

Long-term outcomes after treatment with Optilume BPH: Four-year results from the EVEREST study

Steven A. Kaplan¹, Merycarla Pichardo², Edwin Rijo³, Gustavo Espino⁴, Ramon Rodriguez Lay⁵, Rafael Estrella⁶

¹Department of Urology, Icahn School of Medicine at Mount Sinai, New York City, NY, United States; ²URUS, Santo Domingo, Dominican Republic; ³Centro Médico Dr. Canela SRL, La Romana, Dominican Republic; ⁴Centro Especializado San Fernando, Panama City, Panama; ⁵Edificio Royal Center, Panama City, Panama; ⁶Clínica Unión Medica, Santiago de los Caballeros, Dominican Republic

Acknowledgments: This study was funded by Urotronic, Inc, the manufacturer of the Optilume BPH Catheter System.

Cite as: Kaplan SA, Pichardo M, Rijo E, et al. Long-term outcomes after treatment with Optilume BPH: Four-year results from the EVEREST study. *Can Urol Assoc J* 2024 June 17; Epub ahead of print. <http://dx.doi.org/10.5489/cuaj.8737>

Published online June 17, 2024

Corresponding author: Dr. Steven A. Kaplan, Department of Urology, Icahn School of Medicine at Mount Sinai, New York City, NY, United States; steven.kaplan@mountsinai.org

ABSTRACT

Introduction: The purpose of this study was to gather initial safety and efficacy data with the Optilume BPH Catheter System for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

Methods: A total of 80 men with moderate-to-severe LUTS secondary to BPH were enrolled and treated with the

Optilume BPH Catheter System. Symptoms were evaluated using the International Prostate Symptom Score (IPSS) and Benign Prostatic Hyperplasia Impact Index (BPHII). Improvement in urinary flow and relief of obstruction was evaluated by way of peak urinary flow rate (Qmax) and postvoid residual urine volume (PVR). Subjects were prospectively queried for adverse

KEY MESSAGES

- Symptomatic and function improvements were maintained through four years in men with LUTS secondary to BPH treated with Optilume BPH.
- Improvement was seen in both storage and voiding symptoms
- No late-onset device complications or impact on sexual function.

events at each study visit, and relatedness to the study device were evaluated by the investigators, as well as centrally adjudicated by the study principal investigator.

Results: Previous reports of symptom improvement in this cohort were maintained through four-year followup, with a significant reduction in IPSS and IPSS quality of life maintained through four years (-12.1, -2.8, respectively). Clinically meaningful improvement in Qmax was maintained in the majority of subjects, with an average improvement from baseline of +5.6 mL/sec. No treatment-related adverse events were reported in the long-term followup period.

Conclusions: Long-term followup through four years for subjects treated with the Optilume BPH Catheter System indicates durable outcomes in symptom improvement and functional improvement in flow rate. These results indicate the unique mechanism of action for Optilume BPH successfully achieves an immediate mechanical effect that is maintained long-term through incorporation of paclitaxel to maintain patency.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a prevalent condition in the aging male characterized by a non-malignant enlargement of the prostate gland. Prostatic enlargement is typically accompanied by lower urinary tract symptoms (LUTS) that increase in frequency and severity with age.¹ These LUTS represent a significant burden to patient quality of life as they increase in severity. Generally, LUTS can be divided into those symptoms that are associated with storage of urine such as urgency and frequency and those associated with voiding/emptying such as weak stream and incomplete emptying. Identifying the primary cause of LUTS and the optimal treatment algorithm can be a complex undertaking whereby storage symptoms may be secondary to bladder outlet obstruction (BOO) or may be due to underlying instability/dysfunction of the detrusor and overactive bladder (OAB) or other factors.

