
Early patient experience following treatment with the UroLift prostatic urethral lift and Rezum steam injection

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TUTRONE RF, SCHIFF W. Early patient experience following treatment with the UroLift prostatic urethral lift and Rezum steam injection. *Can J Urol* 2020;27(3):10213-10219.

Introduction: To report the early postoperative patient experience, including symptom response, catheterization, recovery and satisfaction, following treatment with two minimally invasive surgical therapies (MIST) for benign prostatic hyperplasia (BPH): mechanical disobstruction with UroLift prostatic urethral lift (PUL) and tissue ablation with steam injection (Rezum).

Materials and methods: Patient reported outcomes of 53 non-retention patients from two U.S. sites patients who underwent PUL (n = 30) or Rezum (n = 23) were collected within 2 months post-treatment. There were no exclusion criteria for baseline symptoms, prostate size, or BPH medical therapy. Patients completed questionnaires which assessed postoperative BPH symptoms and characteristics. Outcomes were compared between treatment arms with unpaired t-tests and Fisher's exact tests.

Results: PUL and Rezum patients were similar in age and prostate volume; patients completed the questionnaire

an average of 30 ± 11 days post-treatment. Absolute mean International Prostate Symptom Score and quality of life was significantly better for PUL patients. Seven percent of PUL patients were catheterized by postoperative day 3 compared to 55% of Rezum patients (p = 0.0003). PUL patients experienced a rate of 83% treatment satisfaction (versus 65% for Rezum, p = 0.2) and less interference with daily activities (sports interference, p = 0.007; entertainment interference, p = 0.01; community interference, p = 0.04). Both groups reported BPH medication use following treatment (37% PUL versus 91% Rezum), albeit significantly higher for Rezum (p < 0.0001).

Conclusion: Preliminary data suggests UroLift PUL provides a superior patient experience with better sexual function, lower catheterization rates, less daily interference, and higher patient satisfaction in the recovery period compared to Rezum.

Key Words: LUTS, BPH, minimally invasive surgical therapy, MIST, patient reported outcomes, patient experience, prostatic urethral lift, PUL, UroLift system, thermal therapy, Rezum steam injection

Introduction

Minimally invasive surgical therapy (MIST) for the treatment of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) is increasingly relevant as large percentages of men remain underserved by medical therapy and invasive surgery. As high as 70% of BPH patients have been reported to discontinue first line treatment with alpha

blockers and/or 5ARIs,¹ with proportionately few electing to undergo invasive surgery such as TURP or laser photo-vaporization of the prostate (PVP).² MISTs are uniquely positioned to fill the gap in treatment but must address the needs posed by underserved BPH patients.

From both the patient and urologist standpoints, MISTs should provide rapid and durable improvement in symptoms and quality of life, quick recovery with a minimal adverse event profile, and allow for delivery in an ambulatory setting. One element that may make an alternative treatment to medication more desirable to BPH patients could be a low postoperative catheterization rate and duration. Studies have shown that catheter avoidance or early removal improves patient outcomes after surgery.^{3,4} MISTs should elicit

Accepted for publication May 2020

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reduced duration of catheterization postoperatively compared to invasive surgery, and ideally would not require catheterization at all.⁵

The UroLift system prostatic urethral lift (PUL) and Rezum steam injection are MISTs that have demonstrated excellent efficacy in controlled trials⁶⁻¹⁰ and continue to generate evidence of effectiveness in the real-world setting.¹¹⁻¹³ Based on efficacy data from controlled studies, PUL and Rezum demonstrate similar outcomes in symptom relief, i.e. ~10-11 point improvement in International Prostate Symptom Score (IPSS), more than 2-point improvement in IPSS quality of life (QoL) at 12 months post-treatment,^{6,9,10} which has been shown to be sustained through 5 and 4 years, respectively. As indicated by these controlled studies, erectile function is preserved in both MISTs, as are overall mean ejaculatory function scores, although de novo instances of ejaculatory dysfunction are reported with Rezum.¹²

Rezum treatment utilizes steam injection to thermally ablate prostatic tissue based on the principle that steam is rapidly dispersed through tissue to induce tissue necrosis more efficiently than other thermal ablation techniques (e.g. TUNA, TUMT).¹⁰ The affected prostate tissue must then follow an 8 to 12 week process of absorption, scarring and/or sloughing of necrotic tissue.^{14,15} PUL is a technique which uniquely does not employ tissue ablation – instead, permanent implants are delivered across the prostate to mechanically and immediately retract tissue and relieve obstruction,¹⁶ Figure 1. By mechanically opening the prostatic fossa, PUL does not rely upon the lengthy biologic process associated with necrotic tissue. For this reason, we

hypothesized that post treatment adverse effects may be fewer or of shorter duration with PUL than with tissue ablation.

