JOURNAL OF ENDOUROLOGY, SEPTEMBER 2022

Prostatic Urethral Lift for Obstructive Median Lobes: Consistent Results Across Controlled Trial and Real-World Settings

First detailed analysis of patients with an obstructive median lobe (OML) treated with prostatic urethral lift (PUL) using the UroLift® System in controlled and real-world settings compared to subjects treated with TURP or sham in randomized controlled trials.

KEY TAKEAWAYS

- Consistent PUL outcomes for the treatment of median lobe obstruction across controlled and real-world settings
- Men with OML treated with PUL experience symptom improvement sooner, are satisfied more quickly, and indicate with superior ejaculatory function scores at all timepoints after PUL, compared to those treated with TURP
- Patients treated in a real-world setting experienced fewer post-op catheterizations without overall elevated adverse events when compared with the MedLift cohort

Click here to access the full study

CONTEXT AND AIM OF STUDY

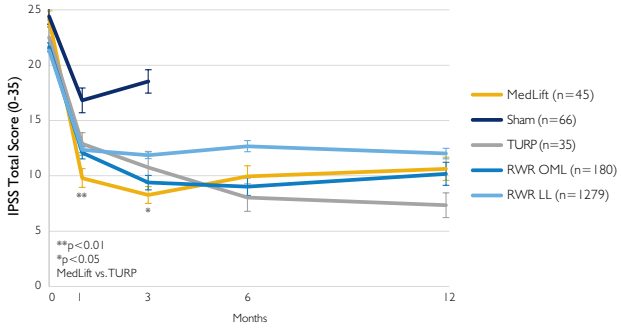
- Median lobe obstruction is **estimated to occur in up to 20% of men diagnosed with BPH**. Although not as common as lateral lobe hyperplasia, population-based studies have shown that an **obstructive median lobe (OML) can pose an increased risk for progression of clinical BPH and bladder outlet obstruction**.[2-3] Common-line treatments include watchful waiting, BPH medical therapy, or invasive surgical therapy such as TURP or GreenLight™ Laser Therapy
- The UroLift System is cleared by the US FDA for the treatment of BPH, including lateral and median lobe hyperplasia, in men with prostates no greater than 100 cc.† This has resulted in extensive use of PUL to treat men with a range of prostate types. The AUA BPH Guidelines currently limit PUL recommendation to only lateral lobe (LL) disease with a maximum prostate volume of 80 cc. Society guidelines often provide recommendations based on a more limited evaluation of published evidence, such as considering only randomized controlled (RCT) and clinical controlled (CCT) studies when crafting evidence-based updates
- **This study compares outcomes of OML patients treated with PUL in controlled and real-world settings to relevant comparator groups (i.e., subjects with lateral lobe obstruction treated with TURP and sham in RCTs) in order to demonstrate similar symptom and safety outcomes, and better patient experience outcomes than TURP**

Type of Study	Patients Used	Outcomes Followed	Comparison
Randomized Controlled Trials (RCT) L.I.F.T. BPH6	• 66 men randomized to sham control • 35 men randomized to TURP	IPSS, QoL, Qmax, PVR, BPHII, MSHQ-EjD function & bother, SHIM, patient satisfaction	vs. MedLift
Clinical Controlled Trial (CCT) MedLift	45 men who met the inclusion criteria of the L.I.F.T. study and had an obstructive median lobe	IPSS, QoL, Qmax, PVR, BPHII, MSHQ-EjD function & bother, SHIM, patient satisfaction	vs. Sham, TURP, RWR-OML
Real-World Retrospective Study (RWR)	180 OML patients filtered based on MedLift enrollment criteria††	IPSS, PVR, Qmax, QoL	vs. MedLift

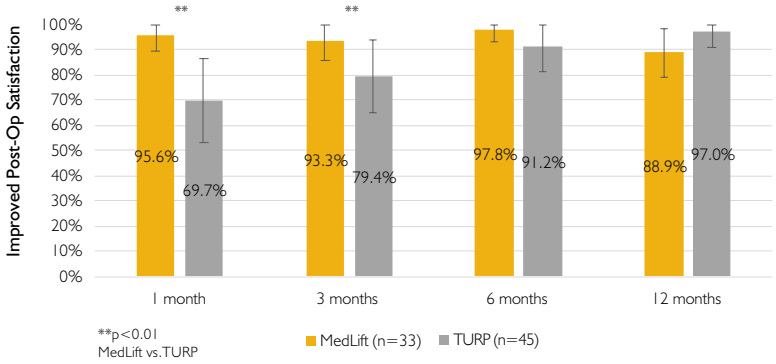
†† 3,226 total patients (2,714 non-retention vs. 512 retention patients) encompass the RWR database. 277 non-retention patients have OML; of these, 180 were filtered to match most MedLift enrollment criteria

