Photoselective vaporization of the prostate with the 180-W XPS-Greenlight laser: Five-year experience of safety, efficiency, and functional outcomes

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Cite as: *Can Urol Assoc J* 2018 March 19; Epub ahead of print.
http://dx.doi.org/10.5489/cuaj.4895

Published online March 19, 2018

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Abstract

Introduction: Transurethral resection of the prostate (TURP) is still considered the gold standard surgical treatment for symptomatic benign prostatic hyperplasia (BPH). However, photoselective vaporization of the prostate (PVP) has gained widespread global acceptance in national guidelines as a safe and effective alternative option. Nevertheless, further evidence is required to assess the durability of Greenlight PVP. Herein, we reported our five years PVP experience with the Greenlight 180W XPS laser system.
Methods: A retrospective analysis was conducted on a prospectively gathered database of 370 consecutive included patients who underwent PVP using Greenlight XPS-180 W laser system (Boston Scientific, Boston, MA, U.S.) performed by a single experienced laser surgeon between 2011 and 2016. Preoperative characteristics, intervention parameters, postoperative functional, uroflowmetry outcomes, and complications were collected. Outcomes are reported over a period of five years.
Results: Mean age was 68 years with a mean prostate volume of 78.8 cc (95% confidence interval [CI] 70.9–78.7]). The mean followup was 59.4 months (55.4–63.5). Mean energy, operative time and energy/cc were 270.2 kJ (255.2–285.2), 62.7 minutes (59.6–65.7), and 3.7 kJ/cc (3.6–3.9), respectively. Compared to preoperative values, International Prostate Symptom Score (IPSS), maximum flow rate (Qmax), and post-void residual (PVR) parameters were significantly improved and sustained over the five postoperative years. To note, only 66 patients (out of 370) had a complete five-year

followup. Prostate-specific antigen (PSA) reached nadir at one year, with a drop of 67% from the mean preoperative value of 6.2 ng/mL. Mean IPSS nadir was reached at three years, with a drop of 80.4% (-21.1 points). Similarly, mean quality of life (QoL) score dropped by 82.8% after three years (preoperative mean of 4.7). With respect to mean Qmax, there was an increase by 72.7% (+14.7 mL/s) at one year, reaching the value of 19.9 mL/s. Moreover, mean PVR was 32.8 mL at four years compared to 345 mL preoperatively. At five years followup, PSA, IPSS, QoL, and PVR dropped by 59.7% (3.7 ng/mL), 75.2% (19.7 points), 78.72% (3.7 points), and 84.4% (291.3 mL), respectively. Qmax increased by 12.9 mL/s. Clavien complication rates were low with bladder neck stenosis observed in seven (1.6%) men. During the five-year followup, only four patients (1%) required BPH surgical reintervention.

Conclusions: This is the first long-term reporting of Greenlight XPS-180W laser system. In experienced hands, the observed outcomes appear to demonstrate that Greenlight XPS-180W laser system is safe, efficacious, and durable for the treatment of bladder outlet obstruction secondary to BPH.

Introduction

Benign prostatic hyperplasia (BPH) is a common condition diagnosed in men with increasing incidence after the age of 50.[1, 2] Clinically, it manifests itself by progressive development of lower urinary tract symptoms (LUTS) that include voiding and storage disturbances.[1, 2] The severity of BPH and the patient's degree of bothersome can be assessed by self-administered questionnaires as the I-PSS score.[1] Medical treatment should be offered to patients with moderate to severe symptoms (IPSS 8-35). According to the American and other international guidelines, surgery should be suggested as an option to patients having one or more of the following: urinary symptoms refractory to maximal medical therapy, gross hematuria, recurrent infections, bladder stones, or deterioration of kidney function.[1-3] Transurethral resection of the prostate (TURP) remains the gold standard treatment for LUTS secondary to BPH.[1] However, this intervention is associated with safety issues, particularly in patients taking anticoagulation therapy and those with larger prostates (> 80 cc).[4, 5]

Over the past decades, Greenlight (GL) 532nm-laser photo selective vaporization of the prostate (PVP) has gained widespread acceptance as a safe and effective alternative to TURP.[3, 6] This technology is based on a 532 nm length laser that vaporizes the highly vascularised transitional prostatic zone by selectively heating the hemoglobin.[7, 8] In the year 2000, the first laser 80W KTP laser was commercialized. It was succeeded in 2006 by the 120W HPS system and most recently, in 2011, by the 180W Light XPS (GL-XPS). Studies have demonstrated that PVP was as safe and efficient as TURP with significant shorter catheterization and hospitalization times.[6, 9, 10] However, durability outcomes have been questioned for the initial 80W and 120W generation systems.[9] Despite the 180W

XPS improved efficiency and short-term benefits, long-term data assessing BPH treatment durability is lacking. As such, we report the efficacy and safety of the 180W XPS system over a five-year experience and followup.

