



## Frequently Asked Questions about HIFU

**Note:** For answers to any health-related questions as they may specifically apply to you, please consult with your treating urologist or other physician. The answers below should only be used as general, illustrative information.

### 1. Where does the procedure take place?

The procedure takes place at the Cleveland Clinic Canada. Cleveland Clinic Canada, the Canadian location of the Cleveland Clinic, is an outpatient facility that specializes in disease prevention, early detection and sports medicine. The clinic overlooks downtown Toronto from the 30th floor of Brookfield Place at 181 Bay Street. See <http://my.clevelandclinic.org/canada> for further information about the treatment facility.

### 2. How long will I be in the hospital?

There is no overnight hospital stay associated with the Ablatherm HIFU treatment. You are required to travel with someone as the treatment is completed with intravenous sedation. You are required to be in Toronto for two nights, so we provide deluxe hotel accommodations for you.

On the day of your arrival you will be seen by one of the treating urologists, one of the anesthesiology staff and the nurse coordinating your treatment plan. This takes about one and a half hours. You will then return to your hotel. On the day of treatment you will come to the hospital one hour in advance of treatment. Treatment takes approximately two hours with recovery lasting another three to four hours. Patients will spend six to seven hours at the hospital on the day of treatment and will be discharged into the care of a family member or friend to return to the hotel. The following day your urologist will call you at the hotel early in the day before you travel home.

### 3. How long until I can have the procedure?

Patients who are interested in Ablatherm HIFU should call toll free 1-877-370-4438. You can also complete the "contact us" portion of this site. One of the nurses will telephone you to begin the process to determine if you are a candidate. Maple Leaf HIFU will assist you to collect all the necessary patient information. During this time one of the urologists will contact you to answer questions and/or concerns. Treatment can generally be arranged within two to three weeks. Patients will be sent a consent package detailing everything that is needed to proceed with treatment.

### 4. How long does the procedure take?

The treatment time ranges from two to two and a half hours depending on the size of your prostate. The urologist will map an outline of the prostate using ultrasound to determine the areas to be treated. 400 to 600 pulses of high intensity, focused ultrasound are then administered to the prostate.

## **5. I am diabetic. Is that a problem?**

Patients who are diabetic can be treated with Ablatherm HIFU. Anyone who is an insulin dependent diabetic is routinely treated as the first case of the day.

## **6. I have a cardiac history? Can I still have HIFU?**

An additional benefit of HIFU is that patients with a cardiac history that would not be a candidate for surgery can still qualify for HIFU. Patients with a history of cardiac problems will be asked to provide a cardiologist consult prior to treatment. Each patient's history is assessed by our anesthesiologist on a case by case basis. All patients need to forward blood work and an electrocardiogram in advance of treatment.

## **7. I'm taking hormone therapy. Do I still qualify?**

Yes, you still qualify. Hormone therapy is not a contraindication to HIFU.

## **8. Will I need a TURP or hormones before the procedure?**

Some patients with large prostates, i.e. greater than 40 cc (or grams), or those with significant voiding symptoms may require pretreatment debulking either by transurethral resection of the prostate (TURP) or hormone treatment. In our experience 1 in 6 men may require this debulking. The size of the prostate is measured by ultrasound at the time of the biopsy.

If a TURP or hormone therapy is required prior to Ablatherm HIFU it accomplishes two things:

a) The Ablatherm HIFU machine works by using a fixed focal length generator to focus the ultrasound waves into the prostate. A TURP reduces the size of the prostate and enables the entire gland to be included with reduced treatment time.

b) By reducing the size of the prostate prior to the Ablatherm HIFU treatment, less tissue is present to be destroyed during the procedure. With a smaller prostate there is less swelling and edema with less likelihood of urine retention post catheter removal.

## **9. Are there any drugs that I should avoid prior to treatment?**

All blood thinners including low dose aspirin must be discontinued seven to ten days prior to treatment due to the spinal anesthetic. In certain situations additional blood work is required prior to treatment. Each case must be assessed individually.

All of the following medications need to be stopped.

