5.2.4 *Tolerability and safety*

Intra-/peri-operative complications

Mortality following open prostatectomy has decreased significantly during the past two decades and is less than < 0.25% in contemporary series (13) (Table 17). The estimated need for blood transfusion following is about 7-14% (9,12,13).

Long-term complications

Long-term complications are incontinence and bladder neck contracture and urethral stricture. The risk of developing stress incontinence is up to 10% (4), while the risk for developing bladder neck contracture and urethral stricture is about 6% (7-9).

5.2.5 *Practical considerations*

Open prostatectomy is the most invasive, but also the most effective and durable, procedure for the treatment of LUTS secondary to BPO. Only Holmium enucleation delivers similar results, but with less morbidity. In the absence of an endourological armamentarium and a Holmium laser, open prostatectomy appears to be the treatment of choice for men with prostates > 80-100 mL and drug-treatment-resistant LUTS secondary to BPO. The choice between the Freyer or Millin procedures depends upon the surgeon's preference.

Table 16: Results of open prostatectomy studies for treating BPH-LUTS or BPO

Studies	Duration (weeks)	Patients (*n*)	Change in symptoms (IPSS)		Change in Q_{max}		Change in PVR		Change in prostate volume		LE
			Absolute	%	mL/s	%	mL	%	mL	%	
Kuntz et al. 2008 (9)	260	32	-18.2	86	21.4	677	-287	98			1b
Skolarikos et al. 2008 (8)	78	60	-12.5	63	7	86	-77	86	-86	88	1b
Naspro et al. 2006 (7)	104	39	-13.2	62	15.9	291					1b
Varkarakis et al. 2004 (12)	151	232	-23.3	84	16.5	329	-104	90			3
Gratzke et al. 2007 (13)		868			13	218	-128	88	85	88	2b

IPSS = international prostate symptom score; PVR = post-void residual; Q_{max} = maximum urinary flow rate (free uroflowmetry)

Table 17: Tolerability and safety of open prostatectomy

	Peri-operative mortality (%)	Postoperative stress incontinence (%)	Re-operation for BPO (%)
Kuntz *et al.* 2008 (9)	0	0	0
Skolarikos *et al.* 2008 (8)	0		0
Naspro *et al.* 2006 (7)	0	2.5	0
Varkarakis *et al.* 2004 (12)	0	0	
Gratzke *et al.* 2007 (13)	0.2		

BPO = benign prostatic obstruction

5.2.6 *Recommendations*

	LE	GR
Open prostatectomy is the first choice of surgical treatment in men with drug-refractory LUTS secondary to benign prostatic obstruction and prostate sizes > 80-100 mL in the absence of Holmium lasers.	1b	A

LUTS = lower urinary tract symptoms

5.2.7 *References*

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5.3 Transurethral Microwave Therapy (TUMT)

5.3.1 *Mechanism of action*

Microwave thermotherapy of the prostate works by emitting microwave radiation through an intra-urethral antenna in order to deliver heat into the prostate. Tissue is destroyed by being heated at temperatures above cytotoxic thresholds (> 45°C) (coagulation necrosis). Heat is mainly produced by electrical dipoles (water molecules) oscillating in the microwave field and electric charge carriers (ions) moving back and forth in the microwave field. It is also thought that the heat generated by TUMT also causes apoptosis and denervation of α-receptors, thereby decreasing the smooth muscle tone of the prostatic urethra.

5.3.2 *Operative procedure*

Transurethral microwave therapy is a registered trademark of Technomed Medical Systems, the pioneer of microwave thermotherapy. Currently, the main devices in the field of microwave thermotherapy are the Prostatron™ device (Urologix, Minneapolis, MN, USA), Targis™ (Urologix, Minneapolis, MN, USA), CoreTherm™ (ProstaLund, Lund, Sweden), and TMx-2000™ (TherMatrx Inc, Northbrook, ILL, USA). Most published data on thermotherapy has been on the Prostatron device.

Conceptually, TUMT devices are all similar in delivering microwave energy to the prostate with some type of feedback system. All TUMT devices consist of a treatment module that contains the microwave generator with a temperature measurement system and a cooling system. The main difference between TUMT devices is the design of the urethral applicator. The applicator consists of a microwave catheter connected to the module, which is inserted into the prostatic urethra. Differences in the characteristics of applicators have a significant effect on the heating profile (1). Other less important differences between TUMT devices are found in the catheter construction, cooling systems, treatment time, and monitoring of TUMT effects (2).