In addition to the two PUL randomized trials, 10 additional studies have been published.^{8,11,17-25} Steam injection is described in 1 randomized trial and 3 additional studies.^{10,12,13,26} As studies continue, it is important to discern to what extent outcomes of the controlled studies are paralleled in broader real-world BPH patient populations. Real-world symptom relief for both MISTs appear to compare favorably with controlled outcomes, whereas elevated infection rates and longer postoperative catheterization time have been observed following Rezum.¹² Real-world evidence depicting recovery experience, impact on daily activities, and treatment satisfaction is lacking for both therapies. Here, we describe results from a pilot study comparing the patient-reported postoperative experience including symptom response, catheterization, recovery and satisfaction after treatment with UroLift PUL or Rezum.

Materials and methods

Protocol and procedure

A two-arm study was conducted at two U.S. sites. Patients treated with either the UroLift system (n = 30) or Rezum (n = 23) were asked to complete a questionnaire within 2 months of their procedure. Eleven urologists performed procedures: three urologists performed both techniques, two performed Rezum only, and six performed UroLift only. PUL using the UroLift system utilizes small permanent implants to anchor onto the fibromuscular capsule wall and immediately mechanically retracts prostatic fossa from the obstructed urethra. UroLift system implants are FDA indicated for men aged ≥ 45 and prostates ≤ 100 cc with no lower limit. The Rezum system is indicated for men ≥ 50 years old and a prostate volume ≥ 30 cc and ≤ 80 cc. The Rezum treatment injects steam into the enlarged prostatic lobes, causing localized necrosis to occur, leading to prostate tissue resorption over a period of several weeks, Figure 1. No exclusion criteria were established for either modality regarding baseline symptom score, prostate size, retention history, bilobar or trilobar prostatic obstruction, or BPH medical therapy, as patients needed only to have undergone a procedure to be enrolled. The study was conducted with IRB approval and patient consent was obtained prior to enrollment.

Study assessments and statistics

Patient reported outcomes were collected utilizing a questionnaire consisting of distinct sections that

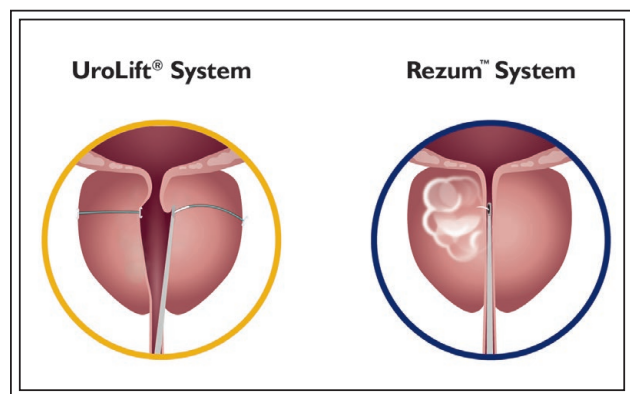


Figure 1. Minimally invasive surgical therapies: UroLift PUL utilizes small permanent implants to mechanically widen the urethral lumen; the Rezum procedure involves steam injection into prostatic tissue to initiate necrosis.

TABLE 1. Patient-reported satisfaction after treatment with UroLift PUL or Rezum

		UroLift (%)	Rezum (%)	p value
A) Rating of urinary symptoms now	≥ a little better	97	70	0.02
	≤ a little worse	3	22	0.07
B) Satisfaction of procedure on voiding symptoms	≥ satisfied	83	65	0.2
	≤ dissatisfied	3	22	0.07
C) Satisfaction with speed and ease of recovery	≥ satisfied	77	65	0.4
	≤ dissatisfied	7	26	0.06

captured patient experiences on the following treatment-related topics: urinary symptoms (IPSS and IPSS QoL), urinary catheter experience, recovery and interference with daily activities, BPH medication use, treatment satisfaction, and sexual function (SHIM and MSHQ-EjD). Patients documented responses directly onto a paper questionnaire form and research staff reviewed questionnaires in the office to ensure completion of all sections before the patient's departure. Research staff completed a medical record case report form (CRF) for each patient and collated data with the patient questionnaire.

