



## Surgery in Motion

# Holmium Laser Enucleation of the Prostate: Results at 6 Years

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### Abstract

**Objectives:** The issue of durability is an important concern when evaluating new surgical modalities. To date, only 24-mo data have been published on holmium enucleation of the prostate (HoLEP) despite its widespread use worldwide although 4-yr data exist for the earlier technique of holmium resection. This study addresses the issue of durability of HoLEP.

**Methods:** All patients who had undergone HoLEP and been evaluated in three prospective trials conducted at this institution between 1997 and 2002 were evaluated. Patients available at follow-up had data assessed on the International Prostate Symptom Score (IPSS), maximal flow rate ( $Q_{max}$ ), quality of life (QOL), International Continence Society Male Short Form (ICS-SF), International Index of Erectile Function (IIEF), Benign Prostatic Hyperplasia Impact Index (BPHII), and continence questionnaire.

**Results:** The mean follow-up was 6.1 yr (range: 4.1–8.1 yr). The mean age of the patients at follow-up was 75.7 yr (range: 58–88 yr). Of 71 HoLEP patients originally studied on the protocol, 38 (54%) were available for analysis, 14 were deceased, and 19 were lost to follow-up. The mean IPSS for this group was 8.5 (range: 0–24) and  $Q_{max}$  19 ml/s (range: 6–28 ml/s). The QOL score was 1.8 (range: 0–5) and the BPHII 2.0 (range: 0–11). One patient (1.4%) had undergone reoperation, an additional HoLEP. Overall, 92% were either satisfied or extremely satisfied with their outcome.

**Conclusions:** HoLEP is durable and most patients remain satisfied or extremely satisfied with the long-term outcome.

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## 1. Introduction

Many minimally invasive procedures, including laser techniques, for the treatment of bladder outflow obstruction due to benign prostatic hyperplasia (BPH) have come and gone over the last 15 yr [1–4]. One of the main issues exposed with years of use of some of these techniques is the failure of the treatment over time and the need for retreatment. Other issues leading to the demise of these procedures include significant patient dissatisfaction with the early results (eg, irritative symptoms or prolonged catheterization), inefficiency of the primary treatment, reimbursement issues, and lack of ongoing support and marketing from the device manufacturer. Commercial issues notwithstanding, durability concerns often become the most important determinant of the ultimate survival of a given technique for the practising urologist.

Holmium laser prostatectomy has been around in various forms since 1994 [5]. In the quest for increasing efficiency and in the pursuit of improved outcomes, the procedure has evolved from a combination procedure (with neodymium:yttrium-aluminum-garnet [Nd:YAG]), to an ablative procedure [6], to excisional techniques involving resection of small fragments [7], and most recently, anatomic enucleation of whole lobes [8]. Holmium laser enucleation of the prostate (HoLEP) has been performed since 1996 [9] and has been adopted in many centers throughout the world [10–13]. Despite numerous single and multicenter studies documenting its efficacy and safety, the durability of HoLEP has not been properly studied.

This analysis of a cohort of closely scrutinized patients from a combination of three prospective studies serves to document the medium- to long-term outcome of this procedure.

## 2. Methods

The patients and data out to 12 mo from the HoLEP arms from three published randomized trials [14–16] were pooled to form the study population. The inclusion and exclusion criteria were similar for all patients apart from variable prostatic volume depending on the study: peak urinary flow rate measurement ( $Q_{max}$ ) <15 ml/s, International Prostate Symptom Score (IPSS) of  $\geq 8$ , postvoid residual (PVR) <400 ml, and Schaffer grade of  $\geq 2$  on video urodynamics. Catheterized patients and those with previous prostatic or urethral surgery were excluded. All patients had an IPSS, single-question quality-of-life (QOL) score and  $Q_{max}$  measurement at all time points. Pressure-flow studies, residual volume estimates, and transrectal ultrasound (TRUS) measurements were performed at baseline and at 6 mo.

Attempts were then made to contact all these patients initially from the study database information, the national



**Fig. 1 – A modified inner sheath (Storz) is used, which contains a metal insert to stabilize the laser fiber.**

hospital database, or telephone book as a last resort. The case notes of patients who were deceased or were not contactable were screened to determine if any further urologic procedures had been performed.

