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# 180W-LBO GreenLight XPS laser vaporization for benign prostatic hyperplasia: our experience with current markers of surgical proficiency for durable and reproducible outcomes

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**Introduction:** This study aims at analyzing the impact of reaching current markers of proficiency on intra and postoperative clinical outcomes of laser vaporization with 180W GreenLight XPS in the treatment of benign prostatic hyperplasia.

**Materials and methods:** A retrospective analysis was conducted on a prospectively collected database of 328 consecutive patients who underwent photoselective vaporization of the prostate (PVP) using Greenlight XPS performed by a single experienced laser surgeon. A logarithmic model was used to evaluate the case number to attain benchmark criteria for durable treatment. We compared clinical outcomes before and after current markers of proficiency, defined as either an energy density of 4kJ/cm<sup>3</sup> or a 6 month prostate-specific antigen (PSA) drop of  $\geq 50\%$ , were attained.

**Results:** Energy delivered per prostate volume increased significantly with experience. The published benchmark values of 4kJ/cm<sup>3</sup> and 6 month PSA drop of 50% were attained after 190 and 155 cases, respectively. There were no significant differences between groups in intraoperative complications or postoperative functional outcomes. However, the number of Clavien-Dindo category I adverse events significantly decreased with experience. Sub-analysis evaluating prostate volumes  $\leq 80$  cm<sup>3</sup> and  $> 80$  cm<sup>3</sup> demonstrated comparable clinical outcomes before and after technical proficiency.

**Conclusion:** In our experience, the case volume required to achieve consistent reference values related to durable clinical outcomes and surgical proficiency was  $> 150$  cases. However, desirable clinical outcomes were attained before reaching current markers of proficiency, regardless of preoperative prostate size. This suggests that current thresholds of technical proficiency may not be a good predictor of satisfying clinical outcomes.

**Key Words:** GreenLight XPS, photoselective vaporization of prostate, proficiency, learning curve, outcomes, BPH, benign prostatic hyperplasia

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## Introduction

Benign prostatic hyperplasia (BPH) affects up to 50% of men as they reach 50-60 years of age.<sup>1</sup> This condition

is responsible for bothering symptoms commonly designated by the term lower urinary tract symptoms (LUTS), related to bladder outlet obstruction.

Depending on the severity of the symptoms and patient's preferences, modalities of treatment range from watchful waiting, lifestyle modifications and phytotherapy,<sup>2</sup> to pharmacotherapy and surgical treatment. Transurethral resection of the prostate (TURP) and open prostatectomy have been the gold standard of surgical treatment for many years depending on prostate volume,<sup>3</sup> however laser-based minimally invasive interventions such as

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photoselective vaporization of the prostate (PVP) and holmium laser enucleation of the prostate (HoLEP)<sup>4,5</sup> have become increasingly attractive and are now well established alternative procedures. Both offer the advantage of increased safety profile in anticoagulated patients at high risk of bleeding.<sup>6</sup>

Several generations of lasers have already been used for PVP, the most recent one being the GreenLight XPS 180W. GreenLight XPS allows for a faster removal of a given volume of prostatic tissue, increased efficacy for treatment of large prostates, and uses more resistant MoXy fibers, resulting in more durable outcomes compared to older laser prostatectomy modalities.<sup>7-10</sup> A recent review concluded that GreenLight PVP is a safe and efficacious procedure regardless of prostate size and a good alternative to HoLEP or TURP, even in prostates over 100 cm<sup>3</sup>.<sup>11</sup>

The novelty of the procedure implies that the amount of cases required to achieve a safe and efficient profile when performing PVP is still poorly defined. A recent study by Misrai et al in 2013 analyzed the learning curve for a surgeon with no previous experience with PVP.<sup>12</sup> Our study explores the evolution of perioperative parameters and postoperative outcomes as experience increases with XPS PVP for a single surgeon with expertise in PVP with the older generations of lasers (GreenLight 80W and 120W XPS)<sup>13</sup> as current markers of surgical and technical proficiency are reached.

## Materials and methods

### *Study population*

The study included 328 patients who underwent PVP using GreenLight 180W XPS. A patient was classified as high risk if his preoperative transrectal ultrasound (TRUS) volume was > 80 cm<sup>3</sup>, American Society of Anesthesiologists (ASA) score was ≥ 3, or if he was under anticoagulation at time of surgery. Patients diagnosed with prostate cancer were excluded. Local ethics committee approval was obtained for this study.

### *Surgical technique*

All procedures were performed at the same tertiary care center by one single senior surgeon who had previous experience using GreenLight 80W and 120W XPS. PVP was carried out using a GreenLight 180W XPS device (Boston Scientific, Marlborough, MA, USA) as previously described.<sup>13</sup> A continuous-flow Storz 23F cystoscope with 0.9% saline irrigation was used for all procedures. Interventions were performed under spinal or general anesthesia. Men using anticoagulants preoperatively were bridged to low molecular weight

unfractionated heparin if the international normalized ratio was over 2.5; otherwise, anticoagulation or antiplatelet were maintained before and after the surgery. A 2-way silicone 20F/30mL catheter was inserted at the end of the procedure. For patient under anticoagulation, a 22F 3-way catheter was used instead.

