CoreTherm®

CORETHERM® CONCEPT

The journey to find the best treatment in the world for BPE

ProstaLund®

Introduction

This is the story of the efforts that have been made to develop the ultimate device for treatment of BPE. It gives a glimpse into all the research and efforts that were undertaken by so many in order to improve the concept. Is CoreTherm® Concept today, the most efficient, well-thought, advanced and well-documented minimal invasive BPE device there is on the market? We think so.

This booklet provides a summary of published pivotal clinical trials and other principal studies of CoreTherm for treating BPE. Many more scientific papers have been published about CoreTherm but, due to space limitations, we have included only the foremost papers that tell the core story – how CoreTherm Concept came to be what it is today, the theory behind it and the clinical evidence.

We are very proud to introduce you to do a very interesting historical journey in the next pages. We hope you will enjoy reading it.

Lund, March 2023

The ProstaLund Team

The development from generic TUMT to CoreTherm Concept

The story of CoreTherm® began 30 years ago. The grand idea to abandon surgery and treat enlarged prostates with heat instead had emerged a decade earlier. At that time, it had led to many different devices of various kinds and brands; some had very low power output, some had very high, some used a cooled treatment catheter, and some did not. Some even heated through the rectum, although that path did not last long. Heating via the transurethral pathway soon became the standard and the TUMT
– transurethral microwave thermotherapy – concept was born.

As always, when a technology is new and pristine, there was a lot of experimentation on optimal treatment time, microwave power, temperature, and things like that. It was the golden age of myth and speculation. Some argued that microwaves had an undefined action on alfa-receptors because patients usually reported improvements in symptoms.

Companies experimented with design and function, but most people had little understanding of the action of microwaves in tissue and the underlying core physics. The clinical outcomes of the early machines were random and inconsistent; some patients did very well, others did not. Yet, there was great optimism about the technology. The reason was the potential of replacing surgery with minimally invasive treatment, due to the surgery being a resource intensive treatment and the intolerance of full anesthesia for some patient groups.

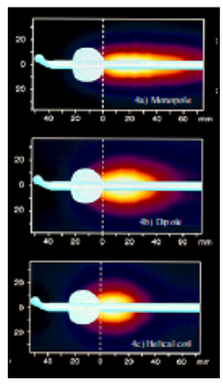
CoreTherm Concept has several components that makes it a unique method, opposed to regular TUMT. Heating the prostatic tissue via an antenna and a device creating microwaves is shared, but the fact that temperatures are measured continuously during treatment makes a crucial difference. Some TUMT-manufacturers focused solely on the transition from low energy TUMT to high-energy TUMT. Additionally, ProstaLund choose to start measuring intraprostatic temperatures and develop a unique feedback technique, which later was named CoreTherm. It is therefore appropriate to regard CoreTherm as a different method versus other variations of TUMT.

Kaye et al (1) has also described these differences: “Although the many available HE-TUMT systems vary in software, microwave antenna designs, and catheters, CoreTherm is unique in its ability to individualize treatments based on a cell kill calculation that incorporates real-time intraprostatic temperature monitoring. In addition, this device’s highest temperatures are reached at the bladder neck, where the α-receptors are located. These features may explain why CoreTherm most closely approximates TURP in many outcome parameters. Other HE-TUMT machines that solely use rectal or urethral probes may be inaccurate because their readings do not necessarily correlate well with prostatic temperature readings. CoreTherm’s constant intraprostatic monitoring maintains temperatures at an accurate optimal set point through power (wattage) adjustments”

Similarly, all medications are not equally effective/safe just because they are administered the same way. CoreTherm should be evaluated on its own documentation, and not mixed with other TUMT devices, since it is a further developed TUMT technique compared to the older “blind” devices, lacking the feedback technique.

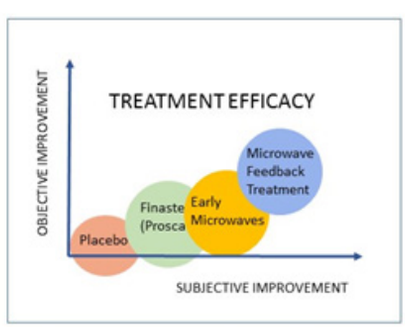
THE START

The year is 1996. ProstaLund had launched its first machine a few years earlier and was now onto the job of designing the next-generation machine. It was brought to life a few years later as “ProstaLund Compact” and the treatment as “ProstaLund Feedback Treatment – PLFT” and later “CoreTherm®” when the device was released in the US market. The design team was asked to create a new device that delivered consistent and superb treatment outcomes. To do that, science had to be done to answer fundamental questions. To bring order to the morass of myth and speculation, the scientific paper *“The heat is on - but how?”* was published in the British Journal of Urology by Bolmsjö et al. [2]. It described the underlying physics of TUMT, its action in the body and why some technical designs were better at focusing microwave heat into the prostate than others. It became the starting point for a quest by research teams to find the common denominator for the perfect microwave treatment.

