

**Rezūm therapy: Outcomes of symptom relief and quality of life in benign prostatic obstruction with three-year followup**

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***Acknowledgements:** The authors are grateful to the administrative teams who supported the prospective registry logistics and follow-up coordination across both centers. Special thanks to all the patients who participated in this study and contributed their time and experiences to further our understanding of Rezūm therapy outcomes.*

**Cite as:** Bitar Siqueira MH, Shprits S, Buksh O, et al. Rezūm therapy: Outcomes of symptom relief and quality of life in benign prostatic obstruction with three-year followup. *Can Urol Assoc J* 2025 December 15; Epub ahead of print. <http://dx.doi.org/10.5489/cuaj.9314>

Published online December 15, 2025

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**ABSTRACT**

**Introduction:** This study evaluated the long-term efficacy and safety of Rezūm water vapor thermal therapy (WVTT) for treating lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). The objective was to assess the durability of symptom relief and sustained LUTS improvement over a three-year followup in a real-world, multicenter cohort.

**KEY MESSAGES**

- Rezūm provides durable improvement in LUTS and quality of life up to 3 years post-treatment.
- Significant reductions were observed in IPSS, IPSS-QoL, PVR, and improvements in Qmax.
- The procedure demonstrates a favorable safety profile, with minimal impact on erectile and ejaculatory function, even in men with median lobe obstruction.

**Methods:** A prospective registry was maintained at two high-volume international centers for men undergoing Rezūm therapy between April 2019 and October 2024. All participants had baseline clinical data recorded, including BPH history, uroflowmetry parameters (peak flow rate [Qmax] and postvoid residual [PVR]), and validated questionnaires (International Prostate Symptom Score [IPSS], IPSS quality of life [QoL], BPH Impact Index [BPHII], International Index of Erectile Function [IIEF-15], and Male Sexual Health Questionnaire for Ejaculatory Dysfunction [MSHQ-EjD]).

**Results:** A total of 712 men with at least one year of followup were analyzed. The mean age was 67.2 years (standard deviation [SD] 8.9), and the average baseline prostate volume was 74.1 cc (SD 34.4). Mean IPSS scores improved from 22 at baseline to 9.8 at 36 months. IPSS QoL scores improved from 4.5 to 1.9. Qmax increased from 8.6 ml/s at baseline to 15 ml/s at 24 months and 12.1 ml/s at 36 months. PVR decreased from 134.9 ml to 38.5 ml. There were no significant changes in IIEF or MSHQ-EjD domains.

**Conclusions:** Rezūm WVT provides significant, durable symptom relief and improved urinary function over three years, with preserved sexual function.

## INTRODUCTION

Benign prostatic hyperplasia (BPH) is a common histological finding in aging men. While BPH itself is not an indication for treatment, it can lead to benign prostatic obstruction (BPO), which may result in lower urinary tract symptoms (LUTS). After the age of 50, 50% to 70% of men experience LUTS, with the prevalence increasing to 80–90% in those over 80 years old. [1]. Also, in a recent systematic review and meta-analysis on the global burden of BPH, it is estimated that the lifetime prevalence at 26.2% [2].

Patients with benign prostatic hyperplasia (BPH) are standardly offered treatments of medication and surgical intervention, with electrosurgical transurethral resection of the prostate (TURP) remaining the most established procedures since its first introduction to the urological community a century ago in 1926 by Maxamillion Stern [3]. Despite its well-researched efficacy, many men remain reluctant to undergo surgery due to its potential impact on sexual function, high degree of retrograde ejaculation occurring in 65% of cases, 5-10% reported erectile dysfunction and high variability in adenoma tissue resection, outcomes durability and retreatment rates amongst urologists [4,5].

Additionally, TURP requires general or spinal anesthesia and typically necessitates a hospital stay of 1–2 days [5]. The procedure carries a 20% risk of significant complications, including urethral stricture, bladder neck contracture, hyponatremia/fluid overload, bladder or surgical capsule perforation, and urinary incontinence. It also has an annual BPH surgical retreatment rate of 1–2% [6].