### *Data collection*

Preoperative parameters as well as perioperative parameters were collected prospectively. Those included: laser and operative time, energy used, energy used per prostate volume, complications (including conversion to TURP), length of hospital stay and duration of urinary catheterization. Postoperative parameters at 6 and 12 months, namely PSA drop, IPSS with QoL, Qmax, and PVR were also collected. Patients lost to follow up were excluded: 176 and 152 men had complete data for analysis at 6 and 12 months, respectively. Finally, postoperative complications before 30 postoperative days were graded retrospectively according to the modified Clavien-Dindo classification<sup>14</sup> as recommended.<sup>15</sup> We divided our postoperative study population into four equal and chronological groups based on the chronology of interventions dates, named A, B, C and D (for 6 month follow up), and A', B', C', and D' (for 12 month follow up).

### *Learning curve parameters and statistical analysis*

In order to assess the learning curve, we did a two step analysis. First, we divided our cohort of 328 patients chronologically into eight equal and consecutive groups of 41 patients. Normality was assessed using Shapiro-Wilk test. All quantitative variables compared between more than two groups were analyzed using Kruskal-Wallis test. A series of Mann-Whitney-Wilcoxon test with Bonferroni correction was used to perform post-hoc analysis.<sup>16</sup>

In a second step, we considered the chronological rank of each intervention individually, as a continuous variable, in order to determine the number of interventions needed to reach a target level of energy delivery per prostate volume of ≥ 4kJ/cm<sup>3</sup> (energy density) and a ≥ 50% PSA drop at 6 months. Those durability targets were selected based on data from previous published studies, both previously reported as being associated with decreased retreatment rates.<sup>17</sup> A logarithmic model was approximated to represent the relation between the rank of interventions and both targets. Number of needed interventions to reach these proficiency markers was calculated using that model and the equation associated with each logarithmic curve.

We then compared our parameters before and after proficiency was reached. Stratification analysis was also performed by preoperative prostate volume ( $\leq 80 \text{ cm}^3$  and  $> 80 \text{ cm}^3$ ). Mean comparison was done using student's t-test if Levene's test for equality of variances was not statistically significant, or a Welch-t test if it was. We used the chi-square test for analysis of categorical variables.

Quantitative variables are presented as their median value (interquartile range or IQR) or as their mean value  $\pm$  standard deviation (SD) when appropriate. Categorical variables are presented as numbers (percentages). Statistical significance was defined as  $p \leq 0.05$ . All statistical analyses were performed using IBM SPSS Statistics Version 23.

## Results

### *Preoperative characteristics*

Preoperative characteristics, Table 1, were similar among our eight equal and chronologically consecutive groups of patients. The distribution of high risk patients was similar among all groups.

### *Perioperative parameters, Table 2*

Median operative time and laser time were respectively 56 min (IQR 40-75) and 27 min (20-39). Both parameters increased as the learning curve progressed ( $p < 0.001$ ). The ratio of laser time to operative time tended to decrease slightly during our learning curve evolution ( $p < 0.001$ ). The ratio of energy used per preoperative prostate volume also significantly increased during learning curve progression.

The length of Foley catheterization significantly increased over time from group 2 (mean  $0.73 \pm 1.05$ ) to group 7 ( $1.54 \pm 1.40$ ),  $p < 0.001$ . Moreover, the duration of hospital stay tended to decrease as experience increased.

### *Intraoperative and early postoperative complications, Table 3*

All groups had similar rates of intraoperative complications including conversion to TURP ( $p = 0.509$ ). As for postoperative adverse events, the rate of hematuria (Clavien-Dindo category I), LUTS (Clavien-Dindo category I), overall number of Clavien-Dindo category I and incontinence (Clavien-Dindo category II) decreased

TABLE 1. Preoperative characteristics of the 328 patients included for analysis

| Clinical preoperative parameters | Median (interquartile range) number (percentage) | Kruskal-Wallis test p value for inter-group*** statistical difference |
|----------------------------------|--|---|
| Age (years)                      | 67 (61-74)                                       | 0.369   |
| BMI (kg/m <sup>2</sup> )         | 26.2 (24.1-29.0)                                 | 0.879   |
| TRUS (cm <sup>3</sup> )          | 63 (49-91)                                       | 0.286   |
| PSA (ng/mL)                      | 3.3 (1.7-5.8)                                    | 0.002   |
| Qmax (mL/s)                      | 5 (4-7)  | 0.805   |
| PVR (mL)                         | 299 (148-508)                                    | 0.038*  |
| High risk patients**             | 189 (57.6%)                                      | 0.894   |
| ASA-PS                           |  | 0.002   |
| < 3                              | 270 (82.6%)                                      |   |
| $\geq 3$                         | 57 (17.4%)                                       |   |
| SHIM                             | 19 (13-22)                                       | 0.035*  |
| IPSS                             | 25 (21-32)                                       | 0.033   |
| IPSS-QoL                         | 5 (4-6)  | 0.285   |

BMI = body mass index; TRUS = transrectal ultrasound; PSA = prostate-specific antigen; Qmax = maximum urinary flow; PVR = post-void residual; ASA-PS = American Society of Anesthesiologists physical status; SHIM = sexual health inventory for men; IPSS = International prostate symptom score; QoL = quality of life

\*p value from Kruskal-Wallis test is statistically significant, however, when comparing group to group using a series of Mann-Whitney test results and applying a Bonferroni correction, there is no statistically significant difference between groups

