Prostatic urethral lift (UroLift) versus convective water vapor ablation (Rezum) for minimally invasive treatment of BPH: a comparison of improvements and durability in 3-year clinical outcomes

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Introduction: *Half of men aged > 60 years will develop benign prostatic hyperplasia (BPH) with 40% of these men having moderate-to-severe lower urinary tract symptoms (LUTS). There is limited knowledge on a head-to-head comparison of prostatic urethral lift (UroLift) and convective water vapor ablation (Rezum) for the treatment of LUTS secondary to BPH. We sought to compare randomized controlled trials with 3-year clinical outcome data.*

Materials and methods: *After a thorough literature search, two multicenter sham-controlled double-blind randomized trials for UroLift and Rezum were identified and compared. Both studies had similar designs, baseline characteristics, reported outcomes, and low risks of bias.*

Results: *Rezum and UroLift resulted in significant improvement of International Prostate Symptom Score (IPSS) at 3 months (51.4% and 49.9%, respectively) and 50% reduction of IPSS Quality of Life that was durable across all time points. At 24 and 36 months, there was a statistically significant difference in IPSS between groups, favoring Rezum (-11.2 ± 7.3 versus -9.13 ± 7.62, p = 0.04, and -11.0 ± 7.1 versus -8.83 ± 7.41, p = 0.04, respectively). While Rezum had greater improvement in Qmax at 3 months (6.4 ± 7.2 versus 4.29 ± 5.16, p < 0.01), there was no difference in improvement from 12-36 months between treatments. Only UroLift experienced improvements of Men's Sexual Health Questionnaire-Ejaculatory Dysfunction (MSHQ-EjD) function from baseline and was better than Rezum at all time points (p < 0.01). Rezum failed to significantly reduce the MSHQ-EjD bother at 3 months, while UroLift demonstrated a significant reduction of 27.56% (p < 0.01). Both systems offered equal improvements in the bother score by 12-36 months. Surgical re-treatment rates favored Rezum over Urolift (4.4% vs. 10.7%, respectively).*

Conclusions: *Rezum achieved a greater improvement in symptom relief compared to UroLift. Improvement in ejaculatory dysfunction in patients treated with UroLift was greater than Rezum.*

Key Words: prostatic urethral lift, convective water vapor ablation, benign prostatic hyperplasia, outcomes, minimally invasive treatment

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Introduction

Benign prostate hyperplasia (BPH) is the non-malignant hypertrophy of the prostate commonly observed in older men.[1] Approximately 50% of

men aged > 60 years will develop BPH with 40% of these men experiencing moderate-to-severe lower urinary tract symptoms (LUTS) secondary to BPH.[2] When a surgical intervention is indicated, the choice of procedure depends on several factors such as severity of symptoms, prostate volume, comorbidities, and patient preference with consideration for the comparable success rate and possible complications of the available options.[3-5]

Transurethral resection of the prostate (TURP) is considered the gold standard intervention for BPH. This is due to limited efficacy, technical challenges, or perioperative morbidities of other options such as transurethral incision of the prostate (TUIP), transurethral microwave therapy (TUMT), or laser procedures.[5,6] However, complications of TURP include retrograde ejaculation (53%-75%), erectile dysfunction (3.4%-32%), urinary retention (3%-9%), urethral stricture (2.2%-9.8%), bladder neck contracture (0.3%-9.2%), bleeding (0.4%-7.1%), and urinary incontinence (< 0.5).[7,8] Moreover, the need for overnight hospital stay (≥ 1 day), return to hospital for re-bleeding, and ~10% lifetime surgical re-treatment rates, along with their associated costs, are other negative factors to be considered with TURP.[9]

Minimally-invasive office-based BPH therapies hold the promise of clinical efficacy approaching that of TURP with the added benefits of a reduced recovery period and a reduced side effect profile when compared to TURP. Recently, prostatic urethral lift (UroLift) and radio-frequency convective water vapor thermal therapy (Rezum) have been introduced as outpatient alternatives to treat BPH symptoms, with a low complication profile and cost.[10,11] The UroLift system (Neotract Inc, Pleasanton, CA, USA) is a minimally-invasive surgical treatment option indicated for LUTS associated with BPH. UroLift is a non-ablative modality and is superior to TURP in regards to the quality of recovery.[12] The aim of the UroLift procedure is to relieve the prostatic obstruction by compressing and displacing the lateral lobes towards the capsule and securing them in that position using small, permanent suture-based implants.[11] The UroLift procedure has been demonstrated to improve LUTS symptoms and patient quality of life with minimum adverse events.[11,13-17]