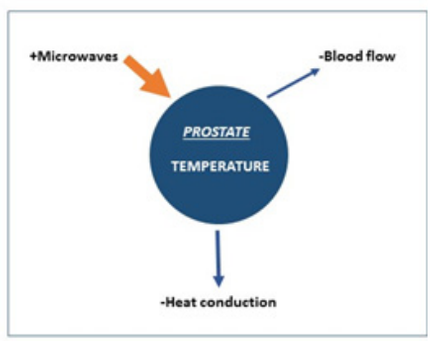


EARLY CLINICAL WORK

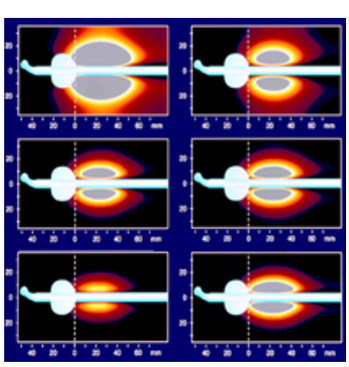
Next, in a paper by Wagrell et al., *“Intraprostatic Temperature Monitoring during Transurethral Microwave Thermotherapy for the Treatment of Benign Prostatic Hyperplasia”* published in the Journal of Urology in 1998, Wagrell showed that intraprostatic temperature was the most important factor for achieving outstanding clinical outcomes [3]. At too low a temperature, the treatment would fail. The paper also launched the idea that blood flow had to be considered because it counteracted the heat due to its cooling effect. Wagrell used color Doppler ultrasound imaging to visualize the prostate during treatment and had observed a huge rise in blood flow during the treatment. The paper established that temperature was the key factor for treatment outcome.



That discovery led to a subsequent paper, *“Optimizing transurethral microwave thermotherapy: a model for studying power, blood flow, temperature variations and tissue destruction,”* published in the British Journal of Urology in 1998 by Bolmsjö et al. [4]. The paper made headlines at the time and was on the cover of the journal. Wagrell’s study established that tissue temperature was the key factor and had to be controlled. Bolmsjö et al. explains that tissue temperature is determined by 3 processes: 1) generation of heat through absorption of the microwaves. 2) dispersion of heat by conduction in the tissue. 3) loss of heat/cooling through the bloodflow.

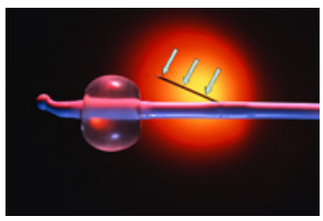


$$\rho c \frac{dT}{dt} = \lambda \Delta T - \omega_b \rho_b c_b \rho (T - T_a) + Q_s + Q_m$$



The paper also discusses the finding in the previous paper that blood flow is not constant, but changes during treatment as the blood circulation reacts to heat. The conclusion was obvious: the intraprostatic temperatures had to be monitored during treatment or the treatment would be unpredictable. Patients with inherent high intraprostatic blood perfusion would be undertreated, while

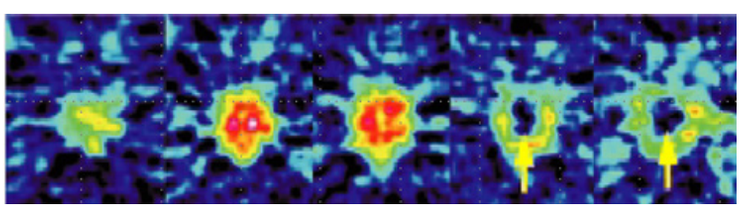
patients with low perfusion were at risk of being overtreated.



This was an important finding because higher-energy devices were about to be brought to the market at the time. From then on, the CoreTherm treatment catheter had an integrated thin monitoring probe, with multiple temperature sensors, that protrudes from the catheter into the prostate and monitors temperature throughout treatment.

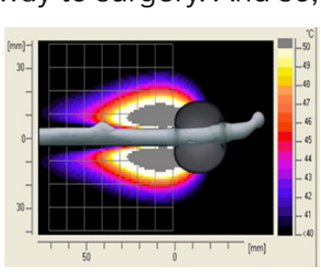
BREAKTHROUGH

Subsequently, in a paper by Wagrell, *"Intraprostatic Blood-Flow Changes during ProstaLund Feedback Treatment Measured by Positron Emission Tomography,"* first presented in his PhD dissertation in 1999 and later published in the Journal of Endourology [5], he used positron emission tomography to map the intraprostatic blood flow at treatment start and after 6, 21, 35 and 55 minutes. Wagrell convincingly demonstrated that there is a dramatic increase in prostatic blood flow during the first phase of treatment when the gland tries to reduce the heat from the microwaves and the subsequent dramatic event when the intraprostatic blood flow collapses some way into the treatment as the microwave heating becomes so intense that the defense mechanism gives up. At that point, the temperature spikes and coagulation necrosis occur within minutes, if not seconds. When this happens, treatment must end. The paper concluded that all treatments should be individualized and intraprostatic temperature must be monitored. Without it, the physician does not know when the temperature breakthrough occurs and when to end the treatment. The paper laid the foundations for understanding treatment dynamics.