Methods

Patient characteristics

In this single institutional retrospective study, we prospectively collected data for 370 men who underwent 180W XPS GL (Boston Scientific, Boston, MA, USA) for BPH between 2011 and 2016. Patients with prostate cancer (n = 16) and those treated with the HPS GL (n = 38) were excluded from the analyses. Indications for treatment were based on the AUA BPH clinical guidelines.[1] Institutional-review board approval was obtained for the study.

Surgical procedures

All men were treated with the 180W XPS GL as previously reported. The surgeries were performed by a single experienced surgeon at our institution. The approach and technical procedure about the GL 180W XPS surgery is well described in Zorn et al. study published in 2011.[11, 12]

Study design

All patients had PSA, IPSS, QoL, PVR, Qmax and transrectal ultrasound prostate volume assessment before surgery. Men were followed up at 3, 6, 12, 24, 36, 48 and 60 months. The outcomes of the patients were documented at each visit. The results were compared to preoperative values. Patients identify as dropout we scheduled for a 5 year visit. Complications were also prospectively described in this study. They included OAB symptoms, stress urinary incontinence, dysuria, urinary tract infection, urinary retention, hematuria, urethral strictures, and erectile dysfunction (EHS & SHIM scores). These complications were categorized according to the Clavien-Dindo classification.[13]

Statistical analyses

Means and standard deviations were reported for continuous variables, and proportions were used for nominal variables. Categories were compared using the Chi-square test and Fisher exact test for continuous variables. A p-value < 0.05 was considered as statistically significant. All analyses were performed using the SPSS software.

Results

After exclusion, the study included 370 men who underwent PVP using the GL 180W XPS. Patients were followed up for a period of 5 years (mean 59.4 months; CI [55.4 – 63.5]; median: 56.3 months). However, only 66 patients (out of 370) had a complete 5-

year follow up. The functional outcomes are comparable between the 66 patients and all other patients during the follow-up period (tables 3 and 4). The mean age of the patients was 68 years. Moreover, the mean prostate was 78.8 cc [70.9 – 78.7]. Mean operative time of the surgical procedures was 62.7 minutes [59.6 – 65.7] with a mean total energy expenditure of 270.2 kJ [255.2 – 285.2] per surgery. Thus, the average energy density utilization was 3.7 kJ/cc [3.6 – 3.9] in the entire cohort.

To note, 7 (1.9%) of the patients were on anticoagulation therapy at the time of surgery knowing that 135 men (36.5%) stopped anticoagulation days before surgery. Patients' perioperative characteristics are summarized in tables 1 and 2.

Functional outcomes were reported preoperatively and at 3, 6, 12, 24, 36, 48 and 60 months (tables 3 and 4). Retrospectively, at pre-op, the mean values for the IPSS, QOL, Qmax, and PVR were 26.2, 4.7, 5.5 mL/s, and 345 mL. After 5 years, the values recorded were 6.5, 1, 18.4 mL/s and 53.7 mL respectively. All functional outcomes significantly improved compared to baseline and appear to be maintained over the follow up period. With respect to the PSA, the average pre-operative value was 6.2 ng/mL compared to 2.5 ng/mL after 5 years (Figure 1).