- 1) Aspirin including baby aspirin
- 2) Plavix (Clopidogrel)
- 3) Coumadin (Warfarin)
- 4) Ticlid (Ticlopidine)

Certain herbal products and vitamins can also have blood thinning components so it is a good idea to discontinue these products as well.

## **10. What type of pain medication will I require following treatment?**

Patients are given pain medication while in the hospital based upon the amount of discomfort they are experiencing. Usually Tylenol with codeine is adequate. On a few occasions something a little stronger may be ordered. A prescription for pain medications is provided for use after discharge. Some patients report that they did not require any medication while others do take some medication for a few days after treatment.

Sitting in a tub of warm water is also helpful for any rectal discomfort or pelvic cramping.

## **11. Will I require other medication after treatment?**

Yes, you will be required to be on an antibiotic during the time you have a catheter as there is a risk that the catheter can cause a urinary tract infection. In addition you will be provided with a prescription to reduce spasm which can occur for a short time after treatment. Sitting in a tub of warm water is also helpful for any pelvic cramping. Another medication, Flomax, is to start a few days prior to having your catheter removed to assist with voiding.

## **12. Is the procedure done with an anesthetic?**

The procedure is completed under spinal anesthesia which is required so the patient remains comfortable and still through the two hour treatment. This is very important. When the machine detects any movement, treatment stops immediately. This is one of the safety mechanisms offered with Ablatherm HIFU as programming and treatment is very precise.

All patients are given intravenous sedation which allows them to sleep throughout the treatment. Most men do not remember any of their treatment. For this reason you are required to be accompanied by someone after treatment.

## **13. The rectal probe looks much larger than the standard biopsy/ultrasound probe. Is that why the spinal is required?**

Actually the probe is not much larger. The procedure is completed under spinal anesthesia which is required so the patient remains comfortable and still through the two hour treatment. This is very important. When the machine detects any movement, treatment stops immediately. This is one of the many safety mechanisms offered with Ablatherm HIFU as programming and treatment are very precise. Another safety feature is that the treatment probe is constantly measuring the distance between the treatment probe and the rectal wall.

## **14. I understand that I have to wear a catheter after treatment. How long must I wear a catheter?**

A catheter must be worn for 14 days following treatment as there will be swelling and edema of the treated prostate. The catheter drains the urine from the bladder until the swelling of the prostate subsides. After the HIFU treatment, the destroyed prostate tissue is passed in the urine. It is common to see this sloughed material in the catheter bag. It has been described as looking like "wet tissue paper" or "cotton candy." You may see blood in the urine up to 12 weeks post treatment. This can be dark brown in color or a bright red color. This is a normal part of the healing process.

The catheter can be removed by the patient's physician in his home town.

### **15. Is there any possibility that I will need to wear my catheter longer than 14 days?**

Some men do require indwelling catheters longer than 14 days. This is more likely with men with larger prostates and in men who experience voiding difficulty prior to treatment. Unfortunately this cannot always be predicted in advance and catheter reinsertion is sometimes required. If the catheter is reinserted it should be left in place several days. It is important to take bladder neck relaxing medication (Flomax) prior to catheter removal.

### **16. How will I know when to have my catheter removed?**

The appropriate timeframe for having the catheter removed is not an exact science. It is a process of trial and error. On occasion patients have had to have their catheter reinserted after removal. Unfortunately this can seldom be predicted in advance as noted above. We think that 14 days is the most appropriate time.

### **17. Can I travel with my catheter?**

Yes, most of our patients travel to have their treatment. While you will be able to drive with the catheter you will not be able to drive the day of treatment due to your anesthetic. The catheter may be a little uncomfortable for the first day or two while driving. Sitting as a passenger is not a problem.

### **18. When I urinate I have no problem other than the stream is steady and small and it takes much longer. Will the stream get stronger as the healing process continues?**

Post HIFU there is edema or swelling which does lead to a reduced stream which can persist over several weeks. Occasionally if the stream continues to be of a reduced nature further investigation and treatment may be necessary due to ongoing sloughing of the prostate tissue. This sloughed tissue may block the urethra so an outpatient cystoscopy may need to be done by your urologist to flush remaining tissue.

