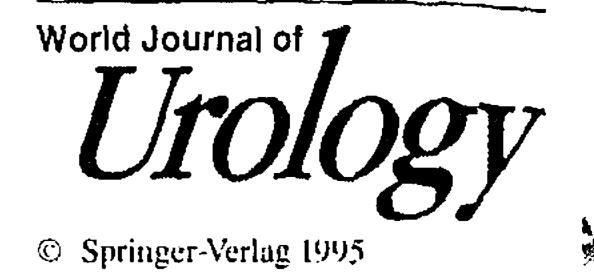
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Experience with the Ultraline and Urolase laser fibers: is there any difference?

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Summary. Laser treatment of benign prostatic hyperplasia has enjoyed growing popularity among urologists over the last few years. Various applicators and techniques have been reported. Because this may result in a different overall performance, we performed a prospective randomized study comparing the results of treatment using the Ultraline fiber (n = 44) with that using the Urolase fiber (n = 44)49). Although different types of fibers and techniques were used, the results of this study were surprisingly similar for both fibers used. The uroflow for the Ultraline group increased from an average of 7.9 ml/s at baseline to 19.3 ml/s at 3 months and 16.9 ml/s at 6 months. In the patients treated with the Urolase fiber the uroflow improved from an average of 7.8 ml/s at baseline to 19.5 and 16.3 ml/s at 3 and 6 months, respectively. The improvement in symptoms, reflected by changes in the I-PSS symptom scores, for the Ultraline group went from 21.0 at baseline to 7.9 at 3 months and 6.0 at 6 months. The Urolase patients improved from 21.0 at baseline to 8.2 and 5.6 at 3 and 6 month, respectively. The morbidity mainly consisted of a prolonged need for posttreatment catheterization and irritative symptoms lasting for about 2–4 weeks. From this study we conclude that the results achieved by laser treatment of the prostate using the Ultraline and Urolase fibers are both equivocal and excellent; however, the morbidity of these treatments remains considerable.

Because of the minor but significant morbidity and the changes in social habits and for economic reasons, a number of alternatives to TURP have emerged in recent years [2-5]. One alternative to TURP that has recently demonstrated significant results is the use of a laser to achieve deobstruction [6-8]. One of the first reports on laser treatment of BPH was published by Costello et al. in 1992 [9]. Since then, various authors have reported their clinical experience in using different types of applicators [7, 8, 10, 11]. These applicators, however, differ in their physical properties, overall performance, and tissue effects.

The question as to the type of applicator that should be used is fundamental. The initial experience with laser treatment of benign prostatic hyperplasia (BPH) involved the transurethral ultrasound-guided laser-induced prostatectomy (TULIP) device and the Urolase fiber [12]. The simplicity of the endoscopy-assisted technique made it more attractive than the ultrasound-guided TULIP device. Moreover, the latter procedure caused more morbidity. Following this experience, we proceeded with the side-firing fiber technique. These fibers possess vaporizing and coagulation properties. In favor of the vaporizing technique is the observation that tissue is vaporized and a lumen is created instantly. On the other hand, a coagulative technique may result in more extensive tissue destruction and, thus, should lead to better results. To date, long-term data have not been available to demonstrate this correlation with clinical results in humans. Therefore, we conducted a study involving a fiber that is primarily used to achieve coagulation (Urolase) and a fiber that can achieve both vaporization and coagulation (Ultraline).

Over the last few decades, transurethral resection of the prostate (TURP) has been the primary choice of treatment to relieve bladder-outlet obstruction and symptoms of prostatism. TURP is reported to be a safe and effective procedure. The mortality has been reduced to 0.2%, but the morbidity remains considerable and constant at 18% [1]. The treatment of BPH is currently undergoing significant reevaluation. The increasing age of the general population and the greater attention paid by older men to the symptoms of prostatism mean that the demand for treatment is almost limitless.

Patients and methods

From April 1993 until July 1994, 94 men aged 50–85 years (average, 65 years) with symptoms of BPH were randomized to receive treatment with the Ultraline fiber (Heraeus) or the Urolase fiber (Bard). The major inclusion and exclusion criteria for treatment are shown in Table 1.

Correspondence to: J. J. M.C. H. de la Rosette, Department of Urology, University Hospital Nijmegen, P.O. Box 9101, NL-6500 HB Nijmegen, The Netherlands, Fax: +31 (80) 541031 Screening included a general history and complete physical examination (including a digital rectal examination), routine blood studies, urine microscopy, and culture. Urinary cytology and prostate-specific antigen (PSA) levels were always measured so as to exclude coexisting malignancy. The severity of symptoms was

