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ORIGINAL ARTICLE

En Bloc enucleation with early apical release technique using MOSES (En Bloc MoLEP) vs. classic En Bloc HoLEP: a single arm study comparing intra- and postoperative outcomes

Moisés Rodríguez Socarrás[1] · Julio Fernández del Álamo[1] · Fabio Espósito[1] · Javier Reinoso Elbers[1] · Diego Carrión Monsalve[1] · Juan Gómez Rivas[1] · Isabella Greco[1] · Luis LLanes González[1] · Vanesa Cuadros Rivera[1] · Fernando Gómez Sancha[1]

Abstract

Background and purpose We aimed to describe the technique and outcomes of En-Bloc MOSES laser enucleation of the prostate (En-Bloc MoLEP) with early apical release comparing it to En-Bloc HoLEP (non-MOSES).

Patients and methods This is a single-arm prospective study, using a historical control. $n = 80$ patients were enrolled to the En Bloc MoLEP group and compared to a retrospective group of $n = 137$ patients treated by En Bloc HoLEP (non-MOSES), in total $n = 217$ patients.

Results En-Bloc MoLEP, showed to significantly improve the surgical time by 32% compared to non-MOSES HoLEP (32.16 ± 14.46 min, 47.58 ± 21.32, respectively; $P = 0.003$). Enucleation time, ablation rate and hemostasis time were also significantly improved ($P < 0.001$, for all three parameters). Enucleation time was 22.10 ± 9.27 min and 31.46 ± 14.85 min ($P < 0.001$), ablation rate 4.11 ± 2.41 and 2.54 ± 1.31 gr/min ($P < 0.001$), Hemostasis time 3.01 ± 2.50 and 8.35 ± 5.38 min ($P < 0.001$), for En Bloc MoLEP and En Bloc HoLEP, respectively. Q-max, PVR, PSA and IPSS showed significant improvement, however, at 12 months no significant differences were observed comparing both groups.

Conclusions En-Bloc MoLEP was significantly better than En-Bloc HoLEP in terms of surgical time, enucleation time, ablation rate and hemostasis time. However, large comparative RCT with long-term follow-up are needed.

Keywords Holmium · Laser · Prostate hyperplasia · BPH · BPE · HoLEP · MOSES · MoLEP

Introduction

Hiraoka described the first surgical technique for endoscopic enucleation of the prostate in 1983 [1], Gilling and Fraundorfer published their three-lobe HoLEP approach in 1996 [2]. Since its introduction in 1992 and due to its versatility for treating urology conditions, the Holmium: yttrium–aluminum-garnet (Ho: YAG) laser is still the most used by urologists worldwide.

En Bloc enucleation with an early apical release introduced by Dr Fernando Gómez Sancha is a safe technique for the treatment of Benign Prostate Enlargement (BPE) [3–5]. It protects the external urinary sphincter, avoiding traction and mucosal injury during dissection, providing excellent preservation of urinary continence [3–5].

Pulse modulation in new Holmium laser generators represents one of the most significant advances in recent years in laser technology [6–8]. MOSES technology is commercially available since 2017 (MOSES™ technology, Lumenis Ltd, Yokneam, Israel), its introduces a pulse-shape modulation for Holmium-YAG emitting two consecutive laser pulses where the first one generates a bubble allowing the second one to travel through it [6, 9]. MOSES optimizes energy delivery to the target tissue, leading to less retropulsion, allowing more efficient lithotripsy on stones [6]. Pulse modulation offers an excellent dissection, cutting and coagulation profile in soft tissues, that we think is especially useful for endoscopic prostate enucleation.

We aimed to assess the feasibility, efficacy, safety, and outcomes and to describe the technique of En-Bloc

Moisés Rodríguez Socarrás
moisessocarras@hotmail.com

[1] Instituto de Cirugía Urológica Avanzada (ICUA), Clínica Cemtro, Madrid, Spain

MOSES laser enucleation of the prostate (En-Bloc MoLEP) with early apical release comparing it to En-Bloc HoLEP (non-MOSES).

