



Benign Prostatic Obstruction

The Diode Laser: A Novel Side-Firing Approach for Laser Vaporisation of the Human Prostate—Immediate Efficacy and 1-Year Follow-Up

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Article info

Article history:

Accepted June 18, 2007

Published online ahead of
print on June 26, 2007

Keywords:

Diode laser
Laser prostatectomy
BPH
Benign prostatic hyperplasia
Bladder outlet obstruction
Benign prostatic
enlargement
BPE
Vaporisation
Diode
Laser

Abstract

Objectives: A prototype diode laser was used to evaluate the feasibility and post-operative outcome of diode laser vaporisation of the prostate in patients with bladder outlet obstruction (BOO) necessitating interventional desobstruction.

Methods: Ten patients were included in this pilot study. The prostate was vaporised via a side-fire laser fibre (diode laser at 1470 nm, 50 W; Biolitec-AG, Jena, Germany). IPSS, quality of life, Q_{max} , and PVR volume were measured pre- and postoperatively and 1 yr after the intervention.

Results: Prostate volumes were 35–78 ml. A mean 121 kJ (61–200 kJ) of energy was delivered. No patient had significant blood loss or fluid absorption. Three-way catheters were removed after a median of 33 h. Q_{max} increased from 8.9 ml/s (3.6–13.2 ml/s) preoperatively to 15.7 ml/s (10.5–22 ml/s) ($p < 0.01$) postoperatively. After the 12-mo follow-up, Q_{max} increased to 22.35 ml/s (± 4.32 ml/s; $p < 0.001$). PVR volume changed from a baseline of 243 ml to 26.9 ml ($p < 0.001$) after 12 mo. Volume reduction was estimated by transrectal ultrasound postoperatively (15 cc \pm 6.39), and by PSA levels before surgery (3.8 ng/ml \pm 2.3) and after 6 mo (2.64 ng/ml \pm 1.51).

No patient is incontinent. Two patients required recatheterisation postoperatively on days 1 and 2, respectively. Two patients required TURP within 2 mo. All patients without reintervention have presented for the 1-yr follow-up examination and are satisfied with the outcome.

Conclusions: Our preliminary findings indicate that 50-W diode laser vaporisation prostatectomy at 1470 nm is feasible and appears to be effective for acutely relieving BOO.

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1. Introduction

Neodymium:yttrium-aluminum-garnet (Nd:YAG) laser was introduced in 1992 [1] as a potential therapy that would be associated with less morbidity than transurethral resection of the prostate (TURP) for bladder outlet obstruction (BOO) due to benign prostatic enlargement (BPE). Although the haemostatic characteristics were excellent, the remaining necrotic tissue caused BOO and related symptoms for several weeks after treatment. Immediate tissue ablation was accomplished when Malek [2] introduced a 60-W potassium-titanyl-phosphate laser (kalium-titanyl-phosphate [KTP] laser) to study the feasibility and functional outcome after vaporisation of the prostate in 10 patients. The capacity to vaporise tissue with a minimal coagulation rim of underlying structures is a feature that makes KTP laser prostatectomy (KTP-LP) an ideal tool for immediate transurethral removal of prostatic tissue in a haemostatic environment [3,4]. Since its introduction, there have been multiple studies showing the safety and early efficacy of this user-friendly technique [5]. Recently, long-term results over 5 yr of follow-up have been published [6]; the authors concluded that significant improvements in symptomatic and urodynamic outcomes of KTP-LP are sustainable. KTP-LP is characterised by excellent perioperative safety and significant improvement in voiding parameters. Because of its immediate haemostatic property, KTP-LP is suitable for patients under antiplatelet therapy and oral anticoagulation [4].

The drawbacks of Nd:YAG's coagulation component include prolonged postoperative irritative symptoms, prolonged length of catheterisation, micturition improvements that are significantly inferior to TURP, and unpredictable outcomes owing to high reoperation rates. These drawbacks have been substantially reduced in the KTP setting.

The 50-W diode laser prototype (Biolitec AG, Jena, Germany) emits a wavelength of 1470 nm. Strong absorption of the wavelength by haemoglobin and water allows a tissue penetration of 2–3 mm (Seitz et al, submitted for publication) so that heat is concentrated in a small volume of tissue and cells are lysed by rapid vaporisation of their cellular water.

The aim of this pilot study was to evaluate, in a clinical setting, the potential of the 50-W diode laser in 10 patients with BOO due to BPE.