1. CONSISTENT SYMPTOM RELIEF IN CONTROLLED AND REAL-WORLD STUDIES

- IPSS, QoL, PVR, and Qmax outcomes were equivalent between MedLift and RWR-OML groups at 3, 6, and 12 months
- The post-treatment, IPSS improvement for MedLift subjects was **170% greater than that of sham at 3 months, with significantly better QoL, Qmax, and BPHII**



2. BETTER SYMPTOM RELIEF AND PATIENT SATISFACTION SOONER VS. TURP



- Compared to TURP, MedLift IPSS and QoL improved significantly more at 1 and 3 months** and were similar at 6 and 12 months
- Significantly more MedLift patients are satisfied sooner after treatment (1 and 3 months)
- Similar rate of patient satisfaction between MedLift and TURP subjects at 6 and 12 months post-treatment

3. BETTER PATIENT EXPERIENCE: LOW RATES OF ADVERSE EVENTS, FEWER CATHETERIZATIONS, AND BETTER SEXUAL FUNCTION

Adverse Events

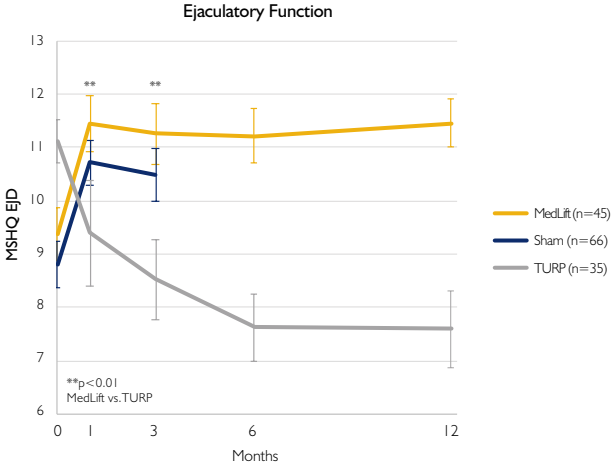
- **Compared with TURP, MedLift subjects experienced no high-severity adverse events (AEs),** while 5 TURP patients reported serious AEs (0.0% vs. 14.3%, p<0.01)
- **RWR-OML patients did not experience higher rates of overall AEs** compared to MedLift and RWR LL groups

Catheterizations

- Non-standard of care catheterization rate was 66.1% for RWR-OML vs. 80% for MedLift (p=0.07)
- **MedLift patients also experienced shorter catheter durations in comparison to TURP (1.24 days vs. 2.2 days, p=0.01)**

Sexual Function

- **Compared to TURP, ejaculatory function and bother scores were significantly better** for MedLift subjects at all time points



Click here to access the full study

Drs. Eure, Rukstalis and Roehrborn are paid consultants of Teleflex Interventional Urology. The study was sponsored by Teleflex.

1. Eure et al. Prostatic Urethral Lift for Obstructive Median Lobes: Consistent Results Across Controlled Trial and Real-World Settings. 2022; 2. Doo CK, Uh HS. Anatomic configuration of prostate obtained by noninvasive ultrasonography can predict clinical voiding parameters for determining BOO in men with LUTS. Urology. 2009;73:232–6; 3. Chia SJ, Heng CT, Chan SP, et al. Correlation of intravesical prostatic protrusion with bladder outlet obstruction. BJU Int 2003;91(4):371–374; 4. Roehrborn, J Urol 2013

†Indicated for the treatment of symptoms of an enlarged prostate up to 100cc in men 50 years or older. As with any medical procedure, individual results may vary. Most common side effects are temporary and include dysuria, hematuria, pelvic pain, micturition urgency, urge incontinence (Roehrborn, J Urology 2013). Rare side effects, including bleeding and infection, may lead to a serious outcome and may require intervention. Consult indications approved for your geography and the Instructions for Use (IFU) for more information. ifu.teleflex.com

Federal Law (USA) restricts these devices to sale by or on the order of a physician.

WARNING: This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

Not all products may be available in all countries. For product information please contact la.cs@teleflex.com or your local representative. Please check your local regulatory approval status.

Teleflex®
INTERVENTIONAL UROLOGY