The Rezum system (Boston Scientific. Marlborough, MA, USA) is an alternative treatment option that uses convective radiofrequency-generated water vapor thermal energy to ablate prostate tissue through a cystoscopic procedure.[18] Similar to UroLift, the Rezum procedure has also been demonstrated to improve LUTS and patient quality of life with minimal adverse events.[18] There is limited data on a head to head comparison as to how these two minimally-invasive procedures compare with respect to sustained symptom relief and quality of life. As such, we sought to explore an indirect evaluation of clinical outcomes and durability. This study presents a comparison of 3-year clinical outcomes from two published, prospective randomized controlled trials on UroLift and Rezum.[13,18] Our primary analysis was a comparison of baseline changes in clinical outcomes between the interventions. A secondary analysis of therapeutic durability within each treatment arm was conducted.

Materials and methods

This study is an unadjusted indirect comparison of 3-year outcomes published for the Rezum and UroLift procedures from two similar pivotal, multi-center, randomized controlled trials.[13,18] These two studies were chosen after a thorough literature search was completed because they were the only randomized controlled trials with sham procedures for each treatment with 3-year outcome data. The study population includes men with moderate-to-severe LUTS associated with BPH. Both the UroLift and Rezum studies were double-blind randomized controlled trials with blinded outcome adjudication.[13,18] The studies report data for intervention arms only, and therefore adjusted indirect comparisons cannot be made. We therefore compared the magnitude of the treatment effects in both studies as compared to their baselines and controls at 3 months that can obtain an unbiased estimate of treatment effect even if treatment and control groups differ in baseline characteristics.[19] Clinical outcomes include mean and mean change values from baseline for the following outcomes: maximum flow (Q-max), International Prostate Symptom Score (IPSS) and the IPSS quality of life domain (QoL), post-void residual (PVR), Benign Prostate Hyperplasia Impact Index (BPHII), Male Sexual Health Questionnaire ejaculatory function (MSHQ-EjD function) and bother (MSHQ-EjD bother). A clinically meaningful difference in IPSS is defined as a change of at least 3 points.[20]

A comparison of the methodology of the studies included in our analysis was conducted, Table 1.

The studies included in this analysis were selected due to robust and similar randomization, blinding, and randomization sequence allocation methods.[13,18] Moreover, the sample populations inclusion criteria for both included studies were similar, including age, baseline IPSS score, Qmax, prostate volume, and washout periods for LUTS/BPH medications.

TABLE 1. **Summary of methodology of included studies**

	L.I.F.T. study	**Rezum study**
Randomization	Block randomization with randomized block size via password protected centralized computer program	Block randomization with randomized block size via password protected centralized computer program
Randomized allocation ratio (Intervention: control)	2:1	2:1
Blinding	Participants and outcome assessors	Participants and outcome assessors
Sample population	I. ≥ 50 years II. IPSS ≥ 13 III. Qmax ≤ 12 IV. Prostate volume 30 cc-80 cc V. PSA < 10 ng/mL unless prostate biopsy negative for cancer VI. Washout period for LUTS/BPH medications VII. Absent active UTI VIII. Obstructive median absent IX. Absent of UTI X. No previous BPH procedures XI. No history of bladder/ prostate cancer	I. ≥ 50 years II. IPSS ≥ 13 III. Qmax ≤ 12 IV. Prostate volume 30 cc-80 cc V. PSA ≤ 2.5 ng/mL prostate biopsy negative for cancer VI. Washout period for LUTS/BPH medications VII. Absent active UTI
Intervention	Prostatic lift procedure (UroLift)	Radiofrequency thermal water vapor thermal therapy (Rezum)
Comparator	Baseline values	Baseline values
Time	3 year change	3 year follow up
Setting	19 centers (Canada, USA, Australia)	15 centers (USA)

Both studies were multi-center, with 19 centers in the UroLift study compared to 15 studies in the Rezum study. However, participants with an obstructive or protruding median lobe were excluded in the UroLift study due to contraindication in the United States.[21] Both study designs were similar, including randomizing patients 2:1 to receive the treatment or a sham procedure, which was used as the control arm in both studies. At 3 months, patients were unblinded and changes from baseline values were compared in the active treatment group at 12, 24, and 36 months. Both studies allowed patients in the control arm after the 3-month unblinding to enter the active treatment arm, both having similar crossover rates (80.3% for UroLift, 86.9% for Rezum).