Table 1. Inclusion and exclusion criteria for laser treatment		Table 2. Baseline characteristics of the patients evaluated in the				
Inclusion criteria	Exclusion criteria Prostatic carcinoma Bacterial prostatitis	present study				
Prostate volume, > 30 cm ³ Age, > 50 years			Urolase, $n = 49$ Mean (SD)	Ultraline, $n = 44$ Mean (SD)		
Age, > 50 years Duration of symptoms, > 3 months IPSS symptom score, > 12	Urethral stricture	Age (years)	64.6 (7.2)	65.0 (6.7)		
		IPSS symptom score	21.0 (5.1)	21.0 (5.9)		
		Prostatic volume (cm ³)	49.7 (17.2)	45.7 (14.9)		
	Neurogenic bladder dysfunction	Qmax (ml/s)	7.8 (3.0)	7.9 (2.9)		
Peak uroflow, < 15 ml/s	Urinary tract infection	Voided volume (ml)	200 (95)	196 (89)		
	Use of drugs influencing bladder function	Residual urine (ml)	86 (76)	86 (79)		
		PSA (ng/ml)	5.3 (4.4)	4.9 (3.9)		
	History of TURP or TULIP			·····		
	Diabetes mellitus					
	Bladder residual urine, > 350 ml	Table 3. Main follow-up indices after Urolase or Ultraline treat-				

ment

scored using the IPSS questionnaire. Men were also questioned regarding their sexual function (erection and ejaculation). Uroflowmetry (peak flow, Qmax) was performed twice with a minimal voided volume of 100 ml. Residual urine was measured with transabdominal ultrasound. To determine the grade of outlet obstruction we performed an advanced urodynamics investigation, including pressure-flow analysis. The upper urinary tract was evaluated using a plain abdominal X-ray and renal ultrasound. Transrectal ultrasound of the prostate (TRUS) was performed to measure the volume of the prostate and to determine the prostate configuration. Flexible urethrocystoscopy was used to verify the patency of the urethra and to look for an enlargement of the middle lobe and for signs of malignancy. All patients with an abnormal rectal examination, a PSA level of more than 10 ng/ml (Hybritech), and/or an abnormal TRUS underwent biopsy.

Patients were randomized after informed consent had been obtained. The Urolase-fiber delivery system consists of a 4-m-long Teflon-coated fiber with a gold-plated dish at the tip, which allows the laser beam to be reflected at a 90° angle. Sterile water is used as an irrigant through a standard 23-F cystoscope with a 30°-angle lens. The Urolase fiber is passed through the working port of the cystoscope. The distribution of the laser energy is customized to the appearance of each prostate. In general, 40 W of energy is applied for 90 s to each lateral lobe at the 2, 5, 7, and 10 o'clock positions. In the case of an enlarged middle lobe or a prostatic urethra exceeding 2.5 cm in length, further applications are provided to ensure complete blanching of the lateral lobes. The Ultraline fiber system also consists of a Teflon-coated fiber and the beam is reflected using a refractive mechanism. The distribution of the laser energy is applied by a dragging or so-called *painting* technique with the fiber in the contact or noncontact mode. A total of 60 W of energy is delivered to the prostate lobes during a certain period. To provide relief of symptoms, this technique relies not on tissue slough but rather on the immediate creation of an open channel. Patients were seen at 1, 6, 12, 26, and 52 weeks after treatment. When the postvoid residual urinary volume was below 100 ml and the micturition was restored satisfactorily, the indwelling catheter was removed.

		Weeks posttreatment				
		0	12	26	52	
Ultraline	(n)	44	42	32	7	
Qmax	(mean, ml/s)	7.9	19.3	16.9	19.7	
IPSS	(mean)	21.0	7.9	6.0	6.6	
PVR	(mean, ml)	86	25	11	32	
Urolase	(<i>n</i>)	49	47	28	3	
Qmax	(mean, ml/s)	7.8	19.5	16.3	12.7	
IPSS	(mean)	21.0	8.2	5.6	1.7	
PVR	(mean, ml)	86	25	12	50	

