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Schelin, Sonny

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LUND UNIVERSITY

PO Box 117
221 00 Lund
+46 46-222 00 00



FEEDBACK MICROWAVE THERMOTHERAPY VERSUS TURP FOR CLINICAL BPH—A RANDOMIZED CONTROLLED MULTICENTER STUDY

LENNART WAGRELL, SONNY SCHELIN, JORGEN NORDLING, JONAS RICHTHOFF, BO MAGNUSSON, MODDY SCHAIN, THAYNE LARSON, EMMETT BOYLE, JENS DUELUND, KURT KROYER, HÅKAN AGEHEIM, AND ANDERS MATTIASSON

ABSTRACT

Objectives. To compare the outcome of a microwave thermotherapy feedback system that is based on intraprostatic temperature measurement during treatment (ProstaLund Feedback Treatment or PLFT) with transurethral resection of the prostate (TURP) for clinical benign prostatic hyperplasia (BPH) in a randomized controlled multicenter study. The safety of the two methods was also investigated.

Methods. The study was performed at 10 centers in Scandinavia and the United States. A total of 154 patients with clinical BPH were randomized to PLFT or TURP (ratio 2:1); 133 of them completed the study and were evaluated at the end of the study 12 months after treatment. Outcome measures included the International Prostate Symptom Score (IPSS), urinary flow, detrusor pressure at maximal urinary flow (Qmax), prostate volume, and adverse events. Patients were seen at 3, 6, and 12 months. Responders were defined according to a combination of IPSS and Qmax: IPSS 7 or less, or a minimal 50% gain, and/or Qmax 15 mL/s or greater or a minimal 50% gain.

Results. No significant differences in outcome at 12 months were found between PLFT and TURP for IPSS, Qmax, or detrusor pressure. The prostate volume measured with transrectal ultrasonography was reduced by 30% after PLFT and 51% after TURP. Serious adverse events related to the given treatment were reported in 2% after PLFT and in 17% after TURP. Mild and moderate adverse events were more common in the PLFT group. With the criteria mentioned above, 82% and 86% of the patients were characterized as responders after 12 months in the PLFT and TURP groups, respectively. The post-treatment catheter time was 3 days in the TURP group and 14 days in the PLFT group.

Conclusions. The outcome of microwave thermotherapy with intraprostatic temperature monitoring was comparable with that seen after TURP in this study. From both a simplicity and safety point of view, PLFT appears to have an advantage. Taken together, our findings make us conclude that within a 1-year perspective microwave thermotherapy with PLFT is an attractive alternative to TURP in the treatment of BPH. UROLOGY 60: 292–299, 2002. © 2002, Elsevier Science Inc.

Serious attempts have been made during the past decade to challenge the position of transurethral resection of the prostate (TURP) as the reference standard for treatment of clinical benign prostatic hyperplasia (BPH). By clinical BPH, we mean patients having not only benign prostatic en-

largement, but also lower urinary tract symptoms with bother and bladder outlet obstruction.¹ There are a number of good reasons to replace TURP, if possible, including the complicated inpatient procedure itself, perioperative and postoperative complications, need for anesthesia, costs, and the pos-

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From the Uppsala University Hospital, Uppsala, Sweden; Kalmar County Hospital, Kalmar, Sweden; Herlev Hospital, Herlev, Denmark; Ljungby Hospital, Ljungby, Sweden; Kristianstad Hospital, Kristianstad, Sweden; Mayo Clinic Scottsdale, Scottsdale, Arizona; Genito Urinary Surgeons, Toledo, Ohio; Frederiksberg

Hospital, Frederiksbergs, Denmark; Hudiksvall Hospital, Hudiksvall, Sweden; and Lund University Hospital, Lund, Sweden

Reprint requests: Lennart Wagrell, M.D., Ph.D., Department of Urology, Uppsala University Hospital, Uppsala SE-751 85, Sweden

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sible negative impact on patients' sex life.²⁻⁵ A number of patients also require a repeated operation after TURP.^{6,7} The goal for those who in recent years have used minimally invasive techniques (ie, lasers, radio waves, focused ultrasonography, warm water, and microwaves) has been to develop a simple, cheap, and safe method with few and transient side effects (ie, a method that can be used under local anesthesia as an outpatient procedure and of course also provide lasting results). One of the most promising, and perhaps even the most promising, technique is represented by the new generation of devices for microwave thermotherapy. Supporting this view, the International Consultation on Urological Diseases stated at the Fifth International Consultation on Benign Prostatic Hyperplasia 2000 that "transurethral microwave thermotherapy has undoubtedly turned the period of adolescence, without the descending slope that other, initially promising modalities, have shown."⁸