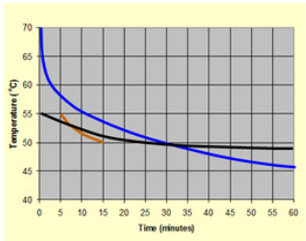
THE CELL-KILL CONCEPT

It was now known that the quality of TUMT treatment was determined by what temperatures were achieved. This in turn was determined by the amount of microwave power administered minus the unknown blood flow. But how could all of this be quantified to make the treatment predictable and understandable? The next paper, *"Cell-Kill Modeling of Microwave Thermotherapy for Treatment of Benign Prostatic Hyperplasia,"* by Bolmsjo et al. [6] published in the Journal of Endourology in 2000 gave the answer: by correlating the intraprostatic temperature to the amount of prostate shrinkage. The paper states that the main purpose of heat treatment is to shrink the prostate in a similar way to surgery. And so, the "cell-kill" concept and algorithms were born and subsequently integrated into the CoreTherm® device to steer treatment. The paper gave the theoretical framework on how to calculate cell-kill during treatment based on microwave power and measured intraprostatic temperatures. But one important riddle remained to be solved: what was the human prostate cell sensitivity to heat? That is, at what thermal dose will the cell be destroyed?

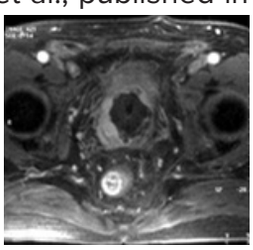


THERMAL DOSE

The answer came in “In vitro assessment of the efficacy of thermal therapy in human benign prostatic hyperplasia” by Bhowmick et al., published in the International Journal of Hyperthermia [7]. The study was performed at the University of Minneapolis and was initiated and sponsored by ProstaLund. It is a cornerstone for understanding the action of heat treatment. The study shows that the time it takes to create tissue necrosis in a human prostate falls exponentially with increased temperature: it takes 1 hour to create tissue necrosis at 45°C, but only 5 minutes at 55°C and 1 minute at 70°C.



In a subsequent paper, “Evaluation of Microwave Thermotherapy with Histopathology, Magnetic Resonance Imaging and Temperature Mapping” by Huidobro et al., published in The Journal of Urology, 2004, it was shown that CoreTherm’s cell-kill calculation was accurate and corresponded to the cell death and shrinkage found by histopathology and MRI [8]. Many other studies followed with the same results: the cell-kill calculation works and is a valuable tool to steer treatment. All the fundamental discoveries for how to use microwave treatment had now been revealed and it was time to transfer all this knowledge to something useful.



Although CoreTherm® around that time was a highly effective and safe treatment with features like real intraprostatic temperature monitoring and automatic cell-kill calculation, it was still a 45 to 60-minute-long treatment, not always comfortable. Due to this, there was still a desire to to further enhance the treatment.

PRIMARY AND SECONDARY ENDPOINT

The new innovative platform, CoreTherm® Eagle, has integrated technology that automatically calculates and measures the primary and secondary endpoints, which increases patient safety and operator convenience.

The endpoints were developed depending on the invention of the Schelin Catheter and possibility to deliver adrenaline and local anesthesia into the prostate (see next page).

In a retrospective analysis by Stenmark et al. [11] of 283 CoreTherm treatments between 2003 - 2008, the median treatment time was 11 minutes and the median microwave energy used was 30 kJoule. In that study, prostate size varied from 28 to 219 grams. This paper showed that when using mepivacaine and adrenaline there is a systematic underestimation of the resulting coagulation necrosis. A calculated cell kill of 21% yielded a volume reduction of 26% for prostate volumes less than 100 ml and a 31% volume reduction in prostates ≥ 100 ml. Based on this paper, the recommended primary endpoint is the cell kill 20%.

The secondary endpoint is based on the solid correlation between pretreatment prostate volume versus total energy deposition as Stenmark et al. [12] showed in another paper. This implies that a pretreatment calculation of an appropriate energy deposition should be used in all treatments as an alternative secondary treatment endpoint. The introduction of pre-calculations of thermal dose to avoid the deposition of excessive energy has further increased patient safety with CoreTherm treatments.

Schelin Catheter®

An important step to perfecting the treatment came with the invention of the Schelin Catheter®. The first version of the catheter was developed 2003. Further product developments were made and the optimized version saw the daylight a few years later. A transurethral catheter with a built-in flexible cannula to inject drugs directly into the prostate in a sterile way. In an instant, it became easy to administer local anesthetics, into the prostate prior to the treatment. By adding adrenaline to the cocktail, the intraprostatic blood flow could be effectively shut off for the 10 minutes or so that it takes the body to wash out adrenaline. The absence of the cooling effect of the bloodflow optimized the CoreTherm treatment to an easier and much faster intervention. In *"Mediating Transurethral Microwave Thermotherapy by Intraprostatic and Periprostatic Injections of Mepivacaine Epinephrine: Effects on Treatment Time, Energy Consumption, and Patient Comfort"* [9], reports the use of the Schelin Catheter and the dramatic effect it had on CoreTherm treatment time and patient comfort.

In a subsequent study, *"Effects of Intraprostatic and Periprostatic Injections of Mepivacaine Epinephrine on Intraprostatic Blood Flow during Transurethral Microwave Thermotherapy: Correlation with [150]H20-PET"* by Schelin et al., the authors demonstrated how injection of adrenaline effectively curbed blood flow during treatment [10].

In the aftermath, no other invention has had greater impact on CoreTherm treatments than the Schelin Catheter. It has transformed CoreTherm treatments from a 45 to 60-minute-long painful procedure into a less than 15-minutes almost painless procedure under local anesthesia.