\*\*criteria to be considered high risk: TRUS volume  $\geq 80 \text{ mL}$ , ASA-PS  $\geq 3$ , surgery under anticoagulation

\*\*\*eight chronologically successive groups of patients have been compared

TABLE 2. Perioperative parameters

| Perioperative parameters                                       | Median (interquartile range) number (percentage) | Kruskal-Wallis test p value for inter-group* statistical difference |
|--|--|---|
| OR time (min)  | 56 (40-75)                                       | < 0.001   |
| Laser time (min)   | 27 (20-39)                                       | < 0.001   |
| Laser/OR time ratio  | 0.51 (0.46-0.57)                                 | < 0.001   |
| Energy used (kJ)   | 236 (153-353)                                    | < 0.001   |
| Energy used/preoperative prostate volume (kJ/cm <sup>3</sup> ) | 3.66 (2.77-4.64)                                 | < 0.001   |
| Hospital stay (days)   | 0 (0-1)  | 0.001   |
| 0  | 234 (71.6%)                                      |   |
| 1  | 68 (20.8%)                                       |   |
| ≥ 2  | 25 (7.6%)  |   |
| Foley catheterization duration (days)                          | (1-1)  | < 0.001   |
| 0  | 58 (17.7%)                                       |   |
| 1  | 227 (69.2%)                                      |   |
| 2  | 17 (5.2%)  |   |
| ≥ 3  | 26 (7.9%)  |   |

\*eight chronologically successive groups of patients have been compared

significantly with gain of experience. One patient who was known for hypertension and prior aortic valve replacement unfortunately died from heart failure postoperatively (group 2). The rates of emergency room visit and re-admission were stable throughout our study ( $p > 0.05$ ).

#### Postoperative functional outcomes, Table 4

Qmax, PVR, IPSS and QoL were all similar across chronologically successive groups at 6 months and 12 months postoperatively. Only PSA drop at 6 months (median 61.5%) varied significantly with increasing experience.

There were only five cases of retreatment in our postoperative follow up (median 12 month, range 1-48): 1 at 6 month (group 7), 2 at 12 month (group 1 and group 2), 1 at 24 month (group 1) and 1 at 48 month (group 1).

#### Substratification analysis

Finally, we performed a stratification analysis, comparing parameters before and after technical proficiency (defined either by an energy density of at least 4kJ/cm<sup>3</sup> used during surgery, or a drop in PSA level of 50% at 6 month postoperatively) was achieved.

Based on the logarithmic model we estimated that we needed 190 interventions to achieve consistently a

laser delivery of  $\geq 4\text{kJ/cm}^3$  and 155 interventions for a PSA drop of  $\geq 50\%$  at 6 month, Figure 1.

After reaching the target of energy density of  $\geq 4\text{kJ/cm}^3$  as a marker, Table 5, median operative time, laser time and energy used significantly increased once proficiency was achieved. Hospital stay significantly decreased ( $0.7 \pm 1.8$  versus  $0.3 \pm 0.9$ ,  $p = 0.006$ ) while catheterization duration increased. Overall rate of complications Clavien-Dindo class I significantly decreased (27.9% versus 4.3%,  $p < 0.001$ ), namely rates of hematuria (11.1% versus 2.2%,  $p = 0.001$ ) and LUTS (16.3% versus 0.7%,  $p < 0.001$ ), as well as rate of retention Clavien-Dindo class II (10% versus 4.3%,  $p = 0.044$ ). Finally, postoperative functional outcomes at 6 and 12 month (IPSS, Qmax, PVR) were similar regardless of reaching proficiency. Comparable outcomes were observed when further sub-analysis was performed for preoperative prostate volume of  $\leq 80\text{ cm}^3$  and  $> 80\text{ cm}^3$  (data not shown;  $p > 0.05$ ).

Using the target of a PSA drop of  $\geq 50\%$  at 6 month, we observed similar results, Table 6. Once again, the rate of Clavien-Dindo class I decreased (34.2% versus 3.5%,  $p < 0.001$ ), namely hematuria (13.5% versus 1.7%,  $p < 0.001$ ), LUTS (20.0% versus 0.6%,  $p < 0.001$ ) and incontinence (5.2% versus 1.2%,  $p = 0.042$ ). Similarly, clinical outcomes at 6 and 12 months were comparable, even when further substratification per prostate size was performed (data not shown).

