



My patient has a prostate the size of a melon. What now?: The essentials of treating BPH

Jason K. Burrus, MD; Brian K. Wade, MD

BPH is Important

Top 10 Diagnosed Diseases in 2006 for Men 50 years and older

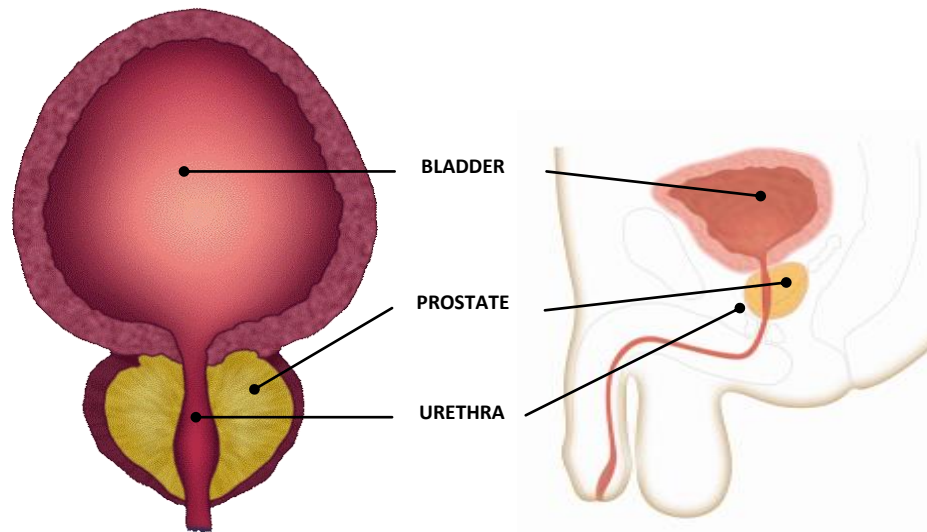
Rank	Disease	1-year prevalence (%) (n = 963,452 person-years)
1	Coronary Artery Disease/Hyperlipidemia	51.3
2	Hypertension	45.2
3	Diabetes Mellitus Type 2	17.5
4	Enlarged Prostate	13.5
5	Osteoarthritis	13.3
6	Arrhythmias	8.8
7	Cataract	8.6
8	Gastroesophageal reflux disease	8.4
9	Bursitis	8.0
10	Prostate Cancer	7.8

Issa MM et al. Am J Manag Care. 2006;12(suppl):S83–S89.

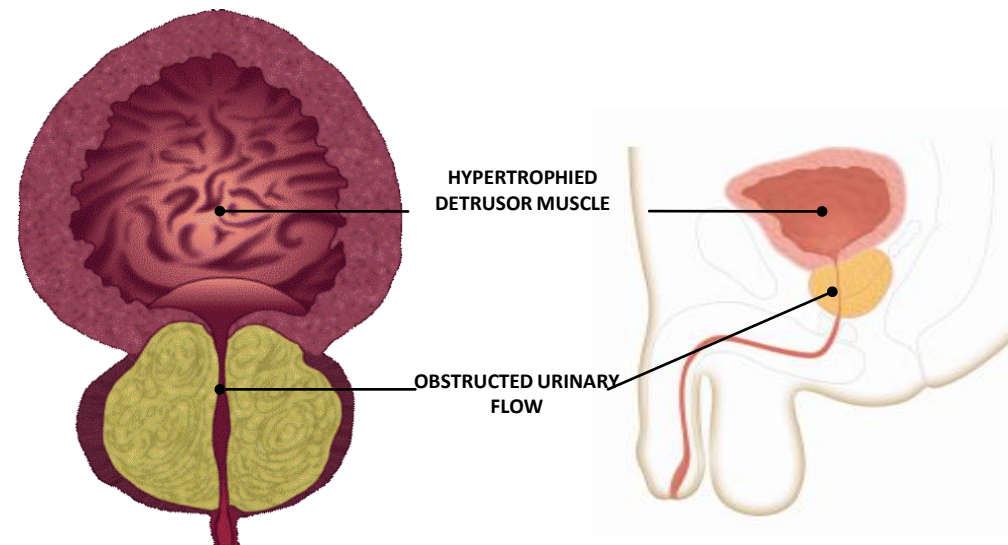
Normal vs. Enlarged Prostate

- As the prostate enlarges, pressure can be put on the urethra
- Causes urinary problems
- In general, the size of the prostate does not correlate to severity of symptoms

