

(PD56-07) HoLEP vs MoLEP, first prospective randomized trial on 140 patients

Yasser Hussein M.I.*, Fausto Petrelli, Francesca Ceresoli, Raffaella Milesi, Mariangela Bellangino,
Ivano Vavassori

Treviglio-Caravaggio Hospital - ASST Bergamo OVEST - Treviglio (BG), Italy



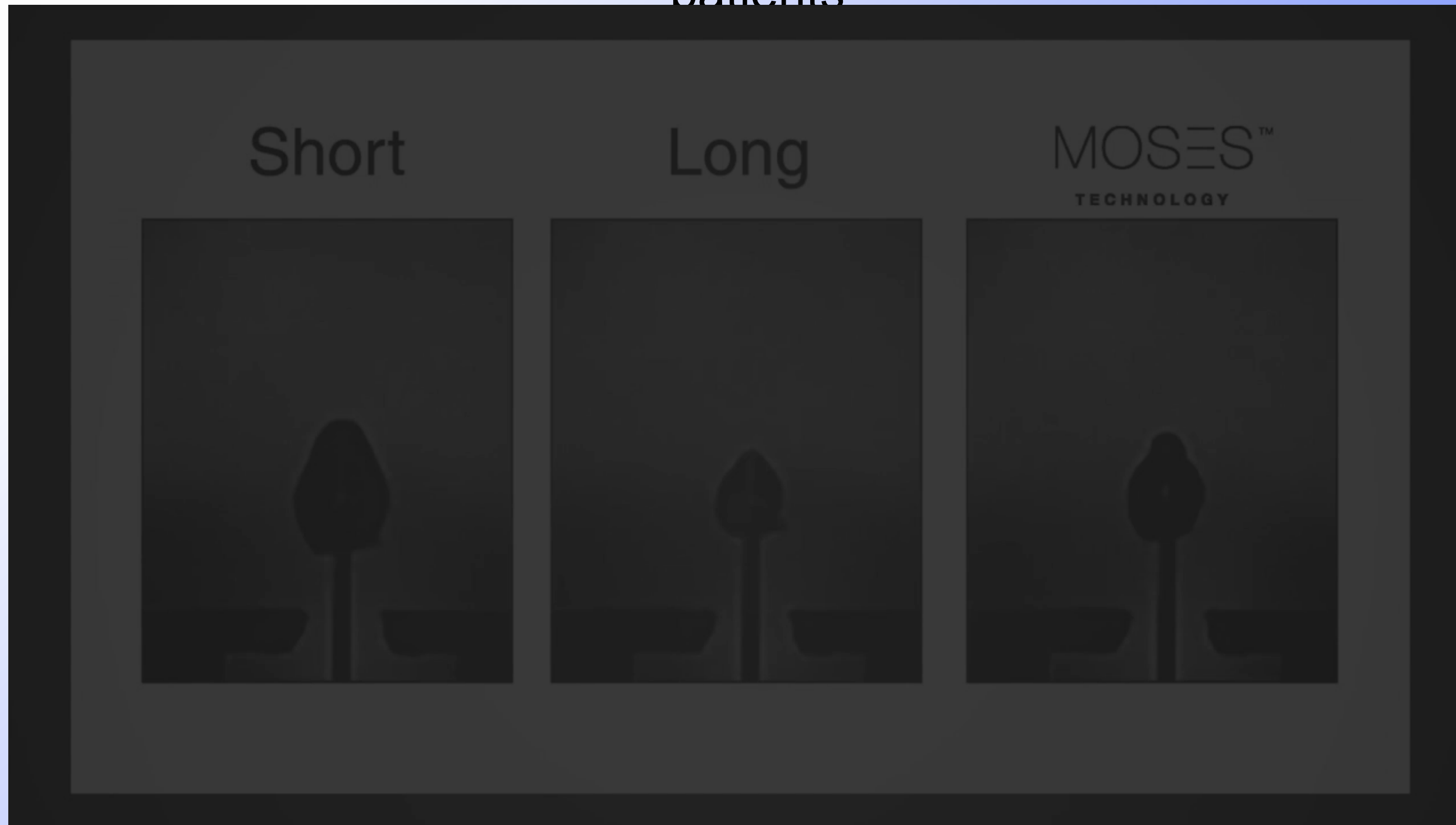
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Holmium Laser with Moses Technology

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Protocol Study Design

Type of Study: single center phase 3b study

Method: Comparative Prospective, Randomized

Endpoints: evaluation of the difference in safety, operation time and laser time



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INCLUSION CRITERIA

- moderate/severe BPH-associated LUTS
- LUTS refractory to medical therapy
- PTS intolerant to medical therapy
- Acute urinary retention PTS
- chronic urinary retention PTS
- prostate volume of >80 ml