The basic management of LUTS necessitates an initial evaluation to identify contributing factors and rule out differential diagnoses (e.g. UTI). For patients with mixed storage and voiding symptoms, pressure/flow urodynamic studies may be helpful in differentiating between predominantly obstructive or predominantly irritative etiologies and inform the appropriate treatment pathway. For patients with confirmed BOO, typical management is characterized initially by lifestyle modifications, with step-up therapy to medical management where necessary. Although medical management has been a mainstay of therapy for decades, increasing attention is being paid to the high rate of patient discontinuation due to side effects and potential for long-term complications from life-long usage.² Patients with symptoms refractory to medical management have historically been managed by the gold-standard surgical therapy of transurethral resection of the prostate (TURP).³ TURP has been shown to consistently deliver significant improvement in symptoms and urinary flow rate post-procedure, however dissatisfaction with the invasiveness and morbidity associated with the procedure have led to the

development of a plethora of minimally invasive surgical therapies (MISTs).^{4,5} These MIST devices have been shown to improve symptoms, and to a lesser extent flow rate, while delivering a more tolerable procedure in an ambulatory setting and without the side-effects such as retrograde ejaculation typically associated with TURP.⁶⁻⁹

The Optilume[®] BPH Catheter System (Urotronic, Inc., Plymouth, MN, USA) is a minimally invasive drug-coated balloon dilation system that allows for mechanical dilation and achievement of an anterior commissurotomy with concurrent circumferential delivery of paclitaxel drug to the dilated area. A randomized, sham-controlled trial has recently been reported that showed significant and sustained improvements in symptoms and flow rate compared to a sham procedure through 1 year.¹⁰ The EVEREST study is a first-in-human study evaluating outcomes after treatment with Optilume BPH in a cohort of 80 men with moderate-to-severe LUTS secondary to BPH. Initial experience with Optilume BPH has been reported for this cohort through 2 years.^{11,12} This report includes results through 4 years of post-procedural follow-up.

METHODS

Study design and participants

The EVEREST study (NCT03423979) is a prospective, single-arm, open label, multicenter clinical study conducted at six centers in the Dominican Republic and Panama. The ethics committee for each center provided review and approval of the study prior to study initiation, and all subjects provided written informed consent prior to participation in the study. Inclusion criteria included men 50 years of age or older, an International Prostate Symptom Score (IPSS) ≥ 13 , peak urinary flow rate (Qmax) 5-15 mL/sec with minimum voided volume of ≥ 125 mL, post-void residual (PVR) urine volume ≤ 250 mL, prostate volume 20-80 grams, and prostatic urethra length 35-55 mm. Patients with prior minimally invasive or surgical interventions, intravesical protrusion > 1 cm, and confounding urologic conditions were excluded. Medication washouts prior to treatment included 6 months for 5-ARIs and 3 weeks for alpha blockers. Transrectal ultrasound (TRUS) was performed to determine prostate dimensions.

The Optilume BPH Catheter System has been described in previous publications.¹⁰⁻¹² Briefly, Optilume BPH is a novel minimally invasive surgical therapy that combines mechanical dilation with the delivery of paclitaxel to treat LUTS secondary to BPH. Mechanical dilation with Optilume BPH achieves an anterior commissurotomy separating the lateral lobes of the prostate, while paclitaxel delivery is intended to maintain luminal patency during healing. A Foley catheter is placed for at least 2 days post-procedure.

After the procedure, follow-up assessments were conducted at 1 month, 3 months, 6 months, 1 year, and annually through 4 years. Assessments included self-administered questionnaires including the International Prostate Symptom Score (IPSS), the BPH Impact Index (BPH-II), the International Index of Erectile Function (IIEF), and the Mens Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD). Post-void residual urine volume and

uroflowmetry were measured at each visit, with a minimum voided volume of ≥ 125 mL needed for a valid reading.

Study endpoints and statistical methodology

The prespecified, hypothesis tested primary and secondary endpoints for this study were planned at 3 months follow-up and reported previously.¹¹ Sample size for the study was based on the primary endpoint analysis at 3 months. Primary endpoints for long-term follow-up included functional assessments and symptomology. Continuous outcomes were summarized using descriptive statistics and categorical variables summarized with frequencies and proportions. Changes from baseline were evaluated using a 2-sided Student's paired t-test with $p < 0.05$ indicating statistical significance. Primary data is reported from the intent-to-treat population, with no imputation for missing data. A sensitivity analysis was conducted utilizing the last observation carried forward (LOCF) methodology for missing data.