Outcomes were compared between arms (PUL versus Rezum). A "satisfaction score" was calculated by pooling responses from Table 1B-C and setting neutral to zero for each question. Unpaired t-tests (pooled) were used to calculate p values between groups for each continuous variable, and Fisher's exact test was used to determine significance for the proportion of each group meeting binary criteria.

Results

Symptom response

Patients included in each treatment group were similar at baseline, with an average age of 69 ± 8.6 y.o. (68 ± 9.4 PUL versus 69 ± 7.8 Rezum, $p = 0.7$) and prostates 56 ± 30.1 g (49 ± 28.4 PUL versus 63 ± 30.9 Rezum, $p = 0.1$). Questionnaires were completed an average of 30 ± 11 days post-procedure (32 ± 12 PUL versus 28 ± 9 Rezum, $p = 0.2$). Baseline IPSS scores were available for 19 PUL and 12 Rezum patients with no significant difference between groups (16 ± 7.0 PUL versus 18 ± 6.6 Rezum, $p = 0.4$).

Post-procedure, mean IPSS improvement (for patients with available baseline) was 8 points for PUL versus 6 points for Rezum ($p = 0.6$). Absolute IPSS scores for all available patients (PUL $n = 29$, Rezum $n = 22$) were significantly better for PUL as compared to Rezum, whose scores still fell in the "moderate to severe" category (IPSS: 8.6 ± 5.0 PUL; 15.6 ± 9.2 Rezum, $p = 0.001$), Table 2. QoL scores aligned with

TABLE 2. Comparison of symptom outcomes following treatment with UroLift PUL or Rezum

Outcome measure (mean $\pm$ SD)	PUL (n = 30)	Rezum (n = 23)	p value
IPSS	8.6 ± 5.0	15.6 ± 9.2	0.001
IPSS QoL	1.5 ± 1.5	2.5 ± 1.9	0.04
SHIM	14.8 ± 8.6	9.2 ± 7.2	0.02
MSHQ-EjD	12.2 ± 2.7	9.2 ± 5.1	0.04
MSHQ-EjD bother	1.1 ± 1.4	1.5 ± 1.6	0.4
% BPH medication usage	37%	91%	< 0.0001
% new BPH medication usage	10%	17%	0.5

IPSS = International Prostate Symptom Score; QoL = quality of life; SHIM = Sexual Health Inventory for Men; MSHQ-EjD = Male Sexual Health Questionnaire-ejaculatory dysfunction; BPH = benign prostatic hyperplasia

IPSS differences, with patients who underwent PUL indicating significantly better quality of life (1.5 ± 1.5) than those who received Rezum (2.5 ± 1.9) ($p = 0.04$), Table 2. Overall measurements for MSHQ-EjD were significantly better in PUL patients (12.2 ± 2.7 versus 9.2 ± 5.1 , respectively, $p = 0.04$), as PUL patients reported the ability to ejaculate more often during sexual activity and trended towards better outcomes in volume of ejaculate. MSHQ-EjD bother score was not different between treatments. Overall SHIM scores were significantly different between PUL and Rezum patients, with scores of 14.8 for PUL and 9.2 for Rezum ($p = 0.02$, Table 2).

Catheterization

The rate of postoperative catheterization was significantly different between treatment groups: 57% (17/30) of UroLift patients and 87% (20/23) of Rezum patients were catheterized after undergoing their procedure ($p = 0.03$, Figure 2A). Reason for catheterization included placement due to physician standard protocol. Of those who had been catheterized, 30% of PUL and 60% of Rezum patients were recorded as performing at least one TWOC. Duration of catheterization also differed significantly between UroLift and Rezum patients. The mean duration for all UroLift patients was 1.2 ± 2.3 days whereas Rezum patients were catheterized for an average of 4.5 ± 3.8 days ($p = 0.0004$, Figure 2C). Seven percent of PUL patients were still catheterized by postoperative day 3 compared to 55% of Rezum patients ($p = 0.0003$, Figure

2B). Catheter duration data was not available for one patient from each group. Of the patients who were catheterized, the mean duration of catheterization for UroLift was 2.2 ± 2.7 days, one of whom had a catheter inserted 2 days post-procedure for a total of 9 days, versus 5.2 ± 3.5 days for Rezum.