USING THE SCHELIN CATHETER®

As described above, no other invention has had greater positive impact on CoreTherm® treatment than the Schelin Catheter®. It is used to inject local anesthetics directly into the prostate prior to treatment. Apart from significant pain-, and treatment time reduction, considerably less microwave energy is used to heat the prostate than before. Does that matter? Yes, it does. Being able to use less energy means lower risk of heating adjacent tissue, such as the external sphincter.

In one of the first clinical papers on the use of mepivacaine and adrenaline, patient comfort was significantly enhanced, treatment duration was halved from 60 minutes to 30 minutes and total microwave energy used decreased from 172 kJoule to 65 kJoule without impairing clinical efficacy [9]. As doctors learned how to perfect the use of the Schelin Catheter, patient comfort during treatment was further enhanced and treatment time shortened even more. Today, the CoreTherm Concept treatment duration is typically 6 to 15 minutes, with an average of 10 minutes.

CoreFlow® Soft Stent

The latest innovation in the CoreTherm Concept is the product CoreFlow. The launch of the product was in October 2020. CoreTherm® treatment causes the prostate to swell. Until the swelling has subsided the patient need relief to be able to empty his bladder. During the healing process the prostatic urethra needs to be separated so that the tissue does not grow together.

Before CoreFlow® Soft Stent was introduced, patients were ordinated indwelling catheters with the risk of urinary tract infections and catheter discomfort.

CoreFlow was invented in order to reduce the risk for urinary tract infections caused by ordinary indwelling catheters. When the rear section of CoreFlow is separated, the device transforms to a temporary prostatic stent, and the patient can urinate on his own or use self-catheterization by pulling the thread.

The idea is to reduce the risk of bacterial growth and invasion via the urethra since the latter is flushed when the patient is voiding. In addition, patients do not have to use a urine bag/valve linked to a catheter but urinate on their own, which has a major impact on quality of life. For patients who have undergone minimally invasive treatments, such as CoreTherm, CoreFlow is suitable to use as relief until the swelling has decreased. Patients can urinate on their own right from day zero.

CORETHERM EAGLE® & THE CONCEPT

The last piece of the puzzle.

In end of 2012, the EU began putting forward proposals to change the regulatory requirements for medical devices as a result of the breast implant scandal in France. This work within the EU culminated in the Medical Device Regulation (MDR) which was established 2017. The purpose of the MDR is to ensure patient safety by means of high requirements for transparency, documentation, tracking and feedback. This meant that ProstaLund began sketching a new version of its platform. Apart from a significant technology and component upgrade, the new platform also features the secondary endpoint, which increases safety and efficiency of the treatment. The new machine is made user friendly with various decision support functions, while maintaining the core features developed and enhanced over 25 years. The first development project was given the working name Eagle by the engineers. The product developed from that project and launched was named ProstaLund Compact. Then followed the new version CoreTherm System. Now that the whole concept is complete and our whole concept consists of several patented and unique inventions where the machine's treatment control is based on research and clinical experience since 25 years. We have tremendous strength and security in our concept and products. Therefore, the choice of name for our new platform was simple:

The eagle has landed - CoreTherm® Eagle

- Improved safety - automated safety stop
- User-friendly Touch Screen
- Sustainable design - 25% reduction in weight
- Integrated computer system
- Automatic Cellkill calculation (1st endpoint)
- Enhanced safety - automized 2nd endpoint calculation (energy point)
- Continuous Temperature Feedback
- Treatment data stored per patient
- Downloading data on USB is possible

CE-marked under MDR

THE CORETHERM CONCEPT

In our quest to, we have not only developed a treatment method for BPH/BPE, but we have also developed an entire concept, the CoreTherm Concept.

Dr. Fredrik Stenmark explains it nicely in his doctoral thesis [20]:
“There seems to be a never-ending flow of new techniques with the intent to cure patients with LUTS or CUR due to BPO. Perhaps this is, to some extent, driven by the conviction that a single method can be the solution for all patients and become the gold standard. This method must, of course, be the prostate size and age-independent and, most importantly, suit all patients regarding efficacy, tolerability, and safety. The CoreTherm Concept does, in many ways, tick those boxes, and is an outpatient option for surgical intervention. Despite that the CoreTherm Concept, in many ways, is a one-size-fits-all solution, it does not fit all men, but it fills the enormous gap between conservative treatment and surgery. In addition to filling a gap, it can also replace medical treatment for those men who wish to be cured instead of being doomed to lifelong medication or replace surgery for those wanting a less invasive procedure.”

The platform itself is a masterpiece and the CoreTherm Concept is probably the best BPE treatment in the world, if you look at parameters such as treatment results, possibility to treat regardless of prostate size, retreatment frequency, treatment time, fewer complications compared to surgical intervention, learning time for treating doctors and cost of treatment, etc.