However, microwave thermotherapy needs to be developed further to improve BPH therapy beyond what can be achieved with TURP. One disadvantage with most microwave systems used today is that they do not take into account the cooling influence of the prostatic blood flow. Large interindividual and intraindividual differences are seen, and overtreatment and undertreatment might very well depend on the inability to control the cooling effect of the intraprostatic blood perfusion during the treatment procedure.^{9,10} To measure the intraprostatic temperature during the procedure, and to tailor the treatment according to the individual response to the exposure to the microwaves, seems therefore a logical step in improving microwave thermotherapy. This is also the principle of the so-called microwave feedback thermotherapy concept (ProstaLund Feedback Treatment or PLFT) developed by ProstaLund (Sweden). The present randomized, controlled multicenter study was undertaken to compare the outcome during a 12-month period of TURP and microwave feedback thermotherapy.

MATERIAL AND METHODS

From October 1998 to November 1999, 154 patients were enrolled in this randomized controlled multicenter study involving 10 centers in Scandinavia and the United States. At the screening visit (visit 1), the baseline characteristics and diagnostic features were recorded for each patient, including the urologic history, concurrent diseases, and medication. The physical examination included cystoscopic examination, and transrectal needle biopsy of the prostate was performed whenever malignancy could not be ruled out. Blood tests included prostate-specific antigen, hemoglobin, and creatinine. The inclusion criteria were symptomatic BPH, International Prostate Symptom Score (IPSS) of 13 or greater, prostate volume of 30 to 100 mL, and peak urinary flow rate (Q_{max}) less than 13

mL/s. The randomization ratio between PLFT and TURP was 2:1. All ethical committees approved the study, and all patients provided written informed consent at the beginning of the study. The patients were seen at the screening visit (0 to 6 weeks before treatment, visit 1), at treatment (visit 2), and during follow-up 3, 6, and 12 months after the treatment (visits 3 to 5). A washout period of at least 6 weeks preceded the treatment for patients who had been using any alpha-receptor blocker or finasteride. A total of 154 patients were included on an intention-to-treat basis. Eight patients (5 in the TURP and 3 in the PLFT group) were withdrawn before treatment, resulting in a total of 146 treated patients; 100 in the PLFT arm and 46 in the TURP arm.

MICROWAVE THERMOTHERAPY DEVICE AND PROCEDURE

With the PLFT technique, the intraprostatic temperature is measured by three temperature sensors placed in a temperature probe that is introduced into the prostate at approximately the 2-o'clock position by way of the urethral treatment catheter. The position of the probe was checked with transrectal ultrasonography when needed. The temperatures were continuously displayed on the device computer. Using the heat equation, the device also calculates the extent of the coagulation necrosis continuously during the treatment, as described previously.^{11,12} Thus, the treatment is individualized and stopped when adequate tissue destruction is considered to have been achieved, as judged from the automatic calculations of the device, but also by direct reading of the recorded intraprostatic temperatures. As a rule, when approximately 55°C has been measured in any part of the treatment zone, the treatment usually can be stopped.

PLFT was given to 97% of the patients as an outpatient procedure. The treatment was generally well accepted and required only sedoanalgesic and/or local anesthetic agents. The treatment time was individually adapted for each patient and ranged from 27 to 80 minutes (mean 57). The most common treatment-related complaint was urgency. This was also usually the reason for additional administration of diazepam, ketorolac, or ketobemidone or combinations of these during the treatment session. After the treatment, an indwelling Foley catheter was placed and remained for 14 ± 8 days (median 12, range 7 to 56) before removal, following the clinical routine of each center. Thus, no attempts were made to minimize the catheter time. Urinary retention reported after removal of the indwelling catheter was registered as an adverse event.

TURP PROCEDURE

Forty-six patients underwent TURP. This was performed as a clinical standard inpatient procedure according to the routines at each center. The urethral catheter was usually removed after 3 ± 4 days (median 2, range 1 to 26). All data were recorded as prescribed in the clinical record form.