Rates of catheter-associated complications (i.e. blood in urine, pain, bladder spasms) in those who were catheterized were comparable between both groups, the most common of which included a sense of urgency or bladder spasms, blood in urine, and pain. Urinary tract infections occurred in approximately 13% of those who were catheterized, and about 40% of patients felt that being catheterized interfered with their daily activities.

BPH medication use

The rate of medication use (either alpha-blocker or 5-ARI) after procedure was 37% for PUL and 91% for Rezum patients ($p < 0.0001$). This rate only considers the usage at the time of taking the questionnaire, regardless of whether patients were previously taking voiding medication. However, de novo medication use reported as a new prescription following the procedure, was 10% for PUL patients and 17% for Rezum patients ($p = 0.5$).

Recovery

A higher percentage of Rezum patients reported interference from daily activity due to post-procedural voiding symptoms. Forty-two percent of Rezum

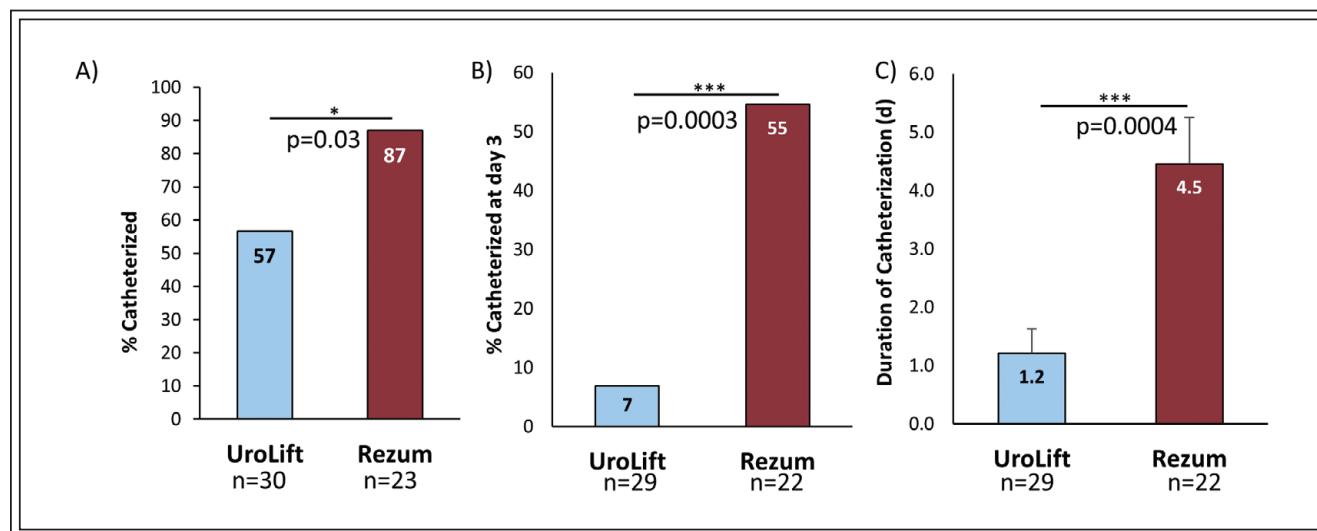


Figure 2. Postoperative catheterization status after minimally invasive treatment UroLift PUL or Rezum **A)** rate of catheterization (%); **B)** percentage of patients catheterized longer than 3 days; **C)** mean duration of catheterization (days). Significance between groups indicated by *.