CORETHERM CONCEPT IN 30 SECONDS

- Fast and effective - maximum 15 min BPE treatment time
- Broad treatment-group; sizes of prostate 20-360 cc
- Low re-treatment rates
- Suitable also for old and fragile patients
- Safe - Several benefits compared to TURP:
  - Lower risk for serious complications
  - Same efficacy
  - Indicated lower PCa risk

The platform

CoreTherm® Eagle

Pre-treatment

Schelin Catheter®

Treatment

CoreTherm® Catheter
(and antenna and safetyprobes)

Post-treatment

CoreFlow® Soft Stent

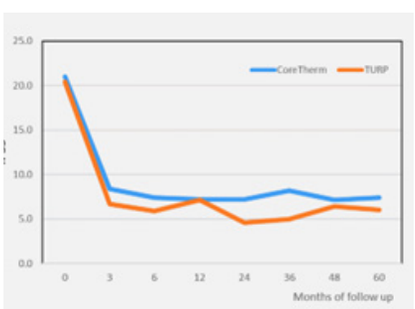
THE CLINICAL EVIDENCE - CORETHERM®

In the beginning of the new millennium, ProstaLund felt that their machine was technically far ahead of all its competitors. The knowledge acquired in the previously described science was incorporated in the new device and it had all the “must-have” features like intraprostatic temperature monitoring and cell-kill control. In a large FDA-controlled randomized multicenter clinical trial (2005) CoreTherm® was compared with the gold standard of the time - TURP. The study design involved 10 hospitals in the US, Denmark, and Sweden, including the Mayo Clinic in Scottsdale and the largest urology center in the Nordic countries, Herlev Hospital in Copenhagen. A total of 154 patients were randomized to either CoreTherm or TURP (ratio 2:1). Patients were followed up at 3, 12, 36 and 60 months [13, 14, 15]. An extract of the 5-year data follows.

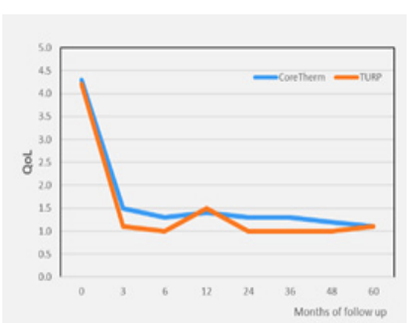
FDA-CONTROLLED RANDOMIZED MULTICENTER STUDY: CORETHREM® VS TURP

Introduction and Objective: A prospective randomized multicenter study of the safety and efficacy of ProstaLund CoreTherm® microwave treatments (PLFT®) for BPH was compared to TURP, 5 years post treatment. Efficacy variables were IPSS, bother score, Qmax, prostate volume, residual urine volume and adverse events.

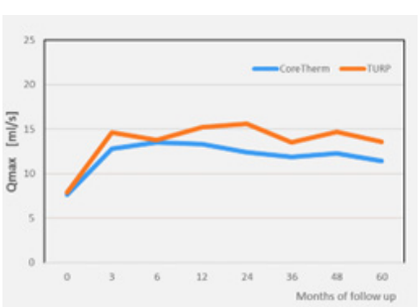
Methods: The study was conducted at 10 centers in the US and Scandinavia. A total of 154 patients with BPH were randomized to CoreTherm or TURP at a 2:1 ratio. The CoreTherm treatments were carried out with intraprostatic temperature monitoring and by adjusting the microwave power for each patient to obtain desired tissue necrosis (≈30% of prostate volume at baseline). The TURP procedures were carried out using the standard protocols at each center.



Results: Subjective improvement, IPSS, was similar in both treatment groups. At 3-months follow-up, there was a marked decrease in mean IPSS from 21 to 8 in the CoreTherm group and from 20 to 7 in the TURP group, sustained over the 5 years with no statistical difference between the two groups. The same pattern was also seen for bother score with no statistical difference between the two groups. Qmax appeared to be somewhat better with TURP (difference vs CoreTherm was 2 ml/s), however there was no statistically significant difference between the two groups.



Over the complete 5-year study, the frequency of severe adverse events reported as related to the treatment was 5% in the CoreTherm group and 17% in the TURP group. Severe adverse events in the CoreTherm group were hematuria, urine retention and bladder calculus. In the TURP group the events were hematuria, UTI, urosepsis, TURP syndrome and clot retention.



Conclusions: 5-year follow-up shows comparable efficacy in both treatment groups. Long term follow-up of adverse events during the post-treatment period up to 5 years reveals no major safety concerns for CoreTherm. Hence, CoreTherm may be one of the best minimally invasive procedures that can be performed in an outpatient setting, challenging TURP as the preferred first-line treatment of patients.

PATIENTS IN URINARY RETENTION

Soon after CoreTherm® was launched, reports started to appear of its use on patients with chronic urinary retention. In one of the early papers on the subject [16], 24 patients in urinary retention and with an indwelling catheter were treated. Of these, 19 (80%) were successfully relieved of their indwelling catheter. This was the era before the Schelin Catheter®, so treatment duration in that study was still about an hour and the corresponding total microwave energy was 211 kJoule. That early study sparked renewed interest in offering treatment to frail and weak patients who were not candidates for surgery and were often on indwelling catheters. Could the CoreTherm treatment be used for them?

