

High Intensity Focused Ultrasound

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Patients diagnosed with prostate cancer are faced with difficult choices regarding treatment options. The historical remedies—radiation therapy, surgery, hormonal therapy, chemotherapy and freezing the cancerous gland—have risks and negative side effects, especially incontinence and impotence. A new technology, however, is coming of age in its ability to diminish these risks and side effects. This nonsurgical outpatient option—high intensity focused ultrasound (HIFU)—takes approximately one to four hours to perform, depending on prostate size, and has a relatively short recovery period.

With HIFU, most patients are up and walking around within two to three hours and may resume normal activities within a couple of days, with minimal discomfort.¹ HIFU patients also experience fewer side effects than those receiving traditional prostate treatments.² During the first one to two weeks after the procedure, patients may experience mild urinary symptoms, such as frequency and/or urgency to void. In the first three months, patients may also pass an occasional small amount of blood or mucus-like materials, which is normal.

HIFU is radiation-free. Unlike radiation, ultrasound energy is non-ionizing, meaning that it will not harm any tissue outside of the targeted area. (Damaged

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HIFU device with probe

tissue could set the stage for a possible cancer recurrence.) Because HIFU is performed without an incision, patients don't experience blood loss and can usually be discharged after recovery from the general or epidural anesthesia. Furthermore, because HIFU uses ultrasound rather than radiation to destroy targeted tissue, the procedure can be repeated if necessary.

During the HIFU procedure, all or part of the prostate is ablated, including the prostatic urethra. The urethra is derived from a different type of tissue (bladder squamous-type epithelium) than the prostate (glandular, fibrotic and muscular) and does restore itself with time. A suprapubic or penile catheter is inserted for one to three weeks until prostate swelling resolves.

The machine used to transmit HIFU uses a computer-controlled device designed for transrectal delivery of energy to the prostate. It features a fully integrated probe with dual treatment transducers that move robotically to follow the physician's precise treatment plan.

Urologists around the globe, as well as those in U.S. involved in clinical trials, have been using HIFU to treat localized prostate cancer and recurrent prostate cancer/radiation failure with both focal therapy and whole-gland therapy. Worldwide, over 7,000 HIFU prostate treatments have been performed to date.

Accurate imaging is a key component. The technology makes use of integrated biplanar ultrasound imaging for real-time treatment monitoring, treatment planning, and pre- and post-treatment imaging of the prostate. Precise focusing of ultrasound energy during HIFU treatment rapidly elevates the temperature of the tissue to 90 degrees Celsius in the focal zone, while intervening tissue between the transducer and the focal zone is kept at a safe temperature.

The result of HIFU therapy is an accurate and repeatable lesion at the target sites that are monitored in real time by the treating physician. All treatment zones are pre-planned and checked by the physician prior to HIFU treatment. The procedure allows for a customizable treatment plan tailored to each patient's prostate cancer diagnosis. The imaging capabilities of the technol-

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ogy also allow for the identification of vital structures, such as the prostate capsule, seminal vesicles, rectal wall, and the physiological location of neurovascular bundles.

A radio frequency (RF) signal is sent to a treatment site prior to delivery of HIFU, and then another signal is sent after delivery to the same site. A sophisticated tissue-change monitoring system calculates the change that took place and displays it on the screen by quantifying tissue changes based on a comparison of RF ultrasound pulse-echo signals at each treatment site. This tracking procedure shows results using real-time ultrasound imaging aided by advanced tissue-change monitoring software.

An integrated Doppler feature in the transrectal probe provides an additional safeguard during treatment. This feature helps physicians identify vital structures that need to be preserved to avoid problems with urinary continence and sexual function. With HIFU's precisely targeted accuracy, there is less damage to the surrounding area, such as the muscle controlling urine flow and the nerves controlling erections.

HIFU technology remains investigational in the United States, but it is being studied for the treatment of prostate cancer in U.S. clinical trials. The technology has been approved in more than 30 other countries in Europe, South America and North America (Canada and Mexico). The Food & Drug Administration has scheduled a panel review of HIFU technology for early October that may result in a decision within 60 days. ◇

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