CLINICAL EFFICACY ASSESSMENT

The primary outcome variable was the IPSS. The secondary outcome variables were objective improvement and safety measures. IPSS and urinary flow measurements with registration of the Q_{max} were performed before treatment and at the 3, 6, and 12-month follow-up visits. Similarly, the prostate volume calculated by transrectal ultrasonography, urodynamics with pressure-flow measurement, and data on sexual function were registered before treatment and at 12 months of follow-up. Responders were defined as those with an IPSS of 7 or less or more than a 50% gain compared with baseline and/or a Q_{max} of 15 mL/s or greater and/or more than a 50% gain.¹³ Patients not fulfilling these criteria were consequently defined as nonresponders.

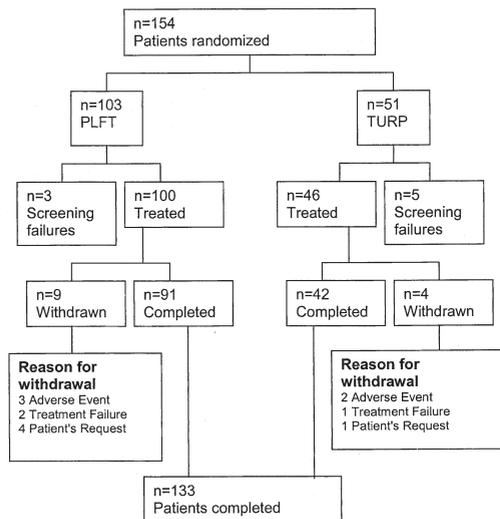


FIGURE 1. Disposition of patients in the study.

ADVERSE EVENTS

All adverse events occurring during the entire study period were reported. A serious adverse event was defined according to International Congress on Harmonization as any untoward medical event that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability or incapacity, was cancer, or required intervention to prevent permanent damage to body functions or structure.

STATISTICAL ANALYSIS

The outcome data for IPSS and Qmax were analyzed using the analysis of covariance technique for repeated measures and the baseline data as the covariate. When assumptions underlying the analysis of covariance model (ie, normal distribution of data) were not fulfilled, log-transformed data were analyzed. The bother score, detrusor pressure and residual urine volume were analyzed using the Mann-Whitney *U* test. All tests were two-tailed, and *P* values of less than 0.05 were considered statistically significant. Data are given as the mean \pm standard deviation unless stated otherwise. The median value and range are shown as appropriate.

RESULTS

The number of patients in different groups and the number and reasons for withdrawals, as well as the number of patients who completed the study, are given in Figure 1. The baseline data for the two groups were comparable and are shown in Table I. The results from both treatment groups are given in Figures 2 and 3 and in Tables II through IV.

RESPONDERS

Using the previously suggested criteria for responders to treatment of clinical BPH, the response rate, expressed as a combination of symptoms

(IPSS) and Qmax, was 82% for the PLFT group and 86% for the TURP group at the end of the study after 12 months of follow-up. This difference was not statistically significant.

The analysis of the separate objective and subjective measures gave the following results:

OBJECTIVE MEASURES

Urinary Flow Rate. Qmax improved significantly and had increased from 7.6 ± 2.7 mL/s to 13.3 ± 6.0 mL/s (+74%) in the PLFT group at 12 months and from 7.9 ± 2.7 mL/s to 15.2 ± 7.8 mL/s (+94%) in the TURP group (Table II and Fig. 3).

Residual Urine. The residual urine volume at screening and at 12 months of follow-up was 106 ± 77 mL (median 100, range 0 to 300) and 49 ± 70 mL (median 30, range 0 to 486) in the PLFT group and 94 ± 82 mL (median 55, range 0 to 300) and 54 ± 77 mL (median 18, range 0 to 350) for the TURP group (Table III).

Detrusor Pressure. After PLFT, the detrusor pressure at study end had decreased from 73.7 ± 29.7 cm H₂O to 48.5 ± 25.0 cm H₂O (-34% compared with baseline); the corresponding figures for TURP were 79.4 ± 35.3 cm H₂O to 41.8 ± 16.6 cm H₂O (-47%; Table III).