RANDOMIZED MULTICENTER STUDY ON CORETHERM® VS SURGERY FOR PATIENS IN PERSISTENT URINARY RETENTION

A prospective study protocol was subsequently designed to investigate CoreTherm® on this patient category: the study was a randomized multicenter study comparing CoreTherm with TURP and prostate enucleation in patients with BPH and persistent urinary retention [17]. The study involved 120 patients and 17 hospitals in Sweden, Denmark, and Norway. The result confirmed earlier studies: 79% of the patients receiving CoreTherm were relieved of their indwelling catheter vs 88% in the surgery group. CoreTherm again confirmed its favorable safety profile: one serious adverse event occurred in the CoreTherm group (hematuria) compared with five cases in the surgery group (hematuria, urinary tract infection, hemorrhage, stroke, and bladder neck sclerosis). The Schelin Catheter® had not yet been launched, so treatment time was still on the high side (47 minutes) and the microwave energy administered was 152 kJoule. Twelve of the patients treated with CoreTherm had a prostate size greater than 100 grams before treatment – the largest was 176 grams. Earlier, there was often a notion that microwaves should not be used for prostates larger than 100 grams. This study clearly showed that large size was not a matter of concern.

DANISH STUDY ON CHRONIC URINARY RETENTION CONFIRMS EFFICACY

In a study at one of the largest Danish urology centers, Faurholt Aagaard et al. used CoreTherm® on patients in chronic urinary retention and unsuitable for surgery [18]. In all, 124 patients were treated with CoreTherm: 77% were relieved of their indwelling catheters, which is consistent with previous results. The authors conclude that CoreTherm is an effective treatment for patients who are not candidates for surgery: “The risks associated with TUMT are substantially lower than those associated with surgery, making it an important complementary alternative in the treatment of BPH for these high-risk patients.”

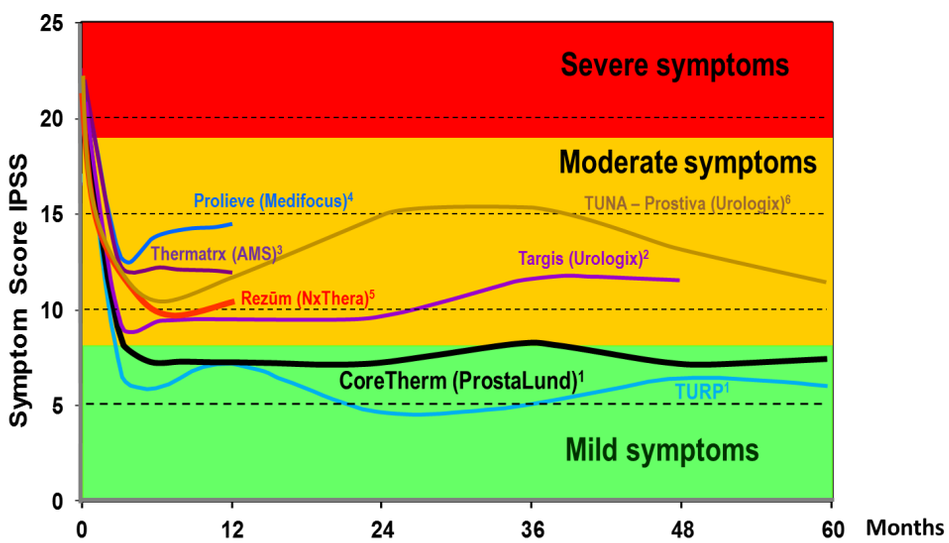
Notably, the Schelin Catheter® was used in most cases, which in this study cut the treatment time from 60 minutes to 15 minutes. A consequence of the positive results of this study is that CoreTherm is now routinely offered to this patient category in many places in Denmark.

CORETHERM IN PATIENTS WITH PROFOUNDLY ENLARGED PROSTATES

Fredrik Stenmarks paper [19] in 2022 retrospectively evaluated 570 patients with prostate volume ≥ 80 ml treated with CoreTherm or CoreTherm Concept. 41.6 % used a catheter due to chronic urinary retention and of these were 81 % catheter-free at follow-up. During the follow-up, mean 10.8 years, only 12.5 % of the 570 were surgically retreated. It is a challenge to address the old patients with profoundly enlarged prostates, where relative or absolute contraindications for surgery often are present. Stenmarks conclusion was that CoreTherm Concept is a suitable outpatient treatment regardless of age, prostate size, reason for treatment in patients with heavily enlarged prostate.

HOW DOES CORETHERM COMPARE WITH OTHER TECHNOLOGIES?

The graph below shows the results from pivotal clinical trials for Prolieve, TUNA, Thermatrx, Targis and Rezūm (the latter is a new TUNA-derivative). When looking at IPSS scores after treatment and over time for the major minimal invasive technologies present on the market today it is notable to see that;
1) CoreTherm is the only minimal invasive device that has outcomes similar to TURP
2) CoreTherm and TURP are the only methods where IPSS falls from severe to mild symptoms (from red to green in picture)
3) Other treatments go from severe to moderate symptoms after treatment



1) Mattiasson A et al, Five-year follow-up of feedback microwave thermotherapy vs TURP for clinical BOH: a prospective randomized multicenter study. Urology 69, 91-97, 2007
2) Trock BJ et al, Long-term pooled analysis of multicenter studies of cooled thermotherapy for BPH: results at three months through four years. Urology 63:716-721, 2004 (Urologix)
3) FDA on Thermatrx: Summary of safety and effectiveness data; http://www.accessdata.fda.gov/cdrh_docs/pdf/p000043b.pdf
4) FDA on Medifocus / Celsion Prolieve: Summary of safety and effectiveness data; http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030006b.pdf
5) McVary et al, Minimally Invasive Prostate Convective Water Vapor Energy Ablation. Article in Press. J Urol 2016
6) Hill B et al, Transurethral needle ablation vs TURP for the treatment of symptomatic BPH: 5-year results of a prospective, randomized, multicenter clinical trial. J Urol, 171, 2336-2340, 2004

Final Words

We are glad you decided to read this booklet – our hope is that you have learned something you didn't know before. It's important to remember that even if someone doesn't agree with everything that we write, they still might learn something valuable from it. Our mission is to make sure that all men with troublesome benign prostate enlargement are seen and treated. We want to make elderly life with BPE worth living through an innovative and cost-efficient curative treatment.