Clavien-Dindo categorized adverse events are listed in table 5. At 3 months, 63 (18.8%) patients had treatment for irritative voiding symptoms with possible pre-existing OAB. This incidence dropped to 16 (8,46%) at 1 year and 0 at 5 years suggesting improvement of irritative voiding parameters after resolution of BOO post operatively. On the other hand, 5 (1.5%) patients had signs of bladder underactivity at 3 months. With respect to dysuria, 14 (4.7%) patients complained of burning sensation 3 months after the surgery compared to 0 patients after 4 years. 8 (2.4%) patients had urinary infections within 3 months postoperatively requiring antibiotic treatment. Concerning bladder neck contracture, cystoscopy confirmed its diagnosis in 2 patients within 6 months, and in 5 (2.6%) patients at 1 year. Only 2 men (0.5%) were reported to have clinically worsening erectile dysfunction at 6 months. Most important with respect to treatment durability, only 4 (1.1%) men required BPH retreatment: 1 at 1 year, 1 at 2 years and 2 at 4 years. Mean procedure prostate volume and kJ/ cc treatment were 87.3 cc and 3.9 kJ/cc in these patients.

Discussion

In 2011, Bachmann et al. were the first to report promising results on the efficiency and safety of the 180W XPS GL treatment for lower urinary tract symptoms.[14] As its predecessors, the 180W is a 532-nm lithium triporate laser, but it is equipped with a MoXy liquid-cooled fiber.[7, 15] This innovative technology was created to enhance the efficiency, durability and safety of GL prostatectomy for patients with BPH. This technique can be offered in the long run to patients with large prostates rather than

undergoing open prostatectomy.[15] Indeed, the 180-W GL safety has been upgraded by an infra-based feedback mechanism at the fiber-tip along with a new-pulsed coagulation device.[7] Such features would allow the rapid control of bleeding intra-operatively. Furthermore, the increased output power allows improvement in the rate of vaporization and therefore a faster operative time.[7,16] Since its introduction to the urological armamentarium, several studies reported its superiority to monopolar TURP with shorter hospitalization, shorter catheterization time and faster time to clinical stability.[16, 17]

More recent studies have demonstrated excellent outcome of 180W XPS GL PVP over a period of 2 years.[6] The current study is unique as it is the first study to the best of our knowledge to report 5-year durability outcomes. To note, only 66 patients (out of 370) had a complete 5-year follow up. In addition, it is important to mention that the patients treated had an average prostate size of 78.8 cc measured by TRUS preoperatively, which is significantly larger than in the Goliath trial (48.6 cc). All functional outcomes demonstrated and sustained significant improvement even after a period of 5 years. Similar

As mentioned previously, the Goliath study is the only prospective randomized clinical trial comparing 180W XPS and TURP with an exclusion of any patient in urinary retention.[6] At 2 years, they reported an IPSS score of 6.9, which suggests a drop of 14.3 points (67.5%) form baseline (21.2 points). Moreover, in our study preoperatively, the IPSS was 26.2 points with 46% of patients in urinary retention at the time of surgery. After initial rapid decline in IPSS postoperatively at 3 months (mean 7.7 points), future decline to nadir was observed at 3 years (mean IPSS of 5.1 points). This suggested the immediate relief of obstructive urinary symptoms with a delay recovery in bladder storage symptoms. At 5-year follow-up, the IPSS was 6.5, meaning a 75.2% (19.7 points) drop from baseline. Similarly, the reported QoL score was 1. This significant improvement was similar to the 71.1% drop (1.3 from 4.6) observed at 2 years in the GOLIATH study.[6]

With regards to urodynamic parameters, we observed that Qmax reached its maximal value at 1 year with an increase of 14.4 mL/s from 5.5 mL/s at baseline. At 5 years, the Qmax was 18.4 mL/s. Such results are comparable to Altay et al. study, which included 68 patients only with prostates larger than 80 mL, demonstrating a significant improvement at 1 year with a Qmax of 16 mL/s compared to 7.6 mL/s pre-op.[15] Furthermore, Bachmann et al. reported an increase of 12.6 mL/s at 6 months with a preoperative Qmax of 8.4 mL/s.[14] When treated with TURP, the mean Qmax before the operation was 7.1 mL/s and reached 20.0 mL/s after 5 years.[18] This increase of 12.9 mL/s is comparable with the increase after 5 years of surgery with the 180W XPS.
PVR is another parameter used to evaluate functional outcome following BPO surgery. Several components play a role in determining the value of the post void residue. Such

components include the duration of BOO and its effect on the detrusor muscle. Other factors like prostatic regrowth, urethral strictures, the usage of anticholinergic medications and age-related detrusor contractibility influence bladder emptying.[1] In our study, the average PVR at 5 years was 53.7 mL compared to 345 mL preoperatively. The PVR nadir was reached at 4 years with a value of 32.8 mL (90.5% drop). The review of the literature made by Castellan et al. revealed that after a 3 and 6 month follow up the PVR decreased significantly.[17] Tasci and al showed that the PVR, after TURP, improved by 116.6 mL after 5 years. The mean PVR was 142 at baseline and 25.4 mL at 5 years.[18]

