

HIFU (High Intensity Focused Ultrasound)
Compiled by Charles (Chuck) Maack – Prostate Cancer Advocate/Activist

DISCLAIMER: Please recognize that I am not a Medical Doctor. I have been an avid student researching and studying prostate cancer as a survivor and continuing patient since 1992. I have dedicated my retirement years to continued research and study in order to serve as an advocate for prostate cancer awareness, and, from a activist patient's viewpoint, to voluntarily help patients, caregivers, and others interested develop an understanding of prostate cancer, its treatment options, and the treatment of the side effects that often accompany treatment. There is absolutely no charge for my mentoring – I provide this free service as one who has been there and hoping to make your journey one with better understanding and knowledge than was available to me when I was diagnosed so many years ago. Readers of this paper must understand that the comments or recommendations I make are not intended to be the procedure to blindly follow; rather, they are to be reviewed as my opinion, then used for further personal research, study, and subsequent discussion with the medical professional/physician providing your prostate cancer care.

If considering HIFU, I would recommend thoroughly reading the following to the end:

The most recent news (2015) : High Intensity Focused Ultrasound/HIFU has recently been approved for administering in the United States though only a handful of physicians, if that many, have the experience and are providing this procedure. This procedure has been provided in Europe for years. HIFU is also considered a “salvage” form of treatment for failed surgical removal as well as failed radiation, so you might want to look into this as a least invasive procedure. If you do so be sure to make sure that the physician providing the procedure accepts your health insurance and that the insurance will cover the procedure.

[FDA approves HIFU for “prostate tissue ablation.”](#)

<http://tinyurl.com/psnlonp>

From the foregoing url: “According to [a media release](#) issued by SonaCare Medical early this morning, the company has received approval from the U.S. Food and Drug Administration (FDA) to market its Sonablate® 450 technology in the U.S.A. for prostate tissue ablation.

This approval of SonaCare’s technology, based on high-intensity focused ultrasound (HIFU), is unusual in a number of ways, and we look forward to seeing documentation of the reasons behind the FDA’s decision:

- The approval is for an older form of the company’s technology and not for the newer Sonablate 500 technology, currently being used in Europe and elsewhere.”

SonaCare Medical media release:

<http://tinyurl.com/p5t79s2>

This is early information and there are still hurdles to likely leap before HIFU is readily available, that Medicare and other health insurers will cover, that medical facilities purchase the equipment/technology for use, and that physicians develop the experience/expertise wherein patients might show more interest in the procedure.

As far as I am aware, there are likely only a handful of U.S. physicians who have been traveling outside the U.S. after having encouraged patients to accompany them for administration of HIFU at outside U.S. locations who may have developed sufficient experience/expertise wherein patients could travel to those physician U.S. facilities for treatment.

Please review this information:

<http://www.charlotteobserver.com/living/health-family/article47397165.html>

The doctor described in the above, Dr. Samuel Peretsman can be contacted here:

201 Queens Rd, Charlotte, NC 28204
(704) 372-5180

And here is info explaining HIFU following failed IMRT:

[http://www.jurology.com/article/S0022-5347\(10\)00792-5/fulltext](http://www.jurology.com/article/S0022-5347(10)00792-5/fulltext)

THE INFORMATION BELOW WAS THAT I PROVIDED PRIOR TO THE ABOVE APPROVAL BY THE FDA. HIFU WENT THROUGH TRIALS HERE IN THE UNITED STATES FOR SEVERAL YEARS, AND ONLY NOW, IN 2015, HAS THE FDA FINALLY PROVIDED APPROVAL, AND THEN FOR ONLY ONE FORM OF HIFU TECHNOLOGY FOR USE IN THE UNITED STATES:

I have no idea if there are any restrictions in Mexico and Canada, or even in Europe, but the criteria in the trials here in the U.S. are quite stringent, and if a Gleason higher than 6, you wouldn't qualify. See below some of the information I have saved to my files regarding HIFU:

First is the email to me:

From:
Sent: Tuesday, June 23, 2009 12:30 PM
To: Chuck M
Subject: HIFU

Do you know about this?