PVR, Postvoid residual urinary volume

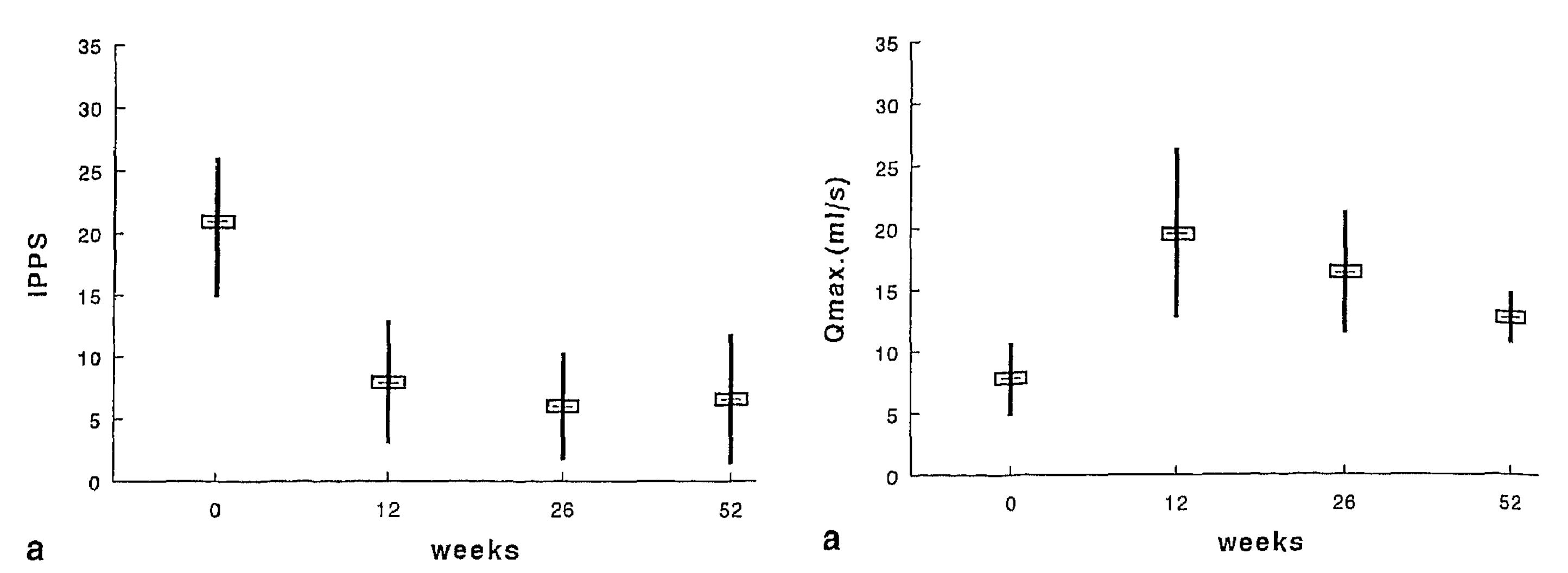
and 49.7 cm³ for the Urolase group. There was no statistical difference between the two groups for any given parameter at baseline (Table 2). In all, 89 patients were available at 12 weeks for assessment and 60 were evaluable at 26 weeks. No patient was lost to follow-up, one patient was treated by TURP, and one patient needed a bladder-neck incision because of a bladder-neck sclerosis. Table 3 shows the subjective and objective changes noted after treatment. For the Ultraline group a significant reduction in IPSS symptom score was shown from an average of 21.0 to 7.9 after 12 weeks, to 6.0 after 26 weeks, and to 6.6 after 52 weeks. In the Urolase group the reduction in symptoms was similar to that seen in the Ultraline group, with changes occurring from 21.0 at the onset to 8.2 after 12 weeks, to 5.6 after 26 weeks, and to 1.7 after 52 weeks (Fig. 1). Statistical evaluation revealed a statistically significant reduction in symptom-score parameters for all values. In the Ultraline group the average improvement was 11.9 ml/s after 3 months and 9.6 ml/s after 6 months. In the Urolase group the average improvement in uroflow was 11.7 ml/s at 3 months and 8.6 ml/s at 6 months (Fig. 2). A comparison between the Urolase and Ultraline groups after 12 and 26 weeks of follow-up showed no statistically significant difference with regard to symptom score (P <0.0001) or peak flow (P < 0.0001). The same result was found for the postvoid residual urinary volume (Fig. 3). The TRUS images obtained after treatment showed cavities at 26 weeks in both the Ultraline and the Urolase

Statistical analysis within each group was done with Wilcoxon's signed-rank test (alpha = 0.05), whereas Student's ttest (alpha = 0.005) was used for comparison between the groups.

Results

The average age of the Ultraline group was 65.0 (range, 50–85) years, and that for the Urolase group was 64.6 (range, 52–79) years. The average prostate volume as measured with TRUS was 45.7 cm³ for the ultraline group