Moreover, PSA reduction has been established in the Holmium laser enucleation of the prostate (HoLEP) literature as a surrogate marker for BPH adenoma removal and thus is another useful parameter to assess the success and durability of BPO surgery.[19] In the present study, with 3.7 kJ/cc the PSA decreased from 6.2 ng/mL to 2.5 ng/mL after 5 years with a 59.3% drop. In comparison to the Goliath study, the PSA drop for the TURP group was around 57.7% from a preoperative value of 2.6 ng/mL.[6] BPH surgical retreatments was only 1% in our observed cohort.

As per international BPH guidelines, TURP is still the gold standard for surgical management of LUTS secondary to BPH for patients with prostate size < 80 cc, because of its efficacy and global access. Unfortunately, bleeding and long term durability are the Achilles heel to this procedure. Reich et al. evaluated the outcomes of 10,654 men who underwent TURP and demonstrated that morbidity and mortality increases with the increase in preoperative prostatic size.[5,20]

Moreover, Holmium laser enucleation of the prostate (HoLEP) is another well-established laser minimally invasive endo-surgical option for the management of BPH. HoLEP has been demonstrated as a size independent procedure with incredible long-term durable outcomes.[21] Table 5 compares outcomes for GL 80W, 120W, TURP and HoLEP.[18, 22, 23, 24]

Complications are part of any surgical procedure. The most commonly reported complication was the clinical symptoms of OAB, which was observed in 63 patients (18.8%) 3 months after the surgery. 1 year post-op, only 16 patients were still medically treated for OAB suggesting BOO relief improvement in detrusor hyperactivity. After 5 years of follow-up, there were no complications reported. Bladder neck contracture has been observed in 1 - 12% after PVP or TURP and as high as 0.5 - 17.5% after radical prostatectomies.[25] In our study, a total of 7 men (1.9%) developed BNC during follow-up. Mean prostatic volume in such patients was 72 cc. Most were diagnosed within 6 months. The other 5 patients were diagnosed 1 year post-operatively. During our 5-year experience, 4 (1.1%) patients needed bladder neck resection; 1 after one year, 1 at two years, and 2 at four years**.** Comparatively, the rate of retreatment after TURP was estimated to be 7.6%.[6] In the literature, many studies didn't experience BNC, but they

only had data collected for 30 days post-op.[26] Therefore, BNC is probably a late surgical complication.

Despite its merits, our study has certain limitations that need to be mentioned. Results are obtained from a retrospective analysis of a prospectively maintained database of single surgeon in a single institution. This is reflected in the loss at follow up at 4 and 5 years with only 42 (88.7% drop) and 66 (82.2 %), respectively. However, the percentage of the patients participating in the study out of the number of eligible patients is 93% and 96% at 4 and 5 years, respectively. Despite these limitations we believe that our results indicate that 180W XPS GL PVP in experienced hands delivering volume appropriate energy (≥ 3 - 4 kJ/cc) is a safe, efficient, and durable procedure.[27] This article can be the backbone for counseling men more accurately and precisely before choosing the surgical procedure for small to medium size BPH.

Conclusion

Greenlight PVP can be considered a safe and durable procedure for patients with BPH needing surgical treatment. This study has shown the effectiveness of this procedure that can be maintained for a period of at least 5 years.

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Figures and Tables

Fig. 1. Functional outcomes. IPSS: International Prostate Symptom Score; PSA: prostate-specific antigen; PVR: post-void residual; Qmax: maximum flow rate; QoL: quality of life.

