

A randomized study comparing the iTind™ device versus UroLift™ (MT-08) - Interim report findings

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Abstract

Purpose:

To report interim safety and efficacy outcomes from an ongoing multicenter, randomized controlled study (MT-08) comparing the Temporarily Implanted Nitinol Device (iTind™ device) and the prostatic urethral lift (PUL; Urolift™) in men with lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH).

Materials and Methods:

This interim analysis assessed the first 81 patients enrolled into the study and randomized 1:1 to the iTind™ device (n=47) or PUL (n=34). The data cut occurred after the first 81 participants reached 3-months post-implantation (n=81). The study evaluated the rate of procedure- and device-related adverse events (AEs) through 3-months, changes from baseline in International Prostate Symptom Score (IPSS), maximum urinary flow rate (Qmax), post-void residual (PVR), and quality-of-life (QoL) measures. Non-inferiority for IPSS improvement was tested with a 4-point margin. Safety event rates are graded by Clavien-Dindo classification.

Results:

Mean age was 64-years in both groups. Baseline prostate volume was smaller in the iTind™ device arm (38 mL) than in the PUL arm (48 mL). At 3-months, overall, AE incidence was 32.6% with the iTind™ device and 47.1% with PUL (difference -14.5%, 95% CI -35.8%–7.8%; $P=0.1897$). No AEs occurred after 1-month in the iTind™ device arm, whereas the UroLift™ arm recorded one case of urinary urgency between months 1 and 3. The mean IPSS improvement was -10.0 ± 7.6 for the iTind™ device and -11.6 ± 7.7 for PUL. Both devices preserved sexual function and improved QoL indices. Qmax increased by +3.7mL/s (iTind™ device) and +4.3mL/s (PUL).

Conclusions:

At 3-months, the iTind™ device demonstrated a favorable safety profile, with no mid-term AEs reported, and similar symptomatic improvement compared to Urolift™. No device malfunctions occurred. Both therapies achieved rapid recovery and preservation of sexual function. Final 3-month data including all planned patients will be used to validate the findings from this interim analysis.

Introduction

Benign prostatic hyperplasia (BPH) is one of the most common causes of lower urinary tract symptoms (LUTS) in aging men. Surgical interventions such as transurethral resection of the prostate (TURP) provide durable relief but carry risks of bleeding, incontinence, and sexual dysfunction¹. Consequently, minimally invasive surgical therapies (MISTs) have emerged as an appealing alternative, offering rapid symptom relief while preserving sexual function.

Among these, the prostatic urethral lift (PUL; Urolift™) and the Temporarily Implanted Nitinol Device (the iTind™ device) represent two distinct mechanical approaches to relieving prostatic obstruction without tissue resection. PUL exerts permanent lateral compression of the prostatic lobes using implants², while the iTind™ device exerts temporary radial expansion and reshaping of the bladder neck and prostatic urethra via a self-expanding nitinol device removed after several days³.

Prior prospective studies have demonstrated the safety and efficacy of both techniques independently. However, head-to-head comparative data are limited. The MT-08 randomized study was designed to directly compare these devices in a controlled, multicenter setting. This interim analysis summarizes safety and early efficacy outcomes through 3-months following treatment, for the first 81 patients enrolled. Final data including all planned patients will be used to validate the findings from this interim analysis.

Materials and Methods

Study Design

MT-08 is a prospective, randomized, global multicenter study evaluating the safety and efficacy of the iTind™ device versus UroLift™ for LUTS secondary to BPH. Eligible participants are men aged ≥ 50 years with prostate volume ≤ 75 mL and baseline IPSS ≥ 13 . Patients with median lobe enlargement, prior prostate surgery, or confounding urologic conditions are excluded. Subjects taking alpha blockers are required to complete a washout period 2 weeks prior to randomization. After screening and informed consent, participants are randomized in a 1:1 ratio to undergo either the iTind™ device or UroLift™. The current interim analysis includes all subjects who completed the 3-month follow up visit by July 2025.

The study evaluated the incidence of all procedure- or device-related adverse events (AEs) within 3 months, including intra- and post-operative events, change in International Prostate Symptom Score (IPSS) from baseline to 3 months (non-inferiority margin = 4 points), maximum urinary flow rate (Qmax), post-void residual (PVR), and sexual and health-related quality-of-life outcomes (SHIM, MSHQ-EjD, SF-6D v2). Exploratory recovery metrics (return to work, physical activity, and sexual activity), AEs categorized by time window (procedure day, ≤ 1 week, 1 week–1 month, 1–3 months) and grading of AEs using the Clavien-Dindo system*⁴ were also included.

