ProstaLund Feedback Thermotherapy: A Review

Benjamin T. Larson, MD*, Magnus B. Bolmsjö, MD, Lennart Wagrell, MD, and Thayne R. Larson, MD

Introduction

The aging prostate accounts for an inordinately high level of discomfort and disease in men. Benign prostatic hyperplasia (BPH) and prostate cancer together account for more surgical procedures for patients older than 50 years of age than any combination of diseases in any other organ. In the past decade, the treatment of BPH and other prostatic diseases has extended beyond the standard of surgical transurethral resection of the prostate (TURP) and open adenectomy and includes various medical and minimally invasive procedures. Among the many new and innovative minimally invasive treatments, transurethral microwave thermotherapy (TUMT) has emerged as a viable alternative to surgery for the treatment of BPH and other prostatic diseases (e.g., cancer, prostatitis, and chronic retention). An advantage common to all of the TUMT devices is the ability to heat the whole intended treatment volume simultaneously instead of several focal points, which is what many other minimally invasive methods do (i.e., transurethral needle ablation, high-intensity focused ultrasound, and interstitial laser) [1].

TUMT treatments reportedly have clinically similar results to TURP in subjective improvements (symptoms score). Objective improvements usually are fewer than they are after surgery in most studies [1–11]. For studies in which higher temperatures are reached in the prostate, objective and subjective TUMT results become closer to the results obtained from TURP.

Transurethral microwave thermotherapy TUMT uses the alternating electromagnetic waves of microwaves to cause oscillation of ions and electric dipoles (i.e., water) to create heat within cells that, after a period of time, exceeds the cytotoxic threshold, thereby inducing cell death [12]. Temperatures in excess of 45°C sustained for a period of 1 hour will cause necrosis in the prostate; higher temperatures will cause necrosis even quicker [13,14]. The extent of necrosis caused by TUMT treatment depends on the temperatures created in the prostate and the amount of time that the tissue is exposed to those temperatures [1,15–18]. This relationship is the bioheat equation and is vital in determining when thermal treatments are effective.

There are many TUMT devices on the market, each offering a different design and different features. Variations exist in antenna design, cooling capabilities, heat fields created, and patterns of necrosis. Some machines are able to create higher temperatures than others. In addition, the results reported vary because manufacturers are improving their products continually. This variation may create confusion regarding the appropriate qualities and applications of the treatment [19].

Most TUMT devices monitor the power output to the prostate and urethral and rectal temperatures to predict the temperatures reached within the prostate. This method may not give accurate predictions of intraprostatic temperatures; however, direct monitoring of prostatic temperatures does [12]. The ProstaLund feedback treatment (PLFT) device recognizes the importance of monitoring intraprostatic temperatures during treatment. It has incorporated temperature sensors into the design of the treatment catheter, which pro-
trudes into the prostate. The design allows for intraprostatic temperatures to be monitored in real time during the treatment in three locations.

ProstaLund also recognizes the importance of considering prostatic blood flow as a factor of efficiency. Blood acts as a heat sink and dissipates the thermal energy, thus lowering temperatures within the prostate. When there is an increase in blood flow within the prostate, more energy is required to make TUMT effective. Because each individual can have a different blood flow through the prostate, ProstaLund considers the inclusion of blood flow into cell kill calculations as one of the characteristics that separates them from other devices. Thus, the advantage of the ProstaLund device is the intraprostatic temperature monitoring and blood flow consideration, which contributes to the ability of the device to be adjusted to the specific needs of each patient during the treatment.

Clinical studies with the PLFT device provide evidence of the effectiveness of this innovated approach to TUMT. Reviews of several studies and summaries of the PLFT design and the science used to develop and test the device are discussed. New innovations using the PLFT machine also are discussed briefly at the end of this paper.

**ProstaLund Feedback Treatment Design**

The PLFT device consists of a control unit, temperature sensors for the rectum and penis, and a disposable microwave catheter. The control unit produces the energy, monitors power output, records temperatures (urethral, rectal, penal, and intraprostatic), and performs calculations based on these readings. The rectal temperature sensor ensures that temperatures do not increase beyond safety margins. The external penile sensor is an innovated device that attaches to the base of the penis and insures that the penis will not be damaged if the antenna shifts during treatment. If the balloon of the catheter deflates, the antenna may slide down and heat the penis; in this case, the external penal sensor will shut down the machine automatically.

The antenna is a helical dipole design contained in a Foley catheter. This design optimizes the delivery of microwave energy to the prostate [20••]. The catheter also contains a needle-like thermosensor that protrudes into one of the lateral lobes of the prostate, ideally at a 2 o’clock position in relation to the urethra (Fig. 1). Three thermistor sensors lay 1 cm apart along the extended needle. Correct placement of the thermosensor can be confirmed by transrectal ultrasound (TRUS), although treatment protocol does not require this. Intraprostatic temperatures are taken during treatment when there are brief moments of suspended microwave energy.

The three temperature readings are fed into a computerized calculation algorithm to predict treatment progress in terms of the amount of tissue that has been coagulated: the cell kill. When actual temperatures created are combined with the energy output of the machine, the prostatic blood flow and the cell kill can be estimated using several equations, which were developed by Jung [21], Henriques [22], and Pennes [23]. Energy, temperature, blood flow, and time are variables in ProstaLund’s cell kill model, which is used to track the amount of tissue ablated during treatment. This real-time estimate can be used by the physician to determine when to terminate treatment (usually between 15 and 60 minutes). Treatment time becomes shorter as physicians become more familiar with equipment and technique. These estimations also allow for adjustments to be made during treatment to customize to the individual (Fig. 2) [24•].

**Basic Science**

Understanding the basic science of a new device is crucial to its development and clinical implementation. TUMT machines must be able to create temperatures high enough to cause necrosis and the pattern of that heat must be known. ProstaLund has performed many studies to determine the basic science, heating capabilities, and heat pattern of the PLFT device. One such study used techniques described by Larson and Collins [25] to map temperatures within the prostate and demonstrated that the heat field created by the PLFT device creates temperatures in excess of 70°C within the prostate. The heat field was found to be in a funnel or cone-like shape that includes parts of the bladder neck and