Lumenis Holmium Solutions for Benign Prostatic Hyperplasia (BPH)

Bibliography of Published Studies & Peer-Reviewed Papers

The use of Holmium Laser for surgical procedures in Benign Prostate Hyperplasia is clinically based in its versatility for different cases, improved outcomes, shorter procedure time, and low complications of the procedure. The following list presents selected publications of the last 10 years, pointing out the advantages of using Lumenis high-power Holmium Laser in the surgical treatment of Benign Prostate Hyperplasia in Urology.
Energy to Healthcare

1990
Introduced
› UltraPulse® CO₂ and VersaPulse® Holmium laser systems

1996
Introduced VersaPulse® C

2000
Introduced VersaPulse® PowerSuite™, world’s first 100W Holmium laser for BPH

2009
Introduced
› AcuPulse™ with SurgiTouch

2010
Introduced
› VersaPulse P20

2012
Introduced
› AcuPulse WaveGuide
› AcuPulse DUO
› FiberLase Robotic DIG
› MicroLase Fiber
› FiberLase GYN Handpieces

2014
Introduced
› Lumenis Pulse 120H
› Xpeeda Fiber
› SlimLine 200 D/F/L Fiber

2015
Introduced
› UltraPulse DUO
› Lumenis Pulse 100H
› Lumenis Pulse 50H

2016
Introduced
› Lumenis Pulse 30H
› Suction hand-piece
› Otolase Fiber Delivery System

2017
Launched MOSES™ technology
› Revolutionizing holmium laser lithotripsy

A Heritage of Innovation
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Peer-reviewed publications of using Holmium Laser for Benign Prostatic Hyperplasia (BPH)

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Holmium Laser Enucleation of the Prostate (HoLEP)