Symptomatic responders to treatment were defined as those experiencing a $\geq 30\%$ improvement in IPSS from baseline to the 4-year follow-up. Symptom scores were further broken into storage (frequency, urgency, nocturia) and voiding (straining, weak stream, intermittency, incomplete emptying) domains. Due to the imbalanced contribution of these domains to the total IPSS score based on the number of questions included in each sub-domain, a mean storage and voiding sub-score was calculated on a scale of 0 (no symptoms) to 5 (greatest symptoms) as described by Barry et al.¹³

Safety was assessed by the type and rate of adverse events (AEs) which were adjudicated by the study principal investigator. Sexual function was evaluated using the Male Sexual Health Questionnaire-Ejaculatory Dysfunction (MSHQ-EjD) questionnaire and the International Index of Erectile Function (IIEF).

RESULTS

Of the 80 men enrolled between December 2017 and February 2019, 59 were evaluable at 4 years. Reasons for missing data included 10 subjects with a missed visit, and 11 early exits. The 11 early study exits included 4 deaths due to non-study related causes (bowel obstruction, covid, 2 cerebrovascular accident), 3 subjects lost to follow-up, 1 subject withdrawing consent, 1 subject who received a prostatectomy due to refractory hematuria with an onset at 18 months, 1 subject with prostate cancer, and 1 subject who withdrew due to an adverse event.

Functional and symptomatic response

Symptoms improved significantly post-treatment and that improvement was maintained through 4 years of follow-up (Table 2). Improvement was seen in both storage and voiding sub-scores, however the improvement was greatest in the voiding domain with approximately 2/3rds of the overall improvement seen in the voiding domain. Maximal improvement in the voiding domain was achieved immediately post-procedure, while maximal improvement in the storage domain was achieved approximately 6 months post-procedure. No differences were noted in IPSS

improvement from baseline to 4 years when comparing the As Observed to the LOCF methodology for missing data (12.1 vs 12.6).

Forty-six (46) of the 59 evaluable subjects at 4 years were symptomatic responders (78.0%, 95%CI 65.3% - 87.7%). Non-responders showed a much smaller improvement in storage symptoms immediately post-procedure as compared to responders (Figure 2). There was no difference in average prostate size or baseline symptom scores (total or sub-scores) for non-responders. Three subjects underwent additional treatment; 2 subjects re-initiated BPH medications and one aforementioned subject underwent a prostatectomy procedure. Conservatively treating the prostatectomy for refractory hematuria as a surgical retreatment, the overall surgical retreatment rate through 4 years remained low at 1.3%. Statistically significant improvements were observed in both quality-of-life measures. The mean IPSS QOL improved from 4.6 at baseline to 1.3 at 1 year and 1.8 at 4-years ($p<0.001$). The BPH Impact Index improved from 6.9 at baseline to 2.0 at 1 year and 2.9 at 4 years ($p<0.001$).

Peak flow rate increased significantly from an average of 10.9 mL/sec at baseline to 17.2 mL/sec at 4 years ($p<0.001$). The majority of patients experienced a clinically meaningful increase in Qmax of at least +2 mL/sec. The paired change in Qmax values from 3 to 4 years was minimal (avg paired change +1.2 mL/sec), indicating stability in Qmax values during long-term follow-up. PVR was reduced from 63.1 mL at baseline to 49.0 mL at 4 years ($p=0.656$).

Safety

A total of 136 AEs were reported in 56 subjects through 4 years. The majority of events (64%, 86/135) occurred within 3 months of the treatment procedure, with only 17 events occurring between 24 and 48 months, none of which were treatment related. Serious adverse events occurring between 24 and 48 months included 4 non-study related SAEs, including cerebrovascular accident, COVID-19, heart failure, and larynx cancer. None of these SAEs were deemed to be related to the Optilume BPH Catheter System.

Sexual function as measured by the IIEF and MSHQ-EjD was preserved at 4 years as there was no statistically significant change in any measure at 4 years (Table 3). There were no device or procedure related adverse events related to erectile dysfunction.

DISCUSSION

Early experience with this cohort of patients treated with the Optilume BPH Catheter System has been promising, showing excellent increases in flow rate and symptom improvement.^{11, 12} This experience was corroborated with outcomes from a randomized, sham controlled trial reporting significant increases in flow rate and durable symptom improvement through 1 year post treatment when compared to a sham procedure.¹⁰ This report represents the first long-term follow-up for patients treated with Optilume BPH, with follow-up through 4 years.