5.3.3 ***Efficacy***

5.3.3.1 Clinical outcome

A systematic review of all available RCTs on TUMT attempted to assess therapeutic efficacy (Table 18) (3) in different TUMT devices and software, including Prostatron (Prostatsoft 2.0 and 2.5) and ProstaLund Feedback. Weighted mean differences (WMD) were calculated with a 95% confidence interval (CI) for the between-treatment differences in pooled means. The review found that TUMT was somewhat less effective than transurethral resection of the prostate (TURP) in reducing LUTS. The pooled mean symptom score for men undergoing TUMT decreased by 65% in 12 months compared to 77% in men undergoing TURP, which is a WMD of -1.83 in favour of TURP. TURP achieved a greater improvement in Q_{max} (119%) than TUMT (70%), with a WMD of 5.44 mL/s in favour of TURP (3).

Similarly, a pooled analysis of three studies (two RCTs and one open label) of ProstaLund Feedback TUMT (PLFT) with 12-month follow-up showed that the responder rate was 85.3% in the PLFT group and 85.9% in the TURP group (4). In addition, pooled IPSS data indicated that a subjective, non-inferior improvement with PLFT compared to TURP (4). However, one-sided 95% CI analysis showed that the non-inferiority of PLFT compared to TURP did not reach the predetermined level, even though both PLFT and TURP appeared to improve Q_{max} significantly.

Previously, urinary retention was considered to be a contraindication for TUMT. Nowadays, level 2b evidence studies have reported an 80-93% success rate for TUMT, defined as the percentage of patients who regained their ability to void spontaneously (5-7). However, these studies had a short follow-up (≤12 months), which makes it difficult to estimate the durability of TUMT outcome in patients with retention. In a study with a longer follow-up of up to 5 years, treatment failure was 37.8% in the retention group, with a cumulative risk of 58.8% at 5 years (8). One RCT compared TUMT with the α_1-blocker, terazosin (9). After 18 months' follow-up, treatment failure in the terazosin-treated patients (41%) was significantly greater than in TUMT patients (5.9%), with TUMT also achieving a greater improvement in IPSS and Q_{max} (10).

5.3.3.2 Durability

Low-energy TUMT has disappointing results for durability. Several studies have reported a re-treatment rate after low-energy TUMT as high as 84.4% after 5 years (11-14), while other studies have reported re-treatment rates of 19.8-29.3% after high-energy TUMT, though with a lower mean follow-up of 30-60 months (15-18). The re-treatment rate due to treatment failure has also been estimated by a systematic review of randomised TUMT trials (3). The trials had different follow-up periods and the re-treatment rate was expressed as the number of events per person per year of follow-up. The re-treatment rate was 0.075/person years for patients treated by TUMT and 0.010/person years for TURP.

However, a prospective, randomised, multicentre study after 5 years has obtained comparable clinical results with TUMT to those seen with TRUP. The study compared TUMT (PLFT; the Core-Therm device) and TURP (19). No statistically significant differences were found in Q_{max} and IPSS between the two treatment groups at 5 years. In the TUMT group, 10% needed additional treatment versus 4.3% in the TURP arm. These data suggest that, at 5 years, clinical results obtained with PLFT-TUMT were comparable to those seen after TURP. It should be noted that most durability studies have a high attrition rate; in this study, less than half of the initial group of patients treated were analysed at 4-5 years. In addition, patients who remained in the study were likely to represent the best data (responders).

5.3.4 ***Tolerability and safety***

Treatment is well tolerated, even though most patients experience perineal discomfort and urinary urgency and require pain medication prior to or during therapy. Pooled morbidity data of randomised studies comparing TUMT and TURP have been published (3,4,20). Catheterisation time, incidence of dysuria/urgency and urinary retention were significantly less with TURP, while the incidence of hospitalisation, haematuria, clot retention, transfusions, TUR syndrome, and urethral strictures were significantly less for TUMT. In a systematic review of randomised trials (3), the re-treatment rate due to strictures during follow-up was estimated and expressed as the number of events per person per year of follow-up. Transurethral resection of the prostate patients (5.85/100 person years) were more likely than TUMT patients (0.63/100 person years) to require surgical re-treatment for strictures (meatal, urethral, or bladder neck). Pooled data showed that TUMT had less impact

on sexual function (ED, retrograde ejaculation) than TURP (3,4,20).