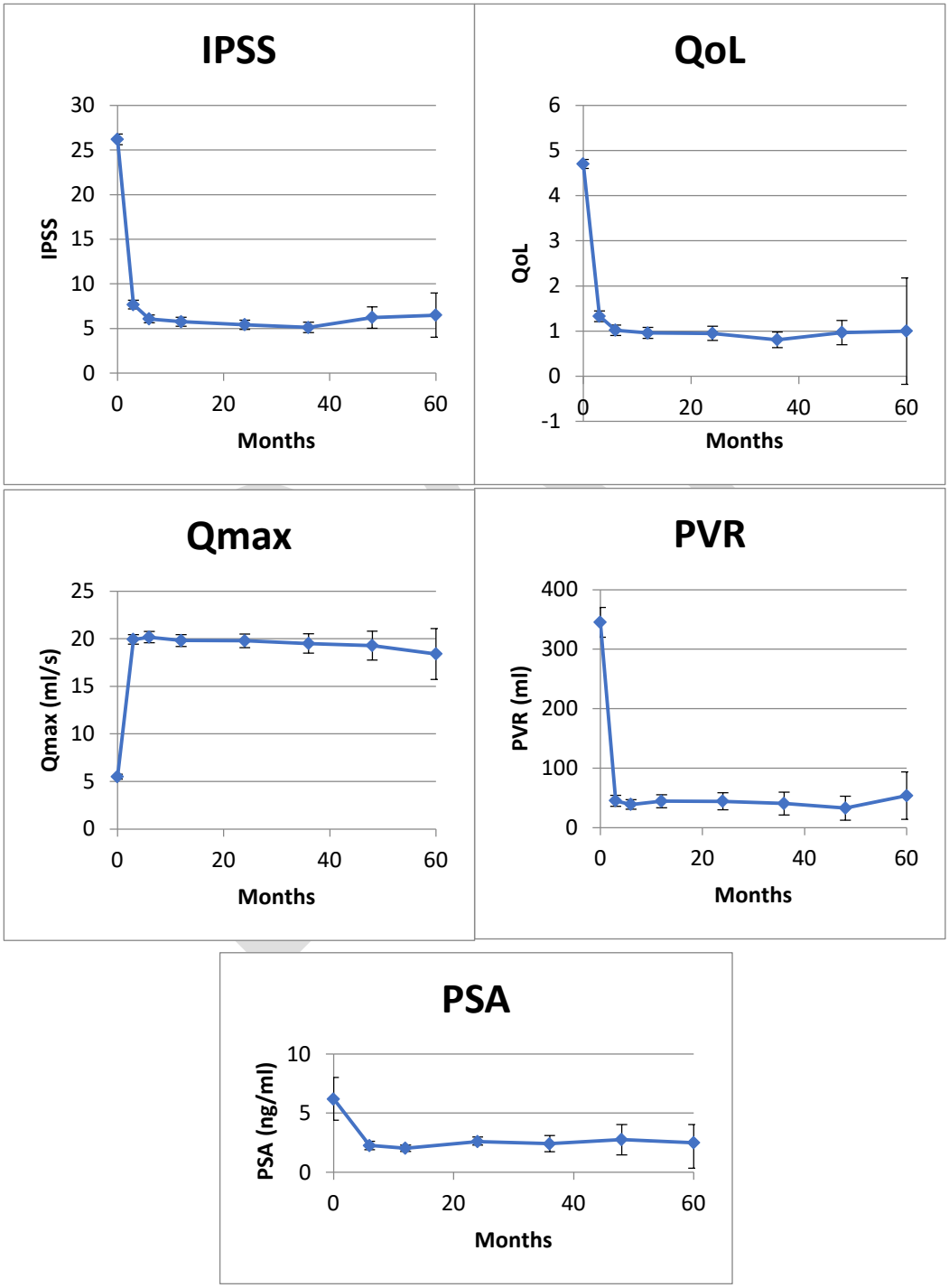

Table 1. Baseline characteristics			
	Number of patients	**Mean**	**Confidence interval**
Age (years)	370	67.8	66.9–68.7
BMI (kg/m^2)	370	26.8	26.4–27.2
Prostate volume (cc)	370	78.8	70.9–78.7
Median lobe (preop ultrasound or cystoscopy)	138 (37.3%)		
Duration on α-adrenergic blockers (years)	370	2.01	1.8–2.2
Duration on 5-alpha reductase inhibitors (years)	241	1.8	1.5–2.1
Retention with urethral catheter at time of surgery	170 (45.9%)		
Anticoagulation stopped before surgery and resumed immediately thereafter	135 (36.5%)		
	Aspirin: 94		
	clopidogrel: 5		
	Aspirin + clopidogrel: 12		
	Coumadin switched to low molecular weight heparin: 15		
	Dabigatran etexilate: 6		
	Aspirin + dabigatran etexilate: 3		
Continued anticoagulation at time of surgery	7 (1.9 %)		
	Aspirin: 3		
	Aspirin + clopidogrel: 3		
	Coumadin switched to low molecular weight heparin: 1		