Materials and methods

Patients and methods

This work is a single-arm prospective study, using a historical control. *n* = 80 patients were enrolled to the En-Bloc MoLEP group from April 2019 to Mach 2020, in one center (Instituto de Cirugía Urológica de Madrid (ICUA), (https://www.icua.es/) and compared to a retrospective group of *n* = 137 patients treated by En-Bloc HoLEP (non-MOSES), in total *n* = 217 patients. All procedures were performed by a single surgeon with extensive experience in laser surgery for BPH (> 9000 cases Dr Fernando Gómez Sancha), using the Lumenis Pulse™ 120H system (Lumenis Ltd, Yokneam, Israel). Inclusion criteria were: IPSS ≥ 12, Qmax < 15 mL/s, candidate for surgery, all prostate sizes were permitted. Exclusion criteria included: need to perform a simultaneous procedure, PVR > 300 mL, prostate or bladder cancer, neurogenic voiding dysfunction, urethral strictures, previous prostatic/bladder neck/urethral surgery, urogenital trauma, bladder neck stricture as the main cause of BPO.

The participants completed several validated questionnaires like IPSS IIEF-15, ICIQ-SF, OAB-qSF, EPIC, uroflowmetry, and PVR volume measurements, the follow-up period was 12 months. The local ethics committee approved the study (NCT: HULP: PI-3637). All procedures performed fulfilled the ethical standards of the national research committee and the 1964 Helsinki Declaration and its later amendments. Before surgery, all patients signed a specific informed consent and understood the benefits and risks of En Bloc MoLEP and possible alternative treatments.

Description of the system and technique

OR setup is shown in Fig. 1. The En-bloc MoLEP procedures were performed using a Lumenis Pulse 120H laser system equipped with Moses 2.0 technology (MOSES™ technology, Lumenis Ltd, Yokneam, Israel). The laser settings used are 2 J/50 Hz for enucleation and 1 J/40 Hz for hemostasis using 550 µm MOSES fibers with Moses 2.0 technology activated. Enucleation procedures (HoLEP non-MOSES) were performed using a 100-W holmium: YAG Laser (PowerSuite™, Lumenis, Yokneam, Israel) in regular mode (Short Pulse) with the same settings (Fig. 1). A comparison was made between Regular and MOSES modes.

En-Bloc enucleation technique was performed as described in previous articles [3], it consists in the initial release of the prostatic apex of the urinary sphincter, then thereafter the enucleation plane is followed circumferentially, progressively approaching the bladder neck. The circumferential nature of the dissection makes it very intuitive, quick and simple (Fig. 2). A 26 F Shark Laser cystoscope (Richard Wolf, GmbH, Knittlingen, Germany) was used, morcellation was performed using Piranha morcellator (Richard Wolf, GmbH, Knittlingen, Germany), PIRANHA

