

HIFU for Prostate Cancer

What is HIFU?

High Intensity Focused Ultrasound (HIFU) is a procedure used for the treatment of prostate cancer. It works by using precision-focused ultrasound waves to rapidly heat and destroy cancerous prostate tissue without affecting healthy surrounding tissue. The ultrasound waves create enough heat to destroy the cancerous cells and treatment is continued until all the targeted cancerous prostate tissue is destroyed. This non-invasive treatment is relatively new in the field of prostate cancer and is performed under a general anaesthetic.

How does it work?

Using intersecting precision focused ultrasound waves, the device destroys diseased tissue within the prostate and leaves healthy cells around the outside of the prostate capsule untouched. In addition to being minimally invasive, HIFU energy is nonionizing 'clean energy' that can be applied repeatedly without damaging other tissue, unlike radiation based therapies.

HIFU energy works like a magnifying glass and sunlight. Using a magnifying glass you can focus energy of the sun and concentrate it over a focal point while allowing safe and harmless energy transfer over the entire course of that beam up until it reaches the point of concentration.

Cancer cells are fortunately more sensitive to higher temperatures; precision focused ultrasound waves raise the temperature of the target tissue to more than 80-90 degrees Celsius in two to three seconds, effectively destroying the targeted cancerous tissues.

HIFU is being used around the world to treat all types of cancer and soft tissue diseases. HIFU has been approved by the National Institute of Clinical Excellence (NICE) for use in the UK in the treatment of prostate cancer. The technique is relatively new in the field of prostate cancer treatments and so there is very little long-term data to verify its clinical effectiveness but the early results are very promising.

What equipment is used?

The HIFU treatment is performed using a Sonablate® 500 which is manufactured by Misonix Inc. (NASDAQ: MSON) of Farmingdale, New York.

The Sonablate® 500 is approved in many countries outside the U.S. as an imageguided acoustic ablation device developed by Focus Surgery to treat prostate disease. The technology behind the device originated at the Indiana University School of Medicine in Indianapolis in the 1970s. It was further developed in leading research centres across the world. The Sonablate® 500 allows a trained urologist to visualize the prostate and plan and monitor the treatment in real time, ensuring maximum precision, flexibility, safety and control.

Undergoing HIFU

Having decided to undergo HIFU treatment you will be taught to pass a drainage tube (catheter) down the penis into the bladder. This straight forward process is a precaution to ensure that you don't block off following the operation. You may be hospitalized the evening before the procedure but usually it is possible to come in the same day as the operation. Either the evening before, or on the morning of the procedure, you need to have a bowel preparation at home. You may drink water until 2 hours prior to the procedure.

How is HIFU performed?

HIFU may be performed under general or spinal anaesthetic. At the start of the procedure a catheter (urine drainage tube) is inserted through the abdominal wall into the bladder. This will be removed 5 days or so later. An ultrasound probe is placed in the rectum and the prostate is imaged. The ultrasound probe is then used to focus high-intensity ultrasound waves on a particular area of the prostate, creating heat in the tissues. This heat causes prostate tissue death. The process is repeated by moving the focal point of the ultrasound over the whole area of the prostate until all the cancerous tissue has been destroyed. Usually you will be discharged home later on the same day as the treatment. You may eat and drink as soon as you are awake and will be encouraged to walk. Your nurse will teach you how to look after the catheter at home. You will usually return after about 5 days to have this removed.

Recovery from the procedure

Some of the symptoms you may experience following HIFU include:

- Scrotal swelling and/or a feeling of pressure/mild pain in the perineum (for 7 – 10 days)
- Rectal bleeding and discomfort If you have existing haemorrhoids, these can be exacerbated by the probe used for HIFU and haemorrhoidal cream post-operatively may provide some relief
- Urethral discharge of blood and/or debris (for 7 – 14 days)
- Blood and/or debris in the urine (for up to 6 -8 weeks)
- Urinary frequency and urgency (for up to 6 weeks)
- A stinging feeling when passing urine (for up to 4 – 8 weeks)

All of these symptoms should settle down spontaneously. Urine infection is not uncommon following HIFU and so antibiotics are given prior to the procedure and to take home. It is sensible to avoid caffeinated drinks (cola or coffee) for the first few weeks as these can aggravate urinary burning and frequency. A PSA blood test is usually done at 3 months and then every 3-6 months while your consultant considers it necessary.