Table 2. Operative parameters			
	Number of patients	**Mean**	**Confidence interval**
Duration of surgery (min)	370	62.7	59.6–65.7
Total energy used (kJ)	370	270.2	255.2–285.2
Energy per g (kJ/cc)	370	3.7	3.6–3.9
Number of fibers used	370	1.12	1.09–1.16
Pathological specimen weight of retrieved tissue removed (g)	370	3.9	3.3–4.5
Hospital stay (days)	370	0.7	0.5–0.8
Foley catherization (days)	370	1.1	1.0–1.2
Conversion to TURP	10 (2.7%)		

TURP: transurethral resection of the prostate.

Table 3. Outcomes of 180 XPS Greenlight									
Outcomes	**Preoperative**	**Months**							**p**
		3	**6**	**12**	**24**	**36**	**48**	**60**	
PSA (ng/mL)	6.2 4.5–8.1	NA	2.3 1.9–2.6	2.0 1.8–2.3	2.6 2.3–2.9	2.4 1.7–3.1	2.8 1.4–4.0	2.5 0.3–4.0	<0.001
IPSS	26.2 25.6–26.8	7.7 7.2–8.2	6.1 5.7–6.5	5.8 5.3–6.3	5.4 4.9–5.9	5.1 4.54–5.70	6.2 5.0–7.4	6.5 4.0–8.9	<0.001
QoL	4.7 4.6–4.8	1.3 1.2–1.4	1.02 0.9–1.1	0.9 0.8–1.1	0.9 0.9–1.5	0.8 0.6–0.9	0.9 0.7–1.2	1.0 0.9–1.48	<0.001
Qmax (mL/s)	5.5 5.3–5.9	19.9 19.5–20.5	20.2 19.5–20.6	19.9 19.2–20.4	19.8 19.1–20.5	19.5 17.8–19.8	19.3 17.7–20.8	18.4 16.5–20.4	<0.001
PVR (mL)	345 320–370	45.1 36.2–54.5	38.9 31.1–46.8	44.3 33.5–55.1	44.2 29.9–55.5	40.4 21.2–59.7	32.8 12.6–52.9	53.7 36.1–71.4	<0.001

IPSS: International Prostate Symptom Score; PSA: prostate-specific antigen; PVR: post-void residual; Qmax: maximum flow rate; QoL: quality of life.

Table 4. Outcomes of 180 XPS Greenlight of the 66 patients with complete 5-year followup									
Outcomes	**Preoperative**	**Months**							p
		3	**6**	**12**	**24**	**36**	**48**	**60**	
PSA (ng/mL)	11.9 8.4–15.0	NA	3.2 1.5–4.9	2.5 1.4–3.7	2.7 1.5–3.9	2.8 1.7–3.8	2.7 1.6–3.8	2.5 0.3–4.0	<0.001
IPSS	25.3 23.5–26.8	7.9 6.8–9.1	6.0 5.1–6.9	5.1 4.3–7.8	4.9 4.3–5.5	4.9 4.3–5.6	5.4 4.5–6.4	6.5 4.0–8.9	<0.001
QoL	4.5 4.2–4.8	1.3 1.0–1.6	0.9 0.7–1.2	0.9 0.7–1.2	0.8 0.6–1.0	0.8 0.6–1.0	0.9 0.7–1.1	1.0 0.9–1.48	<0.001
Qmax (mL/s)	4.5 4.2–4.8	20.3 19.4–21.2	20.5 19.4–21.6	20.3 19.0–21.6	20.8 19.8–21.8	18.8 17.7–19.9	16.8 15.6–18.1	18.4 16.5–20.4	<0.001
PVR (mL)	293.1 229.9–356.2	20.9 11.2–30.6	26.6 12.9–20.3	23.8 12.6–34.9	23.2 10.6–35.7	43.7 15.1–72.3	55.5 31.0–79.9	53.7 36.1–71.4	<0.001

IPSS: International Prostate Symptom Score; PSA: prostate-specific antigen; PVR: post-void residual; Qmax: maximum flow rate; QoL: quality of life.