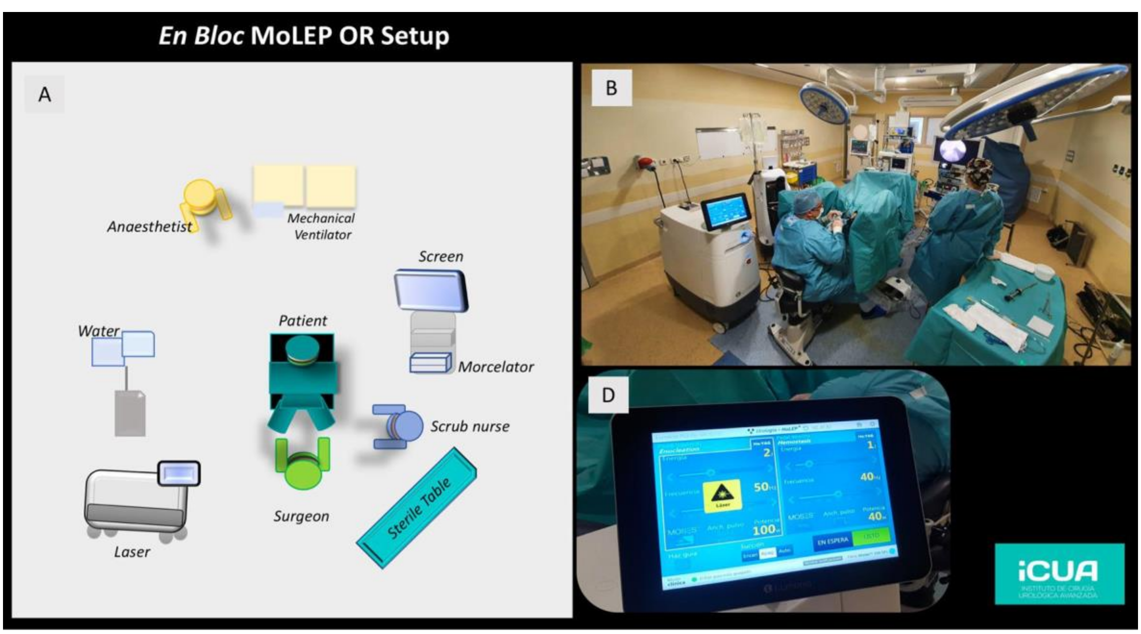

Fig. 1 En Bloc MoLEP OR Setup. **A** Schematic representation of the operating room (OR). **B** Photo with laser generator equipped with MOSES technology and OR distribution. **C** Laser generator screen with settings for En Bloc MoLEP