The ultimate goal of a MIST is to provide functional and symptomatic improvement to a similar degree and durability as more invasive surgical options, while concurrently reducing the risk profile and increasing tolerability and speed of recovery. Optilume BPH appears to address

these goals, providing functional flow improvements that approach that of TURP with a simple, outpatient procedure that appears to be well tolerated.^{10, 14} The current report supports that the significant improvements in flow and symptomology seen post-treatment are maintained through at least 4 years of follow-up. Clinically meaningful improvement in IPSS was maintained in 78% of patients, with an average improvement of 12.1 points (55%) from baseline through 4 years. Flow rate improvements were also maintained through 4 years, with an average peak flow rate of 17.2 mL/sec (+5.6 mL/sec vs baseline). These outcomes compare favorably with long-term outcomes reported with other MISTs.¹⁵⁻¹⁷

Interestingly, although improvement was seen in both the storage and voiding sub-scores of the IPSS tool in the entire cohort, those subjects that did not meet the criteria for being symptomatic responders (overall IPSS improvement $\geq 30\%$) appeared to have significantly lower improvement in the storage sub-score. This may indicate potentially confounding detrusor overactivity or other irritative etiology that was not solely due to underlying bladder outlet obstruction contributing to the unresolved symptomology. Although the guidelines only recommend pressure/flow urodynamic studies in the setting of diagnostic uncertainty, these studies provide invaluable insight into treatment pathways and setting expectations for patients regarding outcomes and are particularly helpful in the setting of mixed OAB/BOO symptomology.

Given the nature of the study as a feasibility study designed to gather initial safety and efficacy data on the Optilume BPH Catheter System, no comparator group was included in the study design. Although the lack of control group represents an important limitation to the results presented herein, a randomized, sham-controlled study evaluating Optilume BPH against a sham procedure reported similar outcomes of IPSS improvement and confirmed the impressive improvements in flow rate through 1 year of follow-up.¹⁰ Other limitations include the reduced number of subjects reporting outcomes during the long-term follow-up period (59/80, 74%). This limitation was mitigated by the incorporation of a sensitivity analysis evaluating the full cohort utilizing a LOCF methodology, which showed minimal differences in the reported outcomes when including the last known status of each patient.

CONCLUSIONS

The Optilume BPH Catheter System represents a unique modality among MISTs, combining mechanical and pharmaceutical aspects for the treatment of BPH. Long-term results appear to support the mechanism of an immediate functional improvement by way of creating an anterior commissurotomy and a sustained anatomic result due to the application of paclitaxel to the prostatic urethra during the dilation. The functional and symptomatic improvements seen after treatment with Optilume BPH are significant and have been sustained through 4 years in this early feasibility study.

REFERENCES

1. Lerner LB, McVary KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline part I-initial workup and medical management. *J Urol* 2021;206:806-17. <https://doi.org/10.1097/JU.0000000000002183>
2. Bortnick EM, Simma-Chiang V, Kaplan SA. Long-term consequences of medical therapy for benign prostatic hyperplasia. *Rev Urol* 2019;21:154-7.
3. Yu X, Elliott SP, Wilt TJ, et al. Practice patterns in benign prostatic hyperplasia surgical therapy: The dramatic increase in minimally invasive technologies. *J Urol* 2008;180:241-5; discussion 5. <https://doi.org/10.1016/j.juro.2008.03.039>
4. Lerner LB, McVary KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline part ii-surgical evaluation and treatment. *J Urol* 2021;206:818-26. <https://doi.org/10.1097/JU.0000000000002184>
5. Elterman D, Aube-Peterkin M, Evans H, et al. Update - Canadian Urological Association guideline: Male lower urinary tract symptoms/benign prostatic hyperplasia. *Can Urol Assoc J* 2022;16:245-56. <https://doi.org/10.5489/cuaj.7906>
6. Chughtai B, Elterman D, Shore N, et al. The itind temporarily implanted nitinol device for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: A multicenter, randomized, controlled trial. *Urology* 2021;153:270-6. <https://doi.org/10.1016/j.urology.2020.12.022>
7. McVary KT, Gange SN, Gittelman MC, et al. Minimally invasive prostate convective water vapor energy ablation: A multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol* 2016;195:1529-38. <https://doi.org/10.1016/j.juro.2015.10.181>
8. Roehrborn CG, Gange SN, Shore ND, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: The L.I.F.T. Study. *J Urol* 2013;190:2161-7. <https://doi.org/10.1016/j.juro.2013.05.116>
9. Roehrborn CG, Preminger G, Newhall P, et al. Microwave thermotherapy for benign prostatic hyperplasia with the dornier urowave: Results of a randomized, double-blind, multicenter, sham-controlled trial. *Urology* 1998;51:19-28. [https://doi.org/10.1016/S0090-4295\(97\)00571-2](https://doi.org/10.1016/S0090-4295(97)00571-2)
10. Kaplan SA, Moss J, Freedman S, et al. The pinnacle study: A double-blind, randomized, sham-controlled study evaluating the optilume bph catheter system for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol* 2023;210:500-9. <https://doi.org/10.1097/JU.0000000000003568>
11. Kaplan SA, Pichardo M, Rijo E, et al. One-year outcomes after treatment with a drug-coated balloon catheter system for lower urinary tract symptoms related to benign