5.3.5 *Practical considerations*

Endoscopy is essential because it is important to identify the presence of an isolated enlarged middle lobe or an insufficient length of the prostatic urethra. Reported low morbidity and the absence of any need for anaesthesia (spinal or general) make TUMT a true outpatient procedure, providing an excellent option for older patients with co-morbidities at high operative risk and, therefore, unsuitable for invasive treatment (21). Independent baseline parameters predicting an unfavourable outcome include advanced age of the patient, small prostate volume, mild-to-moderate BOO and a low amount of energy delivered during treatment (22). However, it should be remembered that a predictive factor for a particular device cannot necessarily be applied to other devices.

Table 18: Efficacy of TUMT. Absolute and relative changes compared to baseline are listed for symptoms (IPSS), maximum urinary flow rate (Q_{max}), post-void residual urine (PVR), and prostate volume (PVol)

Trials	Duration (weeks)	Patients (n)	Change IPSS (absolute [%])	Change Q_{max} (mL/s, [%])	Change QoL (absolute [%])	Change PVR (absolute [%])	Change PVol (absolute [%])	LE
Hoffman et al. (2007) (3)	52	322	-12.7[a] (-65.0)	5.6[a] (70.0)	-2.4[a] (58.5)	NA	NA	1a
Gravas et al. (2005) (4)	52	183	-14.5[a] (-69.0)	8.4[a] (109.0)	-2.97[a] (70.9)	NA	-17.0[a] (-33.0)	1b
Mattiasson et al. (2007) (19)	260	100	-13.6[a] (-61.5)	3.8[a] (50.0)	-3.2[a] (-74.4)	-36.0 (-34.0)	-4.0 (-8.1)	1b
Floratos et al. (15)	156	78	-8.0[a] (-40.0)	2.7[a] (29.3)	-2.0[a] (-50.0)	NS	NA	1b
Thalmann et al. (2002) (17)	104	200	-20.0[a] (-87.0)	7.0[a] (116.6)	-4.0[a] (-80.0)	-143[a] (-84.1)	-17.7[a] (-30.7)	2b
Miller et al. (2003) (18)	260	150	-10.6[a] (-47.0)	2.4[a] (37.0)	-2.3[a] (-54.7)	NA	NA	2b
Trock et al. (2004) (23)	208	541	-8.9[a] (-42.7)	2.8[a] (35.0)	-2.1[a] (-50.1)	NA	NA	2b

a = significant compared to baseline (indexed whenever evaluated); NS = not significant; NA = not available

5.3.6 *Recommendations*

	LE	GR
Transurethral microwave therapy achieves symptom improvement comparable to TURP, but is associated with decreased morbidity and lower flow improvements.	1a	A
Durability is in favour of transurethral resection of the prostate with lower re-treatment rates compared to transurethral microwave therapy	1a	A

TURP = transurethral resection of the prostate

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5.4 Transurethral Needle Ablation (TUNA™) of the prostate

*5.4.1 **Mechanism of action***

The TUNA™ procedure works by inducing a coagulative necrosis within the transition zone of the prostate. As a result of scar maturation, there may be a reduction in transition zone volume and, therefore, a reduction of BPO. There may also be a poorly understood neuromodulatory effect.

*5.4.2 **Operative procedure***

The TUNA™ device delivers low-level radiofrequency energy to the prostate via needles inserted transurethrally into the prostatic parenchyma. The needles are insulated, except at their tips, so that energy is only delivered into the prostatic parenchyma and not to the urethra. Needles are placed under direct vision using an attachment to the standard cystoscope. TUNA™ is carried out under anaesthetic (local or general) or sedation.

*5.4.3 **Efficacy***

Several, non-randomised, clinical trials have documented the clinical efficacy of TUNA™ with a fairly consistent outcome (3-7). Symptomatic improvement has ranged from 40-70%. Improvements in Q_{max} vary widely from 26-121% in non-retention patients. A recent report with 5 years' follow-up in 188 patients demonstrated symptomatic improvement in 58% and improved flow in 41%. However, 21.2% of patients required additional treatment (8).