Over the past decades, several treatment alternatives for LUTS due to benign prostatic enlargement (BPE) or bladder outlet obstruction (BPO) have been introduced, varying in invasiveness and effectiveness [7]. Among these, convective radiofrequency (RF) thermal therapy with the Rezūm system has demonstrated significant and durable improvements in LUTS while preserving sexual function as well as offering a unique MIST treatment for men in urinary retention and with a median lobe [8,9].

Rezūm water vapor thermal therapy (WVTT) achieves its maximum therapeutic effect between 6 weeks and 3 months postoperatively. As such, patient education and realistic expectations are required during counselling [10]. Its notable advantages include a short procedure time, a favorable safety profile, and excellent preservation of sexual function, regardless of age or prostate size [11]. For such reasons, the Rezūm treatment is also a recommended treatment option for medically unfit men who are not able to have general anesthesia [12].

While multiple studies have confirmed the efficacy of Rezūm, further research is needed to assess its long-term outcomes. This study aims to evaluate the clinical outcomes of patients treated with Rezūm WVTT, providing more substantial evidence on the long-term effectiveness of this approach [13].

## METHODS

### Study subjects

This is a retrospective analysis of a prospectively maintained database from two high-volume international centers participating in a real-world registry of WVTT (Rezūm) in Canada and Italy. Institutional ethics board approval was obtained at each center. The cohort comprises patients who underwent Rezūm therapy between April 2019 and October 2024.

### Treatment procedure

The Rezūm water vapour thermal therapy was conducted following the methods outlined in previous studies [14]. Each application of water vapour ablates contiguous regions of the prostatic tissue following the urethra's natural gradient. The number of injections was decided at the surgeons' discretion after analyzing patient's prostatic anatomy. In general, the aim was to provide one treatment for every 1cm length per lateral lobe, followed by dedicated injections for any median lobe (ranging between 1-3 injections depending on the size of the middle lobe). All men were discharged the same calendar day with a 2-way Foley catheter. The duration of catheter drainage varied between 7 to 30 days based on the presence of urinary retention, age of patient, bladder function/contractility and prostate volume/number of injections.

**Bleeding scale**

Intraoperative bleeding was assessed using a standardized 4-point bleeding scale. Grade 1 represented mild bleeding with no impact on visualization and no need for intervention. Grade 2 indicated moderate bleeding that required minor measures such as irrigation or brief cautery, without affecting the completion of the procedure. Grade 3 reflected severe bleeding that impaired visualization and required prolonged cautery or additional hemostatic measures. Grade 4 corresponded to very severe or life-threatening bleeding that necessitated transfusion, surgical takeback, or early termination of the procedure. Bleeding grade was determined intraoperatively by the attending surgeon based on real-time assessment.

**Data collection and outcomes of interest**

Patients were assessed at baseline, 12-, 24-, and 36 months post WVTT, with annual follow-ups thereafter. Evaluations included patient characteristics, prostate volume, International Prostate Symptom Score (IPSS) and its quality of life (QoL) subscale, International Index of Erectile Function (IIEF-15), maximum urinary flow rate (Qmax), post-void residual (PVR). The primary outcome of this study was the long-term effectiveness of Rezūm therapy. Secondary outcomes included the assessment of overall functional and sexual health.

**Statistical analysis**

Patients' characteristics and assessments were reported descriptively. Continuous variables were analyzed using either the Student's t-test or rank sum tests, based on their distribution. Categorical variables were compared using Fisher's exact test. All statistical analyses were performed using Stata 18BE, and a two-sided p-value < 0.05 was considered statistically significant.