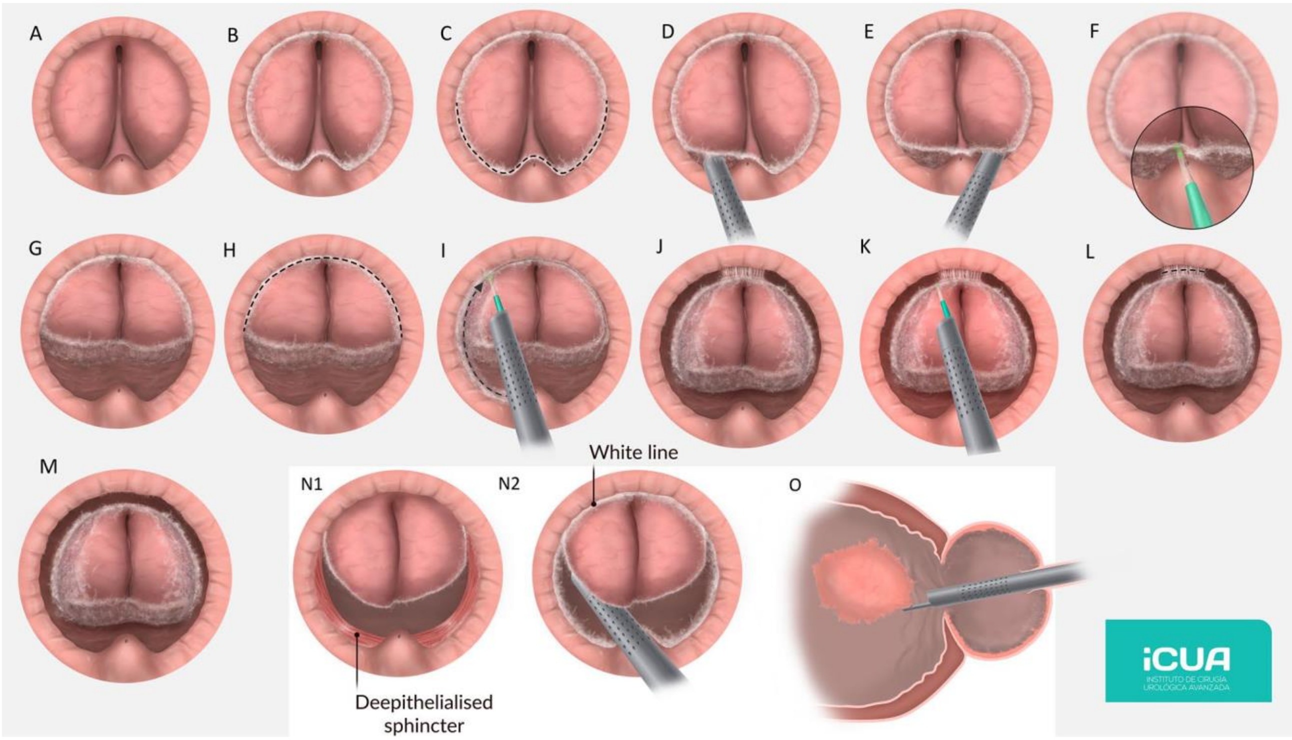

Fig. 2 En Bloc MoLEP. En Bloc MOSES laser enucleation of the prostate (En Bloc MoLEP) with early apical release and sphincter preservation. **A** Urinary sphincter and obstructive prostatic lobules **B**, **C**. Drawing white line with laser delimiting prostatic apex, Verumontanum and external urinary sphincter preservation **D**, **E**. Access to appropriate plane between adenoma and prostatic capsule f. Midline laser cut at 6 o'clock posterior ridge **G**. Prostatic apex separated from urinary sphincter with development of adenoma–capsule plane between 3 and 9 h **H**, **I**. Anterior laser release of apex and external urinary sphincter between 9 and 3 h **J**–**L**. Laser cut at 12' **M**. Prostatic apex released early to preserve urinary sphincter **N1**. Illustrating late release of prostatic apex and urinary sphincter trauma by traction in classical techniques, compared to **N2**. Early release of apex with preservation of urinary sphincter reducing the risk of sphincter injury by traction. **O** Morcellation of the adenoma into the bladder

suction pump set (Richard Wolf, GmbH, Knittlingen, Germany) and 26 Ch Nephroscope, PIRANHA Scope (Richard Wolf, GmbH, Knittlingen, Germany). Foley catheter is removed the next morning, less than 24 h, and after spontaneous urination the patient is discharged.

Study design, endpoints and statistical analysis

The primary endpoints were enucleation efficacy, calculated as enucleation time, ablation rate (gr/min), reduction on prostate volume, PSA, IPSS score change (at 1, 3 and 12 months), uroflowmetry improvement. To evaluate safety, we looked at intra- and postoperative parameters and complications Clavien–Dindo 2 or higher.

Secondary endpoints included: Hemostasis time, conversion to TURP to complete procedure or to maintain hemostasis, blood loss (pre and postoperative hemoglobin), prostate capsule perforation, catheterization time (Hours), hospitalization stay (Hours) and need for re-catheterization.

Data were collected in a prospective database and processed using SPSS V21 (SPSS inc, IBM Corp). A standard statistical approach was used for analysis with T-tests, Chi-square and Anova, $P \leq 0.05$ was considered statistically significant.

Results

217 patients ($n = 80$; En-Bloc MoLEP group, and $n = 137$; En-Bloc HoLEP group) met the eligibility criteria and were included, the patients' characteristics are summarized in Supplementary Table 1. Mean age was 66.73 ± 13.21 and 66.30 ± 7.95 years, Prostate Volume 86.66 ± 50.0 and 75.77 ± 42.25 ml, for En-Bloc MoLEP and En-Bloc HoLEP respectively. 24 patients of the En-Bloc MoLEP group had prostates over 100 ml, in three patients the volume was over 200 ml, the largest prostate size reached 255 ml. No significant differences were observed in the baseline characteristics of patients from both groups. Baseline PSA was 3.88 ± 0.48 (1.52–4.88) and 4.81 ± 0.63 ng/ml, Qmax mean 7.45 ± 3.10 (4.90–10) and 8.05 ± 3.88 ml/seg, IPSS score 22.96 ± 9.54

(18–30) and 21.85 ± 8.70 for the MoLEP and HoLEP group, respectively.