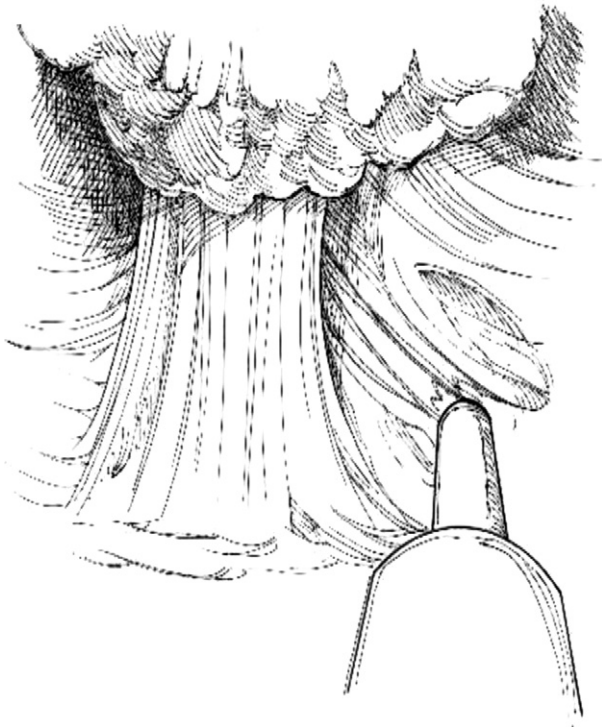
All available patients at follow-up were interviewed and had an IPSS and QOL score,  $Q_{max}$ , BPHII, continence assessment (including an International Continence Society Male Short Form [ICS-SF] questionnaire), International Index of Erectile Function (IIEF), and a general assessment including overall satisfaction.

### 2.1. Procedure

A dedicated inner sheath incorporating a laser guide is used (Fig. 1) in the majority of cases (Storz 27040 XAL) in conjunction with a standard telescope bridge, 30° telescope, and 26F continuous flow resectoscope sheath. Alternatively, a dedicated combined bridge and inner sheath may be used (Olympus A21500A). A 550- $\mu$ m laser fiber is passed through a 6F ureteric catheter for further stability and secured by a Luer lock device. This is connected to a 100-W holmium

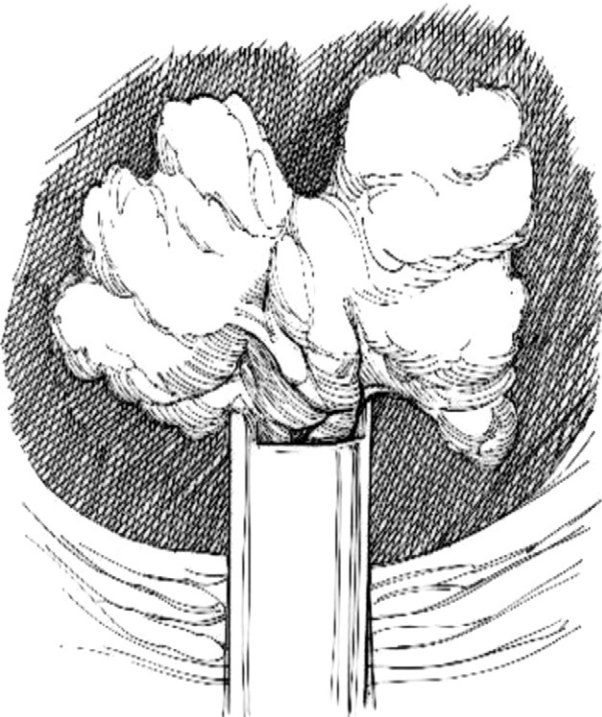


**Fig. 2 – The mechanical morcellator uses reciprocating blades, an ergonomic hand piece, and a two-stage foot pedal attached to a controller box that contains a high-powered suction pump.**



**Fig. 3 – Following bladder-neck incisions the median lobe is enucleated commencing at the verumontanum.**

laser (VersaPulse, Lumenis, Yokneam, Israel). Morcellation takes place through a standard long nephroscope connected by an adaptor (Storz 27040 LB) to the resectoscope sheath. A soft-tissue morcellator (Fig. 2) is used to remove the



**Fig. 4 – A mechanical morcellator is used to extract the tissue fragments.**

tissue fragments from within the bladder (VersaCut™, Lumenis).

## 2.2. Technique

The technique of HoLEP has been described in detail elsewhere [17]. To summarize, the technique involves retrograde enucleation of the anatomic lobes of the prostate following tri-radiate bladder-neck incisions, which define the depth and extent of the median and both lateral lobes (Fig. 3). The plane between the surgical capsule and adenoma is developed and maintained throughout the procedure. Careful hemostasis is obtained prior to morcellation. Once the lobes have been placed in the bladder, a mechanical morcellator extracts the tissue using reciprocating blades and high-powered suction (Fig. 4).