2. Materials and methods

Between January and March 2006, we treated, in the study program, 10 men referred for BOO due to BPE. All patients

failed conservative treatment options and were referred for TURP. All patients received a physical examination including digital rectal examination (DRE), and their symptoms were evaluated according to the International Prostate Symptom Score (IPSS) and a quality of life (QoL) score. Pre- and postoperatively the International Index of Erectile Function questionnaire, 5-item version (IIEF-5) was evaluated. Additionally, postvoiding residual urine volume (PVR) and the peak urinary flow rate (Q_{max}) were measured. All patients underwent transrectal ultrasound (TRUS) to evaluate prostate size and to rule out hypoechoic lesions. Blood tests comprised blood cell count, serum chemistry, serum prostate-specific antigen (PSA), and urine analysis including urine culture. Inclusion criteria were moderate to severe urinary symptoms, as determined by IPSS (score ≥ 8) and Q_{max} of less than 15 ml/s with or without PVR volume, in patients who were judged to be high-risk patients owing to oral antiplatelets therapy and severe cardiopulmonary comorbidities. The detailed history together with Q_{max} were considered to be adequate for the assessment of infravesical obstruction. Pressure-flow studies were therefore not performed. Informed consent of all patients as well as ethical committee approval was obtained. Exclusion criteria were urethral stricture, previous prostatic surgery, prostate cancer, and obvious manifested neurogenic bladder dysfunction.

Laser therapy was conducted in a side-firing technique. The laser fibre was introduced through a 24F continuous flow laser cystoscope. Sterile isotonic saline was used as an irrigant. The procedure was performed under general or, in two cases, spinal anaesthesia. All patients had sterile urine and were treated with ciprofloxacin during and for 5 d after surgery. Antiplatelet medication had been discontinued 3 d before surgery and initiated again 5–7 d after the procedure. All patients had normal bleeding time and international normalised ratio values before surgery.

Vaporisation was performed with the 600-nm Biolitec side-fire laser fibre. Laser energy was generated by a prototype Biolitec AG diode laser generator delivering 50 W in continuous mode. Lasing was performed by changing between a noncontact and a contact technique. The starting point of lasing was at the bladder neck. Subsequently, the laser beam was moved in the 6 o'clock lithotomy position towards the apical region, vaporizing tissue between the bladder neck and the paracollicular region. This procedure was repeated evenly on both lateral lobes in a TUR manner from the 6 o'clock to 12 o'clock position, removing obstructive tissue of the prostate until a TURP-like cavity was attained. Finally, a 20 Charrière three-way catheter (in case of haematuria) was inserted without irrigation.

All 10 patients completed the 1-mo follow-up, whereas 8 of 10 were evaluated after 6 and 12 mo. Mean changes from baseline were assessed as efficacy measures (IPSS, QoL, Q_{max} , and PVR volume). The Mann-Whitney *U* test was used to determine statistical significance. Additionally, fluid absorption during diode laser prostatectomy was evaluated. Irrigation fluid (isotonic saline at 0.9%) was tagged with ethanol (1% w/v). Intraoperatively, a standard breathalyser (Alcotest[®]7410_{plus}, Dräger, Germany) was used to monitor ethanol levels in expired breath before and during surgery (15 min and 30 min

after start of and at end of the procedure). During the procedure, the irrigation fluid bottle was positioned 60 cm above the patient. The amount of fluid absorption was calculated with the Widmark formula. The rectal temperature was monitored during the entire procedure.

3. Results

Patient's characteristics are listed in Table 1. The prostate volumes ranged from 35 to 78 ml with a mean volume of 47.8 ml (standard deviation [SD] \pm 18.6 ml). The mean age of the patients was 75 yr (SD \pm 5). None of the patients was suspicious for prostate cancer on DRE and/or TRUS. Four patients had PSA levels greater than 4 ng/ml. Prostate biopsy ruled out malignancy. The mean lasing time was 40 min \pm 13, during which 61–200 kJ of energy (mean, 121 kJ \pm 38) were delivered. The mean rectal body temperature during the procedure was 35.8 °C (Table 1).

None of the catheters required irrigation and all were removed within 18–168 h (median, 33 h; mean, 49.8 h \pm 46.01). Patients stayed in hospital for 4.7 d (SD \pm 2.3). There were neither serious intraoperative complications nor intraoperative bleeding. One patient with sterile urine preoperatively became febrile 36 h postoperatively as a result of pneumonia. The patient was treated in the intensive care unit for 5 d.

There was no significant immediate postoperative haematuria. None of the patients required blood transfusion after diode LP. Two patients had to be recatheterised for 12 h (on postoperative day 1) and 24 h (on postoperative day 2), respectively. The mild dysuria that developed in two patients resolved within 10 d without any treatment. No patient had urinary incontinence. Two patients (those who

required recatheterisation) were not satisfied with the outcome and underwent conventional TURP within 2 mo of initial laser therapy.

