

The sound of healing? Local business buys in

Device blasts prostate cancer with ultrasonic waves

BY MIKE STOBBE
Staff Writer

As a founder of the rock group Styx, Chuck Panozzo knows the power of sound.

But even Panozzo was impressed by the Sonablate 500 - a machine that uses high-intensity sound waves to burn away prostate cancer.

Panozzo, 55, of Miami, flew to the Dominican Republic in April for the \$20,000 treatment, which is not approved in the United States or covered by health insurers.

Early tests indicate it killed the bass player's cancer, while sparing him the incontinence and impotence many men suffer from more established treatments. Seventeen days later, he said, he was onstage with his band.

"That's the cool part," Panozzo said before a recent show in Charlotte. "I don't look sick up there, or feel like I'm dragging."

Now a Charlotte company is getting in on the act.

U.S. HIFU, incorporated just three months ago, has bought minority ownership in the Indianapolis company that developed the Sonablate 500. It's purchased future distribution rights, and partnered with the doctor who's treated Panozzo and other patients in the Dominican Republic.

The Charlotte company's 23-year-old chief executive, Steve Puckett Jr., is a relative newcomer to the health care business - it was only last year that he graduated from Vanderbilt with a bachelor's degree in history.

But he has the backing of his father, Steve Puckett Sr., the company's founder. The elder Puckett is a powerful health care veteran who founded two hospital chains, MedCath Corp. and Hospital Partners of America.

SEE HIFU | 3D

ABOUT THE TECHNOLOGY

3D | How the Sonablate 500 works.



PAILIN WEDEL - SPECIAL TO THE OBSERVER

Terry Linn (from left), Steve Puckett Jr. and Steve Puckett Sr. helped start Charlotte-based U.S. HIFU, which has distribution rights for a device that uses sound waves to attack cancer.

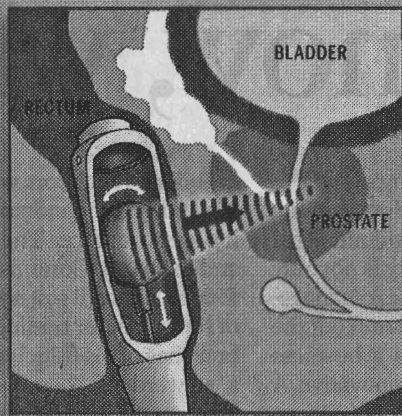
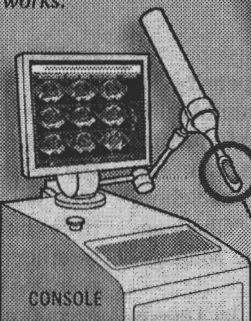
Prostate Cancer Treatment

High-intensity focused ultrasound (HIFU) is a technology designed to destroy diseased tissue without harming healthy tissue around it. Here's how the process works:

Ultrasound imaging

The probe that's used for the procedure is attached to a console that provides a clear ultrasound image of the prostate.

SOURCE: Focus Surgery Inc.



The procedure

A patient receives epidural anesthesia. A doctor uses the device to image the prostate and plan treatment. Then, the probe emits sound waves that pass through the rectal wall and essentially cook the diseased tissue within the prostate.

DAVID PUCKETT - STAFF

Company buys into technique

HIFU from ID

The Pucketts believe the Sonablate 500 will supplant surgery and radiation and become the preferred method to treat early-stage prostate cancer. Some physicians and analysts are skeptical, but patients think the company has captured lightning in a bottle.

"Word of mouth is going to get out," predicted Fayetteville businessman Chris Cammack, 55, who had the procedure last month.

"I think they (U.S. HIFU) are going to make it big time."



Cammack

The technology

HIFU stands for high-intensity focused ultrasound. It involves concentrating sound waves to a tiny area of diseased tissue, heating it to between 175 and 203 degrees and destroying it.

"It literally cooks it," said Ralf Seip, director of research and development for Focus Surgery Inc., the company that developed the Sonablate 500.

The technology's most popular application has been lithotripsy, which shoots a different kind of ultrasonic wave through the body to break kidney stones. Lithotripsy machines hit the U.S. market in the 1980s, and replaced surgery as the most common way to treat stones.

Focus Surgery has worked on using sound waves on other health problems. In the early 1990s, the company developed the Sonablate 200, a machine used primarily to treat enlarged prostates. In the late 1990s, it created the Sonablate 500 for use against prostate cancer.

Miami urologist Dr. George Suarez heard about the company about four years ago, and later flew to Indianapolis to learn the technology. He arranged to place one of the \$1 million machines in the Dominican Republic, where HIFU treatments are allowed.

Suarez said he has used that machine to treat about 100 men since last year. And last year, Suarez met Puckett Sr., who was trying to put together a deal to buy Doctors Hospital of Coral Gables, Fla. Suarez was a potential investor, but the deal fell through.

But Puckett Sr. was fascinated by what Suarez told him about treating prostate cancer with sound waves. He assigned his son, a Hospital Partners employee, to research the business potential of HIFU. He also drafted Suarez and Terry Linn, Hospital Partners' chief development officer, as investor partners.

