

Recent US News & World Report Feature Highlights HIFU as Future of Prostate Cancer Therapy

A recent article found in US News & World Report highlights HIFU and robotic surgery as key treatments of the future in the fight against early stage prostate cancer. The HIFU data sourced is exclusively EDAP material along with a quote from Maple Leaf HIFU, EDAP's Canadian user center in Toronto. The article firmly supports further clinical study and documentation of the HIFU outcomes demonstrated in Ablatherm clinical data to date in order to solidify HIFU's place as a primary treatment choice of the future.

The article also identifies a key benefit of Ablatherm-HIFU - clear outcomes without dependence on surgeon selection for patient efficacy and quality of life preservation.

The article can be viewed online at <u>http://www.b2i.us/external.asp?b=1053&id=40362&from=du&L=e</u>. Text is copied below.

Technologies Tackle Early-Stage Prostate Cancer

Robotic surgery and HIFU are innovative, but it isn't clear that they trump conventional treatments

By Adam Voiland Posted August 23, 2007

Ideally, treating prostate cancer both cures a man and leaves him free of side effects. But standard treatment, though good at eliminating tumors, often leads to impotence, incontinence, or both. Robotic da Vinci surgery and high intensity frequency ultrasound (HIFU) are two of the latest high-tech approaches aimed at avoiding side effects. The first is popping up in hospitals across the nation; the other remains off limits except to Americans with deep pockets and no qualms about traveling overseas to get treatment. Both look promising, doctors say, but more robust research is still needed to prove that either clears tumors as effectively as and with fewer side effects than standard therapies.

Da Vinci. The robotic da Vinci Surgical System, which was approved for use in prostatectomy surgery in 2001, is taking hospitals by storm. In 2005, Intuitive Surgical, the California-based maker of the \$1.5 million device, reported that 324 hospitals worldwide had da Vinci systems. Since then, the number has ballooned to more than 656. Positive feedback from surgeons, consumer interest in the technology, and competition among hospitals to appear on the cutting edge of medicine have fueled the growth.

Employing technology originally developed by the military for remote battlefield surgery, the system offers surgeons a live video feed from inside the body while they do their cutting and suturing through dime-sized laparoscopic incisions. The video offers high-definition, three-dimensional images, and surgeons use joystick devices to control da Vinci's four robotic arms. The arms are designed to eliminate the natural tremor of a human hand, but they do not offer tactile feedback to surgeons.

Evidence is piling up that robotic surgery, with the right person at the controls, is as good as conventional surgery, if not better. But it doesn't blow the older technique away. A recent <u>review article</u> by Vipul Patel, the director of the Center for Robotic Urologic Surgery at Ohio State University, suggests that robotic surgery results in less blood loss, shorter hospital stays, and slightly less post-surgical incontinence. So far, however, it has resulted in about the same rate of impotence and achieved survival rates as those of standard surgery. "We have not been able to identify any disadvantages," says Joseph Smith, a urologist at Vanderbilt University Medical Center who had performed some 1,500 robotic prostatectomy surgeries and 3,000 standard ones. In his experience, he says, the robotic technique seems slightly better on some measures, but not enough to prove that da Vinci is superior.

HIFU. High-intensity focused ultrasound, by contrast, is a less mature technology that's yet to receive regulatory approval in the United States—though it has been approved in Europe, Japan, and other places. The technique aims ultrasound waves so that they pass harmlessly through skin but heat up and kill tumors cells in the prostate. In America, three experimental trials of HIFU are ongoing. Companies that sell HIFU equipment note that the procedure isn't invasive, usually causes no obvious side effects, and seems to eliminate tumors. And doctors using their devices offer to treat Americans at clinics in Toronto, the Dominican Republic, and elsewhere—for \$23,500 to \$30,000 each.

There's some evidence, particularly from overseas researchers, that suggests HIFU works. Some studies (<u>here</u> and <u>here</u>) suggest there's much to be optimistic about in regards to HIFU. Others, however (<u>here</u> and <u>here</u>) argue that the evidence doesn't yet justify its use.

"No, it's not a panacea. No treatment is a panacea," says William Orovan, the president of Maple HIFU, which offers HIFU treatment in Toronto, and a professor at McMaster University. "But the results are very good. The side effects are minimal. The risks low." And if the tumor returns, you can still fall back on radiation or surgery, he says.

Experience counts. Unless HIFU gets the nod from the FDA and insurance plans start covering it, the procedure will be an option only for economically advantaged patients. In the meantime, patients who opt for surgery should consider not only technique, experts say, but also a surgeon's skill.

"The surgeon is more important than the procedure," says Smith. He recommends that men seek out an experienced surgeon whom they can trust, and then let that doctor decide whether to do the procedure robotically or not.

Where to Find Robotic Prostatectomy or HIFU

* Robotic prostatectomy is available at hospitals across the country. Intuitive Surgical, the maker of the equipment, keeps a <u>database of hospitals</u> that have the da Vinci Surgical System.

* While high-intensity focused ultrasound (HIFU) isn't generally available in the United States, you can search for American experimental trials involving the technology at <u>http://clinicaltrials.gov/</u>. Prostate cancer patients who meet certain requirements can join a trial.

* For a hefty fee, companies such as <u>USHIFU</u> and <u>Maple Leaf HIFU</u> will help Americans travel abroad for HIFU treatment.

What do you think?