5.4.3.1 Randomised clinical trials

TUNA™ has been compared with TURP in randomised studies (8-11) with varying follow-up. The studies found both TUNA™ and TURP produced symptomatic improvement. However, TURP produced greater symptom improvement and a better QoL than TUNA™, as well as a significant improvement in Q_{max} after TUNA™ (Table 19). More detailed comparisons between TUNA™ and TURP can be found in some very high-quality and comprehensive, systematic reviews and meta-analyses (12,13).

5.4.3.2 Impact on bladder outlet obstruction

Seven clinical studies on the impact of TUNA™ on BPO (14,15) have demonstrated a statistically significant decrease in maximum detrusor pressure or detrusor pressure at Q_{max}, even though a number of patients were still obstructed following TUNA™ therapy.

There is no convincing evidence that prostate size is significantly reduced following TUNA™ (6). Recent reports have suggested that gadolinium-enhanced MRI can be used to assess TUNA™-related treatment effects (16).

5.4.3.3 Durability

Because most studies have been short-to-medium term, concerns have been risen about the durability of effects. Even short term (12 months), up to 20% of patients treated with TUNA™ need to be re-treated with TURP (1). A recent French report described a failure rate (incorporating re-treatment) of up to 50% over a 20-month period (17).

5.4.4 Tolerability and safety

TUNA™ is usually performed as an outpatient procedure under local anaesthesia, although intravenous sedation is sometimes required (1). Postoperative urinary retention is seen in 13.3-41.6% of patients and lasts for a mean of 1-3 days; within 1 week, 90-95% of patients are catheter-free (1). Irritative voiding symptoms up to 4-6 weeks are common (2). Continence status is not affected.

5.4.5 Practical considerations

Few selection criteria have been identified. However, TUNA™ is unsuitable for patients with prostate volumes > 75 mL or isolated bladder neck obstruction. Because TUNA™ cannot treat median lobes effectively it is not clear whether men with significant median lobes will experience the benefit in published studies. There is anecdotal evidence for TUNA™ in men receiving aspirin and anti-coagulants. TUNA™ can be performed as a day-case procedure and is associated with fewer side-effects compared to TURP (e.g. bleeding, ED, urinary incontinence). However, there remain concerns about the durability of the effects achieved by TUNA™.

5.4.6 Recommendations

	LE	GR
Transurethral needle ablation™ is an alternative to transurethral resection of the prostate for patients who wish to defer/avoid (complications of) transurethral resection of the prostate, but patients should be aware of significant re-treatment rates and less improvement in symptoms and quality of life.	1a	A

Table 19: Summary of comparative level of evidence (LE) 1 data (TUNA™ vs TURP) (12)

	TUNA™	TURP	TUNA™ vs TURP 95% CI	LE
Symptoms (IPSS): mean (% improvement)				
3 months (8,10)	-12 (56%)	-14 (62%)	-2 (-0.9 to 3.1)	1b
1 year (9-11)	-12 (55%)	-15.5 (70%)	3.4 (2.1 to 5.2)[a]	1b
3 years (9,11)	-10 (45%)	-15 (67%)	4.8 (4.2 to 5.4)[a]	1b
Quality of life scores: mean (% improvement)				
3 months (8,10)	-4.5 (54%)	-3.7 (48%)	-0.8 (-1.3 to 0.5)	1b
1 year (9-11)	-4 (50%)	-4.3 (56%)	0.63 (0.1 to 1.2)[a]	1b
3 years (9,11)	-4.2 (50%)	5.2 (67%)	1 (0.2 to 1.9)[a]	1b
Q_{max} (mL/s): mean (% improvement)				
3 months (8,10)	4.7 (54%)	11.5 (150%)	-5.8 (-6.3 to -5.4)[a]	1b
1 year (9-11)	6.5 (76%)	12.2 (160%)	-5.9 (-7.7 to -4.1)[a]	1b
3 years (9,11)	5.6 (66%)	10.8 (141%)	-5.3 (-6.8 to -3.9)[a]	1b
PVR (mL): mean (% improvement)				
1 year (10,11)	-20 (22%)	-42 (41%)	22 (-18 to 27)[a]	1b

IPSS = International Prostate Symptom Score; Q_{max} = maximum urinary flow rate; PVR = post-void residual.
a = TURP significantly better compared with TUNA™.