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<tr>
<td>Evidence-based outcomes of Holmium laser enucleation of the prostate</td>
<td>Curr Opin Urol 28(3); 301-308</td>
<td>Large T, Krambeck AE</td>
<td>2018</td>
<td>A review of the sentinel publications on Holmium laser enucleation of the prostate (HoLEP), which is the mainstay therapy for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostate hyperplasia (BPH) for nearly 20 years</td>
<td>N/A</td>
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<tr>
<td>Current status of Holmium laser enucleation of the prostate</td>
<td>Int J Urol 25(3); 206-211</td>
<td>Shigemura K, Fujisawa M</td>
<td>2018</td>
<td>Current literature continues to support HoLEP as a versatile and durable surgical option for men with LUTS secondary to BPH. Evidence supports durable symptom relief beyond 10 years even in large prostate glands</td>
<td>N/A</td>
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<td>Recent publications continue to show excellent short-term and long-term outcomes after HoLEP in the categories of voiding function and patient satisfaction.</td>
<td>N/A</td>
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<td>A review of the use of Holmium laser enucleation of the prostate in many institutions and by many urologists, accomplishing better outcomes compared with transurethral resection of the prostate.</td>
<td>N/A</td>
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<td>HoLEP is presented in the current literature as superior to other modalities, with regards to post-operative complications and cost-benefit.</td>
<td>N/A</td>
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› HoLEP has become the conceptual and practical paradigm for enucleation thanks to the evidence provided by the literature and excellent outcomes. The level of evidence for other techniques is too low and follow-up time is still too short to offer solid recommendations. | N/A                |
› Holmium laser enucleation of the prostate (HoLEP) is a real alternative to Transurethral resection of Prostate (TURP) and open prostatectomy with proven advantages.                                                                                                                                                                                                                   | Lumenis system 100W |
| In 2013, holmium laser enucleation of the prostate (HoLEP) may be the new ‘gold standard’ | Curr Urol Rep, 13(6): 427-32.         | van Rij S, Gilling PJ           | 2012 | › Assessing why Holmium laser enucleation of the prostate (HoLEP) has become an important treatment modality for Benign Prostatic Hypertrophy (BPH).  
› The learning curve is actually similar to many other current urological procedures, and the efficacy of HoLEP is equal to that of other surgical procedures.                                                                                                                                                                                                  | Lumenis system      |
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</table>
| Long-term outcomes of laser prostatectomy for storage symptoms:     | J Urology                   | Cho MC, Song WH, Park J, Cho SY, Jeong H, Oh SJ, | 2018 | › 60-month follow-up comparison in 266 patients of storage symptom outcomes between HoLEP and photosensitive laser vaporization of the prostate in 2 groups.  
› HoLEP appeared to show a superior degree of improvement in voiding symptoms, QOL or the urine flow rate, the serum PSA reduction and re-treatment rate.  
› Follow-up data suggests that storage symptom improvement is maintained throughout the long-term postoperative period, with a better improvement in voiding symptoms and quality of life after HoLEP procedure. | N/A          |
| Comparison of Serial 5-Year follow-up data between 120 W high performance system photosensitive vaporization of the prostate and Holmium laser enucleation of the prostate. |                            | Paick JS, Son H.                                 |      |                                                                                                        |              |
› HoLEP was found significantly better for the duration of catheterization (1.9 vs. 3.7 days; p = 0.004) and the average length of hospital stay (2.8 vs. 4.0 days, p = 0.01).  
› HoLEP technique appeared to be a less invasive technique, reducing the duration of catheterization, blood loss, and the average length of hospital stay while maintaining good efficacy for the enucleated prostate volume. | N/A          |
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<tr>
<td>Holmium Laser Enucleation of the Prostate Versus Bipolar Resection of the Prostate: A Prospective Randomized Study. “Pros and Cons”.</td>
<td>Urology, 86(5):1037-41.</td>
<td>Fayad AS, Elsheikh MG, Zakaria T, Elfotoh HA, Alsergany R, Elshenoufy A, Elghamarawy H.</td>
<td>2015</td>
<td>12-month follow-up comparison of safety, efficacy, and applicability of Holmium laser enucleation procedure (HoLEP) and Transurethral resection of Prostate (TURP) procedure in 120 patients with BPH. The International Prostate Symptom Score was found to be better in the HoLEP group while operative time was longer in the HoLEP group. HoLEP has proved to be effective in treating large prostates with minimal morbidity, better hemostasis, less blood loss, and better voiding pattern than TURP after a 12-month follow-up.</td>
<td>Lumenis system 100W</td>
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<tr>
<td>Holmium laser enucleation of the prostate versus transurethral resection of the prostate: a randomized clinical trial.</td>
<td>Int Urol Nephrol, 46(7):1277-82.</td>
<td>Sun N, Fu Y, Tian T, Gao J, Wang Y, Wang S, An W.</td>
<td>2014</td>
<td>12-month follow-up comparison of safety, efficacy, and applicability of Holmium laser enucleation procedure (HoLEP) and Transurethral resection of Prostate (TURP) procedure in 164 cases. In a 12-month follow-up, HoLEP group demonstrated better scores in Urine flow rate (Qmax), Post-void Residual urine test (PVR), The International Prostate Symptom Score (IPSS), and Quality of life scale (QOL). Compared with TURP, HoLEP was safer and had better long-term efficacy as assessed by multiple quantitative measures.</td>
<td>Lumenis system 100W</td>
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<tr>
<td>Holmium laser enucleation of the prostate: results at 6 years the prostate: results at 6 years.</td>
<td>Eur Urol, 53(4):744-9.</td>
<td>Gilling PJ, Wilson LC, King CJ, Westenberg AM, Frampton CM, Fraundorfer MR.</td>
<td>2008</td>
<td>6-year follow up in order to assess satisfaction rate and durability of HoLEP in 71 patients. I92% of the patients were either satisfied or extremely satisfied with their outcome. HoLEP is a durable procedure and most patients remain satisfied or extremely satisfied with the long-term outcome.</td>
<td>Lumenis system 100W</td>
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Efficacy of Holmium Laser Enucleation of the Prostate (HoLEP) in Patients with a Small Prostate (≤30 mL).

Retrospective comparison of the effects of holmium laser enucleation of the prostate (HoLEP) in patients with a small prostate (≤30 mL) in 132 patients whom medical treatment was ineffective in 2 groups: prostate ≤30 mL (n=30); and group 2, >30 mL (n=102).

In group 1, the IPSS, QoL, and PVR significantly decreased and the Qmax significantly increased 3 months after surgery. The voiding subscore also significantly decreased 3 months after surgery (p<0.001). In group 2, hemoglobin, the IPSS, QoL, and PVR significantly decreased and the Qmax significantly increased 3 months after surgery. In these patients, both the storage subscore and voiding subscore significantly decreased after surgery (both p<0.001).

When other medical treatments are ineffective, HoLEP is an effective intervention for patients with a small prostate.

Comparing the efficiency of HoLEP for prostates of different sizes in 459 patients in 3 groups: above 100 cc, 100-200 cc, and prostates larger than 200 cc.