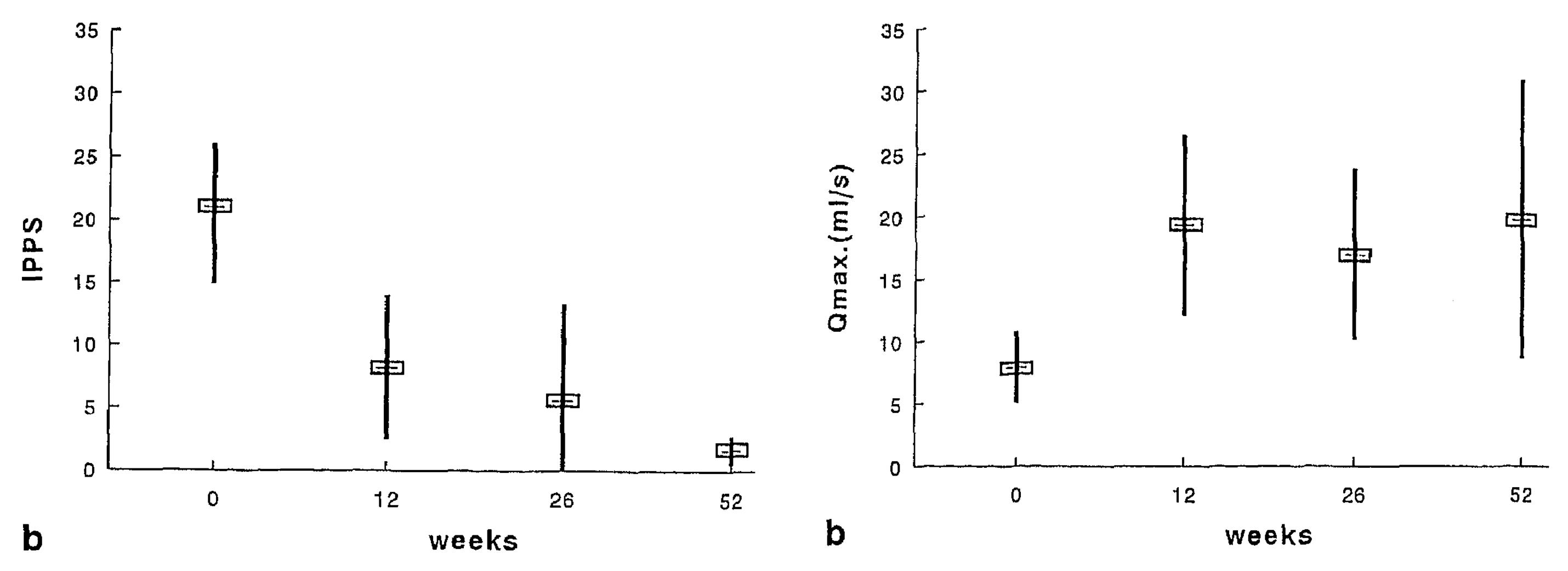


Fig. 1. Improvement in symptom scores (IPSS) noted for the a Urolase and b Ultraline groups

Fig. 2. Improvement in maximal uroflow (Qmax) noted for the a Urolase and b Ultraline groups

groups (Fig. 4). No relation was found between the prostate volume and the subjective and objective results obtained. As shown in Table 2, PSA serum concentrations were normal before treatment. When they were measured at 1 day after treatment, there was an elevation in the average PSA value from 5.1 (range, < 1.0-17) ng/ml to a mean value of 91 (range, 3.2–290) ng/ml. After 3 months, the PSA level returned to normal (Fig. 5).

No complication occurred during the operation. The predominant complications encountered in both groups posttherapy were prolonged catheterization, urinary tract infections, and (irritative) miction complaints. No incontinence occurred. Patients in the Ultraline group needed an indwelling catheter for an average of 18.9 days, and those in the Urolase group did so for 16.9 days (Fig. 6). A retrograde ejaculation was mentioned by 50% of the sexually active patients, whereas 14% of the patients complained of diminished or absent erectile functions.

tissue effect by converting light energy into thermal energy. Prostatic tissue heated to between 60° and 100°C will undergo protein denaturation and coagulation necrosis. Coagulation results in delayed sloughing of the prostate for a variable period, usually for several weeks after the procedure. At temperatures above 100°C, tissue converts into vapors of water and hydrocarbons, thus creating immediate cavitation. In general, laser energy applied to the prostate is aimed at deobstruction, resulting in improvement in objective and subjective parameters.

The ultimate acceptance of this laser technology relies not only on an improvement in treatment-related morbidity but also on results comparable with those of TURP. The most common method of performing laser ablation of BPH has been the noncontact coagulation technique, which uses low power in the noncontact mode to achieve maximal coagulation and minimal evaporation of tissue. Overall laser treatment using the Urolase fiber results in

Discussion

Laser light is a unique form of energy with characteristic and variable tissue effects. The Nd:YAG laser produces a an average improvement in uroflow of 50%-100% and in a significant decrease in symptoms [7, 9, 12-14]. As a result of this early experience, laser prostatectomy has become popular with many urologists because it is associated with morbidity lower than that resulting from TURP. Moreover, the public has become more aware