### **19. What are the chances (%) of urinary incontinence?**

Urinary incontinence is classified as grade 1, 2, or 3, depending on the severity of the incontinence. Grade 1 is minimal stress incontinence which occurs only occasionally and occurs with severe straining. Grade 3 is severe or complete incontinence. After HIFU, Grade 1 incontinence occurs in less than 5% of cases. Grade 2 and 3 incontinence are very rare after HIFU occurring in less than 1% of cases performed as the primary treatment for prostate cancer. After failed radiation therapy or failed brachytherapy (radioactive seeds) up to 8% of patients will have Type 3 incontinence following salvage therapy with HIFU. These rates for treatment of primary prostate cancer and for treatment after failed radiation therapy and failed brachytherapy are both considerably better than for treatment with surgery or cryotherapy.

### **20. What types of activity can cause leakage?**

Incontinence can be of several types. There can be mild incontinence for a few days when a catheter is removed or small amounts of urine can be lost as a result of stressful activities which increase abdominal pressure such as heavy lifting. This type of incontinence (Type 1) is usually time limited and can be eliminated by pelvic muscle exercises known as Kegel exercises. This is not uncommon with HIFU but is not a serious long term problem. More severe incontinence (Types 2 and 3) which requires long term use of incontinence pads and may be found after surgery or radiation treatment is very rarely a problem with primary treatment with HIFU.

## **21. What are the chances (%) of impotence?**

Injury to the neurovascular bundle can largely be prevented by a nerve sparing treatment procedure. Like other treatments including surgery this is not 100% certain but results are as good as nerve sparing surgery and better than with other treatment modalities. Many patients experience temporary erectile difficulties and it is not possible to predict what the final result might be for several months post treatment. The use of pharmaceutical agents at any time can assist with the quality of erectile function.

## **22. Approximately how long will it take for the damaged nerves to repair themselves and return my erectile function? I was told that they would come back and that I may need Viagra or Cialis for a while.**

Injured nerves may regenerate over time but several months, perhaps up to one year, are required before outcomes can be assessed. The literature now suggests that Viagra, Levitra, Cialis etc, assists with healing by increasing blood flow to the area. You may wish to start taking these medications twice a week once your catheter is removed to assist with the quality of erectile function.

## **23. How does the nerve sparing procedure work?**

Ultrasound imaging allows visualization of the neurovascular bundles (blood vessels and nerves) which run immediately adjacent to the prostate. The nerves in these bundles are what control erections. Precise localization of these bundles allows treatment to within 2 to 3 mm of them. This technique is designed to preserve potency with still a high probability of eliminating all cancer. The nerve sparing procedure is done only on prostates which have biopsies that are negative for cancer in the lobe of the gland where the nerve sparing procedure is performed. Only one neurovascular bundle needs to be preserved.

## **24. If I were to have HIFU with a nerve sparing procedure and there was a recurrence, is it possible to have a radical prostatectomy with a nerve sparing procedure?**

If there is a recurrence, HIFU would be the ideal treatment option. Surgery would be possible, but it would be more difficult. As a general rule of thumb, any time you combine treatment you lower the possibility of sparing the nerves. If the tumor recurs after HIFU it is possible to try to save the nerves but there is a significant chance that it would not be successful.

## **25. In the biopsy report it was mentioned that there could be perineural invasion. Does this affect the HIFU procedure and nerve sparing?**

Pathologists often report "perineural invasion" but this carries no prognostic significance and refers to small nerve fibers within the prostate. A tumor around these nerves is an indicator that there is a malignant cancer in the prostate. Surrounding the nerve bundles is an open space that acts as a free passage for cancer cells to grow. The presence of cancer cells in the "perineural space" is one of the factors used in making the diagnosis of prostate cancer (benign tissue will not get into that space). This does not indicate that the cancer has spread outside of the prostate (lymph nodes) but it does suggest that the cancer has been present for a longer period of time. This would not affect HIFU.

These nerves have nothing to do with erectile function so it does not interfere with the nerve sparing technique. The main nerves for erections are outside of the prostate in the neurovascular bundles.