Prostate Volume. Both treatments also resulted in a significant reduction of the prostate volume as estimated at 12 months by transrectal ultrasonography. The reduction was 30% after PLFT and 51% after TURP (Table III).

SUBJECTIVE MEASURES

International Prostate Symptom Score. A significant and pronounced improvement in the symptoms as measured with IPSS was seen after both PLFT and TURP, with a decrease by 66% and 65% in the PLFT and TURP groups, respectively, after 12 months. After only 3 months, the improvement was considerable for both groups. This improvement remained stable during the study period (Table II and Fig. 2).

Quality-of-Life Question (IPSS). A similar pattern was recognized for the quality-of-life question on the IPSS, which improved from 4.3 ± 1.0 to 1.4 ± 1.3 or by 69% in the PLFT group at 12 months compared with baseline. The corresponding figure for the TURP group was 4.2 ± 1.1 to 1.5 ± 1.7 or 64% (Table II).

CATHETER TIME

An indwelling catheter was used after both PLFT and TURP. The mean catheterization time was 14 ± 8 days (median 12, range 7 to 56) after PLFT and 3 ± 4 days (median 2, range 1 to 26) after TURP.

TABLE I. Demographic data at baseline

Variable	PLFT Group (n = 100)	TURP Group (n = 46)
Age (yr)	67 (8)	69 (8)
Weight (kg)	83 (15)	81 (11)
Height (cm)	178 (6)	177 (6)
Residual urine volume (mL)	106 (77)	94 (82)
Detrusor (voiding) pressure (cm H ₂ O)	73.7 (29.7)	79.4 (35.3)
Maximal free urinary flow rate (mL/s)	7.6 (2.7)	7.9 (2.7)
PSA (μg/L)	3.3 (2.2)	3.6 (2.7)
Prostate volume as determined by TRUS (cm ³)	48.9 (15.8)	52.7 (17.3)
IPSS	21.0 (5.4)	20.4 (5.9)
Bother score	4.3 (1.0)	4.2 (1.1)

Key: PLFT = ProstaLund Feedback Treatment; TURP = transurethral resection of the prostate; PSA = prostate-specific antigen; TRUS = transrectal ultrasonography; IPSS = International Prostate Symptom Score.
Data presented as the mean, with the SD in parentheses.

ADVERSE EVENTS

Serious adverse events judged by the investigator to be related to the treatment were reported for 2% of the PLFT group: hematuria in 1 patient and urine retention in 1 patient. In the TURP group, serious adverse events were reported in 17% of patients: hematuria in 4, urinary tract infection in 1, TURP syndrome in 1, urosepsis in 1, and clot retention in 1 patient. All patients with serious adverse events recovered except for 1 patient in the TURP group who died 27 days after treatment. Hematuria classified as a serious adverse event was generally episodes of clot retention requiring hospitalization.

Expected temporary adverse events (nonserious) of mild to moderate severity occurred more often with PLFT than with TURP (eg, urgency, urinary retention, hematuria, and urinary tract infection; Table IV). Most adverse events were of short duration.

COMMENT

We found no statistically significant difference between PLFT and TURP in the ability to abolish the consequences of clinical BPH in this randomized controlled multicenter trial. No significant differences in outcome of the primary efficacy variable (IPSS) were seen at 12 months of follow-up. Similarly, no significant differences were found in the increase in Q_{max}, reduction of residual urine, or decrease of urethral resistance expressed as a pressure flow relation. More tissue was removed with TURP than with PLFT.

Even though normalization, also in comparison with healthy men of the same age^{14,15} was reached in both the PLFT and the TURP arms, it might be argued that the increase in the Q_{max} was less pronounced in the TURP group than what could be expected, especially when the data were compared with those from specialized centers with only a few

surgeons performing TURP.¹⁶ We believe that the present outcome is more representative of the results obtained in clinical everyday work, at least in the involved centers in Scandinavia and the United States. The physicians performing the operations represented an average in terms of age and surgical experience. It might also be expected that with increasing experience with the PLFT method, even better results might be expected. However, to already have reached an outcome with both TURP and PLFT that equals normalization for the patient group involved must in itself be considered very satisfying.

As we have learned from new technologies for the treatment of BPH, care must be taken when extrapolating the results obtained after 1 year to beyond this time. One year is also the recommended minimal time for follow-up in randomized controlled trials (RCTs) on BPH (International Consultation on Urological Diseases, BPH 2000).