Continuous variables are summarized by mean ± standard deviation and compared using t-tests. Categorical data are analyzed by chi-square or Fisher’s exact test. All analyses are performed on the modified intention-to-treat population.

Results

Eighty-one men were enrolled across 15 participating sites in the US and UK. One patient in the iTind™ device arm withdrew from study participation after 1 month, leaving 80 participants with 3-month follow-up for analysis (46 the iTind™ device, 34 UroLift™). Baseline demographics were well balanced, with mean age 64 years and overall average body mass index 28 kg/m². Prostate volume was smaller in the iTind™ device arm (38 ± 13 mL) than the PUL arm (48 ± 16 mL) (P=0.0043) and the iTind™ device group also presented with a slightly higher incidence of certain comorbidities such as hypertension and heart disease. Approximately half of all patients were on α-blockers at baseline, and a greater proportion of the iTind™ device participants had used 5-α-reductase inhibitors. Randomization therefore resulted in broadly comparable baseline profiles, except for prostate volume and some comorbidities (table 1).

Table 1. Baseline characteristics of the study population.

	iTind (n=47)	UroLift (n=34)
Demographics - mean (std dev)		
Age (years)	64.3 (9.2)	64.6 (7.2)
Height (cm)	176.0 (7.6)	177.0 (5.8)
Weight (kg)	88.1 (17.4)	88.1 (13.4)
BMI	28.5 (5.4)	28.2 (4.3)
Prostate Volume (mL)	37.9 (12.8)	47.5 (15.7)
Prostate Length (mm)	43.0 (7.1)	46.3 (9.0)
BPH Characteristics - mean (std dev)		
IPSS	23.5 (6.7)	24.3 (6.2)
SHIM	13.2 (7.8)	13.9 (6.8)
MSHQ	10.1 (3.2)	10.8 (2.6)
SF6D-v2	0.67 (0.26)	0.68 (0.28)
PVR (mL)	73.6 (68.6)	69.2 (55.4)
Qmax (mL/sec)	9.5 (2.6)	9.6 (2.3)
IPSS - Filling Phase (irritative symptoms)	9.9 (2.9)	10.1 (2.8)
IPSS - Voiding Phase (obstructive symptoms)	13.6 (4.8)	14.1 (4.5)
Medication History - count (%)		
BPH medication	22 (46.8%)	17 (50.0%)
5-ARIs	5 (10.6%)	1 (2.9%)
Alpha blockers	20 (42.6%)	17 (50.0%)
PDE5	12 (25.5%)	10 (29.4%)
Anti-coagulant/ Anti-platelet therapy	8 (17.0%)	5 (14.7%)
Comorbidities - count (%)		
Diabetes	8 (17.0%)	7 (20.6%)
Heart disease	13 (27.7%)	6 (17.6%)
High cholesterol	7 (14.9%)	1 (2.9%)
Hypertension	13 (27.7%)	6 (17.6%)

Baseline IPSS was 23.5 ± 6.7 for the iTind™ device and 24.3 ± 6.2 for PUL. At 3 months, mean IPSS decreased to 13.4 ± 8.5 and 12.7 ± 9.1 , respectively. The between-group difference in mean improvement was -1.6 points (95% CI -5.08 to 1.86), which did not exceed the established minimal clinically important difference (MCID) for IPSS of approximately 3 points (table 2). Both groups experienced comparable improvement in IPSS subdomains that exceeded the MCID threshold. Storage symptom scores improved by 3.8 points with the iTind™ arm and 3.7 points in the PUL arm, while Voiding symptom scores improved by 6.1 and 7.9 points, respectively. Qmax increased from 9.5 ± 2.1 mL/s to 13.2 ± 6.3 mL/s in the iTind™ arm and from 9.7 ± 2.3 mL/s to 14.0 ± 6.7 mL/s in the PUL arm. PVR remained essentially unchanged in both groups (table 3).

Table 2. Secondary confirmatory efficacy analysis.