The mean haemoglobin fell from 14.88 mg/dl (SD \pm 0.71) to 14.52 mg/dl (SD \pm 0.71), and the mean haematocrit from 0.44 (SD \pm 0.02) to 0.42 (SD \pm 0.02), indicating that no bleeding occurred during or after laser surgery. Immediate postoperative serum sodium ranged from 137 to 142 mmol/l. None of the patients experienced fluid absorption during diode laser prostatectomy, which was evaluated with a standard breathalyser (Alcotest), perioperatively. The mean PSA level (Elecsys; Roche Diagnostics) fell from 3.8 ng/ml (SD \pm 2.3) to 2.6 ng/ml (SD \pm 1.4) after 6 mo. The mean reduction in prostate volume estimated by TRUS was 15 cc (SD \pm 6.4) after removal of the catheter. Estimation was performed with the use of an ultrasound scanner with a biplane multifrequency transducer (7.5–10 Mhz; Hawk2102; Bruel and Kjaer, Denmark). Reduction volumes were calculated with the prolate ellipse formula.

All patients presented for the 1-mo follow-up; eight patients without reintervention returned for the 6- and 12-mo follow-up. The mean IPSS fell after the treatment. At 4 wk ($p < 0.05$), and 6 and 12 mo ($p < 0.001$), there was a significant difference between the preoperative and postoperative status. The IPSS fell from 16.3 (SD \pm 2.2) to 12.8 (SD \pm 2.7), and 5.3 (SD \pm 1.4) to 5.0 (SD \pm 1.6), respectively. There was also a significant difference in the QoL (baseline, 3.3), which was 2.3 ($p < 0.01$) at 4 wk, 1.1 ($p < 0.001$) at 6 mo, and 0.9 ($p < 0.001$) at 12 mo.

Q_{max} increased from 8.9 ml/s (SD \pm 2.9) preoperatively to 15.7 ml/s (SD \pm 5) after removal of the catheter ($p < 0.01$). At 4 wk, 6 mo, and 12 mo, Q_{max} increased to 18.2 ml/s (SD \pm 5, $p < 0.01$), 23.2 ml/s (SD \pm 4.8, $p < 0.001$), and 22.4 ml/s (SD \pm 4.3,

Table 1 – Patient baseline characteristics

Patient no.	Age (yr)	Prostate volume (cc)	IPSS	QoL	PSA (ng/ml)	Q_{max} (ml/s)	PVR volume (ml)
1	72	35	22	3	3.30	3.6	600
2	77	42	15	3	2.29	7.0	70
3	83	70	17	4	8.90	6.9	180
4	63	23	13	4	1.25	13.2	90
5	73	35	15	3	4.29	6.9	85
6	74	35	17	3	0.60	12.3	300
7	77	65	16	4	6.30	10.3	95
8	77	30	17	3	3.20	12.2	800
9	74	78	16	3	4.64	7.2	90
10	83	65	15	3	3.2	9.3	120
Mean	75	47.8	16.3	3.3	3.8	8.9	243
SD	\pm 5	\pm 18.58	\pm 2.24	\pm 0.56	\pm 2.31	\pm 2.9	\pm 241.6

SD, standard deviation; IPSS, International Prostate Symptoms Score; QoL, quality of life; Q_{max} , urinary peak flow; PVR, postvoid residual urine.

Table 2 – Micturition and clinical outcome of patients (mean values \pm SD)

	Preoperative	At discharge	At 1 mo postoperatively	At 6 mo postoperatively	At 12 mo postoperatively
No. of patients	10	10	10	8	8
IPSS (mean \pm SD)	16.3 \pm 2.24	—	12.8 \pm 2.7 $p < 0.05$	5.3 \pm 1.4 $p < 0.001$	5.0 \pm 1.6 $p < 0.001$
QoL (mean \pm SD)	3.3 \pm 0.56	—	2.3 \pm 0.6 $p < 0.01$	1 \pm 1.1 $p < 0.001$	0.875 \pm 0.9 $p < 0.001$
Q _{max} (mean \pm SD) (ml/s)	8.9 \pm 2.9	15.7 \pm 5 $p < 0.01$	18.2 \pm 5 $p < 0.01$	23.2 \pm 4.8 $p < 0.001$	22.4 \pm 4.3 $p < 0.001$
Mean PVR volume (ml)	243 \pm 241.6	97 \pm 58.7 NS	81 \pm 61.8 $p < 0.05$	22.5 \pm 9.7 $p < 0.001$	26.9 \pm 15 $p < 0.001$
Volume reduction estimated by TRUS (cc)	—	15 \pm 6.39 (–31.4%)	—	—	—
PSA (ng/ml)	3.8 \pm 2.3	—	—	2.64 \pm 1.51 $p = 0.236$	—

SD, standard deviation; IPSS, International Prostate Symptoms Score; QoL, quality of life; Q_{max}, urinary peak flow; PVR, postvoid residual urine; PSA, prostate-specific antigen; NS, not significant; TRUS, transrectal ultrasound.