What are the results so far?

Real time imaging and treatment of the prostate with HIFU offers the possibility of very low rates of erectile dysfunction and negligible rates of incontinence. Neurovascular structures responsible for erectile function and continence can be imaged, and the treatment can be designed to avoid treatment of these sensitive areas. The precise results of clinical studies depend on the surgical protocol adopted by the researchers, but an overall average assessment is that less than 20% of men will have erectile dysfunction.

Studies in Japan have shown that in 90% of the patients studied, HIFU technology produced PSA measurements below 1.0 within one year following treatment, with only 20% of men suffered erectile dysfunction and less than 1% suffering urinary incontinence. More recently, researchers at University College Hospital, London, have presented a research study to fellow surgeons and oncologists at the British Prostate Group with 83% of men treated to a PSA nadir of 0.2ng/ml or less. This very low level of PSA is used by more established techniques such as radiotherapy to predict cancer cure rates at 10 years. The PSA level can be reached after just 3 months with HIFU treatment, giving men the early peace of mind that they have been successfully treated.

Treatment may also be repeated as necessary and HIFU can be used following treatment with other therapies such as radiotherapy. Recently the Journal of Urology published an article authored by Dr Wieland and Dr Blanna from the University of Regensburg (Germany). The study, conducted using a prostate HIFU device from EDAP Technomed, included patients with a five-year follow-up and showed 93.4% constant negative biopsies in the patient population and with only two patients having a PSA level that rose to greater than four. Publications by Dr Toyooki Uchida, M.D., from Tokai University Hospital and John C. Rewcastle, PhD from the Department of Radiology, University of Calgary in Canada reported very similar positive findings.

Who is a suitable candidate for HIFU?

HIFU is one of several treatments available once the diagnosis of prostate cancer has been made. It can be difficult to decide which treatment is best for you and so a careful discussion of the options is vital. HIFU tends to be reserved for those men who are unsuitable for prostate gland removal surgery, as an alternative option to external-beam radiotherapy or brachytherapy. HIFU is the only treatment that can be performed as a day-case under a single general anaesthetic. The prostate cancer needs to be confined to the prostate and in general men with smaller prostates are better candidates but those with larger prostates can undergo hormone therapy to decrease the size of the prostate prior to treatment with HIFU.

Can HIFU be used after previous treatments for prostate cancer?

Yes. An important use of HIFU is for patients who fail or develop recurrence following radiation therapy.

What are the advantages of HIFU?

1. It is a minimally invasive procedure (no cuts or needles inserted into the body)
2. No radiation toxicity
3. A short hospital stay and recuperation period
4. The procedure can be repeated if initial HIFU has failed
5. Radiation therapy and surgery are still options if the procedure fails
6. Urinary incontinence is very uncommon (less than 5% of patients)

What are the disadvantages?

1. Erectile dysfunction is common although most men will maintain adequate erections
2. A urinary catheter is required for 10 -14 days post-treatment
3. Most men will be infertile following HIFU and will experience decreased or no ejaculatory fluid
4. One-third of men will experience some urinary symptoms such as a stinging when passing urine and poor flow of urine for up to 8 weeks
5. A relative lack of long term data on the use of HIFU for prostate cancer compared to the more established alternatives

What are the long term risks associated with the procedure?

- Erectile dysfunction (impotence) is not uncommon – 20-30%
- Urethral stricture (narrowing of the urethra)
- Urinary incontinence or leakage with exertion (<5%)
- Fistula formation

Fortunately fistula formation is rare – a recto-urethral fistula is the most critical concern but has a reported incidence of only 0.5%. This is a channel which is created between the prostate or bladder and the rectum and this may require further corrective surgery. Thus far there have been no cases of fistula reported in the UK.

For more information please visit www.focalprostatetherapy.co.uk or www.prostatecancerhifu.co.uk