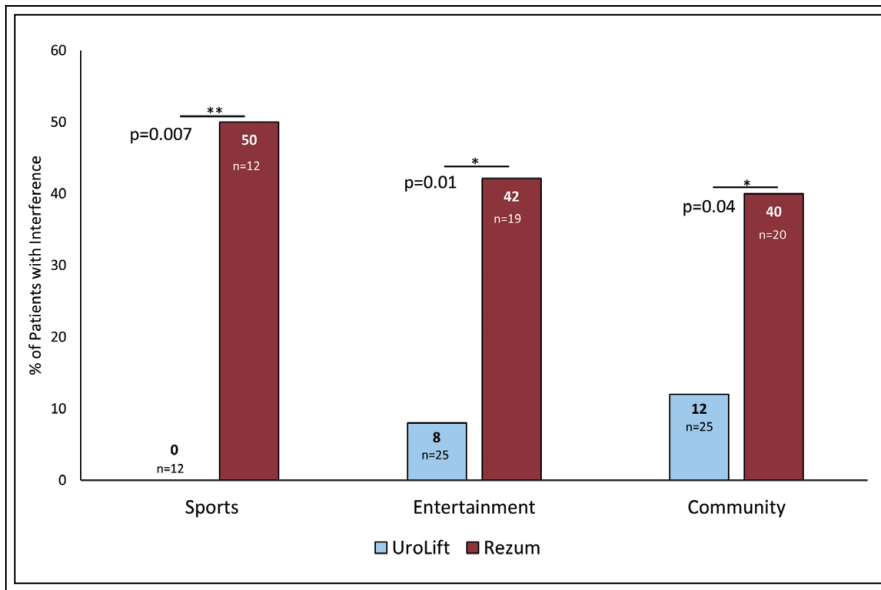


Figure 3. Daily interference of sports, entertainment or community-related activities due to urinary symptoms after UroLift PUL or Rezum. Significance between groups indicated by *.

patients reported interference at least “some of the time” from entertainment related activities, i.e., going to movies, shows, spectator sports, and cultural events, compared to 8% of PUL patients ($p = 0.01$). Similarly, 40% and 50% of Rezum patients (versus 12% and 0% of PUL patients, $p = 0.04$ and $p = 0.007$) reported interference with community-related activities, i.e., volunteering, attending church, cultural activities, visiting with family, and sports-related activities, respectively, Figure 3.

Satisfaction

Nearly all PUL patients rated their urinary symptoms as being at least “a little better” (97%), which is significantly different from the 70% of Rezum patients who met the same criteria ($p = 0.02$, Table 1). Alternatively, 22% of Rezum patients indicated their symptoms were “a little worse” or poorer, compared to 3% of UroLift patients. The same values are reflected in a trend towards the patients’ satisfaction of procedure on their voiding symptoms, with 22% of Rezum versus 3% of UroLift patients ($p = 0.07$) reporting being “dissatisfied” or “very dissatisfied” Table 1. The proportion of patients who were satisfied or better with the speed and ease of their recovery from the procedure did not differ, but 26% of Rezum patients reported being dissatisfied or worse with their recovery (versus 7% of UroLift patients), Table 1. When these satisfaction scores from Table 1B-C were pooled

into a general “satisfaction score,” UroLift patients trended towards being more satisfied than Rezum patients, with a score of 2.5 versus 1.4 ($p = 0.08$).

Discussion

Of the 14 million men in the U.S. being treated for BPH, many discontinue medication and few elect to have surgery, highlighting the need to better understand the patient’s perspective of their symptoms, procedure, and recovery.²⁷ This study sheds light on the early patient experience after treatment with two current MISTs, UroLift PUL and Rezum steam injection, and presents preliminary data suggesting PUL provides a superior experience in terms

of better sexual function, lower catheterization rates, less daily interference and higher patient satisfaction.

Within this early recovery timeframe, PUL patients reported significantly better IPSS, QoL, and SHIM scores compared to Rezum patients. A significant consideration for patients when choosing interventions for BPH is the likelihood and duration of catheterization post-procedure, as catheterization itself can be a deterrent for electing a BPH treatment. This study reports a higher rate of catheterization following both procedures than their respective published randomized controlled data, some of which may be explained by the preference of the facility or urologist to place a catheter as physician protocol. Duration of catheterization and rate of TWOCs performed for each treatment is likely to be more reflective of a true need for catheterization in this study, both of which are significantly elevated in the Rezum patient cohort compared to PUL patients. For patients who underwent the procedure later in the week, they likely would not have their catheter removed until normal office hours, potentially adding 2 days over the weekend regardless of the patient’s ability to void without catheter. Therefore, it is important to note that the proportion of patients still catheterized on postoperative day 3 in UroLift patients is 7%, significantly lower than the 55% rate of Rezum patients. Rate of symptom occurrence after catheterization was equivalent between groups, indicating that symptoms related to catheterization

are not specific to either procedure and instead are associated with catheterization alone. Therefore, it follows that the most effective method of reducing these undesirable symptoms is simply to reduce catheterization.