H_0 : Mean IPSS Change (iTIND) - Mean IPSS Change (UroLift) $\leq$ -4.0

H_1 : Mean IPSS Change (iTIND) - Mean IPSS Change (UroLift) $>$ -4.0

IPSS change: IPSS at Baseline – IPSS at 3-months				
Study Arm	N	Mean	Std Dev	95% CI
iTind	45	9.98	7.64	[7.68,12.27]
UroLift	34	11.59	7.74	[8.89, 14.29]

Mean IPSS Change (iTIND) - Mean IPSS Change (UroLift)

Mean	90% CI (two-sided)	p value for hypothesis testing
-1.61	[-4.52, 1.29]	0.0874

Table 3. IPSS Sub-analysis by phase

Outcome	Metric description	iTind arm	UroLift arm
IPSS	N	45	34
	Baseline	23.4 (6.8)	24.3 (6.2)
	3m Follow up	13.4 (8.5)	12.7 (9.1)
	Change	-10.0 (7.6)	-11.6 (7.7)
	P	<0.001	<0.001
IPSS - Filling Phase (irritative symptoms)	N	45	34
	Baseline	9.8 (3.0)	10.1 (2.8)
	3m Follow up	6.0 (3.3)	6.5 (4.2)
	Change	-3.8 (3.2)	-3.7 (3.2)
	P	<0.001	<0.001
IPSS - Voiding Phase (obstructive symptoms)	N	45	34
	Baseline	13.5 (4.8)	14.1 (4.5)
	3m Follow up	7.4 (6.0)	6.2 (5.4)
	Change	-6.1 (5.3)	-7.9 (5.3)
	P	<0.001	<0.001

Both arms demonstrated no significant changes in SHIM and MSHQ-EjD. Mean SHIM increased from 13.5 to 14.4 in the iTind™ device arm and 13.9 to 14.4 in UroLift™, while MSHQ-EjD rose from approximately 10 to 10.8 in the iTind™ device arm and 10.8 to 11.2 in UroLift™ arm. SF-6D v2 improved by 0.03 in the iTind™ device and 0.07 in PUL (P=0.002 for PUL, P=0.265 for the iTind™ device), indicating enhanced overall health perception. There was no significant difference between-group differences in SF-6D v2 improvement.

The iTind™ device group showed a lower AE incidence compared to UroLift™ patients, both on the day of implantation (6.4% vs 20.6%, $P = 0.0583$) and from one week through one month post implantation (8.5% vs 17.7%). No AEs occurred after 1 month in the iTind™ device arm, whereas the UroLift™ arm recorded one case of urinary urgency between months 1 and 3 (table 4).

Table 4. Safety analysis by time window.

Time Window A	iTind arm				UroLift Arm				Difference in AE rates (iTind - UroLift)	95% CI of AE rate difference
	Total patients	Patients w/ AE	AE rate %	95% CI of AE rate	Total patients	Patients w/ AE	AE Rate (%)	95% CI of AE rate		
on the proc day	47	3	6.38%	[1.34%, 17.54%)	34	7	20.59%	[8.70%, 37.90%)	-14.2%	[-31.9%, 0.9%)
within 1 week post-proc	47	12	25.53%	[13.94%, 40.35%)	34	8	23.53%	[10.75%, 41.17%)	2.0%	[-18.3%, 21%)
1 wk - 1 mo	47	4	8.51%	[2.37%, 20.38%)	34	6	17.65%	[6.76%, 34.53%)	-9.1%	[-26.8%, 6.0%)
1 - 3 mo	46	0	0.00%	[0.00%, 7.71%)	34	1	2.94%	[0.07%, 15.33%)	-2.9%	[-15.3%, 5.2%)

Time Window B	iTind Arm			UroLift Arm			Difference in AE rates (iTind - UroLift)
	Total patients	Patients w/ AE	AE rate %	Total patients	Patients w/ AE	AE rate %	
on the proc day	47	3	6.38%	34	7	20.59%	-14.2%
within 1 week post-proc	47	12	25.53%	34	8	23.53%	2.0%
1 wk - 3 mo	46	4	8.70%	34	7	20.59%	-11.9%

Time Window C (up to 3m FU)	iTind Arm			UroLift Arm			Difference in AE rates (iTind - UroLift)	p value
	Total patients	Patients w/ AE	AE rate %	Total patients	Patients w/ AE	AE rate %		
during procedure	47	11	23.40%	34	7	20.59%	2.8%	0.7635
post procedure	46	6	13.04%	34	12	35.29%	-22.3%	0.0185

Time window C – (for iTind arm, “during procedure” covers the duration of implantation and retrieval, “post procedure” means after retrieval)

At 3 months, procedure- or device-related AEs occurred in 15 of 46 patients (32.6%) treated with the iTind™ device and in 16 of 34 patients (47.1%) treated with UroLift™, corresponding to an absolute difference of –14.5% (95% CI –35.8% to 7.8%, P = 0.1897). No device malfunctions were reported (table 5).