5.4.7 *References*

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5.5 Laser treatments of the prostate

5.5.1 ***Holmium Laser Enucleation (HoLEP) and Holmium Laser Resection of the Prostate (HoLRP)***

5.5.1.1 Mechanism of action

The holmium:yttrium-aluminum-garnet (Ho:YAG) laser (2140 nm) is a pulsed, solid-state laser that has been used in urology for a variety of endourological applications in soft tissues and for the disintegration of urinary calculi (1). The wavelength of the Ho:YAG laser is strongly absorbed by water. This means that the area of tissue coagulation and the resulting tissue necrosis is limited to 3-4 mm, which is enough to obtain adequate haemostasis (2). Peak power produces intense, non-thermal, localised, tissue destruction, resulting in precise and efficient cutting of prostatic tissue. Resection is usually performed when the prostate is smaller than 60 mL, while enucleation is used for larger glands.

5.5.1.2 Operative procedure

Instrumentation for this technique includes a 550 µm, end-firing, quartz fibre and an 80 W Ho:YAG laser. A continuous-flow resectoscope is required with a working element, while physiological saline solution is used as an irrigant. The basic principle of the HoLRP technique is retrograde resection of the prostate and fragmentation of resected tissue inside the bladder to allow its evacuation through the operating channel of the resectoscope (2,3). The introduction of holmium laser enucleation (HoLEP) has been a significant improvement. Mimicking open prostatectomy, the prostatic lobes are completely enucleated and pushed into the bladder, before being fragmented and aspirated afterwards by a morcellator (8).

5.5.1.3 Efficacy

Gilling et al. (4) has presented the results of a prospective RCT comparing TURP with HoLRP. To date, 120 patients have been enrolled with urodynamically-confirmed BPO (Schäfer grade ≥ 2) and prostate sizes < 100 mL (Table 20). Preliminary analysis has revealed a significantly longer mean resection time (42.1 vs. 25.8 minutes) for HoLRP patients, while symptomatic and urodynamic improvement were equivalent in both treatment groups. In 2004, long-term results with a minimum follow-up of 4 years were published (7), which showed that there was no difference in urodynamic parameters between HoLRP and TURP after 48 months.

Gilling et al. (9) reported long-term data with a mean follow-up of 6.1 years, indicating that HoLEP results were durable and most patients remained satisfied with their procedure. Two meta-analyses, which analysed available RCTs comparing HoLEP and TURP (10,11), reported a significantly longer operation time with HoLEP (Table 20). Symptom improvements were comparable, but Q_{max} at 12 months was significantly better with HoLEP (11). In prostates > 100 mL, HoLEP proved to be as effective as open prostatectomy for improving micturition, with equally low re-operation rates at 5-years' follow-up (12).

5.5.1.4 Tolerability and safety

No major intra-operative complications have been described; however, the technique is a surgical procedure that requires relevant endoscopic skills. There are no specific limitations to the procedure. Patients taking anticoagulant medication and those with urinary retention can be treated safely (6). Dysuria was the most common peri-operative complication with an incidence of approximately 10% (2,4,5). Compared to TURP, HoLRP has a significantly shorter catheterisation time (20.0 vs. 37.2 hours), shorter hospitalisation time (26.4 vs. 47.4 hours) (4), and peri-operative morbidity (7). Potency, continence, symptom scores and major morbidity at 48 months were identical between HoLRP and TURP (7). Retrograde ejaculation occurred in 75-80% of patients; no postoperative impotence has been reported (2). Both meta-analyses found that HoLEP resulted in a significantly shorter catheterisation time and hospital stay, reduced blood loss and fewer blood transfusions, but had a longer operation time than TURP (10,11).

5.5.2 ***532 nm ('Greenlight') laser vaporisation of prostate***

5.5.2.1 Mechanism of action

Vaporisation of prostatic tissue is achieved by a sudden increase in tissue temperature from 50°C to 100°C following the application of laser energy. A rapid increase in tissue temperature results in intracellular vacuoles (bubbles), followed by an increase in intracellular cell pressure. Once the cell pressure exceeds that compatible with cellular integrity, the vacuoles are released, as can be seen during the procedure. Because of the way in which tissue interacts with oxyhaemoglobin, laser vaporisation is increased within a wavelength range from 500-580 nm. Because of the green light emitted (λ=532 nm), this laser procedure is known as 'Greenlight' laser vaporisation.

It is important to include the wavelength or crystal used to produce the laser energy when describing the type of laser vaporisation used. This is because tissue interaction caused by laser energy varies according to the wavelength, applied energy, fibre architecture and tissue properties. This also means that the clinical results of different wavelengths are not comparable.