Most likely, the high rate of responders to PLFT reported in this study can be explained by the temperature-guided treatment. This has also been supported by other investigators¹⁷ who studied the relationship between clinical outcome and intraprostatic temperature.

For microwave thermotherapy using other protocols than the feedback technique, so-called high energy protocols, good results compared with TURP have been reported after 1 year in randomized controlled studies^{16,18} and also in open long-term follow-up studies of up to 3 years.¹⁹ However, other investigators have reported less beneficial results, and have, for example, not been able to demonstrate any urodynamic improvement during pressure-flow studies.²⁰ The early low-energy protocols, which for good reasons have largely been abandoned, produced a symptomatic relief, but little to no gain in urinary flow and little to no reduction in prostate size. This has been interpreted as

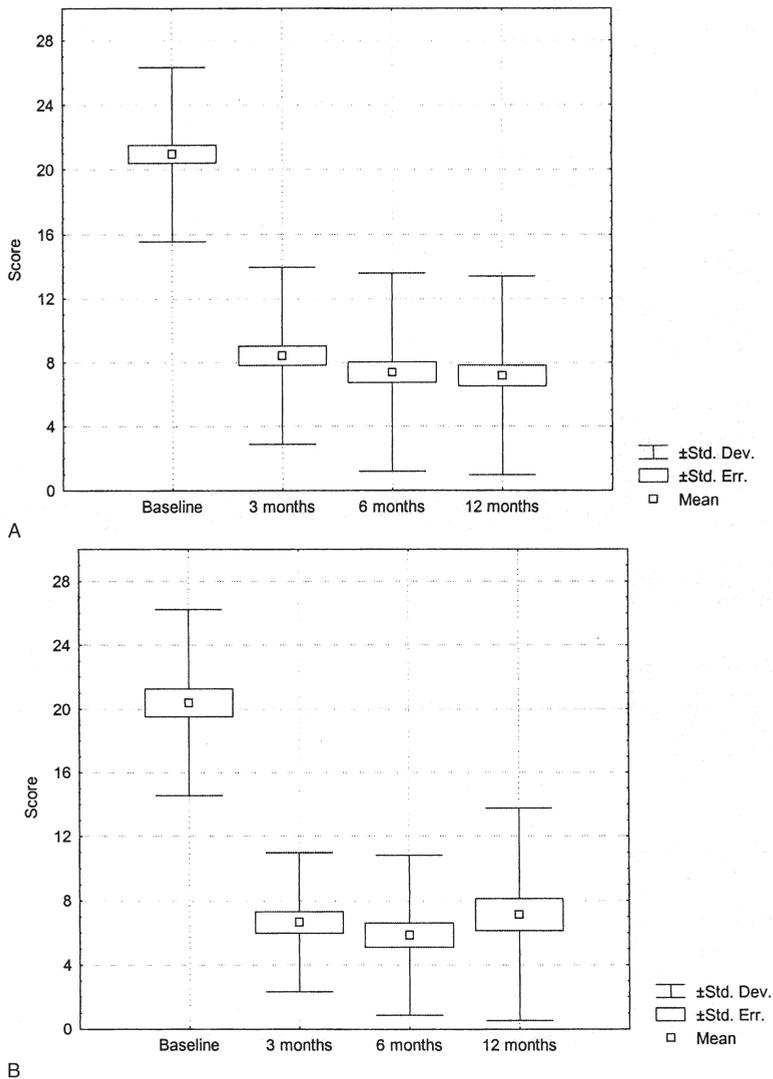


FIGURE 2. Mean value, SD, and SE for IPSS at baseline and 3, 6, and 12 months after (A) PLFT and (B) TURP.

being a consequence of the destruction of superficial nerves in the prostatic urethra²¹ but an insignificant amount of prostatic tissue. The reason why PLFT should be able to offer even better results than the so-called high-energy protocols is that the treatment can be individualized according to the conditions needed to reach the extent of tissue necrosis sufficient for results in the range reported here. This also has the consequence of a variable treatment time. In the present study, the range was 27 to 80 minutes. As has been reported from different groups, the blood flow in the prostate seems to be an important, and even critical, factor to con-

trol to be successful with microwave thermotherapy for BPH.^{10,22} It has been demonstrated that the amount of tissue necrosis is dependent on the temperature and length of treatment. To achieve adequate tissue necrosis within a reasonable treatment time, the tissue temperature must reach the range of 50° to 60°C.²³