A review of the impact of bias was conducted as per the Cochrane risk of bias tool, Table 2.[22] The Cochrane risk of bias tool is a standard approach to evaluate the risk of bias in randomized clinical trials. The overall risk of bias in both studies was assessed as low. We determined that both studies were at a medium risk of performance bias from participant unblinding at 3 months. Participant unblinding may affect behavior in respect to attending follow up visits but may have a low effect on physiological outcomes.[23]

Statistical analysis

Unadjusted indirect comparisons of baseline cohort characteristics and outcomes between patients in the Rezum and UroLift studies were conducted using the summary statistics reported in each study. Individual-level data from each study was not available. Adjusted indirect comparisons were not possible due to the absence of control data in each study. The mean and

TABLE 2. **Summary of risk of bias for included studies**

Bias	Authors' judgment	Support for judgment
Random sequence generation (selection bias)	Low risk	Block randomization to treatment arms with randomized block size.
Allocation concealment (selection bias)	Low risk	Randomization conducted via password protected centralized computer program.
Blinding of participants and personnel (performance bias)	Medium risk	A surgical blinding screen blocked patients' view of the instruments or procedure. As well, the sham procedure was conducted with a rigid cystoscope and sounds to simulate treatment with UroLift. Patients were unblinded after 3 months.
Blinding of outcome assessment (detection bias)	Low risk	Outcome assessment was conducted by a research staff member not involved in the procedure.
Incomplete outcome data (attrition bias)	Low risk	A cross-over study design was used to improve statistical analysis and ensure improve balance between the treatment arms.
Selective reporting (reporting bias)	Low risk	The L.I.F.T. (Clinicaltrials.gov: NCT01294150) and Rezum system (Clinicaltrials.gov:NCT01912339) studies published their protocols.

standard deviation of each baseline characteristic were reported and compared between groups using independent t-tests. For each outcome, the mean changes from baseline and standard deviations at 3, 6, 12, 24 and 36 months are reported for each group, and compared between groups using independent t-tests. The difference in means between groups and its 95% confidence interval was also calculated. Adverse events and treatment failure rates were reported with descriptive statistics. Statistical analyses were conducted using R version 3.6.2. A significance level of 0.05 was used in the study.

TABLE 3. **Baseline characteristics**

	Rezum		UroLift		
	N	Mean	N	Mean	p value
Age	136	63.0 ± 7.1	137	67.0 ± 8.5	< 0.01
Prostate volume (mL)	136	45.8 ± 13	137	44.57 ± 12.47	0.43
PSA	133	2.1 ± 1.6	137	2.34 ± 1.98	0.28
IPSS	134	22.0 ± 4.8	137	22.32 ± 5.47	0.61
IPSS-QoL	134	4.4 ± 1.1	136	4.62 ± 1.06	0.10
BPHII	134	6.3 ± 2.8	136	6.9 ± 2.83	0.08
Qmax (mL/s)*	125	10.0 ± 2.2	136	7.88 ± 2.43	< 0.01
PVR (mL)	133	82.4 ± 51.8	137	85.89 ± 68.99	0.64
MSHQ-EjD (Function)	90	9.3 ± 3.1	104	8.64 ± 3.18	0.15
MSHQ-EjD (Bother)	90	2.2 ± 1.7	104	2.25 ± 1.64	0.84

*assessed in participants with voided volume of ≥ 125 mL; PSA = prostate-specific antigen; IPSS = International Prostate Symptom Score; QoL = quality of life; BPHII = Benign Prostate Hyperplasia Impact Index; Qmax = maximum flow rate; PVR = post-void residual; MSHQ = Male Sexual Health Questionnaire