The data are presented as the mean  $\pm$  standard deviation (range). The values of the scores for IPSS,  $Q_{max}$ , and QOL were compared at different time points (6 mo and 6 yr) using paired t tests. Associations among the variables at 6 yr were tested using correlation coefficients.

## 3. Results

Of 71 eligible patients, 38 patients were available for analysis. A total of 19 patients could not be located and another 14 had died since their surgery.

Table 1 presents the preoperative demographic data of the original patient group ( $n = 71$ ); follow-up data are shown in Table 2. Perioperative data included an operating time of  $47 \pm 28.1$  min (range: 14–176 min), a pathology weight of tissue of  $27.2 \pm 25.2$  g (range: 2–152 g), and a hospital stay of  $24.8 \pm 17.4$  h (range: 7–120 h). Two (2.8%) of the patients had an incidental carcinoma found.

At 6 mo, the TRUS volume had fallen to  $27.2 \pm 9.5$  ml (range: 11–54 ml), a reduction of 54% ( $n = 55$ ). The prostate-specific antigen (PSA) value had fallen to  $1.8 \pm 1.3$   $\mu\text{mol/l}$  (range: 0.1–13.3  $\mu\text{mol/l}$ ), a decrease of 61% ( $n = 34$ ). The PVR was  $33.3 \pm 34.9$  ml (range: 0–173 ml) and the maximum detrusor pressure during voiding ( $P_{det,max}$ ) at the 6-mo urodynamic

**Table 1 – Preoperative demographic data**

Age, yr	69.1 $\pm$ 9.0 (45–84)
IPSS	25.7 $\pm$ 5.9 (14–35)
QOL score	4.9 $\pm$ 1.0 (1–6)
Peak flow rate ( $Q_{max}$ ), ml/s	8.1 $\pm$ 2.7 (2–14)
TRUS volume, ml	58.5 $\pm$ 31.0 (14–152)
Postvoid residual, ml	105.0 $\pm$ 81.9 (5–380)
$P_{det,max}$ , cm H <sub>2</sub> O	73.7 $\pm$ 25.4 (43–145)
Schaefer grade	3.4 $\pm$ 1.2 (2–6)
PSA, $\mu\text{mol/l}$	4.6 $\pm$ 5.2 (0.3–24.8)

IPSS = International Prostate Symptom Score; QOL = quality of life; TRUS = transrectal ultrasound;  $P_{det,max}$  = maximum detrusor pressure during voiding; PSA = prostate-specific antigen.

**Table 2 – Follow-up data on available patients**

	Preoperative (n = 71)	1 mo (n = 68)	3 mo (n = 65)	6 mo (n = 60)	12 mo (n = 59)	6 yr (n = 38)
IPSS	25.7 ± 5.9 (14–35)	9.7 ± 6.7 (0–30)	7.9 ± 6.1 (0–31)	7.5 ± 5.8 (0–26)	6.6 ± 6.4 (0–31)	8.5 ± 6.3 (0–24)
QOL score	4.9 ± 1.0 (1–6)	2.7 ± 1.9 (0–6)	1.9 ± 1.7 (0–6)	1.7 ± 1.3 (0–6)	1.6 ± 1.2 (0–6)	1.8 ± 1.6 (0–6)
Q <sub>max</sub> , ml/s	8.1 ± 2.7 (2–14)	20.3 ± 9.0 (4–50)	20.7 ± 9.6 (3–52)	23 ± 10.7 (5–65)	20.9 ± 7.6 (6–38)	19 ± 11.2 (6–61)

IPSS = International Prostate Symptom Score; QOL = quality of life; Q<sub>max</sub> = maximum flow rate.

**Table 3 – International Index of Erectile Function scores at 6 yr postoperatively**

Erectile function	9.6 ± 7.1 (1–25)
Intercourse satisfaction	2.4 ± 3.5 (0–12)
Orgasmic function	2.6 ± 3.3 (0–10)
Sexual desire	5.2 ± 2.5 (0–8)
Overall satisfaction	4.8 ± 2.6 (0–8)

study was 26.1 ± 12.9 cm H<sub>2</sub>O (range: 5–45 cm H<sub>2</sub>O) with a mean Schaefer grade of 0.5 (range: 0–2).