TABLE 3. Detailed intraoperative and early postoperative adverse events

|  | Group 1    | Group 2    | Group 3    | Group 4   | Group 5   | Group 6   | Group 7    | Group 8  | p value |
|--|------------|------------|------------|-----------|-----------|-----------|------------|----------|---------|
| <b>Adverse intraoperative events</b>               |            |            |            |           |           |           |            |          |         |
| Chest pain   | 0 (0%)     | 0 (0%)     | 0 (0%)     | 1 (2.4%)  | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Transfusion  | 1 (2.4%)   | 0 (0%)     | 0 (0%)     | 0 (0%)    | 1 (2.4%)  | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.538   |
| Urethral stenosis                                  | 0 (0%)     | 1 (2.4%)   | 0 (0%)     | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| TURP conversion                                    | 1 (2.4%)   | 1 (2.4%)   | 0 (0%)     | 1 (2.4%)  | 1 (2.4%)  | 2 (4.9%)  | 3 (7.3%)   | 0 (0%)   | 0.509   |
| Capsular perforation                               | 0 (0%)     | 0 (0%)     | 1 (2.4%)   | 1 (2.4%)  | 0 (0%)    | 0 (0%)    | 1 (2.4%)   | 1 (2.4%) | 0.776   |
| False passage                                      | 0 (0%)     | 1 (2.4%)   | 0 (0%)     | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Total intraoperative                               | 2 (4.9%)   | 2 (4.9%)   | 1 (2.4%)   | 3 (7.3%)  | 1 (2.4%)  | 2 (4.9%)  | 3 (7.3%)   | 1 (2.4%) | 0.910   |
| <b>Adverse postoperative events (&lt; 30 days)</b> |            |            |            |           |           |           |            |          |         |
| <b>Clavien-Dindo category I</b>                    |            |            |            |           |           |           |            |          |         |
| Incontinence                                       | 3 (7.3%)   | 3 (7.3%)   | 2 (4.9%)   | 0 (0%)    | 0 (0%)    | 0 (0%)    | 2 (4.9%)   | 0 (0%)   | 0.134   |
| Hematuria  | 8 (19.5%)  | 10 (24.4%) | 3 (7.3%)   | 0 (0%)    | 0 (0%)    | 2 (4.9%)  | 1 (2.4%)   | 0 (0%)   | < 0.001 |
| LUTS   | 7 (17.1%)  | 14 (34.1%) | 7 (17.1%)  | 3 (7.3%)  | 0 (0%)    | 0 (0%)    | 1 (2.4%)   | 0 (0%)   | < 0.001 |
| Constipation                                       | 1 (2.4%)   | 0 (0%)     | 0 (0%)     | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Vomiting   | 0 (0%)     | 0 (0%)     | 1 (2.4%)   | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Diminution of overall state of health              | 0 (0%)     | 0 (0%)     | 0 (0%)     | 1 (2.4%)  | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Total for category I                               | 16 (39.0%) | 21 (51.2%) | 12 (29.3%) | 4 (9.8%)  | 0 (0%)    | 2 (4.9%)  | 4 (9.8%)   | 0 (0%)   | < 0.001 |
| <b>Clavien-Dindo category II</b>                   |            |            |            |           |           |           |            |          |         |
| Urosepsis  | 0 (0%)     | 0 (0%)     | 1 (2.4%)   | 0 (0%)    | 1 (2.4%)  | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.538   |
| Erectile dysfunction                               | 0 (0%)     | 1 (2.4%)   | 0 (0%)     | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Incontinence                                       | 3 (7.3%)   | 0 (0%)     | 0 (0%)     | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.004   |
| Hematuria  | 2 (4.9%)   | 0 (0%)     | 4 (9.8%)   | 2 (4.9%)  | 2 (4.9%)  | 2 (4.9%)  | 3 (7.3%)   | 0 (0%)   | 0.411   |
| LUTS   | 1 (2.4%)   | 2 (4.9%)   | 1 (2.4%)   | 1 (2.4%)  | 0 (0%)    | 0 (0%)    | 2 (4.9%)   | 1 (2.4%) | 0.770   |
| Retention  | 5 (12.2%)  | 3 (7.3%)   | 4 (9.8%)   | 4 (9.8%)  | 4 (9.8%)  | 3 (7.3%)  | 2 (4.9%)   | 0 (0%)   | 0.560   |
| Urinary tract infection                            | 3 (7.3%)   | 1 (2.4%)   | 0 (0%)     | 1 (2.4%)  | 0 (0%)    | 2 (4.9%)  | 3 (7.3%)   | 2 (4.9%) | 0.439   |
| Fever  | 2 (4.9%)   | 1 (2.4%)   | 1 (2.4%)   | 1 (2.4%)  | 0 (0%)    | 0 (0%)    | 1 (2.4%)   | 0 (0%)   | 0.692   |
| Paraphymosis                                       | 0 (0%)     | 0 (0%)     | 0 (0%)     | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 1 (2.4%) | 0.429   |
| Atrial fibrillation                                | 0 (0%)     | 0 (0%)     | 1 (2.4%)   | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Prostatitis  | 0 (0%)     | 0 (0%)     | 0 (0%)     | 0 (0%)    | 0 (0%)    | 1 (2.4%)  | 0 (0%)     | 0 (0%)   | 0.429   |
| Osteitis pubis                                     | 0 (0%)     | 0 (0%)     | 0 (0%)     | 0 (0%)    | 0 (0%)    | 1 (2.4%)  | 0 (0%)     | 0 (0%)   | 0.429   |
| Gout   | 0 (0%)     | 0 (0%)     | 1 (2.4%)   | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Total for category II                              | 11 (26.8%) | 7 (17.1%)  | 12 (29.3%) | 7 (17.1%) | 7 (17.1%) | 6 (14.6%) | 10 (24.4%) | 4 (9.8%) | 0.328   |
| <b>Clavien-Dindo category IIIb</b>                 |            |            |            |           |           |           |            |          |         |
| Hematuria  | 0 (0%)     | 0 (0%)     | 0 (0%)     | 0 (0%)    | 1 (2.4%)  | 0 (0%)    | 1 (2.4%)   | 0 (0%)   | 0.538   |
| Post-fall fracture                                 | 0 (0%)     | 0 (0%)     | 0 (0%)     | 2 (4.9%)  | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.050*  |
| BNC  | 0 (0%)     | 0 (0%)     | 1 (2.4%)   | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| False passage                                      | 0 (0%)     | 0 (0%)     | 0 (0%)     | 0 (0%)    | 1 (2.4%)  | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Total for category IIIb                            | 0 (0%)     | 0 (0%)     | 1 (2.4%)   | 2 (4.9%)  | 2 (4.9%)  | 0 (0%)    | 1 (2.4%)   | 0 (0%)   | 0.384   |
| <b>Clavien-Dindo category IVa</b>                  |            |            |            |           |           |           |            |          |         |
| Acute renal failure                                | 0 (0%)     | 0 (0%)     | 0 (0%)     | 1 (2.4%)  | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Myocardial infarction                              | 0 (0%)     | 0 (0%)     | 1 (2.4%)   | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Total for category IVa                             | 0 (0%)     | 0 (0%)     | 1 (2.4%)   | 1 (2.4%)  | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.538   |
| <b>Clavien-Dindo category V</b>                    |            |            |            |           |           |           |            |          |         |
| Death from heart failure                           | 0 (0%)     | 1 (2.4%)   | 0 (0%)     | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| Total for category V                               | 0 (0%)     | 1 (2.4%)   | 0 (0%)     | 0 (0%)    | 0 (0%)    | 0 (0%)    | 0 (0%)     | 0 (0%)   | 0.429   |
| <b>Return to hospital</b>                          |            |            |            |           |           |           |            |          |         |
| Emergency room visit                               | 4 (9.8%)   | 2 (4.9%)   | 3 (7.3%)   | 4 (9.8%)  | 4 (9.8%)  | 3 (7.3%)  | 5 (12.2%)  | 2 (4.9%) | 0.924   |
| Re-admission                                       | 4 (9.8%)   | 0 (0%)     | 3 (7.3%)   | 2 (4.9%)  | 1 (2.4%)  | 2 (4.9%)  | 1 (2.4%)   | 1 (2.4%) | 0.445   |