The operative and postoperative outcomes are summarized in Table 1. En-Bloc MoLEP, using the MOSES technology, showed to significantly improve the surgical time by 32% compared to non-Moses short-pulse HoLEP (32.16 ± 14.46 min, 47.58 ± 21.32, respectively; $P = 0.003$). Enucleation time, ablation rate and hemostasis time were also significantly improved ($P < 0.001$, for all three parameters). The mean enucleation time was 22.10 ± 9.27 min and 31.46 ± 14.85 min ($P < 0.001$), ablation rate 4.11 ± 2.41 and 2.54 ± 1.31 gr/min ($P < 0.001$), Hemostasis time 3.01 ± 2.50 and 8.35 ± 5.38 min ($P < 0.001$), for En Bloc-MoLEP and En-Bloc HoLEP, respectively (Table 1, Fig. 3).

For the En-Bloc MoLEP group, morcellation time was 6.16 ± 5.4 (3–7.2) min and total energy (KJ) 117.56 ± 51.99 (80.21–146.37), postoperative Hb was 13.77 (13.35–14.5) gr/dl, Hb drop was 1.53 g/dl, no patient needed transfusion, no significant differences were observed compared to HoLEP.

No patient needed conversion to TURP to finish the procedure, the mean catheterization time was 17.90 ± 10.56 (15–17.12) h and 17.35 ± 11.05 (13.5–21.5) h for both groups. No patient presented complications Clavien–Dindo II–III, only 2 (2.75%) and 13 (9.5%) patients had minor complications Clavien Dindo I–II consisting of hematuria under conservative management. Fifteen (10.9%) patients needed recatheterization in the HoLEP group vs 3 (4%) in the MoLEP group. No patients required to return to the operating room for clot removal or additional coagulation.

In the MoLEP group, prostate volume decreased from 86.66 ± 50.01 to 13.05 ml, PSA dropped from 3.88 ± 0.48 to 0.72 ± 0.13 ng/ml, Q-max improved substantially from 7.45 (6.75–8.14) to 21.93 (16.36–27.50) ml/sec, IPSS also showed a remarkable improvement, with a decrease of 18.38 points from 22.96 ± 9.54 to 4.73 ± 0.64 at 3 months and 5.44 ± 0.96 points at 12 months. No significant differences were observed compared with the non-Moses short-pulse HoLEP group (Supplementary Table 2).

PVR showed a significant difference in favor of the En-Bloc MoLEP group in the first month ($P = 0.002$), however at the 1 year follow-up it was equivalent for both groups. IIEF-15 showed no significant change, and at one year follow-up it was 39.22 ± 24.77 in the MoLEP group.

Table 1 Operative and postoperative outcomes of *n* = 217 patients, *n* = 80-En bloc MoLEP, *n* = 137-En Bloc HoLEP