Table 5. Primary safety analysis.

H_0 : AE Rate (iTIND) $\geq$ AE Rate (UroLift)

H_1 : AE Rate (iTIND) $<$ AE Rate (UroLift)

Study arm	Total patients	Patients with AE within 3 months	AE rate	95% CI of AE rate	Difference in AE rates (iTind - UroLift)	95% CI of AE rate difference	p value for hypothesis testing
iTind	46	15	32.6%	[19.5%, 48.0%]	-14.5%	[-35.8%, 7.8%]	0.09485
UroLift	34	16	47.1%	[29.78%, 64.9%]			

Adverse events included dysuria (the iTind™ device: 4.3%; UroLift™: 8.8%), hematuria (the iTind™ device: 10.9%; UroLift™: 8.8%), and transient urinary retention (the iTind™ device: 10.9%; UroLift™: 14.7%). All were self-limited and resolved with conservative management. Majority of

complications were Grade I Clavien-Dindo grade and were observed in 23.9% of the iTind™ device versus 38.2% of UroLift™ participants (P= 0.167) (table 6).

Table 6. Safety comparison at 3-month FU by Clavien-Dindo classification and AE term.

Clavien-Dindo Classification	AE Term	iTIND Arm (n=46)*		UroLift Arm (n=34)		AE Rate Diff (iTIND - UroLift)
		Patient w/ AE	AE Rate (%)	Patient w/ AE	AE Rate (%)	
Grade I	Anejaculation	1	2.17%	1	2.94%	-0.77%
	Bladder Spasms	1	2.17%	1	2.94%	-0.77%
	Blood Clot in the Urine	0	0.00%	2	5.88%	-5.88%
	Device Pain	2	4.35%	1	2.94%	1.41%
	Dysuria	2	4.35%	3	8.82%	-4.48%
	Hematuria	4	8.70%	3	8.82%	-0.13%
	Hemospermia	0	0.00%	1	2.94%	-2.94%
	Nocturia	0	0.00%	1	2.94%	-2.94%
	Pain	2	4.35%	2	5.88%	-1.53%
	Post Void Dribble	1	2.17%	0	0.00%	2.17%
	Tinea Cruris	0	0.00%	1	2.94%	-2.94%
	Urinary Frequency	1	2.17%	1	2.94%	-0.77%
	Urinary Hesitancy	1	2.17%	1	2.94%	-0.77%
	Urinary Incontinence	2	4.35%	2	5.88%	-1.53%
	Urinary Leakage	1	2.17%	0	0.00%	2.17%
	Urinary Retention	3	6.52%	3	8.82%	-2.30%
	Urinary Urgency	1	2.17%	2	5.88%	-3.71%
	PTS w/ Any Grade I AEs	11	23.91%	13	38.24%	-14.32%
Grade II	Hematuria	1	2.17%	0	0.00%	2.17%
	Urinary Frequency	1	2.17%	0	0.00%	2.17%
	Urinary Retention	1	2.17%	2	5.88%	-3.71%
	Urinary Tract Infection	2	4.35%	0	0.00%	4.35%
	Urinary Urgency	0	0.00%	2	5.88%	-5.88%
	PTS w/ Any Grade II AEs	4	8.70%	4	11.76%	-3.07%
Grade IIIa	Urinary Retention	1	2.17%	0	0.00%	2.17%

Note: Patient 01-039 withdrew from the study after 1 month FU, which is not included in this analysis.

Among the 10.9% of patients who experienced transient urinary retention, only one iTind™ device patient required catheterization, corresponding to a Clavien–Dindo grade IIIa complication; all other cases were ≤ grade II (table 7).

Table 7. Safety comparison at 3-month FU by AE term.

