



## High-Intensity Focused Ultrasound (HIFU) Treatment of Organ-Confined Prostate Cancer

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High-intensity focused ultrasound (HIFU) offers a noninvasive, ambulatory treatment alternative for patients suffering from organ-confined prostate cancer. This technology has been available in Western Europe for more than a decade and in Canada since 2004 when it was approved by Health Canada. A clinical trial in the United States intended to achieve approval by the Food & Drug Administration (FDA) has ceased accrual, allowing data to mature over the next two years at which point application will be made for approval in the United States.

Ablatherm® HIFU is now available at Cleveland Clinic Canada in Toronto and is offered by Maple Leaf HIFU, a limited Cleveland Clinic-Canadian partnership. Treatment is a single session, typically two hours in duration, and is performed on an ambulatory basis. Spinal anesthetic and intravenous sedation is preferred, and patients require an indwelling urethra Foley for a minimum of two weeks.

Data generated by Maple Leaf HIFU on 303 primary treatment patients in the low- and medium-risk category document biochemical progression free survival (BPFS) of approximately 80% in the low-risk category and 70% in the medium-risk category with longest follow-up being five years.

These data are comparable to those produced in Western Europe where published studies with follow-up of up to 10 years are now available.

In addition to being a primary treatment modality, HIFU can also be used in those patients who have failed radiation therapy and can, as well, be repeated in patients who have failed initial HIFU treatment.

To qualify as a candidate for HIFU, patients must have prostate volume less than 40 grams and no evidence of regional or distant spread of disease. Where initial prostate volume exceeds 40 grams prostate size reduction can be done utilizing androgen-deprivation therapy either in the form of luteinizing hormone-releasing hormone (LHRH) agonists or 5 alpha reductase inhibitors. Transurethral resection of the prostate (TURP) can be used and is regularly utilized in the European treatment model, but has not been a common factor in North American treatment protocols.

Common post-treatment sequelae to HIFU include delayed return to normal voiding as a result of post-treatment edema, tissue slough or both, which may impede urine passage in the early weeks post HIFU. Later complications including urethral stricture formation occur in some patients and may require urethral dilatation or transurethral visual urethrotomy.