	En Bloc MoLEP, *n* = 80	En Bloc HoLEP, *n* = 137	*P*
Surgical time (min), mean, ± SD (IQR)	32.16 ± 14.46 (23–40)	47.58 ± 21.32 (30–60)	0.003
Enucleation time (min), mean, ± SD (IQR)	22.10 ± 9.27 (15–26.25)	31.46 ± 14.85 (20–40)	< 0.001
Ablation rate (gr/min), mean ± SD (IQR)	4.11 ± 2.41 (2.52–5.08)	2.54 ± 1.31 (1.70–3.03)	< 0.001
Haemostasia time (min), mean ± SD (IQR)	3.01 ± 2.50 (1–5)	8.35 ± 5.38(5–12)	< 0.001
Morcellation Time (min), mean ± SD (IQR)	6.16 ± 5.4 (3–7.25)	6.93 ± 6.64 (5–8)	0.462
Enucleation energy (KJ), mean ± SD (IQR)	112.79 ± 45.74 (80–139.55)	83.80 ± 37.52 (53.43–101.84)	0.053
Total energy (KJ), mean ± SD (IQR)	117.56 ± 51.99 (80.21–146.37)	125.86 ± 50.36 (90–154.75)	0.713
TURP for haemostasia, *n* (%)	0	4 (2.9%)	0.140
Conversion to TURP, *n*	0	0	NA
Specimen weight (gr), mean (min–max)	56.273 ± 36.93 (28–168.7)	53.00 ± 35.94 (26–113)	0.421
Otis, *n* (%)	31 (38.71%)	48 (35.03%)	0.451
Catheterization time (Hours), mean ± SD (IQR)	17.90 ± 10.56 (15–17.12)	17.35 ± 11.05 (13.5–21.5)	0.276
Hospital-stay (Hours), mean ± SD (IQR)	21.14 ± 6.41 (18–22.0)	22.01 ± 5.71 (19.5–22.60)	0.273
Hb postoperative (gr/dl), mean ± SD (IQR)	13.77 ± 1.07 (13.35–14.5)	13.47 ± 1.05 (13.05–14.50)	0.473
DDHb (Hb pre-Hb post, g/dl), mean ± SD	1.53 ± 0.57	1.73 ± 0.61	0.372
Blood transfusion, *n*	0	0	NA
VAS postoperative, mean ± SD (IQR)	1.1 ± 0.87 (0–2)	1.2 ± 0.75 (0–2)	0.572
Recatheterization, *n* (%)	3 (4%)	15 (10.9%)	0.083
Retention during hospitalization postoperarative, *n* (%)	3 (4%)	15 (10.9%)	0.083
Gross hematuria, n (%)	0 (0%)	4 (2.9%)	0.135
Reoperation	0	0	NA
Clavien I–II, *n* (%)	2 (2.75%)	13 (9.5%)	0.064
Complication Clavien Dindo II–III, *n*	0	0	0.458
Pathological anatomy outcome, BPH / ASAP / PIN / PCa, *n* (%)	73 (91.25%)/2 (2.5%)/1 (1.25%)/4 (5%)	131 (95.6%)/1 (0.7%)/0/5(3.6%)	0.456

BPH benign prostatic hyperplasia, *VAS* visual analogue scale, *TURP* transurethral resection of the prostate