## **26. What happens to the prostate after the procedure?**

Ablatherm HIFU treatment completely destroys the prostate tissue and cancer cells reducing them to protein debris and non-viable tissue. Most of this tissue is sloughed through the urinary tract while some is re-absorbed by the body's natural mechanisms of dealing with injured or non-viable tissue.

## **27. Do some patients require repeat treatment?**

Every treatment, surgery, radiation or HIFU, has a recurrence rate. There is no medical treatment that is 100% guaranteed. Re-treatment rates also vary based on whether a patient is eligible for, and chooses, a "nerve sparing" procedure. The impotency rate is lower in nerve sparing but that can result in an increase in the re-treatment rate. The benefit of HIFU, unlike any other treatment, is that it does not limit future options. Should cancer recur, HIFU can be repeated or a patient can have the choice of surgery or radiation. Surgery and radiation cannot be repeated.

## **28. Is there a chance that the cancer could return at some point after treatment?**

The goal of HIFU and all other treatment modalities is to destroy all the prostate tissue. If the entire prostate is not destroyed, it is remotely possible to develop a recurrence or a new tumor in a remnant of tissue.

With a nerve sparing technique, viable prostate tissue is preserved. Recurrence could result in the remaining prostate margins which are preserved or not treated during nerve sparing procedures or as a result of a large amount of anterior prostate tissue. Recurrence here would be unlikely because the anterior lobe rarely, if ever, is the site of a new malignancy. The benefit of HIFU is that the area could then be retreated.

## **29. Will I need to have a repeat biopsy and if I do what do you biopsy if the prostate is no longer there?**

Biopsies are only done if the PSA continues to be elevated or rise persistently. A repeat transrectal ultrasound (TRUS) will be required to visualize any remaining or recurrent prostate cancer and biopsy of the tissue will be performed. The biopsy is conducted on the scar tissue that is left behind. Negative biopsies indicate that cancer is no longer present.

## **30. What is a normal PSA?**

Each PSA assay technique lists an expected "normal" value. Usually it is about 4.0 ng/ml. There is at least one nomogram that suggests that this level is not always the same and can rise with age. There is more and more evidence that suggests that there is no safe or normal level and prostate cancer can exist in patients with values significantly less than 4.0.

What is more important is the rate of increase (velocity) of PSA year after year or the rate at which velocity is increasing (acceleration). A rate of increase greater than 0.75 per year should trigger a biopsy. There are multiple other factors as well including prostate volume, presence of inflammatory disease (prostatitis), etc that can elevate the PSA.

**31. If my cancer of the prostate has a Gleason score of 8 or greater do I need to have my seminal vesicles treated?**

No. There is no evidence that treatment of seminal vesicles will alter the course of your cancer of the prostate. The leading urologists in Europe, including those from Lyon, France and Munich and Regensburg, Germany who have been doing HIFU for greater than 10 years, do not advise treatment of seminal vesicles. Indeed, when these same urologists were asked about the practice of treating seminal vesicles with HIFU at a recent European Association of Urology Congress, they all condemned this practice. They pointed out that not only are there no clinical publications supporting the use of HIFU for this purpose, but also there is a tremendous risk of overheating the entrance of the ureter into the bladder, which could lead to damage of the kidney.

**32. If my PSA is 10 or greater should my seminal vesicles be treated?**

No. Just as with a Gleason of 8 or greater, there is no evidence that treatment of seminal vesicles with HIFU is of value.

**33. If there is no value in treating seminal vesicles why do the people at USHIFU advocate treatment of the seminal vesicles with the Sonablate 500 if a patient has a Gleason score equal to or greater than 8 or a PSA of 10 or higher?**

We do not know. However, they do charge an additional \$5,000 for this treatment, according to their published information.

**34. How much experience do you have with the technology?**

Treatments in Canada began in April 2005. All our urologists are certified in HIFU technology. Training took place in Germany and onsite in Toronto with the German and French teams participating in mentoring. World wide, greater than 20,000 men have been treated with Ablatherm HIFU with this number increasing weekly.