In the present study, one of the most striking differences between the groups was the significantly higher number of serious adverse events in the TURP group, 17% compared with 2% in the PLFT group. This is an important observation that should be considered when the usefulness of the

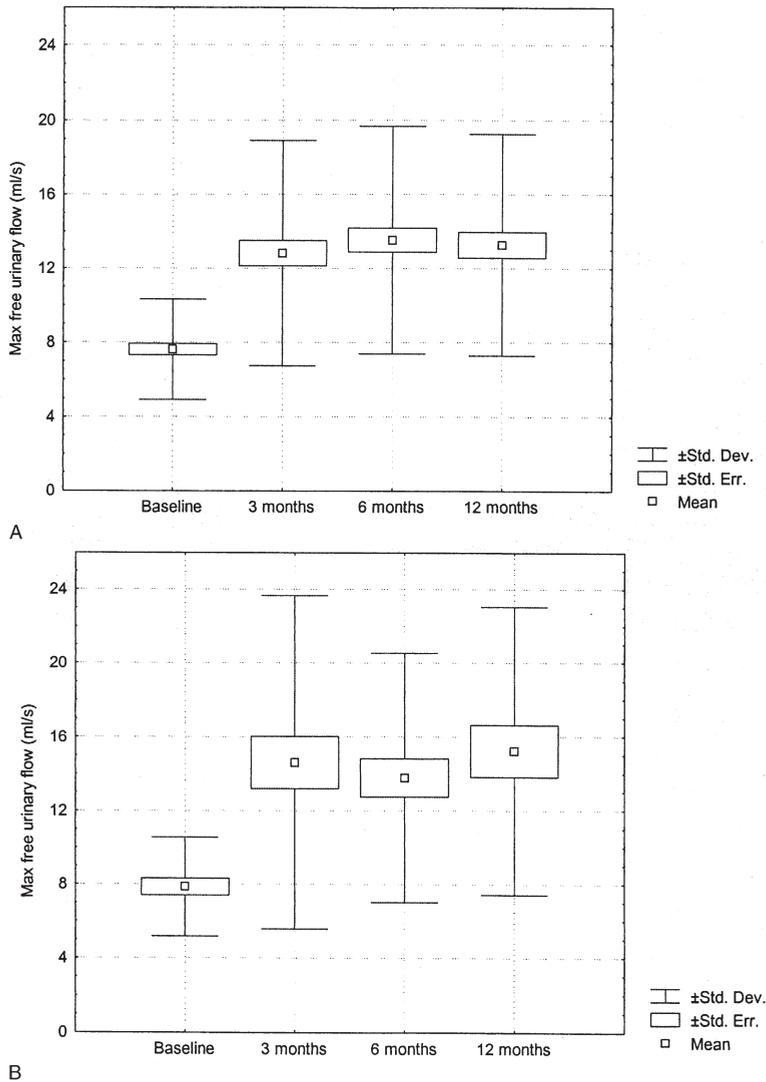


FIGURE 3. Mean value, SD, and SE for Qmax at baseline and 3, 6, and 12 months after (A) PLFT and (B) TURP.

two methods is compared. PLFT seemed both more convenient (ie, easier for the patient to undergo and for the caregiver to handle) and to produce more nonserious adverse events. The long catheter time and micturition difficulties with for example urgency, in the immediate period after removal of the catheter was a disadvantage for the PLFT group compared with those subjected to TURP. PLFT, however, carried less risk of serious adverse events, and although not included in the protocol of this study, it was, in a 12-month perspective, less resource consuming than was TURP. Finally, PLFT

was an outpatient instead of an inpatient procedure. PLFT also appeared to be more favorable in terms of safety.

For TURP, one apparent advantage in this study was that a larger amount of tissue was removed than with PLFT. We could not, however, determine how much of an advantage this was. From a traditional surgical point of view, it is easy to argue that this indeed should be an advantage, because improvement of flow is related to the amount of resected volume.²⁴ Urologists, therefore, try to resect as much of the adenoma as possible.