I was sent an application for this and filled it out and a phone number popped up for me to call. I did not call it. It was in Arlington. This url list by state and the first one in Texas is by the doctor that did my first biopsy.

<http://www.clinicaltrials.gov/ct2/show/NCT00295802>

Following my reply:

Just continuing HIFU trial information. The restrictions for participation will preclude many men being able to participate. And it is interesting to note that even if the trial proves that HIFU alone as well as HIFU directed Cryosurgery are equal in effectiveness and safety, only men with Gleason 6 cancer would qualify. And even then, there are many restrictions as to volume of prostate, no previous therapy of any kind (like shrinking an enlarged prostate, and many others. So, likely many men fail to qualify

even if they wanted to participate. Not sure if all those locations are still accepting patients, since the information is dated 2006, but is interesting to note the several locations so that if someone was interested, they could check a facility in their area to see if they could still participate if they qualified. Taking note of how long these HIFU trials have been going on in the U.S., and even though they are in use in Canada, Europe, and Mexico, it appears it may be a long time before the FDA approves this as an option for treating prostate cancer.....and I wonder that if they do, there will be the same patient restrictions as to Gleason Score and other issues as in the trial.

High fall for HIFU?

“There is often significant initial enthusiasm for new technologies due to huge range of technological innovation in medicine today, however, treatments for localised prostate cancer need at least a 10 year follow-up to show efficacy over standard techniques.”

“Much of this enthusiasm is generated by companies that have invested heavily in these new technologies and often market them aggressively, irresponsibly and unwisely with immature data. It is suggested that HIFU is morbidity-free with better oncological outcomes than traditional treatments.”

“National medical bodies can also be drawn in by publicity; such as the National Institute for Clinical Excellence (NICE) in the UK, which initially supported HIFU but has subsequently changed its guidance and now recommend using it only within clinical trials.”

“In our hands, HIFU was unable to match traditional treatment modalities (minimally-invasive radical prostatectomy, external beam radiotherapy, or brachytherapy) for oncological efficacy. In addition it generated significant and devastating complications in some patients.”

“We would urge urologists against commencing a HIFU programme until high quality long-term data becomes available as we seriously question its safety and ability to cure localised prostate cancer.”

COSTS:

From a patient who had his treatment done in Canada.....(Even Canada health care does not cover this procedure. It is unlikely your U.S. insurance will cover treatment anywhere outside the U.S., but you should certainly check and make sure):

"Sonablate HIFU costs \$22,000 Canadian plus the cost of the hotel and travel expenses, while Ablatherm cost \$21,970 Canadian and includes the cost of the hotel for I believe two days but does not include travelling costs."

I am aware that a urologist in Arcadia, California, Douglas Chinn, provides the service in Mexico, so you would have to make arrangements through him as well as travel to Mexico. And it is my understanding that the procedure also costs somewhere in the vicinity of \$20,000.

From the manager of the John's Hopkins Bulletins:

"Erectile function following any prostate cancer therapy is a major concern for all men. A plus for HIFU is that ultrasound imaging during HIFU allows the surgeon to visualize the neurovascular bundles that are responsible for erectile function.

However, there is a misconception about erectile function and HIFU, with many men led to believe that ED can be completely avoided with this therapy.

According to Duke's Dr. Robertson, when it comes to erection results with HIFU, they're all over the place. He is sensitive to the issue that HIFU is a potency-preserving procedure. He thinks that it has been overhyped and misrepresented. If you read the scientific papers, 50% of patients have severe ED after treatment. One patient treated was 57 years old and had good erections,. He was sexually active six weeks later. However, the typical pattern of HIFU is that erections disappear, and then they recover. They recover slowly, with partial erections. The men will respond to Viagra, Cialis, and Levitra.

Maybe, in a year or so, they finally get back to normal, without the need for medication. Dr. Robertson believes that the delay in return of erections may be due to the damage to arteries that supply blood to the penis, but he admits that no one is actually certain.

