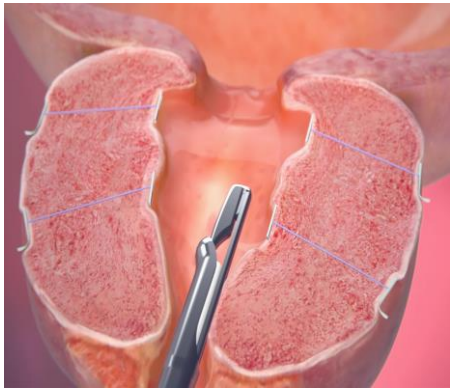
Prostatic Urethral Lift real-world experience is consistent with controlled trials in both non-retention and retention subjects

Gregg Eure, MD

AUA 2020

LBA01-07

Introduction



- The UroLift® Prostatic Urethral Lift (PUL) procedure has been shown to produce rapid and lasting LUTS relief with low morbidity, resulting in improvement in quality of life
- PUL procedure: Small transprostatic implants are placed to mechanically open the obstructed prostatic fossa
- Extensive clinical evidence has been gathered on subjects in a controlled clinical trial setting
  - L.I.F.T. – randomized controlled trial for PUL following non-retention subjects over 5 years (n=140)
    - BPH patients ≥ 50 years, prostate volume 30cc to 80cc, IPSS ≥ 13, peak flow rate (Qmax) ≤ 12 mL/s
    - Randomized to PUL or blinded sham control
  - P.U.L.S.A.R. – controlled study for PUL across 6 U.K. sites following subjects in retention at baseline for 12 months (n=52)
    - BPH patients ≥ 50 years, prostate volume ≤100 cc, AUR with ≥ 1 failed TWOC on alpha blocker
    - Mean catheter dependence prior to PUL 132 days; 40% subjects had LUTS ≥ 6 years

Objective

To assess UroLift System performance within a heterogenous real-world population compared to experience in controlled settings

Controlled Setting

- Hypothesis testing
- Specific selection criteria
- Smaller population
- Fixed timeframe
- Powered

Demonstrated PUL efficacy, safety and durability in studied BPH patients

VS

Real-world Setting

- Observational
- Broad selection criteria
- Hypothesis generating
- Larger population
- Longer time frames
- Flexible

How does PUL perform within a broad population of BPH patients?

PUL Real World Retrospective (RWR) study

Evaluation of **3226** Prostatic Urethral Lift (PUL) cases across 22 sites in USA & Australia

Retrospective Data

Patients who underwent the UroLift procedure after market clearance

Enrollment criteria:

- Baseline IPSS score ≤9 months before PUL
- At least one follow-up IPSS score within 12mo post-PUL

Retention status at baseline

RWR Group A (n=2714) Non-Retention	RWR Group B (n=512) Retention
vs. L.I.F.T. (n=140)	vs. P.U.L.S.A.R (n=52)

Methods

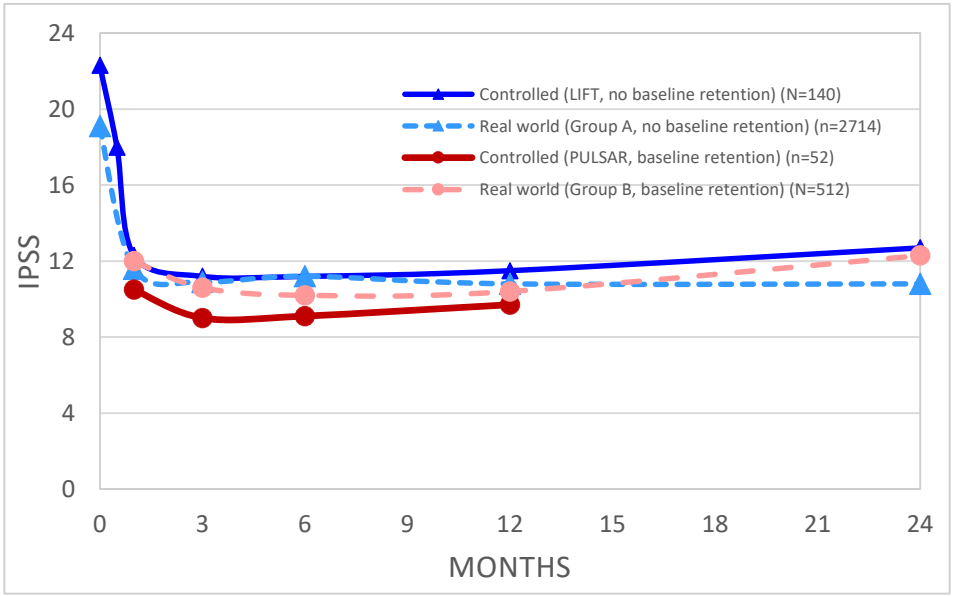
- Absolute IPSS scores across all studies compared at 1, 3, 6, 12 months post-PUL
- AEs and catheterization rates of RWR subjects compared to L.I.F.T. and P.U.L.S.A.R. controlled studies