TURP = transurethral resection of the prostate; LUTS = lower urinary tract symptoms; BNC = bladder neck contracture  
 \*p value from Kruskal-Wallis test is statistically significant, however, when comparing group to group using a series of Mann-Whitney test results and applying a Bonferroni correction, there is no statistically significant difference between groups.

TABLE 4. Clinical outcomes at 6 months postoperative (n = 176) and 12 months (n = 152)

| Parameters  | Median (interquartile range) | Kruskal-Wallis test p value for inter-group statistical difference** |
|---|------------------------------|--|
| <b>6 month postoperative follow up (n = 176)</b>  |                              |  |
| Preoperative PSA (ng/mL)                          | 3.1 (1.7-5.4)                | 0.004  |
| PSA at 6 months (ng/mL)                           | 1.1 (0.51-2.1)               | 0.456  |
| PSA drop (%)                                      | 61.5 (31.2-73.9)             | < 0.001  |
| Qmax (mL/s)                                       | 21 (18-22)                   | 0.955  |
| PVR (mL)  | 14 (5-29.5)                  | 0.367  |
| IPSS  | 5 (4-7)                      | 0.436  |
| IPSS-QoL  | 1 (0-1)                      | 0.564  |
| <b>12 month postoperative follow up (n = 152)</b> |                              |  |
| Preoperative PSA (ng/mL)                          | 2.8 (1.6-5.2)                | 0.262  |
| PSA at 12 months (ng/mL)                          | 1.0 (0.5-2.3)                | 0.417  |
| PSA drop (%)                                      | 54.0 (25.1-74.8)             | 0.094  |
| Qmax (mL/s)                                       | 21 (18-23)                   | 0.701  |
| PVR (mL)  | 11 (5-25)                    | 0.042*   |
| IPSS  | 5 (4-7)                      | 0.928  |
| IPSS-QoL  | 1 (0-1)                      | 0.825  |

PSA = prostate-specific antigen; Qmax = maximum urinary flow; PVR = post-void residual; IPSS = International prostate symptom score; QoL = quality of life

\*p value from Kruskal-Wallis test is statistically significant, however, when comparing group to group using a series of Mann-Whitney test results and applying a Bonferroni correction, there is no statistically significant difference between groups.

\*\*four chronologically successive groups of patients have been compared.

## Discussion

This project aimed at analyzing our experience with the GreenLight 180W XPS in the treatment of BPH. Data is still limited regarding the amount of cases required to reliably achieve safe and satisfying clinical outcomes. Surrogate markers of technical proficiency have been suggested based on the amount of laser energy delivered per volume of prostate or the drop in PSA after surgery. These two aspects have been well reported in the literature with regards to durability. Hueber et al suggested that laser energy per volume ratio of  $\geq 4\text{kJ}/\text{cm}^3$  or a PSA drop of at least 50% at 3-6 months may correlate with more optimal treatment and better outcomes<sup>17</sup> and it had already been shown that PSA itself was a good surrogate for prostate volume reduction.<sup>18</sup> Misrai et al used a threshold of  $5\text{kJ}/\text{cm}^3$  and also looked at a ratio of laser time per operating time of 75% for their learning curve with GreenLight 180W XPS.<sup>12</sup> Given that the value of  $5\text{kJ}/\text{cm}^3$  relied on a mean value obtained by Bachman et al,<sup>8</sup> while  $4\text{kJ}/\text{cm}^3$  was determined based on a correlation with a decreased need for re-treatment as compared to  $2\text{kJ}/\text{cm}^3$  in the multicenter study by Hueber et al,<sup>17</sup> we elected to use the value of  $4\text{kJ}/\text{cm}^3$  as a marker of