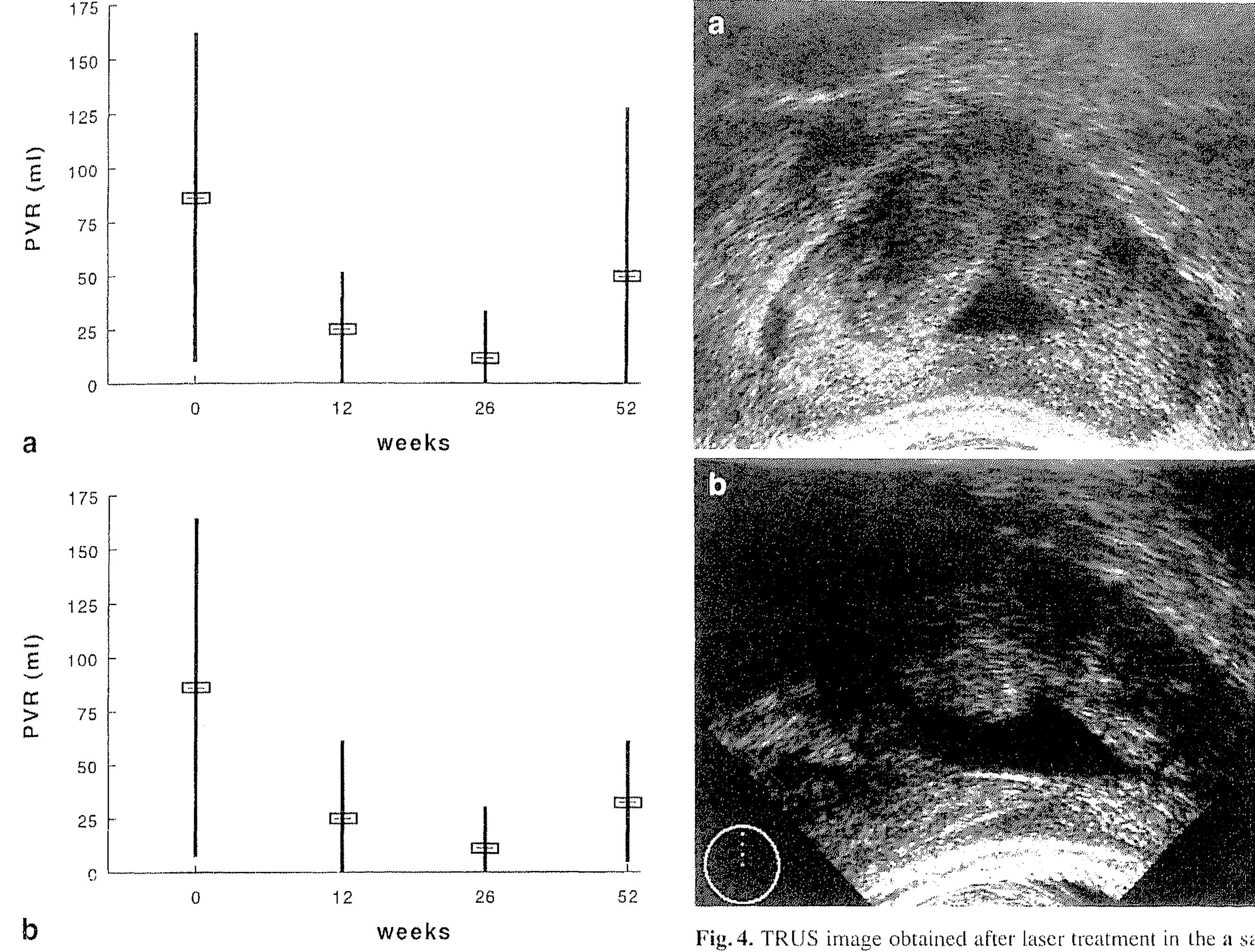


Fig. 3. Improvement in postvoid residual urinary volume (PVR)noted for the a Urolase and b Ultraline groups

Fig. 4. TRUS image obtained after laser treatment in the a sagittal and **b** transverse planes. A nice cavity can be appreciated

of other treatment options for BPH, and many men are hesitant to consider the traditional option of TURP. Men are particularly concerned regarding the risks of bleeding, impotence, and a prolonged postoperative recovery period. Laser treatment meets most of these requirements.

Thus far, the results obtained after laser treatment have been excellent and have approximated those achieved after TURP. The present study shows an increase in uroflow from 7.8 to 19.5 ml/s at 3 months for the Urolase group and an increase from 7.9 to 19.3 ml/s at 3 months for the Ultraline group. The subjective improvement measured with the IPSS questionnaire also showed remarkable results. In Fig.7 the relation between symptom scores and maximal uroflow at baseline and at 3 and 6 months of follow-up is presented.

From this figure it seems obvious that an improvement in uroflow is reflected in a simultaneous improvement in symptoms. However, a significant difference between laser prostatectomy and standard TURP is the lack of immediate effect for the former. A standard transurethral prostatectomy removes tissue at the time of the procedure, and patients often experience a significant improvement in urinary stream as soon as the indwelling catheter is removed. Although the objective and subjective results