Table 20: Postoperative results of holmium resection (HoLRP) or enucleation (HoLEP) vs. transurethral resection of the prostate (TURP) open prostatectomy (OP) and 'Greenlight' laser vaporisation (KTP) vs. TURP. Absolute and relative changes compared to baseline, with regard to symptoms (AUA-SI/IPSS), maximum urinary flow rate (Q_{max}), post-void residual urine (PVR), and prostate volume

Trials	Duration	Patients	Surgery	Change symptoms (IPSS)		Change Q_{max} (mL/s)		Change PVR (mL)		Change prostate volume (mL)		LE
	(months)	(n)		absolute	[%]	absolute	[%]	absolute	[%]	absolute	[%]	
Le Duc et al. (1999) (1)	6	42	HoLRP	-18.4	-84	+15.1	+170					1b
		43	TURP	-17.9	-78	+13.2	+145					
Westenberg et al. (2004) (7)	48	43	HoLRP	-14.7 [a]	-67 [a]	+13.4 [a]	+151 [a]	- 61.1 [a] †	-70 [a] †	- 15 [a] †	-34 [a] †	1b
		30	TURP	-16.4 [a]	-71 [a]	+9.4 [a]	+103 [a]	- 50.4 [a] †	-60 [a] †	- 17 [a]	-39 [a] †	
Fraundorfer et al. (1998) (8)	1	14	HoLEP	-14.0	-66	+18.2	+260					3
Gilling et al. (2008) (9)	72	38	HoLEP	-17.2	-67	+10.9	+135	-71.7 †	-68 †	- 31.3 †	-54 †	3
Tan et al. (2007) (10)	12	232	HoLRP	-17.5 to -21.7	-81 to -83	+13.4 to +23.0	+160 to +470	-232.7	-98			1a
		228	TURP	-17.7 to -18.0	-76 to -82	+10.1 to +21.8	+122 to +370	-189.4	-88			
Lourenco et al. (2008) (11)	12	277	HoLRP	-17.7 to -21.7	-82 to -92	+13.4 to +23.0 [b]	+160 to +470 [b]					1a
		270	TURP	-17.5 to -18.7	-81 to -82	+10.1 to +21.8	+122 to +370 [a]					
Kuntz et al. (2008) (12)	60	42	HoLEP	-19.1	-86	+ 20.5	+540	-269.4	-96			1b
		32	OP	-18.0	-86	+ 20.8	+578	-286.7	-98			
Heinrich et al. (2007) (13)	6	140	KTP (80 W)	-10.9 [a]	-55	+ 5.6	+ 43	-65 [a]	-74 [a]			3
Ruszat et al. (2008) (14)	12	302	KTP (80 W)	-11.9 [a]	-65 [a]	+ 10.2 [a]	+121 [a]	-173 [a]	-83 [a]			3
	48	88	KTP (80 W)	-10.9 [a]	-60 [a]	+ 10.2 [a]	+121 [a]	-179 [a]	-86 [a]			
Hamann et al. (2008) (15)	12	157	KTP (80 W)	-13.4 [a]	-65 [a]	+ 10.7 [a]	+135 [a]	-103.4 [a]	-78 [a]			3
Reich et al. (2005) (16)	12	51	KTP (80 W) OA	-13.7 [a]	-68 [a]	+ 14.9 [a]	+222 [a]	-122 [a]	-83 [a]			3

Ruszat et al. (2007) (17)	24	116	KTP (80 W) OA	-13.0	-70	+ 11.3	+140	-103	-80			3
		92	KTP (80 W) CG	-12.7	-71	+12.0	+168	-160	-78			
Ruszat et al. (2006) (18)	24	16	PVP RUR	-11.1	-72			-280	-88			3
		19	PVP NUR	-12.1	-65	+16.2	+228	-131	-85			
Rajbabu et al. (2007) (19)	24	38	KTP (80 W)	-17.2 [a]	-75 [a]	+11.3 [a]	+141 [a]	-85 [a]	-63 [a]			3
Bouchier-Hayes et al. (2006) (20)	12	38	KTP (80 W)	-14.0 [a]	-50 [a]	+12.0 [a]	+167 [a]	-120 [a]	-82 [a]			1b
		38	TURP	-12.9 [a]	-50 [a]	+8.6 [a]	+149 [a]	-82 [a]	-69 [a]			
Bachmann et al. (2005) (21)	6	55	KTP (80 W)	-12.9 [a]	-71 [a]	+11.2 [a]	+162 [a]	-133 [a]	-91 [a]			3
		31	TURP	-12.5 [a]	-72 [a]	+12.2 [a]	+177 [a]	-106 [a]	-88 [a]	-21	-45	
Bouchier-Hayes et al. (2008) (23)	12	46	KTP (80 W)	-16.4 [a]	-65 [a]	+9.8 [a]	+111 [a]	-107 [a]	-83 [a]	-30	-63	1b
		39	TURP	-14.5 [a]	-57 [a]	+10.5 [a]	+118 [a]	-93 [a]	-84 [a]	-27	-44	
Horasanli et al. (2008) (24)	6	39	KTP (80 W)	-5.8	-31	+4.7	+156	-104	-57			1b
		37	TURP	-13.8 [b]	-68 [b]	+11.5 [b]	+225 [b]	-154 [b]	-87 [b]			