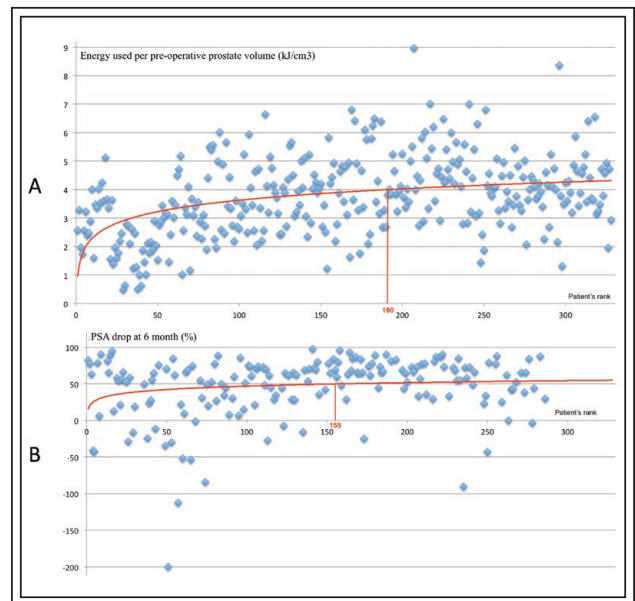


Figure 1. Estimation of the number of cases needed to achieve (A)  $4\text{kJ}/\text{cm}^3$  and (B) 50% PSA drop at 6 month using a logarithmic regression.

TABLE 5. Substratification analysis: before and after technical proficiency  $\geq$  (4kJ/cm<sup>3</sup>) was achieved

| Parameters  | Group   |  | p value |
|---|---|--|---------|
|   | Before technical proficiency was achieved* (n=190)<br>Mean $\pm$ SD | After technical proficiency was achieved* (n=138)<br>Mean $\pm$ SD |         |
| IPSS  | 25.2 $\pm$ 6.2  | 26.9 $\pm$ 6.1   | 0.013   |
| QoL   | 4.6 $\pm$ 1.0   | 4.7 $\pm$ 2.4  | 0.289   |
| Qmax (mL/s)   | 5.7 $\pm$ 2.8   | 5.5 $\pm$ 2.4  | 0.525   |
| PVR (mL)  | 315 $\pm$ 241   | 377 $\pm$ 284  | 0.040   |
| TRUS (cm <sup>3</sup> )                               | 74.3 $\pm$ 35.4   | 73.2 $\pm$ 40.7  | 0.790   |
| PSA (ng/mL)   | 4.3 $\pm$ 3.7   | 4.3 $\pm$ 3.3  | 0.957   |
| High risk**   | 58%   | 59%  | 0.856   |
| Operative time (min)                                  | 54 $\pm$ 25   | 71 $\pm$ 30  | < 0.001 |
| Laser time (min)                                      | 29 $\pm$ 15   | 34 $\pm$ 15  | 0.001   |
| Energy (kJ)   | 250 $\pm$ 151   | 292 $\pm$ 139  | 0.011   |
| Length of stay (days)                                 | 0.7 $\pm$ 1.8   | 0.3 $\pm$ 0.9  | 0.006   |
| Length of catheterization (days)                      | 1.0 $\pm$ 1.1   | 1.3 $\pm$ 0.9  | 0.012   |
| Energy used per prostate volume (kJ/cm <sup>3</sup> ) | 3.4 $\pm$ 1.4   | 4.3 $\pm$ 1.2  | < 0.001 |
| <b>Adverse events &lt; 30 days postop***</b>          |   |  |         |
| Hematuria   | 21 (11.1%)  | 3 (2.2%)   | 0.001   |
| LUTS  | 31 (16.3%)  | 1 (0.7%)   | < 0.001 |
| Total Clavien I                                       | 53 (27.9%)  | 6 (4.3%)   | < 0.001 |
| Incontinence  | 3 (1.6%)  | 0 (0%)   | 0.083   |
| Retention   | 19 (10.0%)  | 6 (4.3%)   | 0.044   |
| Total Clavien II                                      | 41 (21.6%)  | 23 (16.7%)   | 0.262   |
| Total Clavien IIIb                                    | 5 (2.6%)  | 1 (0.7%)   | 0.165   |
| Total Clavien IVa                                     | 2 (1.1%)  | 0 (0%)   | 0.158   |
| Total Clavien V                                       | 1 (0.5%)  | 0 (0%)   | 0.395   |
| TURP conversion                                       | 4 (2.1%)  | 5 (3.6%)   | 0.408   |
| Total intraoperative                                  | 9 (4.7%)  | 6 (4.3%)   | 0.868   |
| <b>Follow up: 6 month</b>                             |   |  |         |
| PSA (ng/mL)   | 2.0 $\pm$ 2.8   | 1.7 $\pm$ 1.5  | 0.391   |
| Drop in PSA   | 44%   | 54%  | 0.118   |
| IPSS  | 6.3 $\pm$ 3.2   | 5.8 $\pm$ 3.6  | 0.313   |
| QoL   | 1.1 $\pm$ 1.0   | 0.9 $\pm$ 1.0  | 0.176   |
| Qmax (mL/s)   | 20.4 $\pm$ 4.2  | 20.7 $\pm$ 6.6   | 0.707   |
| PVR (mL)  | 33 $\pm$ 62   | 52 $\pm$ 83  | 0.108   |
| <b>Follow up: 12 month</b>                            |   |  |         |
| PSA (ng/mL)   | 2.1 $\pm$ 2.8   | 1.9 $\pm$ 2.4  | 0.710   |
| Drop in PSA   | 39%   | 41%  | 0.808   |
| IPSS  | 5.9 $\pm$ 4.0   | 5.8 $\pm$ 4.0  | 0.795   |
| QoL   | 1.0 $\pm$ 0.9   | 1.0 $\pm$ 0.8  | 0.653   |
| Qmax (mL/s)   | 20.2 $\pm$ 4.1  | 18.9 $\pm$ 5.7   | 0.195   |
| PVR (mL)  | 33 $\pm$ 67   | 75 $\pm$ 116   | 0.044   |