AE term	iTind arm (n = 46)			UroLift arm (n = 34)			AE rate difference (iTIND - UroLift)
	AE cases	AE subjects	AE subject %	AE cases	AE subjects	AE subject %	
Urinary Urgency	1	1	2.2%	5	4	11.8%	-9.6%
Blood Clot in the Urine	0	0	0.0%	2	2	5.9%	-5.9%
Dysuria	2	2	4.3%	3	3	8.8%	-4.5%
Urinary Retention	5	5	10.9%	5	5	14.7%	-3.8%
Nocturia	0	0	0.0%	1	1	2.9%	-2.9%
Tinea Cruris	0	0	0.0%	1	1	2.9%	-2.9%
Pain	2	2	4.3%	2	2	5.9%	-1.5%
Urinary Incontinence	2	2	4.3%	2	2	5.9%	-1.5%
Anejaculation	1	1	2.2%	1	1	2.9%	-0.8%
Bladder Spasms	1	1	2.2%	1	1	2.9%	-0.8%
Hemospermia	1	1	2.2%	1	1	2.9%	-0.8%
Urinary Hesitancy	1	1	2.2%	1	1	2.9%	-0.8%
Device Pain	2	2	4.3%	1	1	2.9%	1.4%
Urinary Frequency	2	2	4.3%	1	1	2.9%	1.4%
Hematuria	5	5	10.9%	3	3	8.8%	2.0%
Urinary Leakage	1	1	2.2%	0	0	0.0%	2.2%
Urinary Tract Infection	2	2	4.3%	0	0	0.0%	4.3%

No cases of de novo erectile dysfunction, incontinence, or persistent pain were reported in either arm.

Mean procedure time was shorter for the iTind™ device (6.4 ± 3.7 min) than for UroLift™ (9.8 ± 5.2 min). Foley catheters were placed post-implantation procedure in 4.3% of the iTind™ device versus 21% of UroLift™ patients. Among the iTind™ device recipients, majority (89%) required no catheter after retrieval (table 8). All participants were discharged the same day of procedure.

Table 8. Secondary efficacy analysis.

Outcome	Metric description	iTind arm	UroLift arm
IPSS	N	45	34
	Baseline	23.4 (6.8)	24.3 (6.2)
	3m Follow up	13.4 (8.5)	12.7 (9.1)
	Change	-10.0 (7.6)	-11.6 (7.7)
	P	<0.001	<0.001
SHIM	N	42	33
	Baseline	13.5 (7.7)	13.9 (6.8)
	3m Follow up	14.4 (8.2)	14.4 (8.0)
	Change	1.0 (7.0)	0.5 (5.1)
	P	0.144	0.734
MSHQ	N	45	34
	Baseline	10.0 (3.2)	10.8 (2.6)
	3m Follow up	10.8 (3.8)	11.2 (3.3)
	Change	0.8 (4.1)	0.4 (3.1)
	P	0.083	0.398
SF-6D v2	N	44	33
	Baseline	0.67 (0.26)	0.68 (0.28)
	3m Follow up	0.70 (0.25)	0.76 (0.26)
	Change	0.03 (0.25)	0.07 (0.13)
	P	0.265	0.002
Qmax (mL/sec)	N	31	22
	Baseline	9.5 (2.1)	9.7 (2.3)
	3m Follow up	13.2 (6.3)	14.0 (6.7)
	Change	3.7 (5.9)	4.3 (5.7)
	P	<0.001	<0.001
PVR (mL)	N	31	22
	Baseline	69.3 (60.9)	78.6 (58.9)
	3m Follow up	83.8 (95.8)	81.9 (78.4)
	Change	14.5 (82.0)	3.3 (78.3)
	P	0.481	0.851

Discussion

This interim analysis provides the first prospective randomized comparison of the iTind™ device and Urolift™, two non-ablative, mechanical MISTs for BPH. Both techniques achieved clinically meaningful symptom improvement at 3 months, with comparable early functional outcomes.

Both devices achieved robust IPSS improvements. The pattern of improvement, marked gains in both storage and voiding subdomains, mirrors prior studies.⁵⁻⁷ UroLift™ demonstrated a slightly greater but not significant ($p = 0.7235$) increase in Qmax, whereas the iTind™

device showed shorter procedural duration and reduced need for catheterization.