TABLE 4. **Reported changes in outcomes measurements from baseline**

	3 months					12 months				
	Rezum		UroLift			Rezum		UroLift		
	N (paired)	Mean change	N (paired)	Mean change	p value	N (paired)	Mean change	N (paired)	Mean change	p value
Qmax (mL/s)‡	125	6.4 ± 7.2	122	4.29 ± 5.16	<0.01	112	5.5 ± 6.4	102	4.03 ± 4.96	0.06
IPSS*	134	-11.3 ± 7.6	136	-11.14 ± 7.72	0.86	121	-11.6 ± 7.3	123	-10.61 ± 7.51	0.3
IPSS-QoL*	134	-2.1 ± 1.6	136	-2.22 ± 1.78	0.56	121	-2.2 ± 1.6	123	-2.31 ±1.6	0.59
PVR (mL)*	133	10.6 ± 68.3	136	-9.01 ± 85.01	0.87	118	-3.9 ± 82.7	120	-12.11 ± 100.39	0.49
BPHII*	134	-3.4 ± 3.5	136	-3.99 ± 3.23	0.15	121	-3.9 ± 3.3	123	-3.98 ± 3.3	0.85
MSHQ-Function‡	90	0.3 ± 4.3	91	2.31 ± 2.58	< 0.01	78	-0.3 ± 3.5	87	1.56 ± 2.68	< 0.01
MSHQ-Bother*	90	-0.3 ± 1.9	91	-1.07 ± 1.44	< 0.01	79	-0.7 ± 1.8	87	-0.76 ± 1.55	0.82
	24 months					36 months				
Qmax (mL/s)‡	99	4.8 ± 6.1	86	4.21 ± 5.09	0.48	80	3.5 ± 4.7	69	3.47 ± 5.00	0.97
IPSS*	109	-11.2 ± 7.3	103	-9.13 ± 7.62	0.04	97	-11.0 ± 7.1	93	-8.83 ± 7.41	0.04
IPSS-QoL*	109	-2.2 ± 1.5	103	-2.19 ± 1.72	0.96	97	-2.2 ± 1.6	93	-2.25 ± 1.72	0.84
PVR (mL)*	106	-0.3 ± 85.3	102	9.6 ± 134.06	0.52	92	-26.4 ± 63.9	88	-7.56 ± 91.64	0.11
BPHII*	109	-3.8 ± 3.1	103	-3.78 ± 3.49	0.97	97	-3.7 ± 3.3	93	-3.78 ± 3.3	0.87
MSHQ-Function‡	70	-0.5 ± 4.2	72	1.08 ± 2.51	< 0.01	63	-1.4 ± 3.8	66	0.56 ± 2.48	< 0.01
MSHQ-Bother*	70	-0.5 ± 1.7	72	-0.63 ± 1.51	0.63	63	-0.5 ± 1.6	66	-0.59 ± 1.52	0.74

Qmax = maximum flow rate; IPSS = International Prostate Symptom Score; QoL = quality of life; PVR = post-void residual; BPHII = Benign Prostate Hyperplasia Impact Index; MSHQ = Male Sexual Health Questionnaire

Results

At baseline, 137 participants reported baseline outcomes in the UroLift group compared to 136 in the Rezum group, Table 3. The Rezum study reported the presence of a median lobe in 30 participants (22%) at baseline, with all 30 participants completing a 3-year follow up.[18] The mean age in the UroLift group (67.0 years ± 8.5 years) was higher than the average age in the Rezum group (63.0 years ± 7.1 years) ($p < 0.01$). Prostate volume between groups (UroLift: 44.6cc ± 12.5cc; Rezum: 45.8cc ± 13cc) was not statistically different ($p = 0.43$) at baseline. Baseline IPSS in the Rezum (22.0 ± 4.8) and UroLift (22.3 ± 5.5) groups were not significantly different ($p = 0.61$). Other baseline survey scores were also not significantly different, including IPSS-QOL, BPHII, MSHQ-EjD (Function), and MSHQ-EjD (Bother), Table 3. Baseline Q-max values were statistically different between-groups (UroLift: 7.9 ± 2.4 mL/s; Rezum: 10.0 ± 2.2 mL/s) ($p < 0.01$). Concerning follow-up, both studies had similar paired outcomes at each time point during the study periods, Table 4.

The general trend in IPSS outcome was reported, Figure 1. The Rezum and UroLift systems resulted in a mean improvement of 51.4% and 49.9%, respectively, at 3 months. For intention to treat analysis comparing the treatment arm with the sham group at 3 months, Rezum had a reduction of IPSS of -11.2 ± 7.6 points compared to control of -4.3 ± 6.9 points while UroLift had a reduction of -11.1 ± 7.7 points compared to control of -5.9 ± 7.7. Following this point, the IPSS increased with UroLift and decreased in the Rezum group, such that at 24 months and 36 months there was a statistically significant difference between groups ($p = 0.04$) in favor of the Rezum group, Table 4.

