be recommended for women with five to 30 small fibroids, 1 to 2 cm in size; pedunculated fibroids; fibroids suspected of being cancerous based on the prescreening MR examination; or those less than 4 cm from the sacral nerve.

The procedure also is recommended only for women who do not plan to become pregnant—but this too may change. According to Farnsworth, the FDA is currently evaluating whether to remove this specification. "A clinical trial, slated to begin in about 6 months, has been designed not only to confirm a positive decision, but also to examine whether the procedure should be recommended for women who wish to become pregnant," he says.

During the procedure, practitioners take care to assure the beam path is clear. "We cannot treat through scars, surgical clips, or the bowel," he explains, noting that mitigating steps, such as filling the bladder to migrate the bowel, can be taken.

Group Benefits

Patients are not the only ones who benefit from MRgFUS. SightLine was formed specifically to offer the service to patients; the organization partners with radiology and gynecology groups. "We are not interested in the diagnostic side. We go into imaging centers with the ablation equipment and perform our surgery on site," Farnsworth says. If one center does not have an approved MR machine, SightLine will lease time on a GE Healthcare MR in another facility to treat the first center's patients.

Radiology groups benefit from prescreening MR examinations and leased MR time. "MRgFUS brings in a significant number of billable study referrals," he says. "We refer to our radiology group anywhere between 40 and 70 pre- and post-contrast MRIs on a monthly basis." Because SightLine owns the ablation equipment, no capital expenditure is required from the physician group.

SightLine also handles the marketing. Because there is not yet standard reimbursement, the organization markets directly to patients. Depending on the city, this may take the form of billboards, television, print, radio, and/or Internet marketing.

As a result, centers offering MRgFUS often become women's "health hubs." OB/GYNs who refer MRgFUS to patients expand to other services. "The radiology group we partner with in Houston is performing therapies that it did not do before," Farnsworth explains.

Should payors decide to reimburse MRgFUS, more patients are likely to opt for the procedure.

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