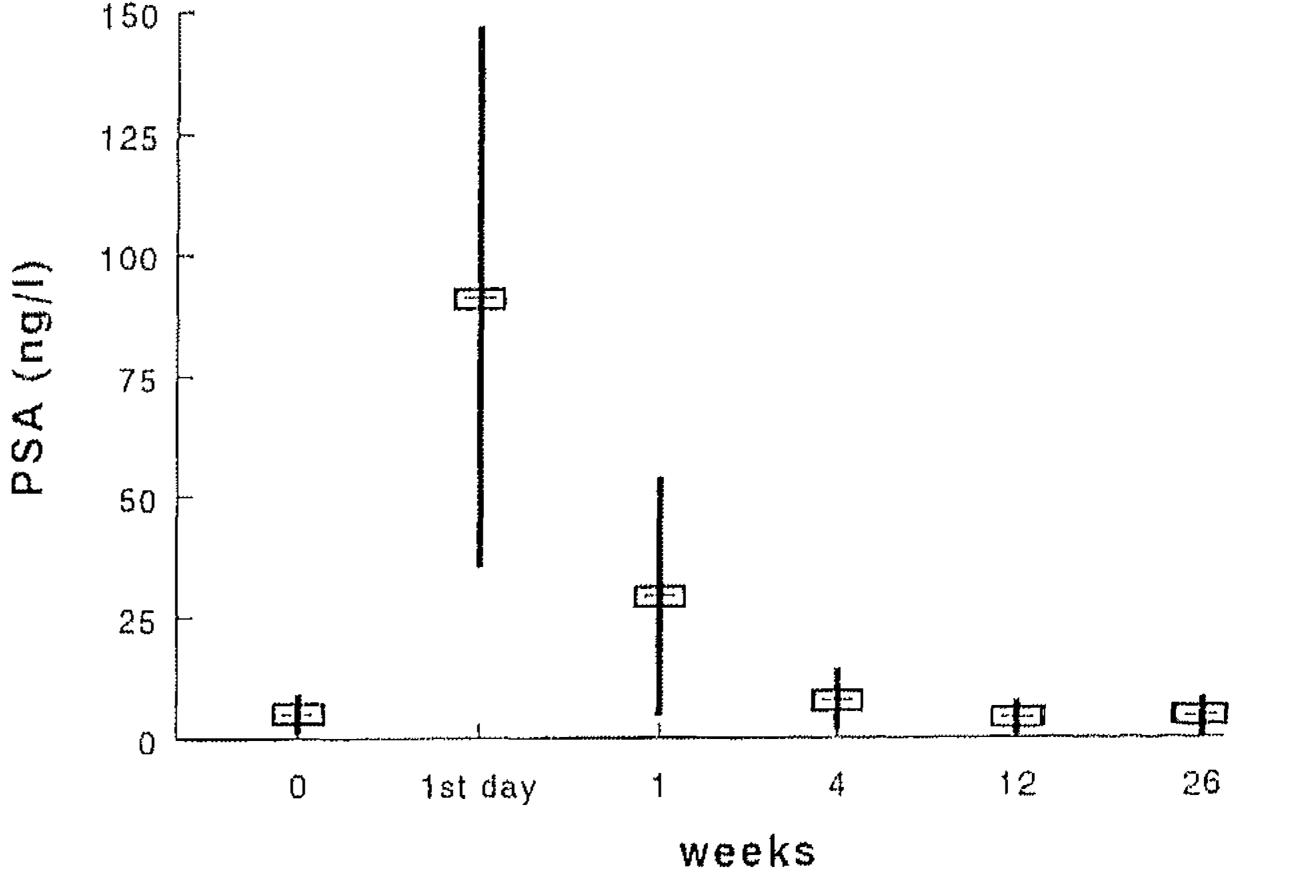


Fig. 5. Changes observed in PSA levels after Urolase and Ultraline treatment

achieved in the present study by laser therapy using the Urolase or Ultraline fiber were good, considerable morbidity was noted. There appeared to be a prolonged need for catheterization in both groups. The need for prolonged catheterization can be explained by the laser-light effect itself. When a Nd:YAG laser beam is incident on prostatic tissue at