TABLE II. Results of IPSS, QOL (IPSS), and maximal free urinary flow rate 3, 6, and 12 months after treatment compared with baseline

	Baseline		3 Months		6 Months		12 Months		P Value*
	Mean (SD)	n							
IPSS									
PLFT	21.0 (5.4)	99	8.4 (5.5)	85	7.4 (6.2)	95	7.2 (6.2)	93	0.603
TURP	20.4 (5.9)	46	6.7 (4.3)	41	5.9 (5.0)	43	7.1 (6.6)	43	
QOL (IPSS)									
PLFT	4.3 (1.0)	99	1.5 (1.4)	84	1.3 (1.4)	93	1.4 (1.3)	93	0.972
TURP	4.2 (1.1)	46	1.1 (1.6)	41	1.0 (1.5)	42	1.5 (1.7)	43	
Qmax									
PLFT	7.6 (2.7)	79	12.8 (6.1)	81	13.5 (6.1)	91	13.3 (6.0)	73	0.944
TURP	7.9 (2.7)	35	14.6 (9.0)	41	13.8 (6.8)	43	15.2 (7.8)	31	

KEY: QOL = quality of life; Qmax = peak urinary flow rate; other abbreviations as in Table I.

* P values derived from tests of differences between the methods.

TABLE III. Results of detrusor pressure, postvoid residual urine volume, and prostate volume 12 months after treatment compared with baseline

	Baseline		12 Months		P Value*
	Mean (SD)	n	Mean (SD)	n	
Pdet (cm H ₂ O)					
PLFT	73.7 (29.7)	99	48.5 (25.0)	82	0.124
TURP	79.4 (35.3)	45	41.8 (16.6)	39	
PVR (mL)					
PLFT	106 (77)	99	49 (70)	86	0.680
TURP	94 (82)	45	54 (77)	38	
Prostate volume (mL)					
PLFT	49 (16)	99	34 (16)	90	
TURP	53 (17)	46	26 (13)	41	

KEY: Pdet = detrusor pressure; PVR = postvoid residual (volume); other abbreviations as in Table I.

*P values derived from tests of differences between the methods.

TABLE IV. Frequency of adverse events (nonserious) registered during treatment or during the 12-month follow-up period

Preferred Term	PLFT (%)	TURP (%)
Micturition urgency	37	13
Urinary retention	19	13
Urinary tract infection	18	20
Hematuria	13	39
Impotence	6	11
Transient incontinence	3	13

Abbreviations as in Table I.

It is important to stress that TURP is also generally considered to be an excellent treatment for clinical BPH.²⁵ However, it does have disadvantages, as reflected by the 17% of lower urinary tract serious adverse events. Along with other possible problems, there is no clear view of the impact of TURP on sexual function.⁴ Impotence and transient incontinence occurred in the present study two and four times more frequently in the TURP

group than in the PLFT group. Even if the numbers were small and not statistically significant, the pattern tells us that this relation should be investigated further. For comparison, the results from sham studies would have been interesting, but, for several reasons, were not possible to obtain.

With PLFT, the symmetric distribution around the circumference of the microwaves might explain why less tissue must be removed to obtain the same results as with TURP. The conditions for flow seem to be better after PLFT, because the same clinical improvement was achieved with the removal of less tissue. If the tendency for recurrent symptoms is directly proportional to the amount of tissue left behind, this could, over the years, mean that TURP offers an advantage over PLFT. This has not been shown. It might be that the location of the tissue that is removed, and its impact on lower urinary tract dynamics, is a more critical factor than the absolute amount of tissue removed. This could be part of the reason why not all men with enlarged prostates have symptoms or are ob-

structured. Finally, it can even be argued that PLFT was more efficient than TURP when relating the degree of improvement to the amount of tissue removed. The patients in this study have been offered participation in a 5-year follow-up study; the 5-year data should be available in 2005.

CONCLUSIONS

This is the first randomized controlled study comparing PLFT with TURP. The outcome after PLFT could not symptomatically or urodynamically be separated from the outcome after TURP at 3, 6, and 12 months. More prostatic tissue was removed with TURP than with PLFT. When the simplicity and safety of the PLFT method are taken into account, it might be possible to assume, even before the long-term data are at hand, that this method may be one of the best minimally invasive procedures challenging TURP as the preferred first-line routine treatment of clinical BPH.

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