**RESULTS**

A total of 712 men with a mean age of 67.2 years (range 61.3–72.9) and median prostate volume of 66 cc (interquartile range 49- 94.8 mL), with 471 (66.1%) exhibiting a median lobe who underwent WVTT between 2019 and 2024 by experienced fellowship trained experts (beyond learning curve). A history of urinary retention with pre-operative catheter was observed in 150 men (21 %). On average, 9.6 injections ( $\pm$  4.3) were administered per procedure for the entire cohort, with a mean procedure duration of 6.5 minutes. A total of 287 patients (40.3) were taking pre-operative alpha blockers, while 108 patients (15.2%) were taking 5AR inhibitors (5ARI). Baseline characteristics are shown in Table 1.

**Functional score**

IPSS significantly decreased from  $22.0 \pm 6.5$  at baseline to  $9.1 \pm 6.1$  at 12 months, with symptom reduction remaining stable at  $9.8 \pm 6.9$  at 36 months (Fig 1A). Baseline IPSS QoL was  $4.5 \pm 1.1$ , improving to  $1.8 \pm 1.2$  at 24 months and maintaining an improvement of

1.9±1.4 at 36 months (Fig 1B). BPHII showed a significant reduction from 7.7±3.4 at baseline to 2.2±2.9 at 12 months and 2.7±2.9 at 36 months.

### **Uroflowmetry**

The Qmax exhibited a notable improvement from 8.6±5.7 mL/s at baseline, peaking at 15.0±6.6 mL/s at 12 months, before slightly declining to 12.1±6.3 mL/s at 36 months (Fig 2A). The mean PVR volume showed a significant reduction, decreasing from 134.9±146.8 mL at baseline to 38.6±52.7 mL at 36 months. The percentage decrease in PVR ranged from -62.5% at 12 months to -69.6% at 36 months, indicating a sustained improvement (Fig 2B).

### **Sexual function**

IIEF-15 at baseline was 40.2±21, showing minor fluctuations at 34.7±20.3 at 12 months and improving to 50.8±19.3 at 36 months (Fig 3A). MSHQ function scores remained stable, from 7.9±3.8 at baseline to 8.9±4.2 at 12 months and 9.2±3.9 at 36 months. MSHQ bother scores showed minimal variation, fluctuating from 2.4±1.7 at baseline to 1.9±1.6 at 1 year and 2.1±1.9 at 36 months, indicating no statistically significant changes in sexual function scores (Fig 3B).

Changes in outcomes from baseline to 12-, 24-, and 36 months follow-up are shown in Table 2.

### **Postoperative outcomes**

At 3-year follow-up after the Rezūm procedure, 34 patients (4.7%) required additional surgical intervention: 20 (2.8%) underwent GreenLight photovaporization, 6 (0.8%) underwent TURP, 3 (0.4%) had a repeat Rezūm, 2 (0.3%) underwent prostatic artery embolization (PAE), and 1 patient each (0.1%) underwent TIND, ThuLEP, or HoLEP. Additionally, 27 patients (6.8%) were unable to discontinue BPH medications. Urinary retention in patients who were already catheter-dependent prior to the Rezūm procedure occurred in only 6 patients (4.0%), all of whom required either clean intermittent catheterization (CIC) or a Foley catheter.

## **DISCUSSION**

Water vapor thermal therapy (WVTT) has seen exponential growth in recent years due to its fewer complications, shorter hospital stays, and superior overall safety compared to transurethral resection of the prostate (TURP) [15]. Additionally, most adverse effects associated with WVTT are transient, with a Clavien-Dindo classification of <3, and its minimal impact on erectile function and ejaculatory capacity makes it an appealing option for sexually active patients [16]. Furthermore, early outcomes demonstrate significant improvements in urinary function for patients undergoing this procedure [17] also in a wider spectrum of indications [18,19]. However, the long-term efficacy of Rezūm remains a topic of discussion among specialists and patients