Puckett Jr. was named U.S. HIFU's chief operating officer, then promoted to chief executive. The company negotiated an agreement with Focus Surgery to be-

come exclusive distributor of the Sonablate 500 in the Americas.

It also agreed to pay the \$4.2 million tab for additional clinical trials of the device needed to prove to the U.S. Food and Drug Administration it is safe and effective enough to be sold in the United States.

The company also will start placing machines in Mexico, through a partnership with AmeriMed, a company that operates American-style hospitals at Mexican resort communities. Suarez said a hospital in Cabo San Lucas is to start offering the treatment by the end of this month.

U.S. HIFU's start-up funds come from just two sources: current investors and the clinics in Latin America. There are no plans to seek additional financing, Puckett Jr. said.

Common form of cancer

Prostate cancer is a practical target for HIFU technology. It's a stationary target, unlike, say, a beating heart. Also, it's easy for a sound-wave-emitting probe - inserted in the rectum - to get close to a tumor without surgery.

As the second most common form of cancer in U.S. men, prostate cancer is big business. About 231,000 U.S. cases will be diagnosed this year, and 30,000 men will die from it, according to the American Cancer Society.

Some estimates put annual spending on prostate cancer treatment at somewhere between \$1.7 billion and \$4 billion, said Dr. Kevin Schulman, a Duke University professor of medicine and business administration.

That would make prostate cancer treatment about as big as the U.S. cotton industry.

Current treatments include surgery, radiation, hormones and a relatively new procedure called cryosurgery (in which doctors destroy the prostate by freezing it). Each has drawbacks.

With radical prostatectomy, the long-standing surgical option, studies have found the surgery leaves a significant number of patients incontinent. One large study found that two years after the surgery, 28 percent of patients wore pads to keep dry.

In addition, reported impotence rates from the surgery range from 25 percent to as high as 80 percent.

The other treatments also carry risks of impotence and other problems, doctors say.

U.S. HIFU executives believe sound wave technology is as good as those treatments at killing cancer, but less likely to cause side effects. They think HIFU one day will capture the lion's share of the prostate treatment market.

Other companies do, too.

U.S. HIFU's most established competitor is a French company named EDAP Technomed, founded in 1979 to make and sell lithotriptors. But the company is increasingly concentrating its resources on its Ablatherm HIFU

device, approved for marketing in Europe in 1999.

But EDAP Technomed is struggling. Last year, the company lost \$5.9 million on operations, and \$4.2 million of that - or 71 percent - was blamed on its HIFU division.

Puckett Jr. believes EDAP Technomed made pricing errors he hopes to avoid. And his company is partnering with Focus Surgery, which he says makes a superior machine.

Industry observers say the Sonablate 500 is most likely to get FDA approval first.

"Focus Surgery is the leading HIFU company in terms of time to market," said Tim Nelson, a Minneapolis-based research analyst who studies medical technology companies for Piper Jaffray.

But that doesn't mean the company is bound to succeed.

EDAP Technomed has complained about problems getting adequate reimbursement in most countries where it has machines. That could be a problem for companies in the United States as well, some business experts said.

"Most medical device companies die on the shores of reimbursement," Schulman said.

Several companies have won FDA approval for medical devices, but suffered losses because it took years more for the federal Medicare program to sign off.

Intensive medical treatments usually cost far more than most individuals can afford. Without the backing of Medicare or other large public and private health insurers, a HIFU device won't get used much, experts said.

The road to approval

Some U.S. HIFU officials said they aren't concerned about getting insurers' approval. They said the benefits of HIFU will quickly become evident to insurers, who probably will endorse HIFU quickly. Even if they don't, the income from wealthy patients able to pay should sustain the company for a while, they said.

A full weekend of treating men

in the Dominican Republic brings gross revenues of \$100,000 to \$200,000, Suarez said. "That's just one weekend," he added.

Puckett Sr. voiced more concern. The next rounds of clinical trials have yet to begin, and FDA approval isn't expected for three to five years. But even so, U.S. HIFU representatives plan to begin meeting with Medicare officials this fall, he said.

Focus Surgery and U.S. HIFU cite studies from Europe that found more than 70 percent of prostate cancer patients treated with sound waves were cancer-free. They also note that HIFU treatments can be repeated if cancer grows back.

But those arguments may not win over many U.S. doctors, said Dr. Cary Robertson, who directs Duke University's Morris Center for Urologic Research.

Physicians want treatments to rid the body of cancer, not just beat it back temporarily. Many U.S. doctors will want to see HIFU's effectiveness against cancer proven in long-term U.S. studies, Robertson said.


It's possible such studies won't find HIFU as effective at destroying cancer as current treatments. U.S. HIFU may be able to do a fair amount of business before then, given its growing popularity with patients, he added.

"This company could have a built-in grace period," he said.

Many patients are enthusiastic. Panozzo, the musician, said he opted for HIFU in part because a 55-year-old college buddy became incontinent after a radical prostatectomy. "There's a certain amount of humiliation to know you're urinating on yourself every day," he said.

For him, the HIFU procedure seems to have succeeded. A measurement of prostate-specific antigens in his blood, used to indicate the presence of cancer, dropped from 4.5 before the procedure to 0.3 after, he said. HIFU didn't even hurt, he added.

"The most painful part was writing the check," he joked.



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