We are excited to be part of a movement that encourages people to talk openly about their problems. We can equip individuals with the knowledge they need to take action for treatment. We are committed to doing our part to ensure that BPE patients can get the help they need to live their best lives.

We are from Lund - ProstaLund!

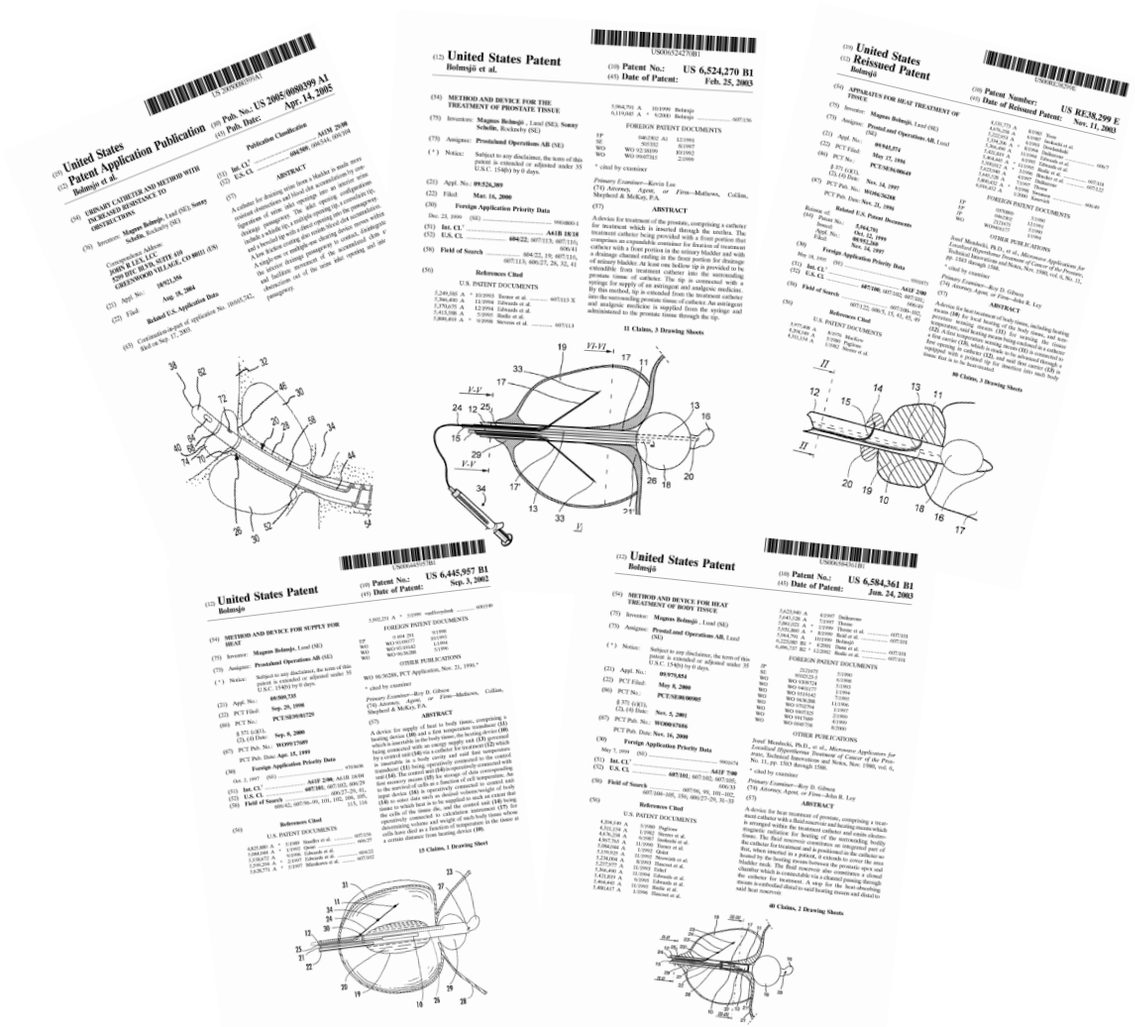


Fig. 1 - Some of the granted patent

References

1. Kaye J, Smith A, Badlani G, Lee B, Ost M.: High-energy transurethral thermotherapy with CoreTherm approaches transurethral prostate resection in outcome efficacy: a meta-analysis. J Endourol 22 (4), 713-718, 2008

2. Bolmsjö M, Wagrell L, Hallin A, Eliasson T, Erlandsson BE, Mattiasson A.: The heat is on – But how? A comparison of TUMT devices. Br J Urol 78:564-572: 1996