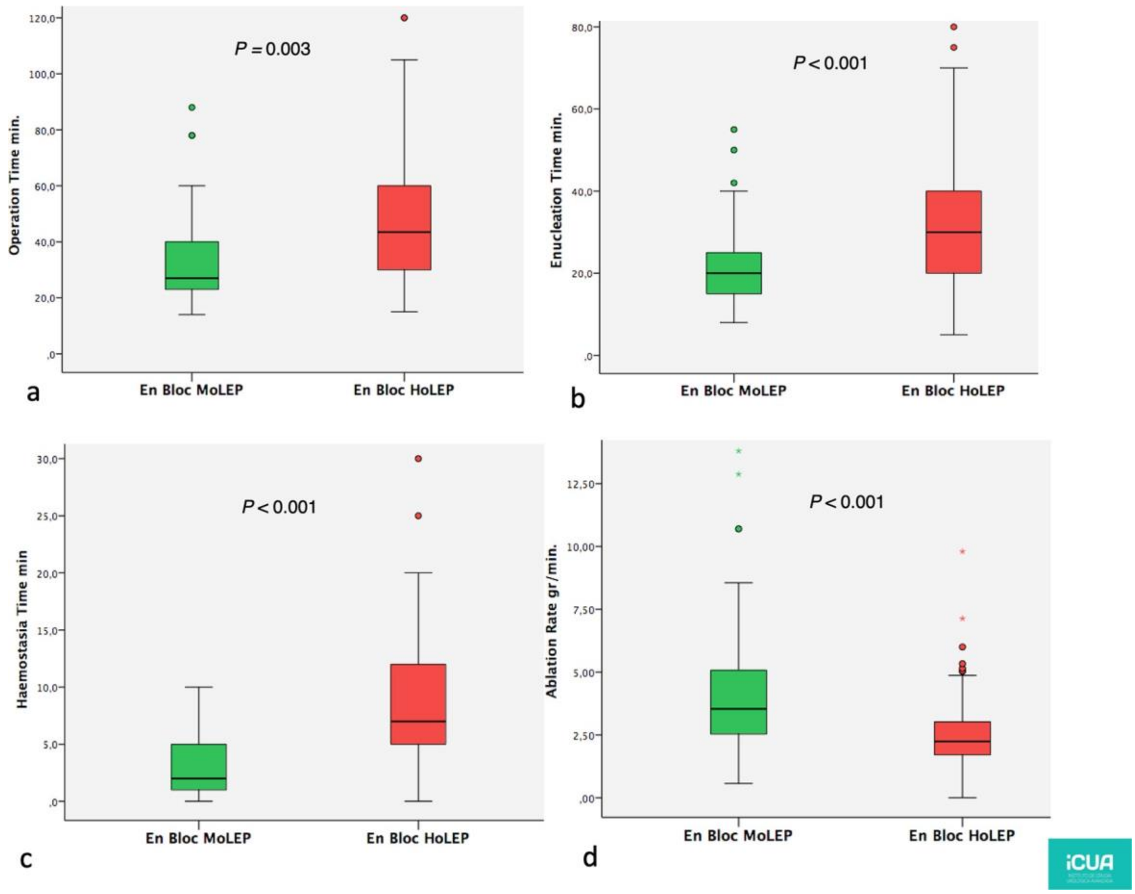

Fig. 3 En Bloc MoLEP vs. En Bloc HoLEP operative outcomes. En Bloc MoLEP was significantly superior to En Bloc HoLEP in terms of, **a** operation time ($P = 0.003$), **b** enucleation time ($P < 0.001$), **c** ablation rate ($P < 0.001$), and **d** hemostasis ($P < 0.001$)

SUI was observed in 2 (2.5%) patients in the MoLEP and 7 (5.1%) in the HoLEP group during the first month; however, from month 3 it was no longer observed in the MoLEP group.

Retrograde ejaculation (RE) was observed in 62 (77.5%) and 103 (75.18%) in the MoLEP and the HoLEP group, respectively. However, RE was present in 28 (35%) patients at baseline in the MoLEP group and 45 (32.84%) in HoLEP group; thus, De Novo RE was observed in 34 patients (42.5%) in the MoLEP and 58 (42.3%) in the HoLEP group respectively. There were no reports of erectile dysfunction due to MoLEP within the follow-up of the study.

Discussion

This is a single arm study, and the first evaluating En-Bloc MoLEP with early apical release compared to En-Bloc HoLEP. According to our results En-Bloc MoLEP, using the MOSES technology, is feasible, safe and effective. En-Bloc MoLEP showed a 32% improvement in surgical time, compared to non-Moses short-pulse En-Bloc HoLEP (32.16 ± 14.46 min vs. 47.58 ± 21.32 min, respectively; $P = 0.003$). Enucleation time was shortened by 29.7% (22.10 ± 9.27 min for MoLEP and 31.46 ± 14.85 min for HoLEP; $P < 0.001$), ablation rate was 4.11 ± 2.41 vs. 2.54 ± 1.31 gr/min ($P < 0.001$) and hemostasis time 3.01 ± 2.50 vs. 8.35 ± 5.38 ($P < 0.001$) for En-Bloc MoLEP and En-Bloc HoLEP respectively. No patient needed transfusion, no Clavien–Dindo II–III complications were observed. The parameters Q-max, PVR, IPSS and PSA also showed significant improvement.