Our study analyzes the outcomes up to three years post-procedure, demonstrating stable improvements in uroflow parameters over time. Similar findings were reported in a study with the same follow-up period, where Qmax improved from a baseline of  $10.0 \pm 2.2$  to  $14.7 \pm 6.1$  at two years and  $13.2 \pm 4.8$  at three years. Additionally, post-void residual volume (PVR) decreased from a baseline of  $82.4 \pm 51.8$  mL to  $55.1 \pm 61.9$  mL after three years [20]. Moreover, several studies have highlighted that the efficacy of Rezūm extends beyond uroflow parameters, demonstrating significant improvements in urodynamic measures such as bladder capacity, voiding efficiency, and bladder outlet obstruction [21,22].

Interestingly, a high percentage of our patients (66.8%) presented with an obstructing median lobe. Rezūm has proven to be an effective and minimally invasive treatment option even for patients with median lobe obstruction, providing significant improvements in both urinary and sexual function. According to Campobasso et al. (2023), the presence of a median lobe does not negatively impact outcomes after Rezūm, supporting its use in patients with obstructive trilobar anatomy [23]. A retrospective analysis of a multiethnic population treated with Rezūm at a single center between 2017 and 2019, with a four-year follow-up, demonstrated significant improvements in IPSS and IPSS QoL, regardless of age or ethnicity [24]. Also, one of the longest randomized studies on Rezūm patients showed that IPSS scores remained consistently improved over time, with a nearly 48% reduction (mean $\pm$ SD,  $11.1 \pm 7.8$ ) from baseline at five years [25].

Similarly, the IPSS QoL score showed sustained improvement, decreasing from a baseline mean $\pm$ SD of  $4.4 \pm 1.1$  to  $2.3 \pm 1.5$  at three months, and further to  $2.2 \pm 1.4$ , representing a 45% reduction at five years [25]. Our findings align with this trend, as IPSS significantly decreased from  $22.0 \pm 6.5$  at baseline to  $9.8 \pm 6.9$  at three years. Additionally, baseline IPSS QoL improved from  $4.5 \pm 1.1$  to  $1.9 \pm 1.4$  at three years.

A recent study comparing erectile dysfunction (ED) at 48 months in two cohorts of patients who underwent Rezūm found that the cohort without ED experienced no significant changes in any IIEF domains, while the ED cohort showed a significant 30% increase in erectile function ( $P = .01$ ) [26]. Additionally, a systematic review analyzing 47 studies reported that Rezūm had a minimal impact on sexual function, with IIEF score changes ranging from -1% to -3% [27].

In our study, no significant differences were found in ejaculation rates as measured by MSHQ-EjD function scores. However, previous studies have associated improved ejaculation both scores with significant improvement at 12- and 24-months post-treatment [28]. Likewise, a study of 197 patients with a five-year follow-up demonstrated sustained ejaculation preservation, with no significant differences in function or bother scores over time [29].

This study is a retrospective review of prospectively collected data, which inherently carries several limitations, including potential selection bias, missing data, and

the inability to fully adjust for confounding variables. A significant limitation is the notable loss to follow-up, particularly among patients who traveled long distances or returned to their primary urologists for ongoing care. This is especially evident in the uroflowmetry data (Qmax), where follow-up at three years was limited, likely due to challenges patients faced in returning for in-clinic testing.

Additionally, the lack of a control group or direct comparison to other treatment modalities limits the ability to contextualize the effectiveness of Rezūm relative to alternative therapies. While the study provides valuable insight into outcomes up to three years post-procedure, its ability to speak to the long-term durability of Rezūm. Another important limitation is the lack of data on PSA outcomes, which are relevant for evaluating treatment response and disease progression. Furthermore, the analysis does not stratify results by prostate size or the presence of a median lobe—factors that may significantly impact both the effectiveness and durability of the Rezūm procedure.