- prostatic hyperplasia. *Prostate Cancer Prostatic Dis* 2021;24:1073-9. <https://doi.org/10.1038/s41391-021-00362-z>
12. Pichardo M, Rijo E, Espino G, et al. Durable benefit after treatment of obstructive benign prostatic hyperplasia with a novel drug-device combination product: 2-year outcomes from the everest-i study. *World J Urol* 2023;41:2209-15. <https://doi.org/10.1007/s00345-023-04473-1>
 13. Barry MJ, Williford WO, Fowler FJ, Jr., et al. Filling and voiding symptoms in the american urological association symptom index: The value of their distinction in a veterans affairs randomized trial of medical therapy in men with a clinical diagnosis of benign prostatic hyperplasia. *J Urol* 2000;164:1559-64. [https://doi.org/10.1016/S0022-5347\(05\)67028-0](https://doi.org/10.1016/S0022-5347(05)67028-0)
 14. Gilling P, Barber N, Bidair M, et al. Water: A double-blind, randomized, controlled trial of aquablation((r)) vs transurethral resection of the prostate in benign prostatic hyperplasia. *J Urol* 2018;199:1252-61. <https://doi.org/10.1016/j.juro.2017.12.065>
 15. Roehrborn CG. Prostatic urethral lift: A unique minimally invasive surgical treatment of male lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Urol Clin North Am* 2016;43:357-69. <https://doi.org/10.1016/j.ucl.2016.04.008>
 16. Amparore D, Fiori C, Valerio M, et al. 3-year results following treatment with the second generation of the temporary implantable nitinol device in men with luts secondary to benign prostatic obstruction. *Prostate Cancer Prostatic Dis* 2021;24:349-57. <https://doi.org/10.1038/s41391-020-00281-5>
 17. McVary KT, Rogers T, Roehrborn CG. Rezum water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. *Urology* 2019;126:171-9. <https://doi.org/10.1016/j.urology.2018.12.041>

FIGURES AND TABLES

Figure 1.