IPSS = International prostate symptom score; QoL = quality of life; Qmax = maximum urinary flow; PVR = post-void residual; TRUS = transrectal ultrasound; PSA = prostate-specific antigen; LUTS = lower urinary tract symptoms; TURP = transurethral resection of the prostate

\*technical proficiency defined as energy used  $>$  4kJ/cm<sup>3</sup>. \*\*criteria to be considered high risk: TRUS volume  $\geq$  80mL, ASA  $\geq$  3, surgery under anticoagulation. \*\*\*only complications with statistical difference between the two groups are shown in this table.

TABLE 6. Substratification analysis: before and after technical proficiency (50% PSA drop) was achieved

| Parameters  | Group   |  | p value |
|---|---|--|---------|
|   | Before technical proficiency was achieved* (n=155)<br>Mean ± SD | After technical proficiency was achieved* (n=173)<br>Mean ± SD |         |
| IPSS  | 25.2 ± 6.1  | 26.6 ± 6.2   | 0.030   |
| QoL   | 4.7 ± 1.0   | 4.7 ± 1.1  | 0.944   |
| Qmax (mL/s)   | 5.7 ± 2.9   | 5.4 ± 2.4  | 0.265   |
| PVR (mL)  | 319 ± 253   | 361 ± 267  | 0.147   |
| TRUS (cm <sup>3</sup> )                               | 72 ± 29   | 76 ± 44  | 0.324   |
| PSA (ng/mL)   | 4.0 ± 3.7   | 4.5 ± 3.4  | 0.138   |
| High risk**   | 56%   | 61%  | 0.346   |
| Operative time (min)                                  | 50 ± 22   | 70 ± 30  | < 0.001 |
| Laser time (min)                                      | 27 ± 14   | 35 ± 16  | < 0.001 |
| Energy (kJ)   | 232 ± 135   | 300 ± 151  | < 0.001 |
| Length of stay (days)                                 | 0.6 ± 0.9   | 0.4 ± 1.8  | 0.488   |
| Length of catheterization (days)                      | 0.9 ± 1.2   | 1.3 ± 0.9  | 0.001   |
| Energy used per prostate volume (kJ/cm <sup>3</sup> ) | 3.2 ± 1.3   | 4.2 ± 1.3  | < 0.001 |
| <b>Adverse events &lt; 30 days postop***</b>          |   |  |         |
| Incontinence  | 8 (5.2%)  | 2 (1.2%)   | 0.042   |
| Hematuria   | 21 (13.5%)  | 3 (1.7%)   | < 0.001 |
| LUTS  | 31 (20.0%)  | 1 (0.6%)   | < 0.001 |
| Total Clavien I                                       | 53 (34.2%)  | 6 (3.5%)   | < 0.001 |
| Incontinence  | 3 (1.9%)  | 0 (0%)   | 0.083   |
| Total Clavien II                                      | 36 (23.2%)  | 28 (16.2%)   | 0.112   |
| Total Clavien IIIb                                    | 3 (1.9%)  | 3 (1.7%)   | 0.892   |
| Total Clavien IVa                                     | 1 (0.6%)  | 1 (0.6%)   | 0.938   |
| Total Clavien V                                       | 1 (0.6%)  | 0 (0%)   | 0.319   |
| TURP conversion                                       | 3 (1.9%)  | 6 (3.5%)   | 0.398   |
| Total intraoperative                                  | 8 (5.2%)  | 7 (4.0%)   | 0.631   |
| <b>Follow up: 6 month</b>                             |   |  |         |
| PSA (ng/mL)   | 2.0 ± 2.7   | 1.8 ± 2.1  | 0.576   |
| Drop in PSA   | 38%   | 58%  | 0.001   |
| IPSS  | 6.4 ± 3.2   | 5.8 ± 3.5  | 0.205   |
| QoL   | 1.1 ± 1.0   | 0.9 ± 0.9  | 0.037   |
| Qmax (mL/s)   | 20.4 ± 4.3  | 20.5 ± 5.9   | 0.890   |
| PVR (mL)  | 31 ± 61   | 48 ± 78  | 0.087   |
| <b>Follow up: 12 month</b>                            |   |  |         |
| PSA (ng/mL)   | 2.0 ± 2.7   | 2.1 ± 2.7  | 0.793   |
| Drop in PSA   | 35%   | 46%  | 0.223   |
| IPSS  | 5.8 ± 4.0   | 6.1 ± 4.0  | 0.661   |
| QoL   | 0.9 ± 0.9   | 1.0 ± 0.9  | 0.603   |
| Qmax (mL/s)   | 20.4 ± 4.0  | 19.2 ± 5.2   | 0.132   |
| PVR (mL)  | 32 ± 71   | 61 ± 96  | 0.039   |