## CONCLUSIONS

Rezūm water vapor thermal therapy provides sustained improvements in urinary symptoms and quality of life while preserving sexual function. The procedure demonstrates a favorable safety profile with minimal impact on erectile function and ejaculation. However, while mid-term results are promising, further studies are needed to assess its long-term durability beyond five years.

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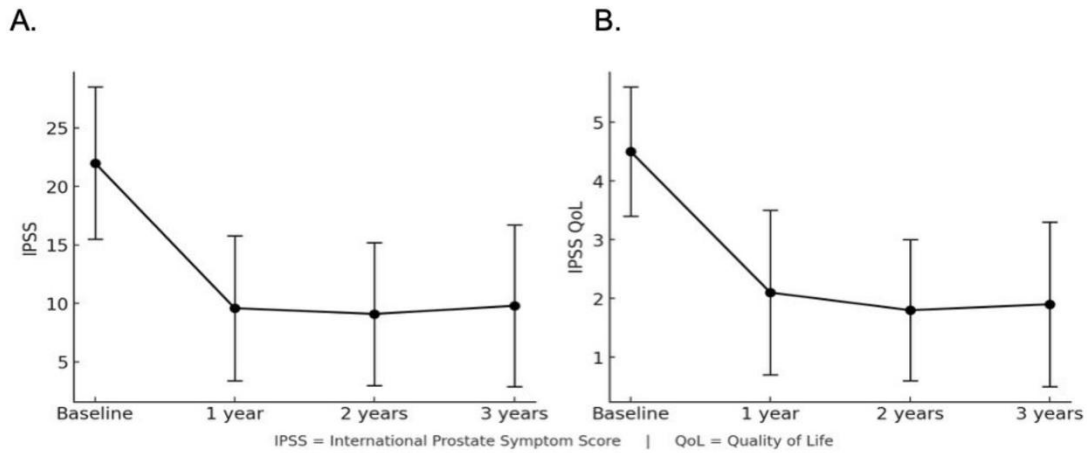
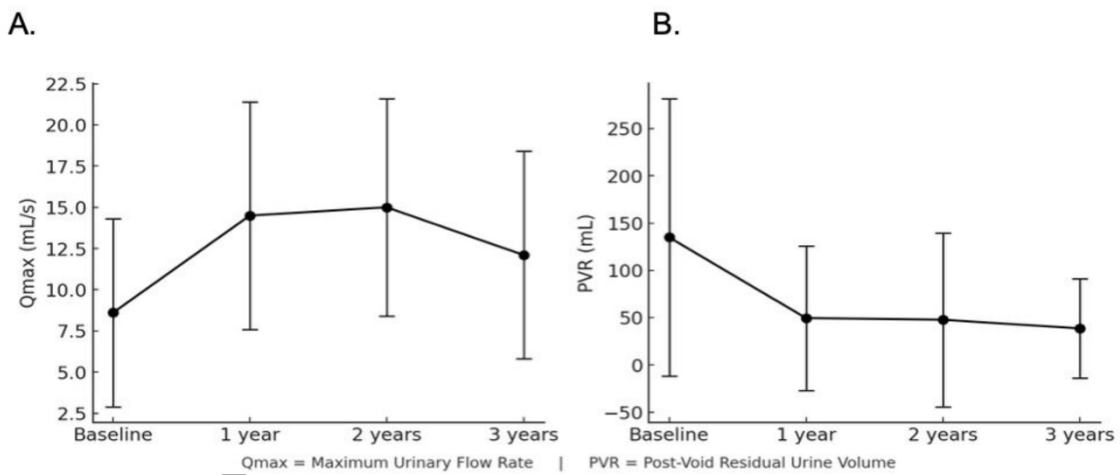
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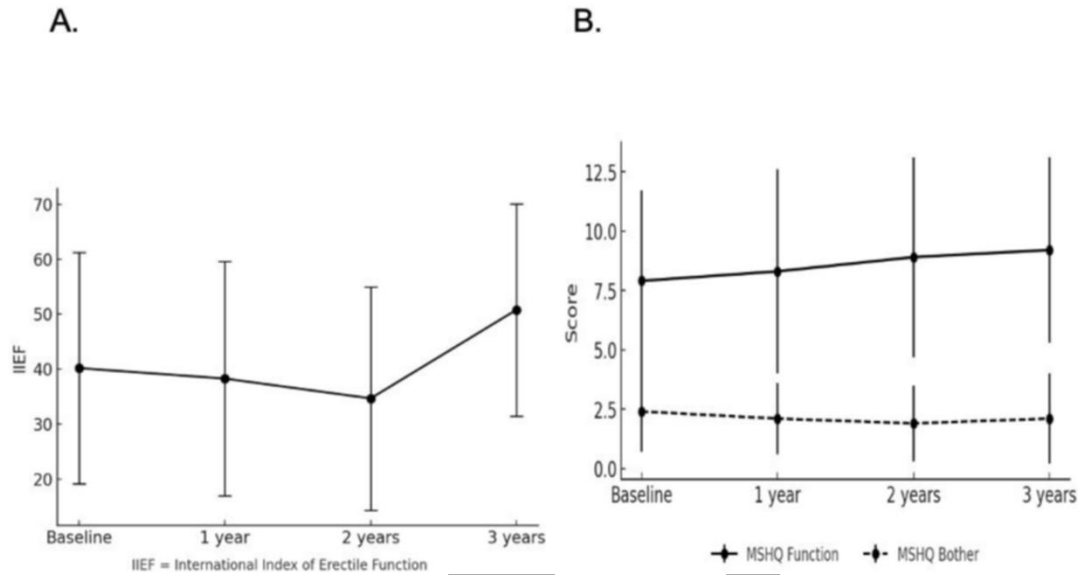
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*Disclosures: Dr. Elterman and Dr Zorn are consultant/investigator for Boston Scientific, Procept Biorobotics, Olympus, Urotronic, Prodeon, and Zenflow. Dr. Chughtai is a consultant for Boston Scientific, Olympus, and investigator for Teleflex and Abbvie. Dr. Bhojani is a consultant/investigator for Boston Scientific, Procept BioRobotics, and Olympus. Other authors have no potential conflicts of interest to disclose. Boston Scientific funded the Rezum International Registry*