$p < 0.001$), respectively. These figures differed significantly from baseline data before surgery.

PVR volume fell substantially from the preoperative levels. After removal of the catheter, the mean PVR volume fell from 243 ml (SD \pm 241.6) to 97 ml (SD \pm 58.7); this change was not significant. However, the PVR volume at 4 wk was estimated sonographically to be 81 ml (SD \pm 61.8, $p < 0.05$), 22.5 ml (SD \pm 9.7) at 6 mo, and 26.9 ml (SD \pm 15) at 12 mo, which was highly significant compared with baseline ($p < 0.001$; Table 2).

4. Discussion

BPE is the most common cause of BOO in elderly men, and the most frequent pathology necessitating surgical treatment in men. Among the surgical techniques, TURP has been applied with great success for decades as the gold standard treatment. It significantly improves urinary symptoms and urinary flow. Despite its general acceptance and widespread application, complications are seen in up to 20% of patients following a successful intervention [7,8]. Currently, a number of minimally invasive procedures are available as effective alternatives entailing less morbidity and shorter hospital stays. Among these, promising surgical techniques are any kind of visual laser ablation procedures such as KTP-LP, holmium laser enucleation of the prostate (HoLEP), and others [7–9].

The results of LP depend on several factors including wavelength, power, duration, and technique. Some tissue characteristics that make LP with an Nd:YAG laser appear to be an attractive alternative are its excellent coagulation and haemostatic properties [1]. However, the limited cutting effect, the prolonged catheterisation time, the inferior micturition outcome, and the high reoperation rates explain why Nd:YAG LP has never become widely accepted. The holmium:YAG wavelength is

absorbed more strongly by water. It cuts tissue better, but is less haemostatic. Nevertheless, HoLEP became accepted as a safe and effective alternative to open prostatectomy and TURP with minimal blood loss, short catheterisation time, and hospital stay as proven by several studies, including randomised trials with follow-up data over 6 yr [10–16].

Today, KTP-LP is a commonly used laser procedure, which is able to achieve tissue vaporisation and haemostasis with a minimal coagulation rim (1–2 mm). At the same time, the procedure provides good immediate voiding outcomes. The 532-nm wavelength is strongly absorbed by haemoglobin, so that the heat produced is concentrated in a small volume, which causes rapid vaporisation of cellular water, especially in well-perfused tissue. Numerous studies demonstrated the safety and efficacy of 80-W KTP-LP [4,5,17,18]. However, major drawbacks of LP at 532 nm are the lack of long-term follow-up data, the lack of tissue obtained for histology, and the significantly lower volume reduction compared with HoLEP and TURP.

Sarica et al [19] claim that KTP-LP is a significant challenge to the gold standard status of TURP. KTP-LP has been found to be effective enough, with short-term (1-yr) results similar to those produced by TURP. A multicentre study from the United States presenting 3-yr results of the 80-W KTP-LP showed a sustained improvement in all relevant efficacy outcomes that was maintained for 3 yr, irrespective of the serum PSA and prostate volume [20].

Any innovative laser therapy of the prostate must stand up to comparison with 80-W KTP-LP in terms of safety, efficacy, and durability. One potential candidate to challenge KTP laser might be the diode laser (1470 nm). In contrast to the 80-W KTP laser, energy is absorbed by haemoglobin but also by cellular water and penetrates 2–3 mm into the tissue in diode laser. Thus, heat becomes concentrated in a small volume of tissue, and the high-energy density degrades tissue by rapid vaporisation. The