The enucleation efficiency in group 3 (1.70 g/min) was higher (p<0.05) than in group 1 (1.05 g/min) and group 2 (1.23 g/min). There were no significant differences (p>0.05) in International Prostate Symptom Score, Qmax, quality of life and postvoid residual volume in a 18-months follow-up after surgery.

HoLEP is a safe, highly efficacious and a size-independent procedure.
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</table>
› HoLEP can be applied to the majority of patients with BOO from BPH regardless of prostate size, previous operations, or the condition of the detrusor. HoLEP can also be carefully considered in patients equiring anticoagulation or patients with low-risk prostate cancer. Immediate complication rate is low and incontinence is rare. The retreatment rate for HoLEP is lower than other endoscopic procedures.  
› HoLEP is clinically established in the management of BOO from BPH. Its success has been reproduced in a diverse array of patients including those on anticoagulation, with detrusor underactivity/acontractility, prostate cancer, and in the retreatment setting. | N/A |
› Mean operative time was reduced in the HoLEP cohort (103 minutes vs 274 minutes, p<0.001). Patients undergoing HoLEP had lesser decreases in hemoglobin, decreased transfusions rates, shorter hospital stays, and decreased mean duration of catheterization. There was no difference in the rate of complications.  
› In expert hands, HoLEP appears to have a favorable perioperative profile. Further studies are necessary to compare long-term efficacy, cost, and learning curve influences. | Lumenis system 100W |
# Low Post Operative Complications

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<th>morcellation system</th>
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<tr>
<td>Patient satisfaction after holmium laser enucleation of the prostate (HoLEP): A prospective cohort study.</td>
<td>PLoS One, 9;12(8): e0182230.</td>
<td>Lee YJ, Oh SA, Kim SH, Oh SJ.</td>
<td>2017</td>
<td>74 (35.3%) patients were discharged as true day-cases and a further 84 (40.0%) discharged within 23 hours. Re-admission rate was 5.5%, with all complications Clavien–Dindo grade I or II.</td>
<td>Lumenis system 100W</td>
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<tr>
<td>Experience with more than 1,000 holmium laser prostate enucleations for benign prostatic hyperplasia.</td>
<td>J Urol, 189(1 Suppl):S141-5.</td>
<td>Krambeck AE, Handa SE, Lingeman JE.</td>
<td>2013</td>
<td>Day-case HoLEP is both feasible and safe, with low readmission rates.</td>
<td>Lumenis system 100 W</td>
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Most patients (91.8%) were satisfied after the surgery. Only 3.3% patients responded with 'dissatisfied', and no patients replied with 'very dissatisfied'. All patients (99.4%) experienced an improvement.

Report of experience with more than 1,000 Holmium laser enucleation procedures (HoLEP).

Complications occurred in only 24 cases (2.3%).

The complication rate is low in Holmium laser prostate enucleation, and incontinence and the need for ancillary procedures are rare with durable long-term results.

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*PB- 2007973 Rev C*
A Prospective, randomized clinical trial comparing plasmakinetic resection of the prostate with holmium laser enucleation of the prostate based on a 2-year followup.

Peri-operative Complications of Holmium Laser Enucleation of the Prostate: Experience in the First 280 Patients, and a Review of Literature.

Comparing plasmakinetic resection with holmium laser enucleation for BPH in 280 patients in 2 groups.

Patients in the holmium laser enucleation group displayed a lower risk of hemorrhage, shorter bladder irrigation and catheter times, and shorter hospital stays.

Plasmakinetic resection and HoLEP of the prostate are effective and safe treatments for BPH. HoLEP can be applied to prostates of all sizes, and involves less complications.

Evaluating complications in 280 patients undergoing Holmium laser enucleation procedure (HoLEP).

Transient urinary incontinence was the commonest complication after HoLEP (10.7% of patients) but recovered spontaneously. A blood transfusion was required during HoLEP in only one patient.