## FIGURES AND TABLES

**Figure 1.** (A) International prostate symptom score (IPSS) and (B) IPSS quality of life (QoL scores) (95% confidence interval) over time.**Figure 2.** (A) peak urinary flow (Qmax) and (B) post-void residual (PVR) volume (95% confidence interval) over time.

**Figure 3.** (A) International index of erectile function (IIEF-15) and B) Make Sexual Health Questionnaire for Ejaculatory dysfunction (MSHQ-EjD) scores (95% confidence interval) over time.



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<b>Table 1. Baseline characteristics</b>	
<b>Characteristics</b>	<b>Values</b>
Age at Rezūm (years)	
Mean	67.2 (8.9)
Median (Q1–Q3)	67.4 (61.3–72.9)
Range (min–max)	17–100.7
Median lobe (n, %)	471 (66.1%)
Hypertension (n, %)	186 (26.1%)
Diabetes (n, %)	50 (7%)
Baseline prostate volume (mL)	
Mean	74.1 (34.4)
Median (Q1–Q3)	66.0 (49.0–94.8)
Range (min–max)	16.9–271.0
Chronic retention using foley catheter (n, %)	83 (11.7%)
Current medication	
Alpha-blockers (n, %)	287 (40.3%)
5-ARI inhibitors (n, %)	178 (25.0%)
Anticoagulants or antiplatelet use (n, %)	108 (15.2%)
<b>Procedural characteristics</b>	
Total number of vapor injections	
Mean (n)	9.6 (4.3)
Median (Q1–Q3)	9.0 (6.0–13.0)
Range	2–28
Scope in/out time (minutes)	
Mean	6.5 (23.9)
Median (Q1–Q3)	4.0 (3.0–6.0)
Range	0–600
Bleeding scale (1–4)	
Mean	1.1 (0.3)
Median (Q1–Q3)	1.0 (1.0–1.0)
Range	1–4

5-ARI: 5-alpha reductase inhibitor; IQR: interquartile range.