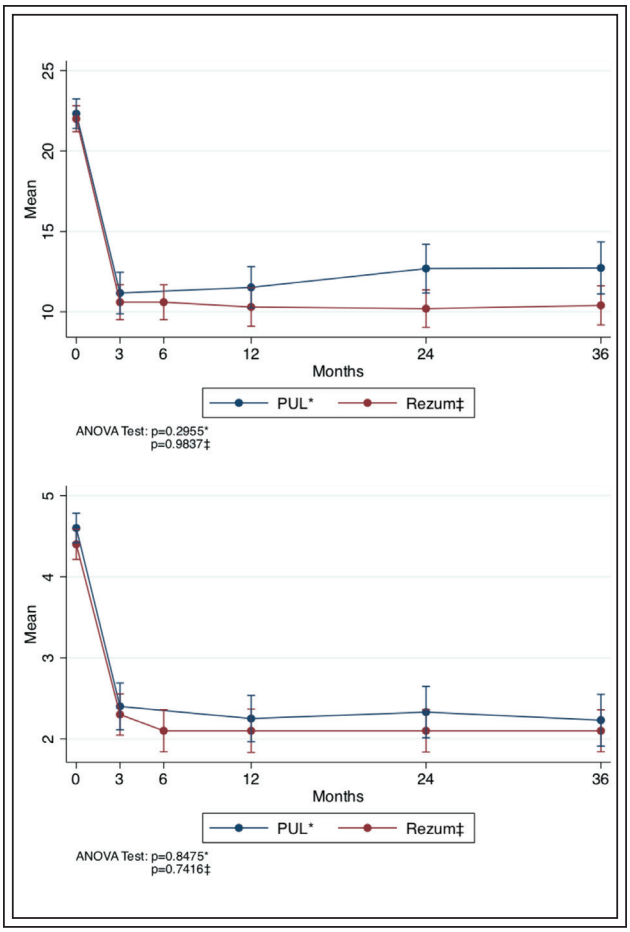

Figure 1. International Prostate Symptom Scores (IPSS) and Quality of Life (QoL) of UroLift and Rezum over 36 months of follow up.

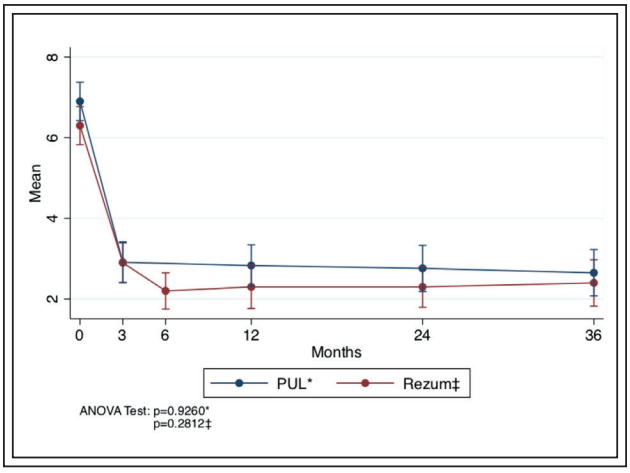

Figure 2. Benign Prostatic Hyperplasia Impact Index (BPHII) values for UroLift and Rezum over 36 months of follow up.

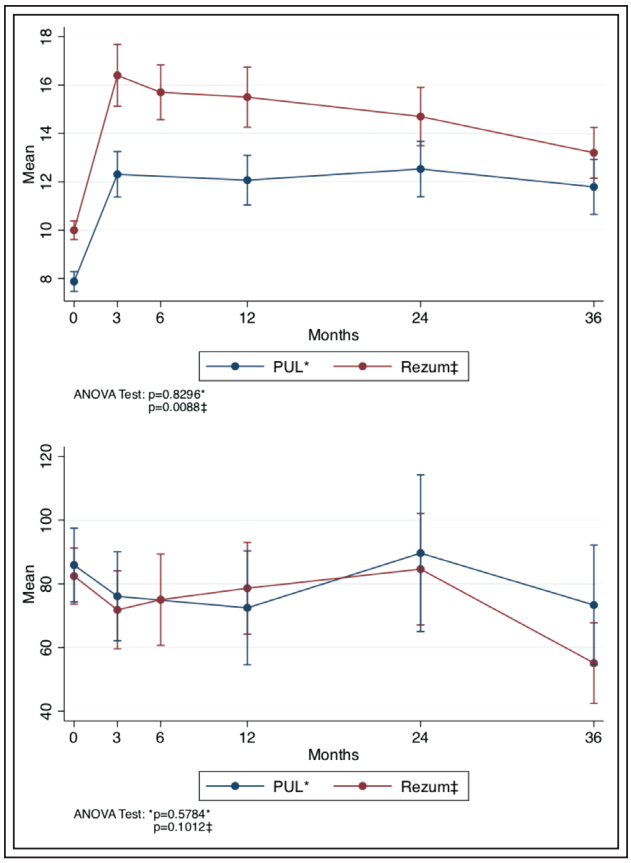

Figure 3. Qmax and Post-Void Residual (PVR) values for UroLift and Rezum over 36 months of follow up.