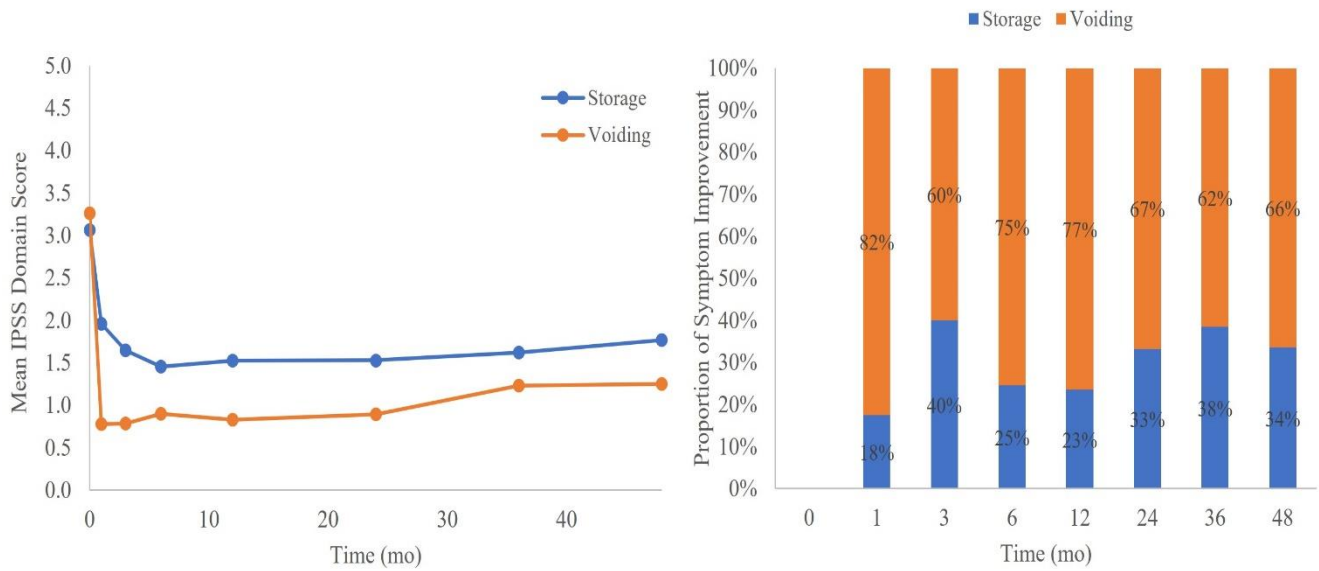


Figure 2.

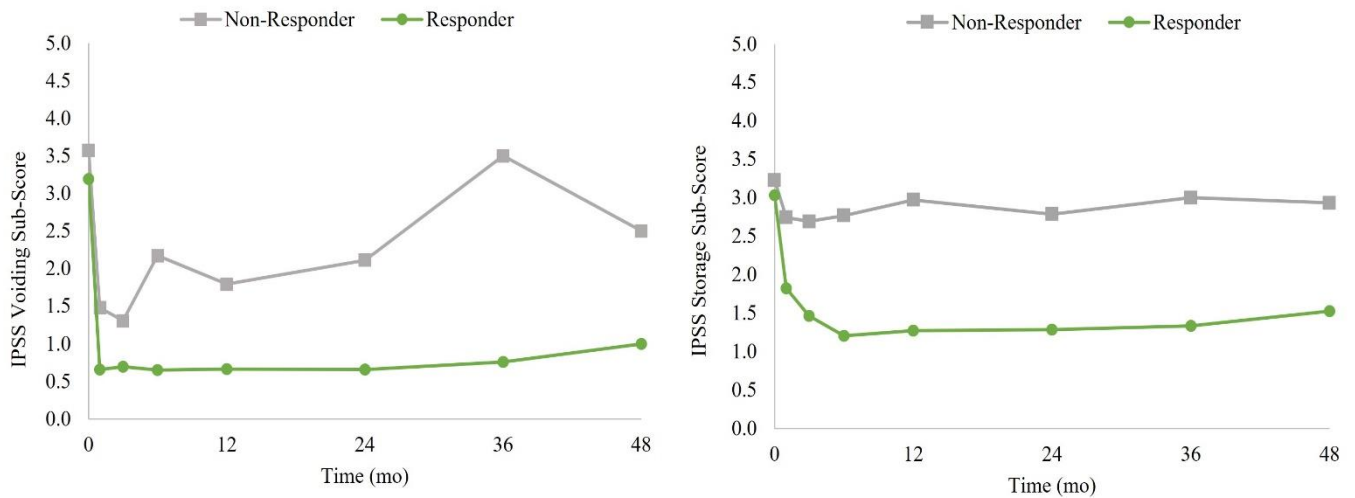


Table 1. Subject demographics and baseline characteristics	
Characteristic	Mean (SD, range) N=80
Age (years)	65.8 (7.82, 52–87)
Race/ethnicity, n/N (%)	
Black or African origin	10/80 (12.5%)
Caucasian	2/80 (2.5%)
Hispanic or Latino	68/80 (85.0%)
History of incontinence, n/N (%)	2/80 (2.5%)
Genitourinary history, n/N (%)	
Erectile dysfunction	6/80 (7.5%)
Kidney stone	1/80 (1.3%)
Urinary tract infection	2/80 (2.5%)
Prostate volume, g	35.9 (13.2, 20.9–77.0)
Intravesical prostatic protrusion, n/N (%)	10/80 (12.5%)
PSA (ng/mL)	3.01 (2.98, 0.24–14.39)
IPSS	22.3 (4.9, 14–35)
Moderate (IPSS ≤18), n/N (%)	20/80 (25%)
Severe (IPSS ≥19), n/N (%)	60/80 (75%)
IPSS QoL	4.6 (0.86, 1–6)
Qmax (mL/sec)	10.9 (2.9, 5–15)
PVR (mL)	63.1 (55.0, 0–225)