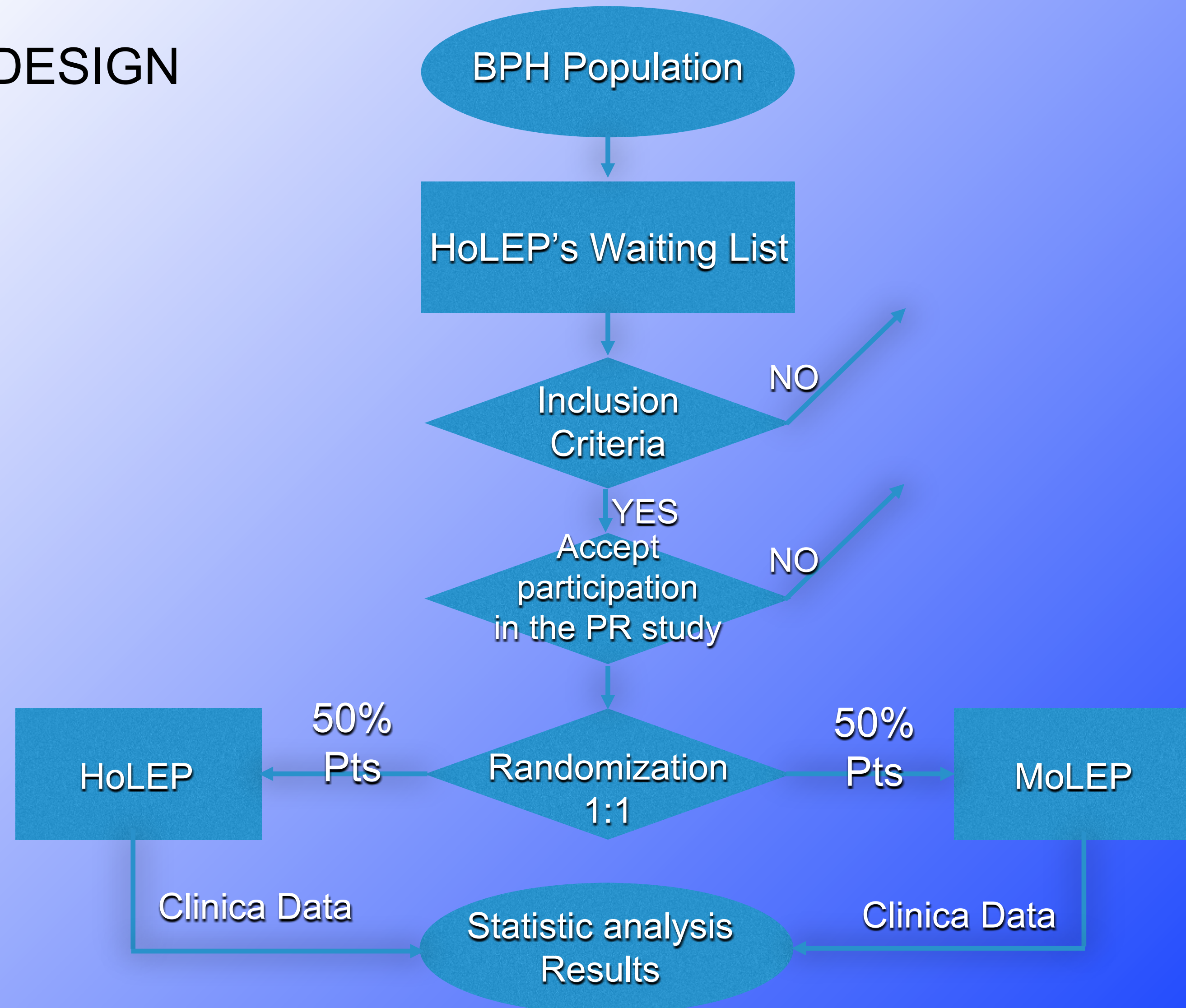
EXCLUSION CRITERIA

- prostate volume of >80 ml
- previous surgery
- untreated UTI
- neurological bladder
- severe cardiovascular disease



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PROTOCOL STUDY DESIGN



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PROTOCOL STUDY DESIGN: Surgical Data

- Single experienced operator - 20 years expertise in HoLEP
- All procedure performed with traditional 3 lobes technique
- Same OR setting (video system, endoscope, morcellation system)
- Same Laser's Power Setting: 2 Joule, 50 Hz
- Just a difference: Holmium Laser with or without Moses Technology

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Characteristics of the Enrolled Population

	Group A HoLEP	Group B MoLEP	P (0.05)
Patients Age	68.5	69	0.33
Prostate Volume	84	85	0.16

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Surgical Data

	Group A HoLEP	Group B MoLEP	P (0.05)
Enucleation Time (mean)	30.5	27.1	0.03
Haemostasis Time	5.9	5.3	0.13
Laser Time (mean)	36.4	31.5	0.01
Morcellation Time	11.7	13.1	0.21
Fiber Consuming (mm)	3.3	2	<0.001

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Perioperative Data

	Group A HoLEP	Group B MoLEP	P (0.05)
Hb Variation	-1.01	-0.95	0.43
Hematocrit Variation	-3.02	-2.89	0.44
Hospital Stay (days)	2.7	2.8	0.32

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Conclusions

This study shows that MoLEP (HoLEP with Holmium laser pulse modied with MOSES™technology [Lumenis®]) has:

- 5 minutes shorter mean laser timing
- laser duration is shorter due to a brief enucleation time
- maintain the safety guaranteed by HoLEP's surgical technique as prooven by similar bleeding, complications and hospital stay.

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Thank You!