<b>Table 2. Changes in outcomes from baseline to 12-, 24-, and 36-month followup</b>					
<b>Measure</b>		<b>Baseline</b>	<b>12 months</b>	<b>24 months</b>	<b>36 months</b>
PVR	n	598	262	114	18
	Baseline	134.9±146.8	131.9±136.3	115.1±126.3	127±65.8
	Followup		49.5±76.2	47.8±91.9	38.6±52.7
	Change		-82.4±123.1	-67.3±111.1	-88.4±64.1
	% change		-62.5	-58.4	-69.6
	p		<0.001	<0.001	<0.001
QMax	n	584	139	103	17
	Baseline	8.6±5.7	8.7±7.2	8.8±7.9	8.4±3.7
	Followup		14.5±6.9	15±6.6	12.1±6.3
	Change		5.8±9.4	6.2±10	3.7±7.3
	% change		66.4	70.9	43.7
	p		<0.001	<0.001	0.066
IPSS	n	627	335	207	64
	Baseline	22±6.5	22.1±6.4	22±6.1	22.5±6.1
	Followup		9.6±6.2	9.1±6.1	9.8±6.9
	Change		-12.4±7.9	-12.9±7.7	-12.7±7.9
	% change		-56.3	-58.6	-56.4
	p		<0.001	<0.001	<0.001
IPSS QoL	n	627	334	207	64
	Baseline	4.5±1.1	4.5±1.1	4.4±1.1	4.4±1.1
	Followup		2.1±4	1.8±1.2	1.9±1.4
	Change		-2.4±4	-2.6±1.5	-2.5±1.6
	% change		-54.1	-59.6	-57.4
	p		<0.001	<0.001	<0.001
IIEF	n	552	243	156	40
	Baseline	40.2±21	37.6±21.4	33.2±21.1	46.5±20.7
	Followup		38.3±21.3	34.7±20.3	50.8±19.3
	Change		0.7±11.7	1.5±10.6	4.3±16.6
	% change		1.9	4.5	9.2
	p		0.028	0.006	0.264
MSHQ Function	n	426	136	70	35
	Baseline	7.9±3.8	8.5±3.7	8.7±3.8	8.6±3.8
	Followup		8.3±4.3	8.9±4.2	9.2±3.9
	Change		-0.2±4.4	0.2±4.6	0.5±5.4
	% change		-2.7	1.8	6.3
	p		0.722	0.864	0.574

MSHQ Bother	n	425	134	70	35
	Baseline	2.4±1.7	2.3±1.7	2.2±1.7	2.5±1.8
	Followup		2.1±1.5	1.9±1.6	2.1±1.9
	Change		-0.2±2	-0.3±2.1	-0.3±2.3
	% change		-8.1	-14.1	-12.8
	p		0.377	0.223	0.474
BPHII	n	489	210	105	51
	Baseline	7.7±3.4	7.4±3	7.4±3.1	7.6±2.7
	Follow up		2.9±2.9	2.2±2.9	2.7±2.9
	Change		-4.6±3.5	-5.1±3.5	-4.8±3.2
	% Change		-61.4	-69.8	-63.8
	p-value		<0.001	<0.001	<0.001

BPHII: Benign Prostatic Hyperplasia Impact Index; IIEF-15: International Index of Erectile Function; IPSS: International Prostate Symptom Score; MSQH-EjD: Male Sexual Health Questionnaire for Ejaculatory Dysfunction; PVR: postvoid residual volume; Qmax: peak urinary flow; QoL: quality of life; SD: standard deviation.

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