An aim for surgical intervention, whether invasive or minimally invasive, is to reduce dependence on medical therapies when possible. In this study, baseline medication status was determined by patient report rather than based on a medical record. Although BPH medication may be prescribed by urologists post-procedure in anticipation of adverse effects, the high rate (91%) of patients taking BPH medication after the Rezum procedure in the peri-operative period suggests an expectation of elevated symptoms with Rezum compared to UroLift ($p < 0.0001$). Ten percent of PUL patients and 17% of Rezum patients indicated they newly began taking an alpha-blocker and/or 5ARI post-procedure to treat their voiding symptoms. More thorough characterization of medication usage before and after the procedure with larger sample sizes will be necessary to determine any possible effects of procedure on medical therapy.

Perhaps most telling of the early patient experience is the patient's own satisfaction rating of their urinary symptoms and recovery. All but one PUL patient reported that their urinary symptoms were at least a little better since undergoing the procedure, and 22% of Rezum patients indicated that they were dissatisfied with their symptoms since having the procedure. Approximately a quarter of Rezum patients were dissatisfied with their recovery process from the procedure, and the "satisfaction score" reveals a higher level of satisfaction in PUL patients overall with their procedure. As Rezum is reliant on tissue necrosis and tissue sloughing has been described as spanning 8-12 weeks following steam injection, it is possible the difference in patient satisfaction observed in this study reflects the need for additional recovery time following Rezum, compared to the immediate mechanical retraction provided by PUL.^{14,15}

Growing real-world data for both MISTs have demonstrated consistent improvement in symptoms and quality of life compared with randomized controlled trial outcomes.^{12,13} However, increased catheterization rates, catheter duration, and adverse events, specifically urinary tract infection, have emerged after treatment with Rezum.¹² Here we report similarly elevated rates of postoperative catheterization and duration (5.2 days) following Rezum compared with results presented in the multicenter randomized controlled study (3 days).²⁸

The large real-world retrospective (RWR) study of PUL reported a 16% postoperative catheterization rate (excluding catheters placed for standard of care).¹¹ The catheterization rate for PUL in this study is higher than both RWR and L.I.F.T. results but includes catheters placed due to physician/facility protocol.

These results are the first direct comparison of real-world recovery experience and patient satisfaction between these two technologies. Although not significantly different, average prostate sizes varied between arms (49 ± 28.4 PUL versus 63 ± 30.9 Rezum, $p = 0.1$), which may be reflective of the lack of a lower limit for prostate size in the UroLift PUL indication, whereas Rezum is contraindicated for prostates less than 30 cc. It's also important to note that when drawing comparisons between this study and those previously published for Rezum, the reporting range described here may provide an earlier window into the postoperative period than previously assessed. Limitations of this study include the self-reported nature of the study which may lead to bias or errors in recall. The small sample size and use of only 2 sites in this study could inflate results due to differences in level of experience or postoperative care protocols at each site. Moreover, baseline scores for IPSS were not sufficiently available for this study, and medication usage prior to and post-procedure are patient self-reported. Despite the limitations of this study, preliminary results indicate the early patient experience post-PUL is considerably less invasive than that associated with Rezum. A larger prospective study, ideally randomized, is necessary to fully differentiate the total patient experience between these MISTs. This study should include clearly defined catheterization protocols, assessment of de novo sustained erectile and ejaculatory dysfunction, rigorous baseline data, void trial testing and information about medical therapy usage before and after the procedure.

Conclusion

This study advances the field of MIST for BPH by elucidating the early patient experience following treatment with UroLift PUL or Rezum. Although both treatments alleviate bothersome LUTS, UroLift PUL offers the unique advantage of providing rapid recovery with a lower rate of postoperative catheterization, which may be reflected in higher treatment satisfaction compared with Rezum. The results summarized in this study are based on patient reported outcomes, an important perspective to consider when assessing the risk/benefit profile of current and newly emerging MISTs.

Acknowledgements

The authors thank clinical research coordinators and supporters of this study, as well as Jacqueline Nerney Welch, MD, PhD, Allison Najafi, PhD, and Emma Flores-Kim, PhD for their collaboration during the preparation of this manuscript. □

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