Both the Rezum and UroLift groups achieved a 50% reduction in IPSS-QoL score at 3 months ($p < 0.01$ and $p = 0.01$, respectively). The Rezum and UroLift group appear to demonstrate improvement of IPSS QoL outcomes across all time points, Figure 1. Group comparisons of improvements achieved at 3, 12, 24, and 36 were not statistically significant, Table 4. At 3 months the Rezum and UroLift systems achieved an average 3.4 (54.0%) and 3.99 (57.8%) improvement in BPHII score, which were not significantly different, Table 4. The improvement of BPHII in both groups as the observed fluctuations were not apparent, Figure 2. The average improvements from baseline did not differ between groups at across all comparable time points, Table 4.

At 3-months both the Rezum and UroLift systems achieved their greatest improvements in Q-max outcomes, Figure 3. The Rezum achieved a 64.0% improvement at 3 months while the UroLift demonstrated a 53.5% improvement. Although at 3 months the improvement was significantly higher with Rezum, the improvements during the subsequent visits were not different between groups, Figure 3. The

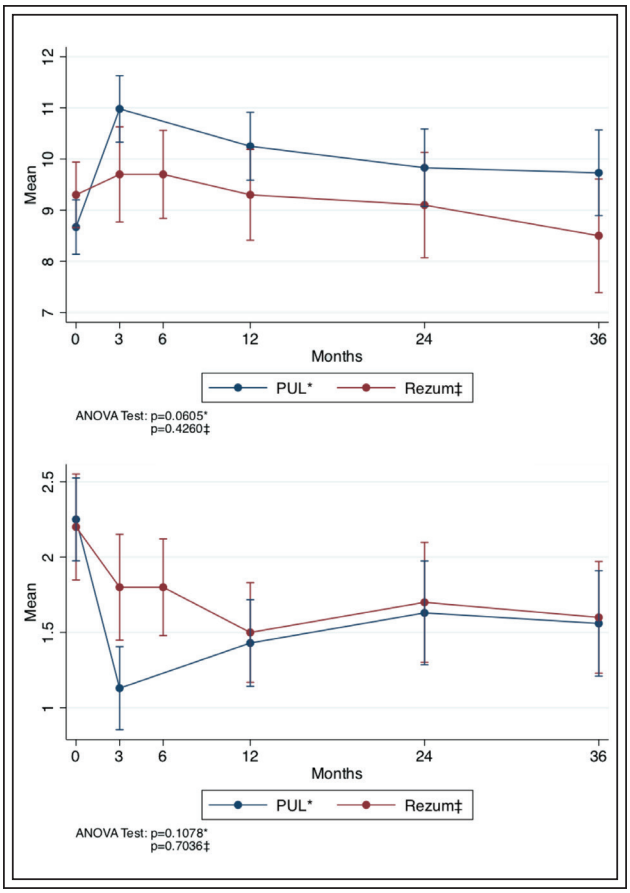

Figure 4. Male Sexual Health Questionnaire Ejaculatory Dysfunction (MSHQ-Ejd) Function and Bother Values for UroLift and Rezum over 36 months of follow up.

spontaneously, with no need to remove the implants. It should be mentioned that removing the UroLift stitches was reportedly necessary for 10 patients but for reasons other than incontinence (protrusion of stitches to bladder in 8 patients and prophylactically in 2 patients).[13,18] The most common complication for each treatment was dysuria, occurring in 34.3% of UroLift patients and 16.9% of Rezum patients while hematuria occurred in 25.7% of UroLift patients and 11.8% of Rezum patients.[11,18] Neither system reported any de novo sustained erectile or ejaculatory dysfunction.