IPSS = International prostate symptom score; QoL = quality of life; Qmax = maximum urinary flow; PVR = post-void residual; TRUS = transrectal ultrasound; PSA = prostate-specific antigen; LUTS = lower urinary tract symptoms; TURP = transurethral resection of the prostate

\*technical proficiency defined as PSA drop at 6 months > 50%. \*\*criteria to be considered high risk: TRUS volume ≥ 80 mL, ASA ≥ 3, surgery under anticoagulation. \*\*\*only complications with statistical difference between the two groups are shown in this table.



technical proficiency for our analysis. We also used a PSA drop of at least 50% as an alternate marker since it had been associated with less need for re-treatment.<sup>17</sup>

In our initial experience with XPS in a socialized medical system, more than 150 cases were needed to reach our target values used as markers of technical proficiency, Figure 1. However, apart, from a significant decrease in rates of Clavien Dindo 1 complications, Table 3, there was no improvement in clinical outcomes after those arbitrary markers of technical proficiency were attained. More importantly, satisfying improvements in symptoms, quality of life, and objective measurements were already obtained long before reaching markers of technical proficiency, Table 5 and 6. The results obtained before markers were met were indeed close to the mean values obtained at 6 months in the GOLIATH study for IPSS ( $6.8 \pm 5.2$  versus  $6.3 \pm 3.2$  in the present study) and Qmax ( $23.3 \pm 10.1$  versus  $20.4 \pm 4.2$  in the present study), in which those values were comparable to the ones obtained with TURP.<sup>19</sup> Although the length of hospital stay decreased with gain of experience after reaching our marker of  $4\text{kJ}/\text{cm}^3$ , Table 5, an increase in duration of Foley catheterization was noted, Table 5 and 6. This was attributable to a change in practice over the years in our institution, since the catheter used to be occasionally discontinued on the same day as the surgery, then was always kept until the following day with discontinuation at outpatient local primary care centers.

Furthermore, our results highlight that the selection of relevant durability markers of technical proficiency continues to be a challenge and that previously suggested ones may not reflect clinical prospects such as IPSS adequately. Better characterization of surrogate values that could be used to ascertain the learning curve for GreenLight 180W XPS in the treatment of BPH will require additional work and may prove challenging given the inter-individual heterogeneity of mean values obtained for parameters such as laser energy delivered per prostate volume, even among experts of the procedure. Given its correlation with prostate volume reduction, PSA drop may nonetheless remain for now one of the better values to follow when assessing ones learning curve with GreenLight.

Compared to TURP, GreenLight has been associated with an increased difficulty in achieving adequate treatment of larger prostates (more than  $80\text{ cm}^3$ ) because of insufficient tissue removal.<sup>17,20,21</sup> One of the advantages of this new generation of GreenLight over the older 120W and 80W is its better capacity for treatment of larger prostates with improved hemostasis.<sup>17</sup> Our analysis demonstrated no difference

in postoperative outcomes and complications for small versus large prostates, except for a higher rate of conversion to TURP. The rate of conversion to TURP had already been shown to be higher for large-volume prostates in previous studies, consistent with our findings and most likely explained by an increased difficulty for optimal tissue removal in larger prostates.<sup>8,17</sup> Our rate of TURP conversion in prostates larger than  $80\text{ cm}^3$  was 8%, comparable to that reported by Huebert et al (8.4%).<sup>17</sup> This contrasts with the initial XPS experience conducted in 2012 by Bachman et al in which a 16% TURP conversion rate was observed in a mean prostate volume of  $67\text{ cm}^3$ .<sup>8</sup>

Moreover, this study has several limitations. First, the data was collected from a single institution and a single surgeon with previous expertise in laser PVP, which may not be reflective of the learning curve of surgeons who are newly trained in 180W XPS PVP. Second, while our surgeon was acquiring experience with XPS 180W as a pioneer in the field, currently suggested markers of proficiency were still in the process of being determined. Therefore, someone who would benefit from mentorship in order to reach established targets may achieve those surrogates of proficiency faster than in the current study. Finally, our study lacks in power for analysis of long term outcomes.

## Conclusion

In our pioneering experience, our surgeon with expertise in older generations of GreenLight required approximately 150 consecutive patients to reach durability-proficiency markers. However, excellent clinical outcomes, which were similar to previously described benchmark values by experts in the field, were obtained long before reaching those markers of questionable significance. Given this discrepancy, our study sheds light on the need for further work to determine more appropriate surrogate markers that correlate better with improved clinical outcomes. □

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