† 6-month data; CG = control group; RUR = refractory urinary retention; OA = oral anticoagulation; NUR = no urinary retention

[a] significant compared to baseline (indexed whenever evaluated)

[b] significant difference in favour of indicated treatment

5.5.2.2 Operative procedure

Laser vaporisation of the prostate using an 80 W, 532 nm laser is performed by using a 600 µm side-firing laser fibre with a 70°-deflecting laser beam and a 30°-deflecting laser cystoscope. Cold sterile saline or water can be used for irrigation during the procedure. Under direct vision, vaporisation is performed with a fibre-sweeping technique, usually starting at the bladder neck and continuing with the lateral lobes and the apex (13). The visible, side-fired, laser beam leads to an immediate and apparent tissue ablation.

5.5.2.3 Efficacy

Numerous studies, predominantly with 80 W lasers, have been published in recent years (Table 20). The lack of long-term data means it is not yet possible to make final conclusions about the duration of improvement. A significant improvement in symptoms and voiding parameters and a re-operation rate comparable to TURP was reported in a 5-year follow-up study of 500 patients (14). Despite ongoing oral anticoagulation in 45% of the patients (n = 225), no severe intra-operative complications were observed. The mean catheterisation and post-operative hospitalisation time was 1.8 (0-10) and 3.7 (0-35) days, respectively.

Three years after photolaser vaporisation in men with mean vaporised prostate volumes of 28 ± 42 mL, the mean IPSS was 8.0, QoL score was 1.3, and Q_{max} was 18.4 mL/s. The re-treatment rate was 6.8%. Urethral and bladder neck strictures were observed in 4.4% and 3.6% of patients, respectively. However, follow-up was available only in a few patients. Significant improvements in voiding parameters at a follow-up of 12 months were demonstrated with urodynamic investigation (15). At 12 months' follow-up, the mean urethral opening pressure (Pdetopen; 76.2 vs. 37.4 cm H_2O) and detrusor pressure at Q_{max} (Pdetmax; 75 vs. 36.6 cm H_2O) were significantly reduced compared to baseline. The Q_{max} improved by 113% (mean 18.6 mL/s) compared to pre-operative Q_{max} (mean 7.9 mL/s).

To date, only two prospective RCTs and three non-randomised trials have been published. The longest available follow-up of an RCT is only 12 months; this trial indicated that 532 nm laser vaporisation was equivalent to TURP in symptom improvement (20). Both groups showed a significant increase in Q_{max} from baseline. In the TURP group, flow increased from 8.7 to 17.9 mL/s (149%) and in the laser vaporisation group from 8.5 to 20.6 mL/s (167%). The IPSS decreased from 25.4 to 12.4 (50%) in the TURP group and from 26 to 12 (50%) in the laser vaporisation group. Laser vaporisation also resulted in significant decreases (averaging 119 mL pre-operatively in the TURP group and 147 mL in the laser vaporisation group), with reductions to 37 and 27 mL, respectively. Similar trends were seen concerning bother and quality of life scores.

5.5.2.4 Tolerability and safety

Safety was shown in various, prospective, non-randomised trials in patients with oral anticoagulation, urinary retention, or prostates > 80 mL (16-19). Regarding intra-operative safety, 532 nm laser vaporisation was reported to be superior to TURP in non-randomised trials (21,22). It is also an effective technique when compared to TURP, producing equivalent improvements in flow rates and IPSS with the advantages of markedly reduced length of hospital stay, duration of catheterisation, and adverse events in a randomised trial. The duration of catheterisation was significantly less in the laser vaporisation than the TURP group, with a mean (range) of 13 (0–24) hours vs. 44.7 (6–192) hours. Additionally, the length of hospital stay was significantly shorter with laser vaporisation, with a mean (range) of 1.09 (1–2) and 3.6 (3–9) days in the laser vaporisation and TURP groups, respectively (23).