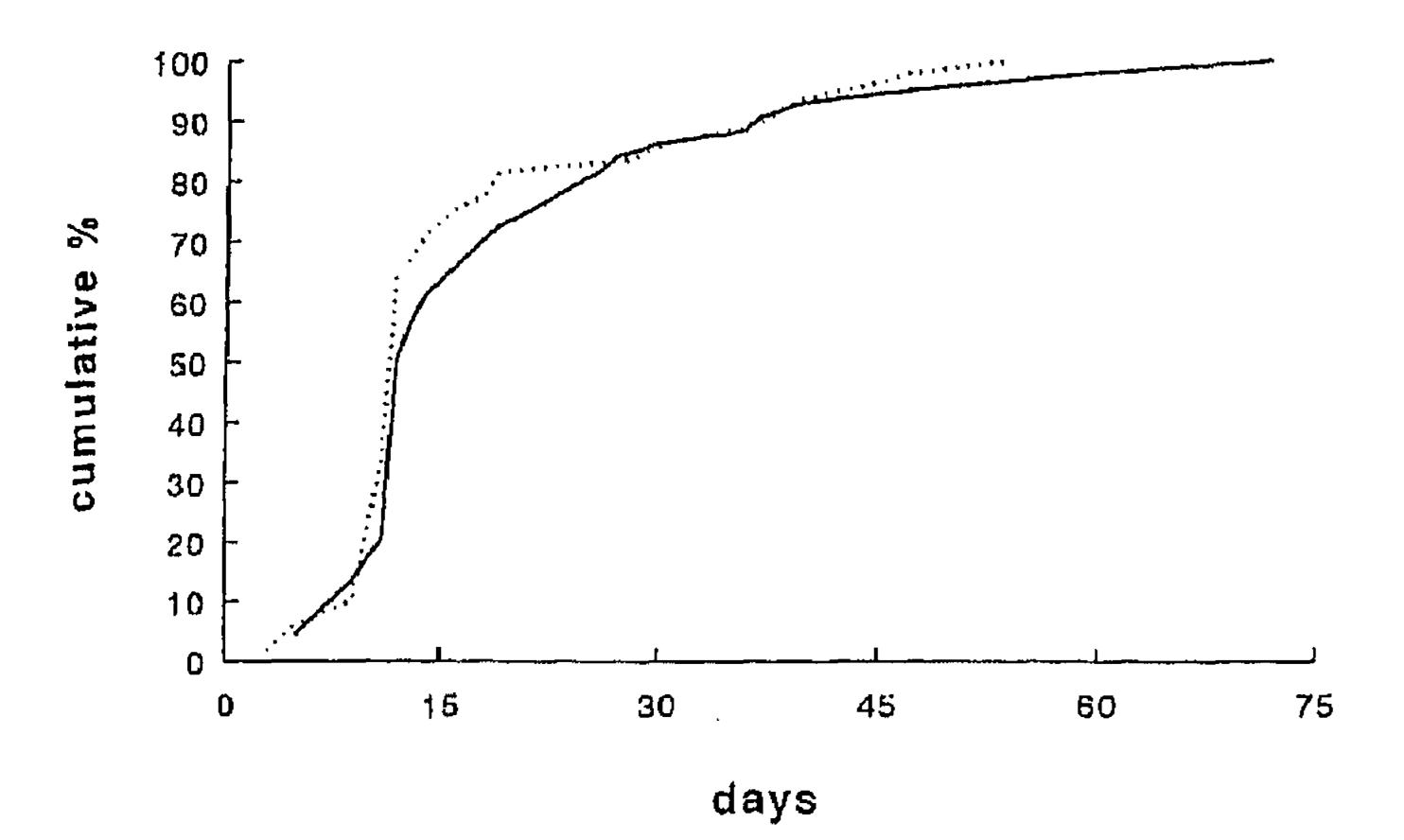
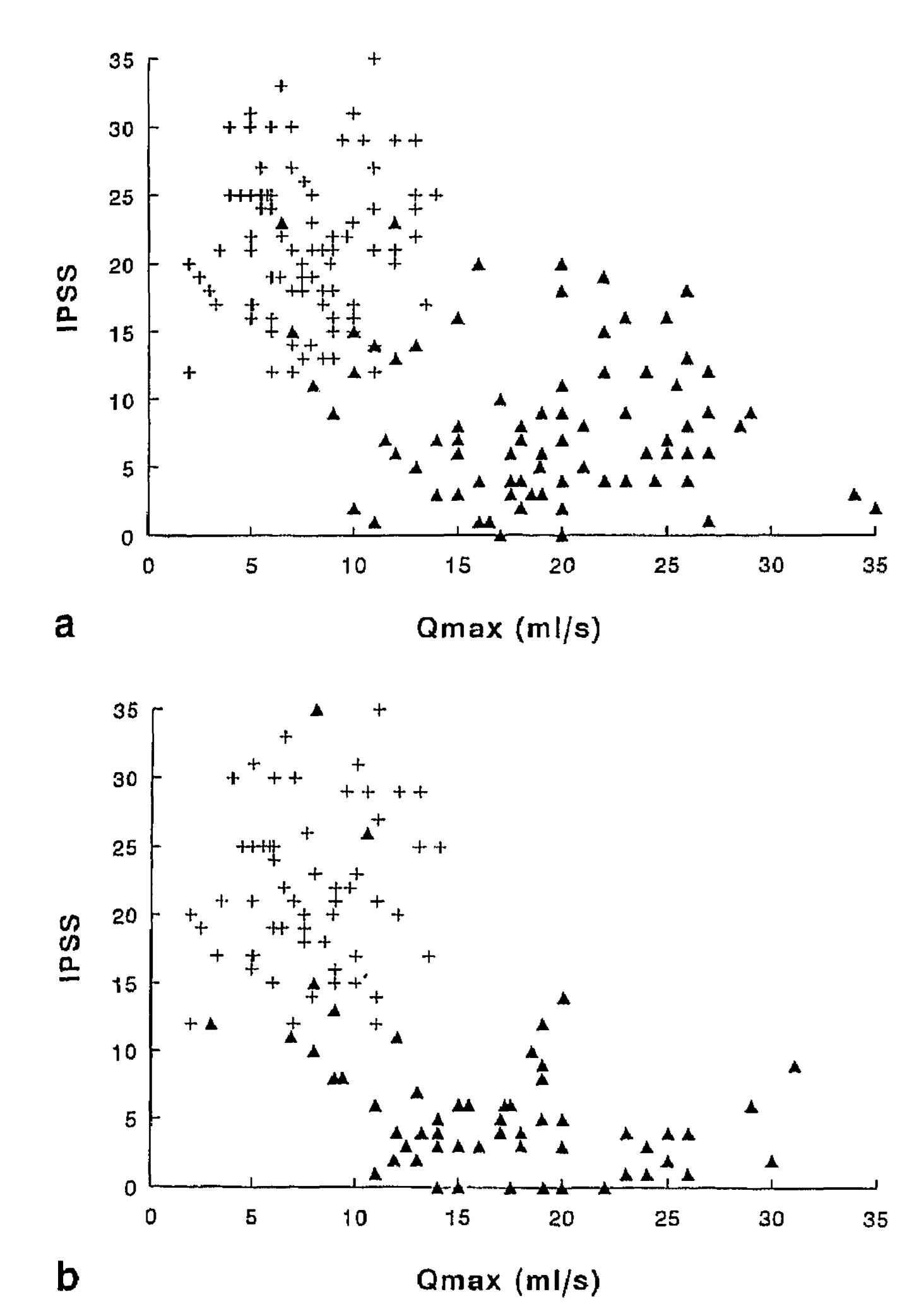
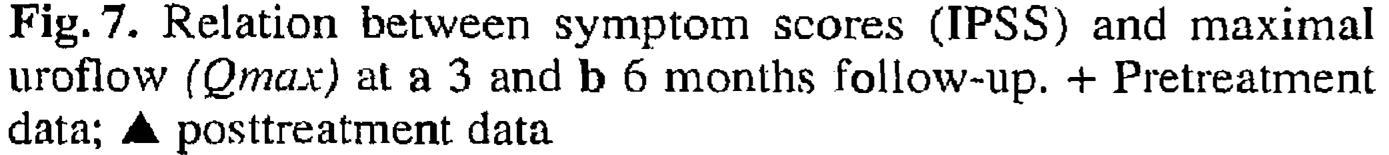