Low incidence of complications with HoLEP. Most complications were minor and easily managed. HoLEP is safe and reproducible procedure.
## Benefits of Using Prostate Morcellation Procedure

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› The VersaCut™ was significantly more efficient in morcellation (4.9% vs. 3.8% g/min, p= 0.03). There was no significant difference in terms of complication rates (7.3 vs. 2.4%, P=0.1). The cost of disposable instruments of the VersaCut were also lower compared to the DrillCut (247.5 vs. 160.9 CAD $, p<0.01).  
› The Lumenis VersaCut Morcellator was associated with significantly higher morcellation efficiency and lower cost of disposables when compared with the DrillCut morcellator. |
› Cost analysis favored the VersaCut significantly, despite the fact the Piranha achieved a slightly non significant higher morcellation rate at 5.6 gm per minute compared to the VersaCut at 4.8 gm per minute.  
› Morcellation rates for the two devices are comparable, with the Piranha having a statistically significant increased cost, more complicated design and less user-friendly. |
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<tr>
<td>Ex-Vivo Comparison of Available Morcellation Devices During Holmium Laser Enucleation of the Prostate Through Objective Parameters.</td>
<td>J Endourol 28(10):1237-40.</td>
<td>Cornu JN, Terrasa JB, Lukacs B.</td>
<td>2012</td>
<td>In vitro evaluation of two morcellators (Lumenis VersaCut and Wolf Piranha) and two nephroscopes during HoLEP. For the Wolf and Lumenis morcellators, aspiration power parameters were 20.4 mL/s and 22.2 mL/s, and morcellating power parameters were 2.5 g and 6 g of tissue per minute, respectively. The Lumenis morcellator is faster than the Wolf morcellator.</td>
<td>Lumenis VersaCut</td>
</tr>
<tr>
<td>An improved morcellation procedure for holmium laser enucleation of the prostate.</td>
<td>J Endourol, 26(12):1625-8.</td>
<td>Chen Q, Chen YB, Wang Z, Peng YB, Zheng DC, Cai ZK, Li WJ, Zhou J.</td>
<td>2012</td>
<td>Modification of the conventional morcellation procedure for holmium laser enucleation of the prostate (HoLEP) at 395 patients in two groups. The improved VersaCut morcellation procedure can be used in various situations of suction and can be performed in a more fluent manner and with better efficacy.</td>
<td>Lumenis VersaCut</td>
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Vaporization Techniques Used with Holmium Laser (HoIVAP)

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› Post-operatively, American Urology Association score (AUA), Post-Void Residual Urine Test (PVR), and Urine flow rate (Qmax) were improved significantly (9.4 versus 24.1, 33 versus 175, and 15.3 versus 8.2, respectively). Intraoperative visualization and surgeon satisfaction has been excellent. Patients were treated with no hospital admission unless other comorbidities were present.  
› Experience with HoIVAP using 120 W Holmium laser system has demonstrated significant improvements in both subjective and objective parameters. The increase in overall power and advancements in the laser fiber technology provide greater hemostasis and a shorter operative time. | Lumenis system 120W       |
› Patients in the HoIVAP group had significantly shorter operative times (77 versus 119 minutes). No significant differences were found in flow rate outcomes between groups.  
› Both HoLEP and HoIVAP are appropriate surgical procedures for the management of BPH. When performed correctly, HoIVAP technique produces similar results to HoLEP, and may present a shorter operative time. | Lumenis system 120W       |
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<tr>
<td>Holmium laser ablation of the prostate (HoLAP): intermediate-term results of 144 patients.</td>
<td>World J Urol, 31(5):1253-9</td>
<td>Thurmond P, Bose S, Lerner LB.</td>
<td>2013</td>
<td>› Holmium laser vaporization of prostate (HoLVAP) is an alternative to Transurethral resection of Prostate (TURP) for small to medium-sized prostates, and recommended in severely anti-coagulated patients.</td>
<td>Lumenis system 100W</td>
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Risk information: The use of the Lumenis laser systems, accessories, their delivery devices and Lumenis morcellator in urology is contraindicated for patients who are unable to receive endoscopic treatments or are intolerant to prolonged anesthesia, as well as for resection or excision of large vascularized organs. Lumenis Holmium laser systems and accessories are solely intended for use by physicians trained in the use of the Ho:YAG (2.1 μm) wavelength. Incorrect treatment settings can cause serious tissue damage. The laser should be used only on tissues that are fully observable. See the system user manual for a complete list of contraindications and risks. The use of the Lumenis VersaCut morcellator and accessories is contraindicated for morcellation of bone and for use in liposuction procedures, Gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy and removal of uterine tissue containing suspected fibroids in patients who are peri- or post-menopausal, or candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision. Lumenis VersaCut is intended solely for use by physicians trained in the use of the VersaCut morcellator. The Lumenis VersaCut and accessories should only be used under direct or endoscopic visualization in a fluid environment. See the system user manual for a complete list of contraindications and risks.