3. Wagrell L, Schelin S, Bolmsjö M, Brudin L.: High-energy transurethral microwave thermotherapy (TUMT) with intraprostatic temperature monitoring. J Urol 159:1583-1587: 1998

4. Bolmsjö M, Sturesson C, Wagrell L, Andersson-Engels A, Mattiasson A.: Optimizing transurethral microwave thermotherapy: a model for studying power, blood flow, temperature variations and tissue destruction. Br J Urol 81:811-816: 1998

5. Wagrell L, Sundin A, Norlén BJ.: Intraprostatic blood flow changes during ProstaLund feedback treatment measured by positron emission tomography. J Endourol 19 (7); 873-877: 2005

6. Bolmsjö M, Schelin S, Wagrell L, Larson T, de la Rosette J, Mattiasson A.: Cell-kill modeling of microwave thermotherapy for treatment of benign prostatic hyperplasia. J Endourol 14 (8); 627 – 635; 2000

7. Bhowmick P, Coad J, Bhowmick S, Pryor J, Larson T, de la Rosette J, Bischof J.: In vitro assessment of the efficacy of thermal therapy in human benign prostatic hyperplasia. Int J Hyperthermia 20(4):421-439; 2004

8. Huidobro C, Bolmsjö M, Larson T, de la Rosette J, Wagrell L, Schelin S, Gorecki T, Mattiasson A.: Evaluation of microwave thermotherapy with histopathology, magnetic resonance imaging and temperature mapping. J Urol 171; 672-678, 2004

9. Schelin S.: Mediating transurethral microwave thermotherapy by intraprostatic and periprostatic injections of mepivacaine epinephrine: effects on treatment time, energy consumption and patient comfort. J Endourol 16 (2), 117-121, 2002

10. Schelin S, Claezon A, Sundin A, Wagrell L.: Effects of Intraprostatic and Periprostatic Injections of Mepivacaine Epinephrine on Intraprostatic Blood Flow during Transurethral Microwave Thermotherapy: Correlation with [150]H20-PET. J Endourol 18(10), 965-970, 2004

11. Stenmark F, Brudin L, Stranne J, Peeker R.: High-energy feedback microwave thermotherapy and intraprostatic injections of mepivacaine and adrenaline: an evaluation of calculated cell kill accuracy and responder rate. Scand J Urol 48: 374 - 378, 2014

12. Stenmark F, Brudin L, Kjölhede H, Peeker R.: Prostate volume and age are predictors of energy delivery using the CoreTherm Concept in patients with LUTS/BPO: a study on thermal dose. Scand J Urol 54 (3): 248 -252, 2020

13. Wagrell L., Schelin S., Nordling J, et al.: Feedback microwave thermotherapy versus TURP for clinical BPH-a randomized controlled multicenter study. Urology 60,292-99, 2002

14. Wagrell L., Schelin S., Nordling J, et al.: Three-year follow-up of feedback microwave thermotherapy versus TURP for clinical BPH: a prospective randomized multicenter study. Urology 64, 698-702,2004

15. Mattiasson A., Wagrell L., Schelin S, et al.: Five-year follow-up of feedback microwave thermotherapy versus TURP for clinical BPH: a prospective randomized multicenter study. Urology 69, 91-97, 2007

16. Schelin S.: Microwave thermotherapy in patients with benign prostatic hyperplasia and chronic urinary retention. Eur Urol 39, 400-04, 2001

17. Schelin S, Geertsen G, Walter S, Spångberg A, Duelund Jacobsen J, Kröyer K, Hjertberg H, Vatne V, Richthoff J, Nordling J.: Feedback microwave thermotherapy versus TURP/Enucleation surgery in patients with benign prostatic hyperplasia and persistent urinary retention: a prospective randomized, controlled, multicenter study. Urology 68 (4) 795 – 799, 2006

18. Faurholt Aagaard M, Hartwig Niebuhr M, Duelund Jacobsen J, Kröyer Nielsen K.: Transurethral microwave thermotherapy of chronic urinary retention in patients unsuitable for surgery. Scand J Urol 48: 290 – 294, 2014

19. Stenmark F, Brudin L, Kjölhede H, Peeker R, Stranne J.: Treatment with CoreTherm in 570 patients with prostate volumes of 80-366 ml: an evaluation of short- and long-term retreatment risk. Scand J Urol. 2022 Aug;56(4):336-341

20. Stenmark F: Transurethral microwave thermotherapy and transurethral resection of the prostate. Evaluation and development. Doctoral Thesis, Sahlgrenska Academy. May 2021

ProstaLund AB is a Swedish company with its head office in Lund. The company has been active since the early 1990s and operates in the medical technology field.

ProstaLund develops and sells equipment for treating benign prostatic hyperplasia based on patented, personalized thermal therapy known as CoreTherm®.

More than 50,000 men have undergone treatment with CoreTherm®. The method is currently being used in hospitals and doctor's clinics in Sweden and around the world.

Read more at: www.coretherm.com

ProstaLund AB
Scheelevägen 19, 223 63 Lund
Phone: +46 (0)40 - 12 09 04 · info@prostalund.com · www.prostalund.com

M-2023-006