5.5.2.5 Practical considerations

Despite the efficacy of TURP in terms of tissue removal and reduction of BPO, a higher rate of peri-operative complications has resulted in an ongoing search for less invasive and safer surgical techniques. Based on the wavelength and power, laser can be used either for coagulation, vaporisation, or cutting ('enucleation'). Non-thermal effects, also known as 'ablation', also result in tissue destruction. Functional results will therefore differ in terms of peri-operative handling of different laser devices, including learning curve, debulking issue, durability of results, and type of complications. The treatment choice how to reduce BPO is dependent on the availability of the armamentarium, patient's choice, concomitant morbidity or drug use, and experience of the surgeon.

Several types of new generation lasers for prostate surgery have emerged during the last decade, including the holmium:YAG, potassium titanyl phosphate:yttrium aluminum garnet (KTP:YAG), thulium:yttrium aluminium garnet (thulium:YAG), light blue optics:yttrium aluminium garnet (LBO:YAG) and the diode lasers. Energy can be transmitted through a bare, right-angle or interstitial fibre. Each laser has wavelength-specified energy–tissue interaction. Prostatic tissue destruction results from both thermal and non-thermal effects. In 2009, published data were only available for HoLEP, 80 W Greenlight PV (photoselective vaporisation), and thulium:YAG laser prostatectomy. Only a few articles have been published on thulium:YAG prostatectomy, which may be used as a vaporising, coagulating, or cutting laser. The lack of published data means that firm conclusions are not yet possible with regard to the different laser treatments.

5.5.2.6 Recommendations

	LE	GR
HoLEP and 532 nm laser vaporisation of the prostate are minimally-invasive alternatives to TURP in men with LUTS secondary to BPO which lead to immediate, objective and subjective improvements comparable to TURP.	1b	A
With regard to intra-operative safety, 532 nm laser vaporisation is superior to TURP and should be considered in patients receiving anticoagulant medication or with a high cardiovascular risk.	3	B
With regard to long-term complication rates, results are only available for HoLEP, and are comparable to TURP.	1b	A

TURP = transurethral resection of the prostate; LUTS = lower urinary tract symptoms; BPO = benign prostatic obstruction

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5.6 Prostate stents

5.6.1 ***Mechanism of action***

The use of an endoprosthesis to preserve luminal patency is a well-established concept, while in 1980 Fabian first describing stenting of the prostatic urethra to relieve BPO (1). Prostatic stents were primarily designed as an alternative to an indwelling catheter in patients unfit for surgery because of co-morbidity. However, prostatic stents have also been assessed by several studies as a primary treatment option in patients without significant co-morbidities (2,3).

A prostatic stent requires a functioning detrusor, so that the bladder still has the ability to empty itself. This is in contrast to an indwelling catheter, which drains the bladder passively (4). Stents can be temporary or permanent. Permanent stents are biocompatible, allowing epithelialisation, so that eventually they become embedded in the urethra. Temporary stents do not epithelialise and may be either biostable or biodegradable. Temporary stents can provide short-term relief from BPO in patients temporarily unfit for surgery or after minimally invasive treatment (MIT) (4).

5.6.2 ***Operative procedure***

Stent insertion is mostly performed in an outpatient setting under local anaesthesia. Prior to stent insertion, the length of the prostatic urethra is measured to determine the stent length. After the patient has been placed in the lithotomy position, the stent is advanced through the urethra until the tip of the prostatic urethral segment is positioned in the bladder. It is important that the stent is not positioned inside the external urethral sphincter as it may cause stress urinary incontinence. To confirm proper positioning, abdominal ultrasound or cystoscopy is performed. Removal of a temporary stent is achieved by pulling the retrieval suture, until the stent is completely retracted, or by using graspers under endoscopic guidance. It can be difficult to remove permanent stents in cases of stent migration, stent encrustation or epithelial in-growth, and general anaesthesia is usually needed. In general, antibiotic prophylaxis is not necessary unless there has been a positive urine culture.