Baseline Demographics

Baseline measurement (mean, SD)	RWR-A (n=2714) Non-Retention	L.I.F.T. (n=140)	p-value	RWR-B (n=512) Retention	P.U.L.S.A.R. (n=52)	p-value
Age	69 ± 9.0	67 ± 8.6	0.003	71 ± 10.6	71 ± 7.9	0.8
Prostate volume, cc	46 ± 19.6	45 ± 12	0.3	48 ± 20.6	55 ± 23	0.3
IPSS	19.0 ± 6.9	22.2 ± 5.5	<0.0001	N/A	N/A	N/A
QoL	3.9 ± 1.5	4.6 ± 1.1	0.0001	N/A	N/A	N/A
Qmax, mL/s	11.9 ± 7.9	7.9 ± 2.4	0.0001	N/A	N/A	N/A
Implants per subject	4.7 ± 1.4	4.9 ± 1.6	0.1	4.7 ± 1.4	4.8 ± 1.3	0.6

- RWR non-retention subjects are less symptomatic at baseline with lower IPSS and QoL scores compared to L.I.F.T. subjects
- Real-world retention subjects were similar to P.U.L.S.A.R. subjects in measurable baseline demographics

IPSS scores equivalent between all groups throughout follow-up



(1 month, p=0.4; 3 months, p=0.3; 6 months, p=0.2; 12 months, p=0.5)

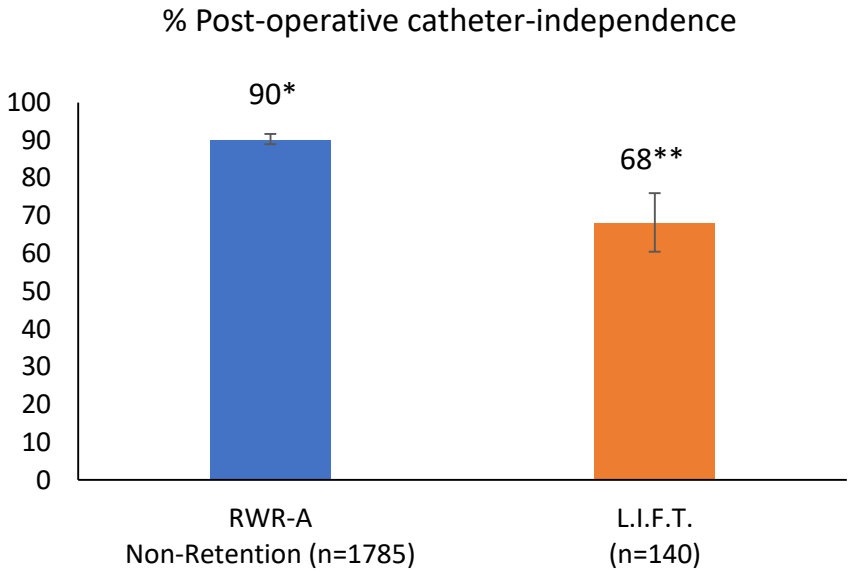
- Similar absolute IPSS scores among all groups at all timepoints following PUL
- No differences in symptom outcomes after treatment between real-world and controlled studies

12-month outcomes similar between RWR subjects and controlled studies

RWR Groups vs. Controlled Studies						
Measurement (mean ± SD)	**RWR-A Non-Retention**	**L.I.F.T.**	**p-value**	**RWR-B Retention**	**P.U.L.S.A.R.**	**p-value**
IPSS	10.8 ± 7.0 (628)	11.5 ± 7.3 (123)	0.3	10.4 ± 6.5 (81)	9.7 ± 7.4 (46)	0.6
IPSS QoL	2.1 ± 1.5 (513)	2.3 ± 1.6 (123)	0.2	2.1 ± 1.4 (67)	1.4 ± 1.5 (46)	0.02
Qmax, mL/s	21.2 ± 111.3 (202)	12.1 ± 5.3 (102)	0.4	13.2 ± 7.0 (34)	11.7 ± 9.3 (37)	0.9