technique, which is similar to KTP-LP, is equally user-friendly, and the procedure is safe and essentially bloodless. The patients do not need postoperative irrigation, there is no significant decrease in the preoperative and postoperative haemoglobin and haematocrit ($p = 0.248$), and none of the patients shows fluid absorption or any significant decrease in the serum sodium level. The heat generated by the energy applied appears to be negligible because rectal temperature never exceeds 36.4°C and a new onset of erectile dysfunction (IIEF-5) or urinary incontinence has not been observed. The mean prostate volume was estimated at 47.8 cc, with a mean lasing time of 40 min and the mean energy delivered at 121 kJ. These figures are consistent with the data of Sarica et al [19] who reported a mean lasing time of 45 min, a mean energy of 104.6 kJ, and a mean prostate volume of 52.1 cc with the KTP laser system. In the same report a reduction of prostate volume by TRUS of 28% after 6 mo and 53% after 12 mo compared with baseline was achieved. These results are comparable to our data, which show a decrease of 31.4% immediately after surgery. However, in comparison with large glands (>125 cc) in which a reduction of more than 80% [21] was achieved by HoLEP, diode LP, and KTP-LP seems less effective, but comparative large-scale studies on this matter are necessary to identify superiority of either technique.

The change in PSA in our patients 6 mo after surgery, as a function of the weight of prostate tissue removed by diode LP, showed a reduction of serum PSA of 1.2 ng/ml (from baseline 3.8 ng/ml to 2.6 ng/ml). In comparable adenomas (mean volume, 47.6 cc) Lloyd et al [22] have shown that for every gram of resected tissue by TURP (mean resection, 21.3 g), serum PSA decreased on average by 0.096 ng/ml. Accordingly, a decrease in PSA of 1.2 ng/ml after diode LP would account for 12.5 g of removed prostate tissue, which is consistent with the estimated reduction of 15 cc by TRUS. Therefore, one can assume that removing 15 cc of tissue in 50-cc adenomas contributes to a reasonable TURP-like cavity, which may guarantee a satisfactory mid- to long-term outcome.

With diode LP, morbidity is low overall. Immediately after the procedure, two patients (20%) experienced mild dysuria, which resolved within 10 d without any specific treatment. Mild dysuria occurs in 5–10.8% [4,5,19,23] of the KTP-LP patients. Our own database of more than 500 consecutive KTP-LPs since 2003 reveals dysuria in 14%. None of the diode patients had transient haematuria or urgency, which is consistent with the early reports on KTP-LP [2]. The mean catheterisation time of

49.8 h (SD \pm 46.01) is reasonable and concordant with 7.6 h [24] to 43 h [4] reported in the literature. In light of one patient requiring transurethral catheterisation for 168 h and intensive care for 5 d owing to a sepsis, mean catheterisation time would account for 36.6 h (SD \pm 25.1) only. Therefore, the median catheterisation time of 33 h should be emphasised. Comparison with TURP or KTP-LP is certainly premature because of the short follow-up and the limited number of patients in this pilot study, but it has to be mentioned that all the potential short-term complications such as urinary incontinence, urethral strictures, and bladder-neck contractures did not occur. Pooled results of large case series (Nd:YAG, HoLEP, KTP) revealed low complication rates such as 2.3% urinary tract infection and 3.2% urethral stricture/bladder-neck contracture [25]. However, recatheterisation was seen in two diode patients (20%) and both patients required TURP within 2 mo. In both cases laser failure was due to a prominent midlobe. Literature surveys on KTP-LP have revealed recatheterisation rates between 0% and 15.4% [24,26].

The mean IPSS in the patients available for follow-up shows a significant decrease to 12.8 ($p < 0.05$) in the 1-mo follow-up and a highly significant decrease to 5.3 and 5.0 ($p < 0.001$) in the 6-mo and 12-mo follow-up, respectively, compared with the baseline IPSS of 16.3, which was reported by others for KTP-LP and TURP. The same applies to QoL, which improved significantly from baseline value of 3.3 to 2.3, 1.1, and 0.9 after 1, 6, and 12 mo, respectively. Compared with KTP-LP and TURP, urinary baseline Q_{max} (8.9 ml/s) at 1 mo (18.2 ml/s), 6 mo (23.2 ml/s), and 12 mo (22.35 ml/s) postoperatively improved significantly along with PVR volume ($p < 0.001$), which is in accordance with the literature [4–6,18,19,24,27].

One of the drawbacks of LP is that no tissue is retrieved for histology. Therefore, it is important to exclude cases of prostate cancer before surgery.

5. Conclusion

To our knowledge this is the first study on side-firing diode LP of the prostate. Our early and limited results are very encouraging, but randomised clinical studies with mid- to long-term follow-ups are needed to evaluate the safety, efficacy, limitations, and durability of the diode LP at 1470 nm. Furthermore, the diode laser is not a “benign-prostatic-hyperplasia-only-instrument,” but might also be used as a multifunctional endourologic

device for the treatment of condylomas and upper urinary tract tumors.

Conflicts of interest

The authors have nothing to disclose.

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