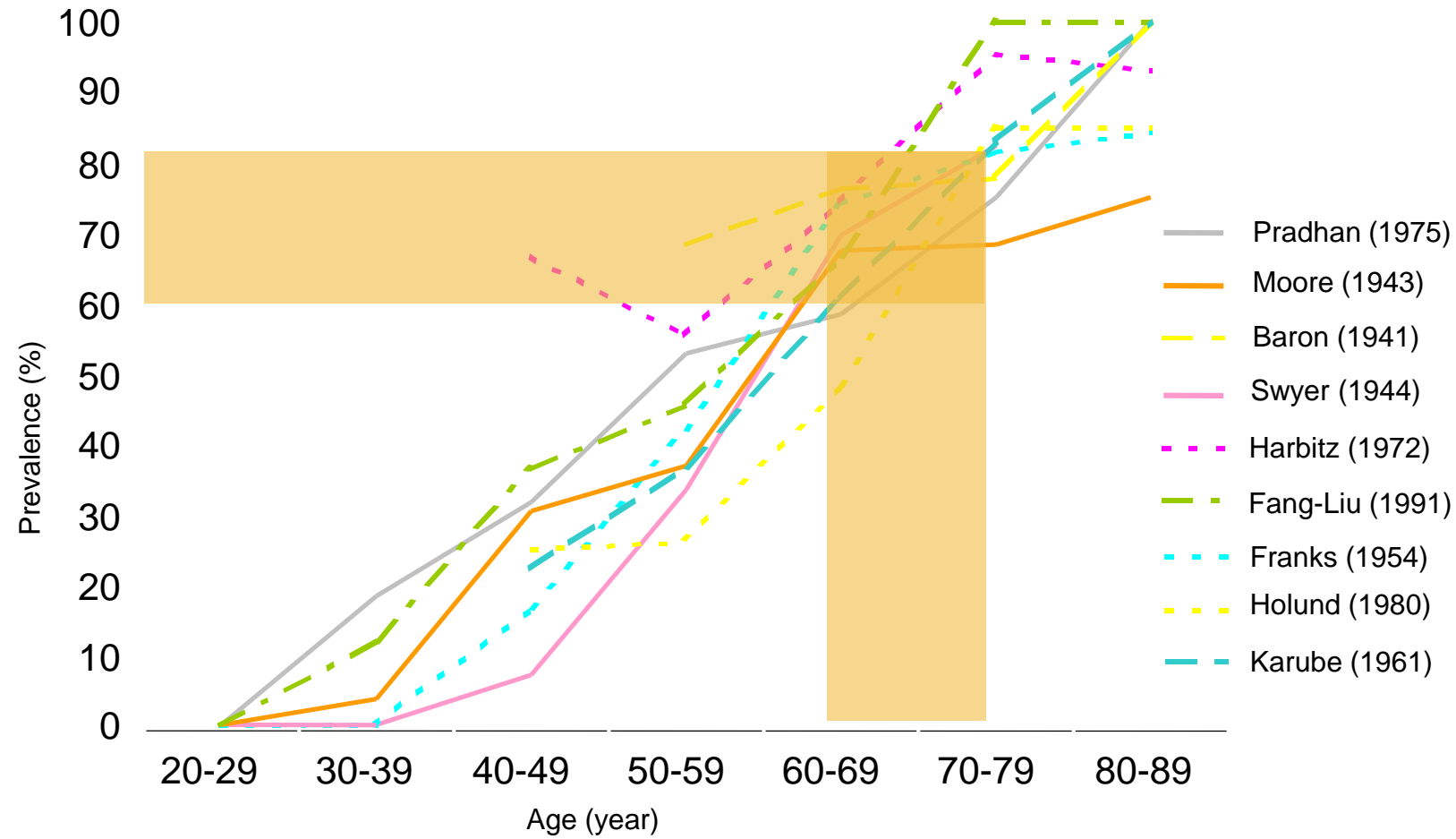
Normal Prostate Anatomy



Enlarged Prostate (BPH) Anatomy