It has been hypothesized that the better energy delivery from the MOSES technology increases the efficiency during enucleation, with more effective tissue ablation and separation, allowing faster development of the surgical plane and better hemostasis [10]. Our study confirms, in line with recent studies, that enucleation time is significantly shorter for MoLEP than for HoLEP.

Enucleation techniques are possible using different energy sources including monopolar, bipolar and laser; confirming that "enucleation is enucleation" regardless of the energy source [11]. HoLEP adoption is growing and has demonstrated lower bleeding, transfusion rates, catheterization and hospitalization time than OP and TURP, with good long-term functional outcomes [12–19]. En Bloc HoLEP with early apical release has been published by our team as an effective technique for prostates of all sizes; it preserves the urinary sphincter, maintaining urinary continence and provides a lower rate of SUI [3, 4, 20].

Holmium laser due to its high peak power, allows dissection between capsule and adenoma anatomical plane, but in regular mode coagulation efficacy is sparse. Holmium pulse modulation, such as MOSES technology, achieves this appropriate balance for HoLEP [4, 21], providing cutting and coagulation balance, at the same time facilitate dissection of the right anatomical plane between capsule and adenoma, increases visibility and can be particularly useful to surgeons on the learning curve, reducing stress and improving efficiency [4, 18, 21, 22]. Recently, other pulse modulations for Holmium laser were introduced, named Vapor-tunnel, Virtual-Basket and Bubble-Blast [7, 23], but have still little studied in clinical practice and without consistent evidence so far.

Thulium fiber laser (TFL), has gained attention due to its efficient lithotripsy; it can reach very low energy pulses and very high frequencies, allowing better dusting. TFL enucleation (TUFLEP) shows similar results to HoLEP or monopolar enucleation, but there are no long-term results published so far [24]. However, TFL has a cutting effect and lacks the ability to generate shock waves to develop the enucleation plane, which is reminiscent of the Thulium laser, although it has different wavelengths (1940 nm vs. 2040 for Tm:YAG) and less tissue penetration (0.15 TFL vs. 0.2–0.4 Tm:YAG) [25].

Other technologies such as Aquablation and Rezum have emerged as a treatment for BPE, which are reproducible and applicable to prostates of all sizes, however, their results in terms of efficacy, ablation and reduction of PSA are more comparable to TURP than prostatectomy or HoLEP [26, 27].

Limitations should be highlighted from this study. First, it is a single-center and single arm study, using a historical control, although the results show a superiority of MoLEP and come from a very experienced centre and surgeon (Dr Fernando Gómez Sancha, with more than 9000 prostate laser surgeries performed), should be interpreted with caution as it is not an RCT, the control group is retrospective, no propensity matched scoring was performed and the results may not be reproducible in the same degree by urologists on learning curve, there are no long-term follow-up results at 2 years. Finally, other aspects like cost-effectiveness of En Bloc MoLEP or outpatient same-day surgery discharge [18] scheme were not considered here and should be the subject of further studies.

Conclusions

En-Bloc MoLEP was significantly better than non-Moses short-pulse En-Bloc HoLEP in terms of surgical time, enucleation time, ablation rate and hemostasis time. However, large comparative RCT with long-term follow-up are needed.

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Author contributions MRS: protocol/project development, data collection and management, data analysis, manuscript writing/editing. JFA: protocol/project development. FE: data collection, data analysis, manuscript writing/editing. JRE: protocol/project development. DCM: protocol/project development. JGR: protocol/project development. IG: protocol/project development. LLG: protocol/project development VCR protocol/project development, data collection and management, data analysis. FGS: protocol/project development, data collection or management, manuscript writing/editing.

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Declarations

Conflict of interest FGS is a consultant for Lumenis Ltd.

Patient confidentiality and consent to publication A written informed consent was obtained from all patients.

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