The overall AE rate was lower in the iTind™ device arm, particularly during and immediately following implantation. While the difference did not reach statistical significance at this interim timepoint, the trend favors the iTind™ device for early and mid-term safety, with no AEs after 1 month, underscoring its transient and self-limited profile. The absence of mid-term events following the iTind™ device removal suggests minimal ongoing tissue reactions or mechanical sequelae. Most events were mild (grade I–II), consistent with prior studies such as MT-03 and MT-06 for the iTind™ device and the LIFT pivotal study for PUL. No cases of device malfunction, migration, or chronic pain were observed in either arm.^{5–7}

Both treatments preserved erectile and ejaculatory function, an essential advantage over any cavitating or energy-based surgery. Return to work and activity occurred within one week for most participants, aligning with expectations for both procedures.

The interim findings reinforce that mechanical MISTs offer meaningful relief with minimal morbidity and rapid recovery. The iTind™ device's temporary implant, removed after only 5–7 days may appeal to men seeking a solution without permanent implants. Procedure duration and anesthesia requirements were lower for the iTind™ device, improving workflow efficiency in outpatient or office settings. The higher proportion of UroLift™ patients requiring general or regional anesthesia in this study likely reflects a combination of factors, including longer procedure times, varied clinician preference, or established institutional pathways for this intervention.⁶ This difference further highlights the iTind™ device's potential for utilization in settings with limited anesthesia resources or for patients seeking to avoid general anesthesia. These characteristics support its positioning as a minimally invasive, low resource-intensity therapy within the expanding BPH treatment continuum.

This analysis reflects an interim dataset at 3 months and was not powered for formal superiority testing. Limitations of this study include baseline prostate size was smaller in the iTind™ device group, which could influence outcomes, and the iTind™ device group also presented with a slightly higher incidence of certain comorbidities. Additionally, despite a 1:1 randomization protocol, an unequal distribution of patients was observed in this cohort analyzed (n = 47 the iTind™ device, n = 34 UroLift™). This imbalance was primarily due to a higher rate of post-randomization, pre-procedure withdrawals in the UroLift™ arm, which should be considered when interpreting the results. Moreover, functional parameters such as PVR may fluctuate early post-intervention; in the present analysis, PVR remained largely unchanged between treatment groups at early follow-up, suggesting stable bladder emptying during the initial postoperative period. Final results will provide definitive evaluation of durability and safety.

Strengths of this study include its prospective randomized design, which offers the first head-to-head controlled comparison between two mechanical MISTs, the iTind™ device and PUL. The study captures early outcomes, including IPSS subdomains, Qmax, catheterization rates, sexual function, return to daily activity, and AE timing, allowing characterization of each device's early therapeutic profile. Procedural metrics such as operative time, anesthesia requirements, and perioperative catheter use were also assessed. Safety data were collected, with severity grading and documentation of both peri-operative and post-removal events. This study provides high-quality evidence for the use of the iTind™ device within the contemporary BPH treatment paradigm.

Conclusions

At 3 months, both the iTind™ device and PUL provided clinically meaningful improvement in LUTS secondary to BPH. The iTind™ device achieved symptom relief with a favorable early safety profile, shorter procedure time, and minimal post-operative catheterization. No mid-term or serious device-related events occurred.

These interim results support the continued investigation of the iTind™ device as a safe and effective option for men seeking a minimally invasive BPH therapy which does not preclude or complicate future therapy. Final results from the MT-08 study will further demonstrate long-term durability and functional outcomes.

Declarations

Competing Interests

Dr. Bilal Chughtai is a consultant for Olympus.

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Author Contribution

All authors contributed equally and reviewed the manuscript.

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None.

Data Availability Statement

The datasets generated and/or analyzed during the current interim analysis are not publicly available at this time because the study remains ongoing and the final analysis have not yet been completed. Following completion of the final study analyses, de-identified data may be made available from the corresponding author upon reasonable request, subject to institutional approval and applicable ethical, regulatory, and data-sharing requirements.

Ethics Declaration

This interim analysis was conducted as part of an ongoing study performed in accordance with the principles of the Declaration of Helsinki and applicable institutional and regulatory requirements. The study protocol was reviewed and approved by the appropriate Institutional Review Board/Ethics Committee prior to study initiation. Written informed consent was obtained from all participants before enrollment, as applicable. Participant data were de-identified and handled in accordance with approved study procedures and patient confidentiality requirements.

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