Take a 55 year old with a high pre-treatment score on the IIEF [International Index of Erectile Function] and give him a high-quality

retropubic radical prostatectomy with nerve sparing technique—the “Johns Hopkins technique”—and he is probably going to come out with a better return of erections than he would with HIFU, according to Dr. Robertson. “At this point, I can’t see how we can create an ablative thermal energy treatment that is going to be as good as a quality nerve sparing procedure.”

FROM PC PATIENT JOHN VIG in an email:

"I did look at both HIFU and cryo prior to my RP (as I've described in my experiences at Yananow.net) (MY NOTE: www.yananow.net) .

The problem with both techniques is a matter of anatomy and physics (I have a Ph.D. in physics). The anatomy problem is that the urethra goes thru the prostate. The physics problem is that nature is continuous, i.e., two objects in contact must be at the same temperature at the interface (at steady-state).

HIFU is just a different way of generating heat. As the ultrasonic waves are absorbed by the (prostate and urethra) tissues, the tissues heat up. Cancer cells are destroyed by the heat.

Think of trying to make a well-done steak which has a plastic straw going thru its middle - without melting the straw. You can make the steak well done everywhere except at the surface of the straw, i.e., where the steak touches the straw. Either you keep the steak cool near the straw, in which case the steak won't be well done there, or, you make the steak just as hot near the straw as everywhere else, in which case you melt the straw.

Studies have shown that, in a small but significant percentage of cases (I give the reference to a Mayo study in my Yananow writeup), there are cancer cells right up against the urethra. So, the dr has the choice of keeping the heat away from the urethra, and thereby, possibly not destroying 100% of cancer cells, or, cooking the urethra too. If someone could guarantee that there are no cancer cells at the urethra, HIFU should work, but, why take a chance?

In a RP, the urethra in the prostate is cut out with the prostate. The remaining urethra is then reconnected to the bladder."

FROM JOHN'S HOPKINS "PROSTATE DISORDERS" August 21, 2008 and reviewed again in July 2009:

" The jury's still out ... While HIFU is a technology with considerable promise, many doctors agree with Dr. Robertson of Duke University who remarked, "Although many centers in Europe have used it and achieve varying results with many patients, there have not been a lot of scientific publications. We are in the dark about how effective this treatment is long term."

H. Ballentine Carter, M.D., Professor of Urology at Johns Hopkins, has performed more than 3,000 radical prostatectomies. His two words of advice for men contemplating HIFU therapy for prostate cancer: "Buyer, beware!"

THE FOLLOWING IS ALSO AN IMPORTANT URL TO OPEN AND READ:

HIFU - High Intensity Ultra Sound? Don't Rush To Treatment!

<http://tinyurl.com/25fws5>

and HIFU is not necessarily as safe as suggested

<http://tinyurl.com/yz2wuml>

To be fair, the URL below leads to a lengthy discussion by patients and others regarding this procedure. And as is usually the case, those who post the most have experienced a successful result up to the time of the posting. Effects that may occur over time have not yet been sufficiently determined

<http://tinyurl.com/yku3xfy>

And now we find this more recent study in 2010:

If considering High Intensity Focused Ultrasonography (HIFU), please note the following remark from this six-year study:

<http://tinyurl.com/26ss6tk> (You may be required to subscribe to URO Today to read the full article. However, URO Today has significantly reduced its usual subscription price to only \$39.00 per year for cancer patients. The daily URO

Today email reports provide the latest in prostate cancer research and technology and well worth the subscription price).

“In our experience, Ablatherm(TM) treatment for clinically localized prostate cancer was associated with a high rate of biochemical failure as determined by the 'Stuttgart' definition, and did not achieve effective cancer control. The PSA nadir value after HIFU treatment was a significant predictor of treatment failure.”

The “Stuttgart” definition is a new, more accurate, definition of biochemical failure. See:

<http://www.ncbi.nlm.nih.gov/pubmed/19388986>

Best advice: Beware!