Fig. 6. Need for suprapublic catheterization in patients treated with the Ultraline (-) and Urolase (.....) fibers

for an average of 5–20 days. Norris et al. [7] decided to leave the catheter indwelling for 5–7 days postoperatively, and only 17% of the patients required reinsertion of the catheter because of retention. In the present study we inserted a suprapubic catheter prior to treatment. Patients treated with the Ultraline fiber needed catheterization for an average of 18.9 days, whereas those treated with the Urolase fiber had their catheter removed at average on day 16.9. This may also explain the discomfort caused, expressed as irritative symptoms.

Therefore, it was suggested that one should move away from purely coagulative techniques, which do not debulk the prostate to any measurable extent, toward a more vaporizing-oriented approach. This treatment modality causes tissue to convert into vapors of water and hydrocarbons, thus creating immediate cavitation. Although we expected to create immediate cavitation using the Ultraline fiber, this did not occur. The results achieved with the Ultraline fiber are comparable with those found after treatment with the Urolase fiber. Evaporation of tissue is favored by high-power density, and to obtain maximal power density it is important to keep the fiber close to (i.e., in contact with) the tissue. That we did not use the Ultraline fiber in constant contact with the tissue may explain why the extent of evaporation was less than expected. The main reason for not working in constant contact was that we assumed a more rapid decay of the fibers as a result of contact lasing. Therefore, we think that the effect of the Ultraline fiber, at least in our hands, is a result of coagulation and vaporization. Narayan et al. [8] presented the results they obtained using the Ultraline fiber at a higher power setting. The main findings of their study were that in the short term transurethral evaporation of the prostate provided symptomatic relief and improvement in uroflow comparable to that of TURP [8]. As pointed out above, we could not confirm this observation in using the Ultraline fiber. From our study we conclude that a significant reduction in symptom scores and improvement in peak uroflow can be reached with this fiber. The present technique did not, as we expected, result in an earlier recovery of adequate spontaneous micturition and diminution of the symptoms. We think that the side-firing fibers, which are mainly used in the noncontact mode and at a relatively low power setting, are currently incapable of creating sufficient cavitation. The results presented by Narayan et al. suggest that besides being applied in contact, this fiber should be used at a higher power setting. The results of contact lasing are also very promising. These lasing devices seem to be capable of deobstructing prostates immediately [11]. As over 20 different devices are available at the moment, one would expect that these would differ in terms of response and outcome. The question as to the type of applicator that should be used is fundamental. In favor of a vaporizing technique is the observation that tissue is vaporized and a cavity is created instantly. To our surprise, the results achieved with the fibers used in this study were similar. One might think that the general effect of laser light on tissue would be most important, not the device or technique used. However, Ansen and Watson [15] showed that pure coagulation treatment using the side-firing fibers





power densities sufficient to coagulate the prostate, the gland shrinks to a minor extent due to the coagulation effect on protein and to the desiccation of the tissue. The prostate becomes rigid. This is followed by a period of cellular infiltration and swelling of the tissue. The patients will almost universally have a period of retention lasting

appeared to show a higher success rate for the Urolase fiber as compared with the Myriadlase system. Another argument that fibers really differ in both their abilities and the outcome of treatment is provided by the results achieved with the contact lasing devices [11].

Besides the outcome of treatment and the morbidity caused, quality of life is another item to be addressed. An increasing number of (young) men with symptomatic BPH requiring treatment are concerned about their sexual functions. In the present study, retrograde ejaculation was found in 50% of the patients who were sexually active, whereas 14% mentioned diminished or absent erectile functions. Norris et al. [7] reported retrograde ejaculation in 3 of 37 sexually active men. According to Childs et al. [14], absolutely no retrograde ejaculation was found after laser prostatectomy. Shanberg et al. [16] stated that all patients who were sexually active prior to therapy maintained their potency and described no change in their erections. All but one patient maintained normal antegrade ejaculations as well. This discrepancy may have been caused by more extensive treatment near the bladder neck. Although the results of laser treatment are encouraging, the morbidity is considerably high. This is related to the device and technique used, among other factors. The optimal Nd:YAG power setting, time for energy delivery, and type of applicator used for laser treatment of the prostate have not yet been defined. The objective of laser treatment must be to find the technique that will maintain a clinically significant outcome while causing minimal posttreatment morbidity. In conclusion, it is important to recognize that the term laser prostatectomy encompasses a wide variety of instruments and techniques. The question regarding the appropriate technique and dosimetry has remained an enigma for all urologists. Each laser fiber has its own advantages and limitations, and no single formula exists for the ideal

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