At 3-years post-procedure, 15 patients in the L.I.F.T study (10.7%) were reported to have undergone surgical intervention for persistent LUTS (6 patients received more UroLift implants and 9 underwent TURP/PVP).[13] The surgical intervention rate at 3-years post-procedure in the Rezum group was lower at 4.4% (6 participants out of 135). The author reports that 4 of these patients had median lobes that were not treated at the time of primary water vapor thermal therapy.[18]

At 3 years of follow up, as compared to baseline, both UroLift and Rezum had significant improvements in IPSS, IPSS_QoL, BPHII, and Q-Max. Only Rezum had a significant increase in PVR. UroLift had no change in MSHQ-EjD Function score and a positive change in MSHQ-EjD Bother scores. Rezum had worse MSHQ-EjD Function and Bother scores.

Discussion

This indirect analysis of UroLift versus Rezum has several important findings. First, Rezum had a higher reduction in IPSS than UroLift at 3 months of follow up when comparing both treatment arms to their control arms before the unblinding at 3 months. Additionally, short term (3 months) advantage in Qmax improvement favored Rezum when compared to the UroLift procedure, though this difference equalized between treatment modalities at further follow up. Rezum also delivered a more significant reduction in IPSS scores at 24 and 36 months. Both interventions showed clinically significant durability to at least 3 years post-intervention. The surgical retreatment of 10.7% and 4.4% for the UroLift and Rezum, respectively, are similar to other published studies. UroLift was shown in a systematic review of six studies to have a progression to TURP of 6.9% at 12 months of follow up while Rezum had retreatment rates that varied between 3%-5%.[24,25] When comparing healthcare utilization costs, UroLift was 1.64x and Rezum was 1.05x as much as a year of medical therapy.[26] Inpatient TURP, however, was 2.64x as expensive as a year of medical therapy, showing the potential of healthcare cost savings with UroLift or Rezum as the worldwide impact of BPH continues to grow rapidly.[26,27] The relative cost of these therapies in general is notable. Researchers from the Cleveland Clinic Foundation demonstrated that the Medicare costs for UroLift were $2949 higher than Rezum,[28] which is in-line with an economic analysis published elsewhere showing UroLift as being $3000 more expensive than Rezum. As the size of the prostate, particularly its length, increases, additional UroLift implants are required which increases cost, whereas a single Rezum handpiece can treat a wide range of volumes for a single fixed lower cost.[29]

We also observed that the effect on sexual function appears to be better in those treated with UroLift than those treated with Rezum. The durable superiority of MSHQ-EjD function was demonstrated in UroLift while MSHQ-EjD bother seems to be equally improved by both systems from 12 months to 36 months. These

findings were corroborated by Woo et al when the authors addressed the sexual safety of treatment with UroLift system by using Sexual Health Inventory for Men (SHIM) and Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD). The authors reported no cases of retrograde ejaculation among the 64 men who were enrolled in the study and followed for 12 months and the erectile function was improved during the follow up.[30] At 5 years of follow up, UroLift continues to have a good sexual side effect profile with no de novo sustained erectile or ejaculatory dysfunction.[31] Nevertheless, both modalities did not report any de novo erectile dysfunction. Preservation of sexual function is of major importance to men seeking treatment for LUTS secondary to BPH.[32] As compared to TURP that can have rates of retrograde ejaculation of 75% and impotence of 32%, UroLift and Rezum both relieve LUTS while preserving sexual function.[7]

Overall, both procedures have demonstrated a good non-sexual safety profile. Rates of urinary tract infections (UTI) were low, 3.7% for the Rezum and 0.7% for the UroLift system.[13,18] In a comparison of TURP to photoselective prostatic vaporization with the GreenLight photovaporization of the prostate (PVP), reported UTI event rates were 9.8% and 18.4%, respectively.[33] Moreover, adverse events experienced by both treatments, such as dysuria and hematuria, were mild with low rates of serious adverse events such as sepsis or death, which can occur with TURP.[7]

Finally, Rezum is approved to be performed in men with an obstructive median lobe. UroLift, on the other hand, which had previously been contraindicated in men with an obstructive median lobe as it was an exclusion criterion in the pivotal L.I.F.T. trial, has emerging evidence from the MedLift study demonstrating effectiveness and safety in these patients.[34] However, AUA guidelines recommend the use of UroLift in the absence of a middle lobe.[35,36] A sub-analysis in the Rezum study has shown that patients with median lobes not only had similar improvements in their IPSS and Q-max but also had lower PVR values at 24 and 36 months compared to patients without a median lobe.[18]