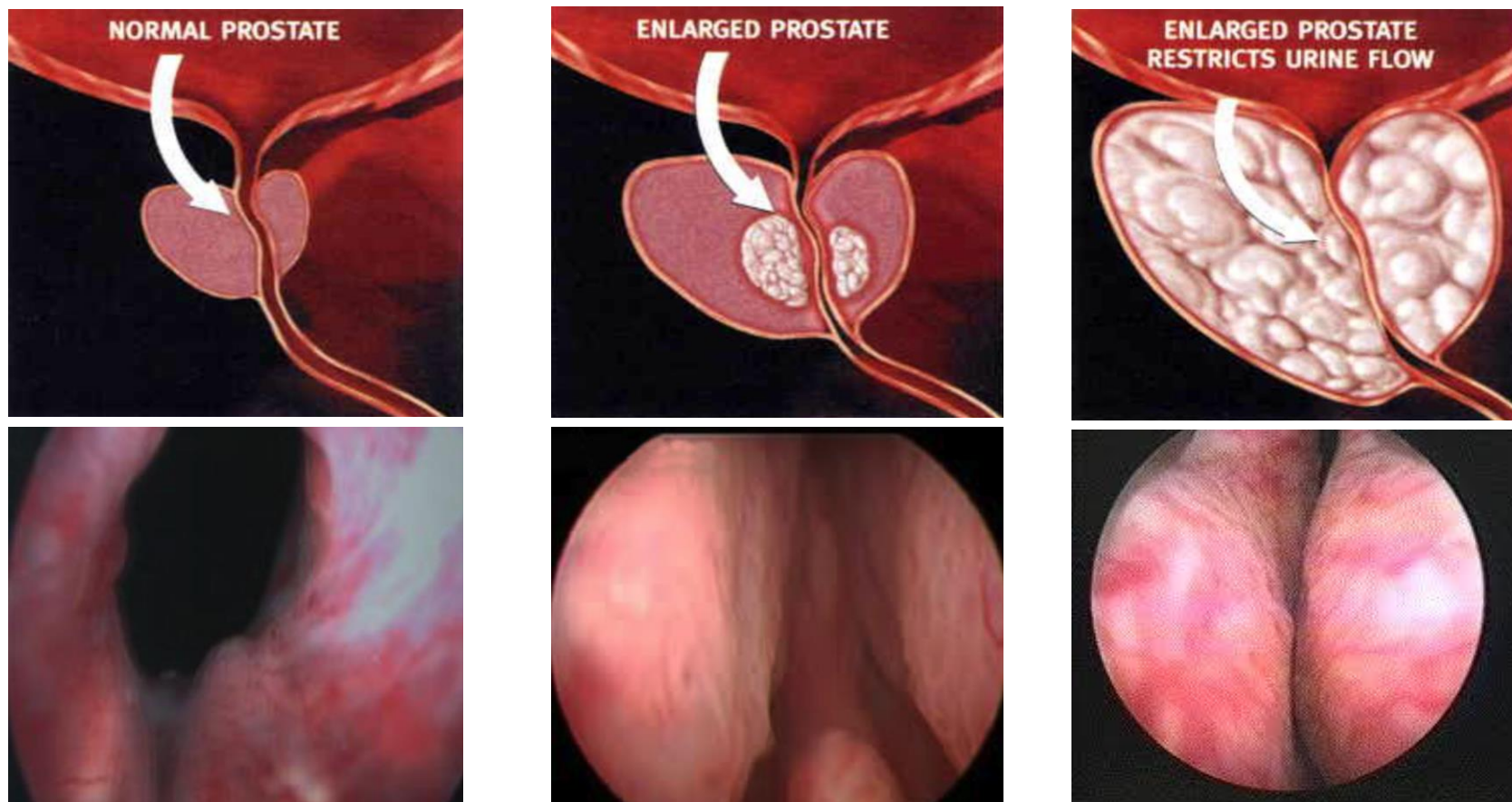


Prevalence of Histologic BPH Increases With Age



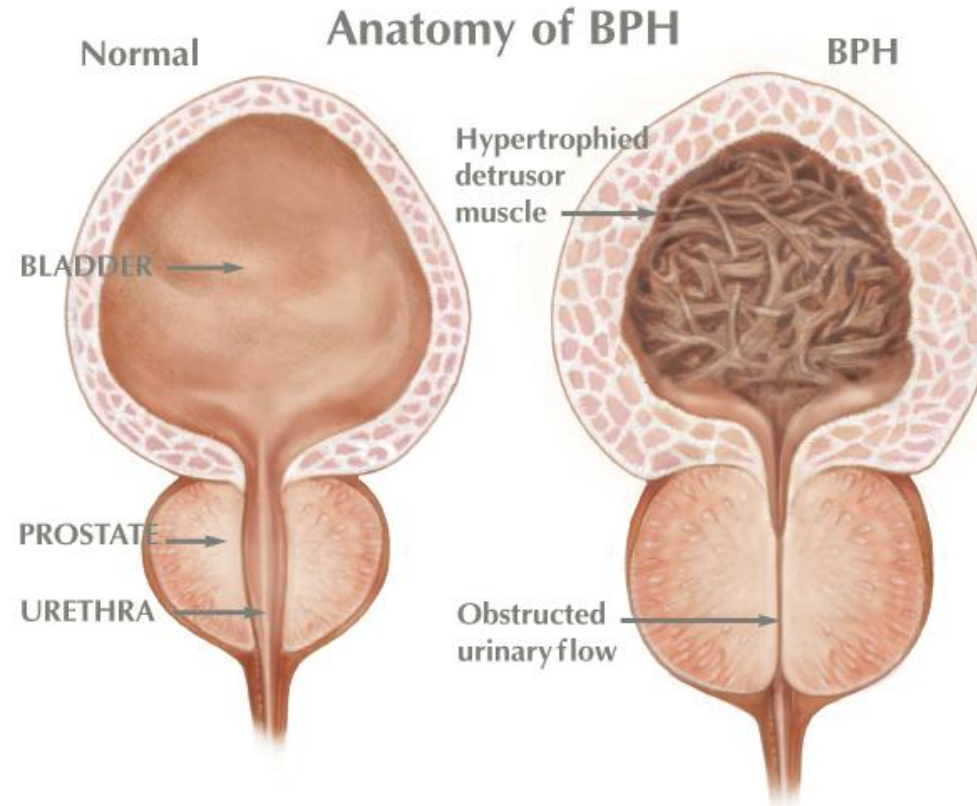
Roehrborn CG, McConnell JD. In: Walsh PC et al, eds. Campbell's Urology. 8th ed. Philadelphia, Pa: Saunders; 2002:1297-1336.