**35. Do you have recent statistics regarding success rates and side effects?**

HIFU was first used to treat prostate cancer in approximately 1997. There have been many improvements in the technology since that time which took an already safe treatment and made it safer. Since 2002 the statistics indicate that cure rates showing negative biopsy is 93% and 87% showing constant PSA of less than 1 in a study of 146 men treated in Regensburg, Germany. Ablatherm HIFU's ten year data was recently released in Berlin. It will be available for circulation in the near future. Prior to 2002 there was a small risk of rectal injury. Since the parameters changed in the technology in 2002, and patients with a rectal wall thickness of greater than 6 mm have been excluded, very few cases of rectal fistula have been reported using Ablatherm® HIFU technology. Please contact us for peer reviewed journal articles.

**36. Why can't I have this procedure done in the United States?**

Ablatherm HIFU is currently under clinical trials by the United States Food & Drug Administration (FDA). FDA requires that clinical trials be performed in the US, whereas Canada accepted the European clinical trial data. After many years of development and testing, Ablatherm HIFU was approved throughout the European Union in 2000 and in Canada in March 2003.

[Click here to see Health Canada license.](#) (PDF file will open in new window)

**37. My doctor tells me that HIFU is “experimental”. I thought it had been in use for over a decade.**

HIFU is relatively new to North America, so some physicians may not be aware of the non-invasive approach to treating prostate cancer.

As of April 2003, Health Canada, which is the equivalent to the FDA in the United States, approved Ablatherm HIFU to be a safe and effective method of treating prostate cancer. Ablatherm HIFU has also been approved by the European Union and many other countries including Great Britain. Tens of thousands of treatments have been performed worldwide and the results have been published in peer reviewed medical journals. Please contact us if you would like us to send you or your doctor peer reviewed journal articles.

**38. Will my insurance cover the cost?**

The cost of the procedure is typically covered by the patient. While there have been no instances of pre-approvals granted for HIFU, we are aware of a number of insurance companies that have provided reimbursement for the procedure. We will be pleased to provide you with documentation to assist you as you attempt to claim benefits. More detailed information [can be found here](#). Canadian and American patients can defray some of the cost of treatment when filing their annual tax returns. Contact us for further information.

**39. Will I be able to deduct the cost of HIFU from my income taxes?**

Canadian patients are only eligible to claim medical expense tax credits with respect to HIFU treatment that is provided by and billed through a medical doctor or to a public or licensed private hospital. The ability to claim the medical expense tax credit can result in a substantial tax savings which can reduce the after tax cost of the HIFU treatment by up to 30%. The actual tax savings available to each Canadian patient with respect to HIFU treatment will depend on the patient's particular circumstances including the patient's marginal tax rate, province of residence and whether the expense is paid for out of a private supplementary health plan.

US patients are able to deduct medical expenses that exceed 7.5% of their adjusted gross income. Details can be found at [www.irs.gov/taxtopics/tc502.html](http://www.irs.gov/taxtopics/tc502.html) .

Contact us directly if you have any further questions about this important issue of tax deductibility. Note that the information contained in this FAQ is for general information purposes only, and is not intended as legal or tax advice. We encourage you to consult with your personal tax and legal advisor regarding the best tax strategy for you concerning your HIFU related costs.

**40. Do you offer a payment plan?**

Yes. For Canadian patients, financing is offered through Credit Medical. They can be reached at 1-800-270-9290. For American patients, financing is offered through two different companies, MedicalFinancing.com and MedChoiceFinancial.com. You can get additional info at [www.medicalfinancing.com](http://www.medicalfinancing.com) (888-502-8085) and at [www.medchoicefinancial.com](http://www.medchoicefinancial.com) (800-358-8980).

#### **41. Who makes the machine?**

The entire unit which includes the bed, computer console, and transrectal probe is manufactured by EDAP (<http://www.edap-hifu.com>). EDAP is based in Lyon, France. Due to large investments in research and development, EDAP ensures its capacity to maintain its position as a pioneer in the area of therapeutic ultrasound. The strong distribution network reinforces the leadership position of EDAP in the area of High Intensity Focused Ultrasound.

EDAP SA is an EDAP TMS company. Listed on the US NASDAQ National Market System, the Group develops, manufactures and distributes a portfolio of minimally invasive medical devices mainly for the treatment of urological diseases.