Despite its merits, this study has some limitations as it is a qualitative assessment of two published prospective studies and therefore provides a lower quality of evidence compared to a randomized control trial. Furthermore, we only included one study for each treatment due to low number of published studies with long term outcome data. Additionally, because control arm data was not reported in the studies past 3 months, only unadjusted indirect comparisons were possible. The use of unadjusted indirect comparison methods increases the risk of bias through ignoring the effects of randomization.[24] Both studies had similar baseline demographics except for age, which differed significantly as Rezum patients were on average 4 years younger than UroLift patients. Different inclusion/exclusion criteria may have resulted in a significantly higher baseline mean Q-max levels in the Rezum study and higher BPHII in the L.I.F.T study, Table 3. There is a possibility that the differences observed in outcomes between the groups may be partially due to these variations in the patients. Moreover, both studies had lost to follow up due to various reasons. Additionally, because the cohorts and data collection of monopolar TURP are different, we are limited to only comparing Rezum to UroLift and unable to compare these MIST therapies to monopolar TURP. Similar indirect comparison of surgeries, including in the field of BPH, have been published routinely using the same methodology described above.[37-42] There is significant cost and logistic challenges when performing two already commercially available treatments, and often those studies would be difficult if not impossible to perform due to surgeon or patient preference. Given the accepted technique of indirect analysis which has been previously utilized, this study answers an important clinical concern assessing the outcomes of these two technologies. We acknowledge that a direct, head-to-head, randomized, study would be the ideal method to compare two similar technologies.

Despite these limitations, the results are reliable as both randomized controlled trials are multi-center and reported the use of random allocation sequence generation, allocation concealment, participant blinding, and blind outcome assessment. Both studies had similar exclusion criteria, including age, IPSS, prostate volume, and PVR. Both had similar overall designs with 2:1 randomization and unblinding at 3 months of the control arm and were at low risk of bias. Lastly, both studies had similar rates of follow up at every time point, reducing the potential bias that could have resulted.

Several other factors are relevant when comparing Rezum versus UroLift which are worth mentioning. based upon their respective pivotal studies. Certainly, some physicians may choose to treat larger glands, and other countries such as Canada do not have an explicit upper limit of prostate volume. The second consideration is post-procedure catheterization. While the LIFT study had 32% of patients catheterized after their UroLift, the mean duration of catheterization was 0.9 days. In general practice, the majority of UroLift cases do not require any post-procedure catheterization. In contrast, the mechanism of action

of Rezum is heat-based ablation from water vapor. The resultant edema requires catheterization. In the Rezum II pivotal study, all patients received a catheter for a mean duration of 72 hours. In general practice, nearly all Rezum cases will requires post-procedure catheterization for 1-7 days. Due to their different mechanism of action, the time with irritative symptoms and return to normal function is variable with UroLift patients tending to recover sooner.[43]

This study highlights the need for further long term outcomes of both Rezum and UroLift and direct comparisons of long term outcomes between Rezum and UroLift. Head-to-head comparison of minimally-invasive procedures are required to evaluate each procedure's comparative efficacy and safety profile in reducing LUTS associated with BPH compared to other MIST procedures. In light of the need to be able to compare MISTs directly, a randomized long term, head-to-head comparison between UroLift and Rezum should be conducted. The CLEAR study (NCT04338776) is scheduled to begin soon comparing short term patient experience in men randomized between UroLift and Rezum.

Conclusions

Rezum achieved greater improvement in prostate symptom relief when compared to UroLift that was significant in Qmax at 3 months and IPSS at 24 and 36 months, but not statistically significant in other parameters. MSHQ-EjD function was significantly better in UroLift across the 36 months period, while bother only at 3 months. There is a notable difference in surgical retreatment rates between the two therapies at 3 years follow up. The relief of LUTS with acceptable morbidity and functional outcomes warrants further comparison amongst minimally-invasive surgical therapies for BPH. Larger RCTs with longer duration of follow ups are required for a statistically robust comparison of these novel procedures. Furthermore, a comparative evaluation of the cost-effectiveness of these treatments is an opportunity for further research.

Disclosures

Dean Elterman is a consultant for Boston Scientific, Meditate, Prodeon, Procept, Olympus and Urotronic. Naeem Bhojani is a consultant for Boston Scientific, Olympus and Procept. Kevin Zorn is a consultant for Boston Scientific and Procept. Bilal Chughtai is a consultant for Boston Scientific, Olympus, Procept, and Meditate. Other authors have no conflicts of interest. □

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