- All absolute symptom outcomes are equivalent between RWR non-retention subjects and L.I.F.T. subjects
- IPSS and Qmax are similar between RWR retention and P.U.L.S.A.R. subjects
  - QoL is better in P.U.L.S.A.R. subjects than in RWR retention subjects

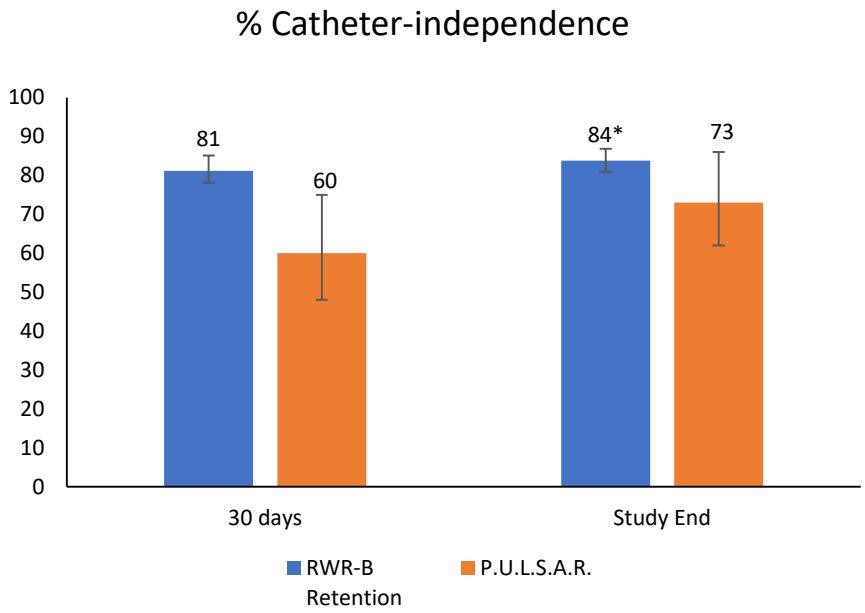
Real-world catheter-independence rate better than in controlled studies



- 90% of RWR non-retention subjects were catheter-free post-PUL, which is slightly better than the 68% catheter-free rate of the L.I.F.T. trial

*Excluding catheters placed as part of standard of care
**Of those void trial tested

Real-world catheter-independence rate also better for retention subjects



- At 1 month post-treatment, 81% of RWR retention subjects were catheter-free, which is significantly better than P.U.L.S.A.R. results (p=<0.001)
- Catheter independence was better in real-world subjects by end of study: 84% RWR retention and 73% P.U.L.S.A.R. (p=0.05)

*Longest available follow up

Real-world adverse events not elevated compared to controlled studies

	RWR-A Non-Retention	L.I.F.T.	p-value
Total AEs	36%	89%	<0.0001
Dysuria	8%	36%	<0.0001
Hematuria	17%	29%	0.0006
Pelvic pain	2%	18%	<0.0001

- Total AE rate was not elevated in real-world non-retention vs. L.I.F.T. controlled subjects
- High-frequency AEs were not elevated in RWR non-retention vs. L.I.F.T. subjects

Real-world adverse events also not elevated in retention subjects

	RWR-B Retention	P.U.L.S.A.R.	p-value
Total AEs	35%	46%	0.1
Dysuria	5%	15%	0.006
Hematuria	15%	15%	1.0
Blood clot in urine	0%	10%	<0.0001

- Total AE rate was not elevated in real-world retention vs. P.U.L.S.A.R. controlled subjects
- High-frequency AEs were not elevated in RWR retention compared to P.U.L.S.A.R.

Conclusions

- PUL real world symptom response, safety and patient experience outcomes are consistent with results from controlled trials
  - Symptom outcomes
    - Equivalent 12-month absolute IPSS, QoL, Qmax values between RWR groups and controlled studies
  - Safety
    - Total AE rates and rates of high-frequency AEs in RWR groups equivalent to or lower than controlled trials
  - Catheterization
    - Lower post-operative catheterization rate in real-world non-retention subjects vs. L.I.F.T.
    - Greater rate of catheter-independence at 1 month and study end in real-world retention subjects vs. P.U.L.S.A.R.
- PUL has broad applicability to safely and effectively treat heterogenous populations of non-retention and retention subjects in the real world