IPSS: International Prostate Symptom Score; PSA: prostate-specific antigen; PVR: postvoid residual; Qmax: peaks flow rate; QoL: quality of life; SD: standard deviation.

Measure	Baseline	3-month	6-month	1-year	2-year	3-year	4-year
IPSS							
n	80	79	77	75	68	63	59
Mean ± SD	22.3±4.9	8.1±6.1	8.0±7.2	7.9±7.6	8.2±7.3 ^a	9.8±8.0 ^a	10.3±8.0 ^a
Change		-14.2±7.0	-14.4±7.7	-14.4±7.8	-14.4±6.4	-12.7±7.9	-12.1±8.5
% change		63.0	64.0	64.9	65.3	56.8	54.5
IPSS QOL							
n	80	79	77	75	68	63	59
Mean ± SD	4.6±0.9	1.5±1.3	1.6±1.6	1.3±1.4	1.6±1.6 ^a	1.8±1.7 ^a	1.7±1.8 ^a
Change		-3.1±1.6	-3.0±1.9	-3.3±1.5	-3.0±1.7	-2.7±1.9	-2.8±1.0
BPH Impact Index							
n	80	79	77	75	68	63	58
Mean ± SD	6.9±3.0	3.4±3.4 ^a	2.6±3.3 ^a	2.0±3.1 ^a	2.3±3.5 ^a	2.7±3.6 ^a	2.9±3.9 ^a
Change		-3.5±4.5	-4.3±4.5	-5.1±4.3	-4.7±4.4	-4.2±4.4	-4.1±4.8
Qmax (mL/sec)							
n	80	77	74	74	56	58	53
Mean ± SD	10.9±2.9	20.5±9.5	19.6±8.7	18.4±8.2	17.2±9.0 ^a	16.7±10.7 ^a	17.2±9.7 ^a
Change		+9.6±9.45	+8.8±8.5	+7.4±8.2	+6.2±8.9	+5.3±10.6	+5.6±9.7
PVR (mL)							
n	80	77	74	74	56	58	53
Mean ± SD	63.1±55.0	34.3±33.1	28.8±29.5	34.4±32.3	45.0±50.9	49.1±79.3	49.0±81.1
Change		-30.0±58.9	-35.0±51.6	-30.1±51.6	-12.9±66.8	-5.6±80.9	-5.2±84.0

^aChange from baseline, paired t-test, p<0.05. BPH: benign prostatic hyperplasia; IPSS: International Prostate Symptom Score; PSA: prostate-specific antigen; PVR: postvoid residual; Qmax: peaks flow rate; QoL: quality of life; SD: standard deviation.

Measure	Baseline	3-month	6-month	1-year	2-year	3-year	4-year
IIEF EF							
n	80	79	77	75	68	63	58
Mean ± SD	17.6±11.0	17.8±10.9	19.3±10.7	19.8±10.2	18.4±10.6	21.0±9.7	16.3±10.8
MSHQ-EjD function							
n	80	79	77	75	68	62	58
Mean ± SD	9.4±4.3	8.7±5.6	8.1±5.8	9.1±5.7	8.9±5.2	8.7±5.1	8.3±5.1
MSHQ-EjD Bother							
n	80	79	77	75	68	62	58
Mean ± SD	1.2±1.4	1.2±1.5	1.3±1.6	1.2±1.5	1.4±1.6	1.1±1.3	1.5±1.4

BPH: benign prostatic hyperplasia; IIEF: International Index of Erectile Function; MSHQ-EjD: Male Sexual Health Questionnaire - ejaculatory dysfunction; SD: standard deviation.

DRAFT