Table 5. Complications of 180W XPS Greenlight								
		Months						
		3	**6**	**12**	**24**	**36**	**48**	**60**
	Number of patients	336	221	189	144	89	42	66
	Number of eligible patients	343	246	200	144	89	45	69
Clavien-Dindo grade								
Minor: I/II								
	OAB (%)	63 (18.8)	29 (13.1)	16 (8.46)	10 (6.9)	7 (7.9)	4 (9.5)	0
	SUI (%)	17 (5.1)	4 (1.8)	6 (3.17)	2 (1.4)	2 (2.2)	2 (4.8)	0
	Dysuria (%)	14 (4.6)	4 (1.8)	3 (1.6)	1 (0.7)	4 (4.5)	0	0
	UTI (%)	8 (2.4)	3 (1.4)	2 (1.1)	0	0	0	0
	Bladder underactivity/ retention (%)	5 (1.5)	3 (1.4)	1 (0.5)	4 (2.8)	1 (1.1)	0	0
	Hematuria (%)	6 (1.8)	2 (0.9)	1 0.5)	4 (2.8)	2 (2.2)	0	0
Major: IIIa/IIIb								
	Urethral stricture (%)	0	1 (0.5)	2 (1.1)	0	0	0	0
	Bladder neck contracture (%)	1 (0.3)	1 (0.5)	5 (2.6)	0	0	0	0
	BPH recurrence requiring repeat BPO surgery (%)	0	0	1 (0.5)	1 (0.7)	0	2 (4.8)	0

BPH: bengign prostatic hyperplasia; BPO: benign prostatic obstruction; OAB: overactive bladder; SUI: stress urinay incontinence; UTI: urinary tract infection.

Table 6. Literature review of other modalities				
Parameter	**80W (Guo et al)**	**120W (Cho et al)**	**TURP (Tasci et al)**	**HoLEP (Elmansy et al)**
Number	**120**	**85**	**3589**	**949**

of patients								
	Preoperative	**60 months**	**Preoperative**	**36 months**	**Preoperative**	**120 months**	**Preoperative**	**120 months**
Mean prostatic volume (cc)	52.3 33–72.6	NA	50 33–67	NA	62.4 50.4–74.4	NA	81	NA
Energy delivery (kJ/cc)	225.8 129.6–332	NA	92.35 16.5–168.2	NA	NA	NA	96.0	NA
OR time (min)	72.7 49.9–95.5	NA	60.3 28.7–92.5	NA	42 30.3–53.3	NA	NA	NA
PSA (ng/ml)	3.5 0.1–7.1	2.2 0.3–4.1	4 0.8–7.2	NA	3.9 3–4.8	2.3 0.4–4.2	4.3	0.69
IPSS	19.4 13.1–25.7	6.6 4.7–8.5	21.7 13.8–29.6	13.4 11–15.8	26 23–29	6.9 2.8– 11	19 0–35	3.6 0–12
QoL	3.7 2–5.4	1.3 0–3.1	4.2 3.0–5.4	2.3 1.6–3	4 3–5	1.8 1.3–2.3	3.8 0–6	0.7 0–3
Qmax (ml/s)	8.3 2.3–14.3	6.8 2.6–11	8.7 5.6–11.8	13.9 12–14	7.1 4.7–9.5	20 11.5–28.5	8 1.3–20	26.9 6.6–44.5
PVR (ml)	119.5 35.7–203.3	34.5 0–114.5	93.5 2.3–184.7	35.3 15–55	142 131–153	25.4 17.3–33.5	311 102–500	20.7 0–654
BPH retreatment (%)		10.2		NA		4.4		0.7
Mean followup (months)		12		36		42*		62

BPH: bengign prostatic hyperplasia; IPSS: International Prostate Symptom Score; OR: operating room; PSA: prostate-specific antigen; PVR: post-void residual; Qmax: maximum flow rate; QoL: quality of life.