The mean follow-up for the current analysis was 6.1 ± 1.43 yr (range: 3.8–8.9 yr) and the patient age at follow-up was 75.3 ± 8.7 yr (range: 57–88 yr). The BPHII was 2.0 ± 3.2 (range: 0–11) at this assessment. The IPSS, QOL score, and BPHII were all highly significantly correlated ( $p < 0.001$ ) in these patients, for example, QOL score and BPHII,  $r = 0.815$ . The IPSS, QOL, and Q<sub>max</sub> data were compared at 6 mo and 6 yr to further assess durability (ie, the stability of each parameter). No significant differences were found for each parameter between each time point apart from the Q<sub>max</sub> values between 6 mo and 6 yr ( $p = 0.004$ ).

Thirty-five 35 (92%) of the 38 patients were satisfied or extremely satisfied with the surgery overall. Of the dissatisfied patients, one had required revision surgery (HoLEP), one had symptoms that were unchanged, and one had mixed stress and urge incontinence.

Incontinence of some kind occurred in eight (21%) patients at follow-up, three with urge, four with mixed, and one with stress by symptoms. The ICS incontinence score I1–I6 was 2.6 ± 2.7 (range: 0–10) and the voiding score V1–5 was 4.6 ± 4.4 (range: 0–18). The ICS QOL score was 0.7 ± 1.0 (range: 0–3).

The current sexual function as measured by the IIEF is listed in Table 3. The reported incidence of retrograde ejaculation was 25 of 33 (76%) sexually active patients. Only one patient (1.4%) of the original cohort had required reoperation (HoLEP), 5 yr after the original procedure. One patient had required an urethrotomy at 6 mo.

#### 4. Discussion

“Monopolar” transurethral resection of the prostate (TURP) in various forms has been the predominant

procedure performed worldwide over the past 50 yr. Despite this, only a handful of studies have prospectively documented the medium- and long-term efficacy of the technique. Most studies have provided retrospective data of variable quality [18].

As a new surgical modality, many issues including feasibility, safety, and cost effectiveness have needed to be addressed for HoLEP [9–14,19]. The learning curve, use in different patient groups, comparison to open prostatectomy, and sexual function have also been studied in detail [20–24]. Efficacy, including changes in symptoms, flow rates, and QOL have been studied in detail for this procedure but only to 24 mo postoperatively [23,25]. The present study documents a 6-yr follow-up in a well-characterized cohort of urodynamically obstructed patients and includes assessments of current continence and sexual function.

The reoperation rate of 1.4% (one patient) is robust because the records of patients lost to follow-up were also retrieved to determine whether any operative intervention had been undertaken. This compares well with TURP data where a reoperation rate of 3–8% (1–2%/yr) is currently accepted [18,26]. This improvement is most likely due to the more complete adenoma removal with anatomic enucleation. The significant fall in Q<sub>max</sub> value to 19 ml/s in matched patients at 6 yr from the 6-mo value (23 ml/s) is therefore unlikely to represent regrowth of prostatic tissue because the symptom and QOL scores are maintained and the patients remain satisfied with their surgery. Age-related deterioration of bladder function is a likely contributor to this flow rate alteration because all patients were urodynamically unobstructed at 6 mo and the Q<sub>max</sub> value is similar to that at 12 mo (20.9 ml/s). Although this is a well-documented cohort of patients, the relatively small sample size, protocol-defined inclusion criteria, and significant drop-out rate mean that the results may not be fully generalizable to an unselected population.

Both incontinence and voiding as measured by the ICS-SF questionnaire (IS and VS scores) compare favorably with TURP data from historical controls [27] and the global impact of urinary symptoms (BPHII) at 2.0 is similar to that expected following successful BPH treatment [28]. The erectile function

score of the IIEF at 9.6 implies that overall this group of men had severe erectile dysfunction likely due to their advanced age [29].

HoLEP represents a paradigm shift in the endoscopic management of BPH in that the adenoma is approached from the apex and enucleated intact rather than being removed in a piecemeal fashion commencing at the bladder neck as occurs with TURP. In that way it is analogous to open prostatectomy, which is considered the standard for relief of bladder outflow obstruction due to BPH. Further improvements in instrumentation and in particular morcellation will be necessary to improve on the excellent results already being achieved in many institutions worldwide. This study documents the long-term results of this procedure.

### Conflicts of interest

The authors have nothing to disclose.

### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.eururo.2007.04.052](https://doi.org/10.1016/j.eururo.2007.04.052) and via [www.europeanurology.com](http://www.europeanurology.com). Subscribers to the printed journal will find the supplementary data attached (DVD).

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