BPH Disease Progression



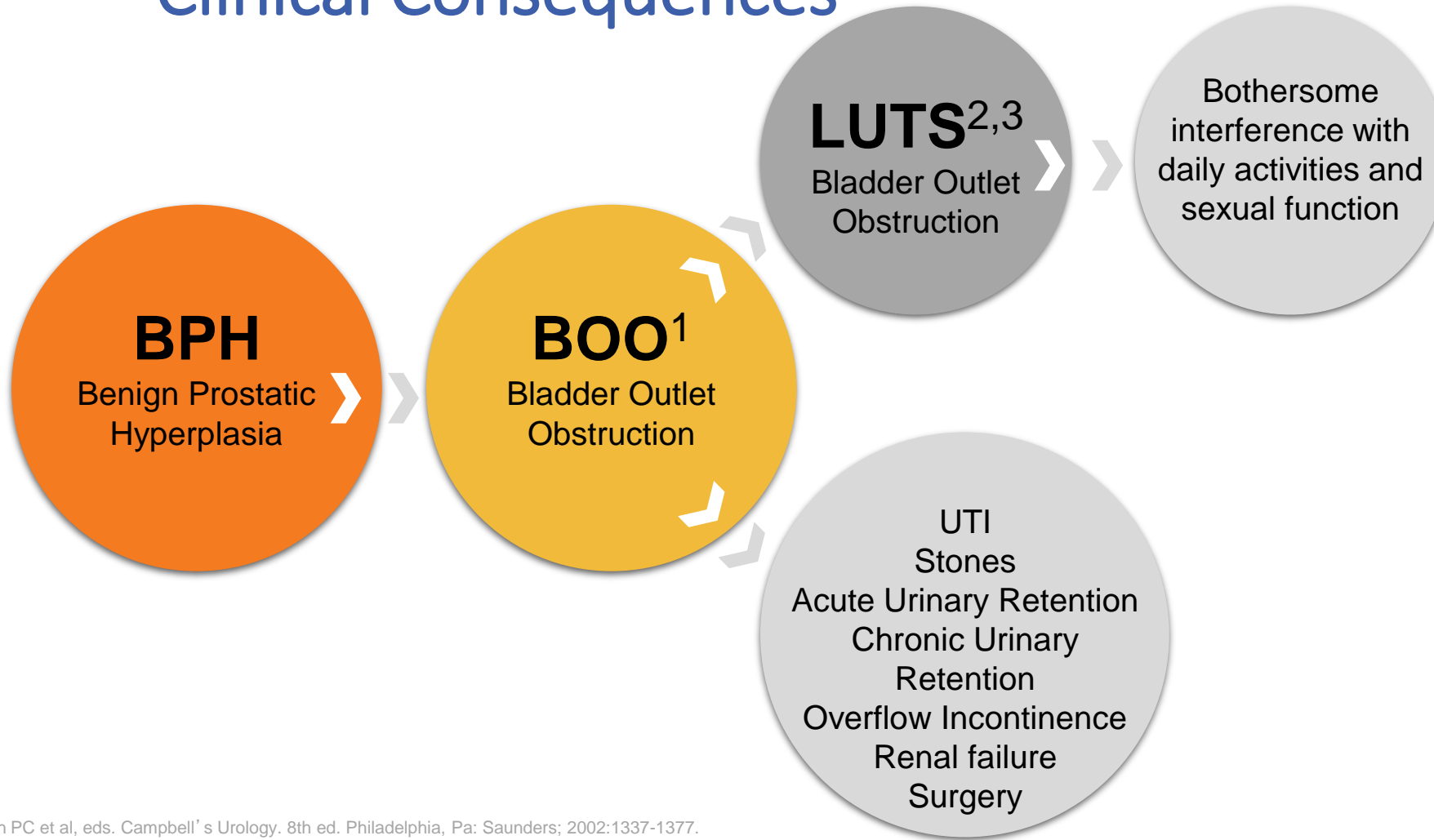
Images courtesy Dr. Steven Gange

What Happens if BPH is Not Treated?



Not treating enlarged prostate can lead to bladder deterioration

Histologic BPH Leads to BOO, LUTS and Clinical Consequences



1. Lepor H, Lowe FC. In: Walsh PC et al, eds. Campbell's Urology. 8th ed. Philadelphia, Pa: Saunders; 2002:1337-1377.

2. Rosen R et al. Eur Urol. 2003;44:637-649.

3. AUA Guidelines Committee. J Urol. 2003;170:530-547.

● Recognizing the Symptoms of BPH

- Frequent urination
- Multiple trips to the bathroom at night
- Sudden urge to urinate
- Difficult or painful urination
- Weak or slow urine flow
- Incomplete elimination of urine
- Stopping and starting of flow
- Straining to urinate

How is the IPSS scored?

0-7 | Mild

8-19 | Moderate

20-35 | Severe

How is Quality of Life scored?

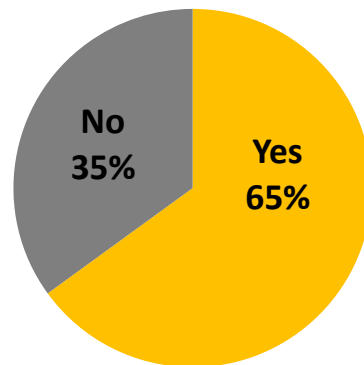
0-6

Regardless of the score, if your symptoms are bothersome you should notify your doctor

● Patient Urinary Symptoms Satisfaction Survey

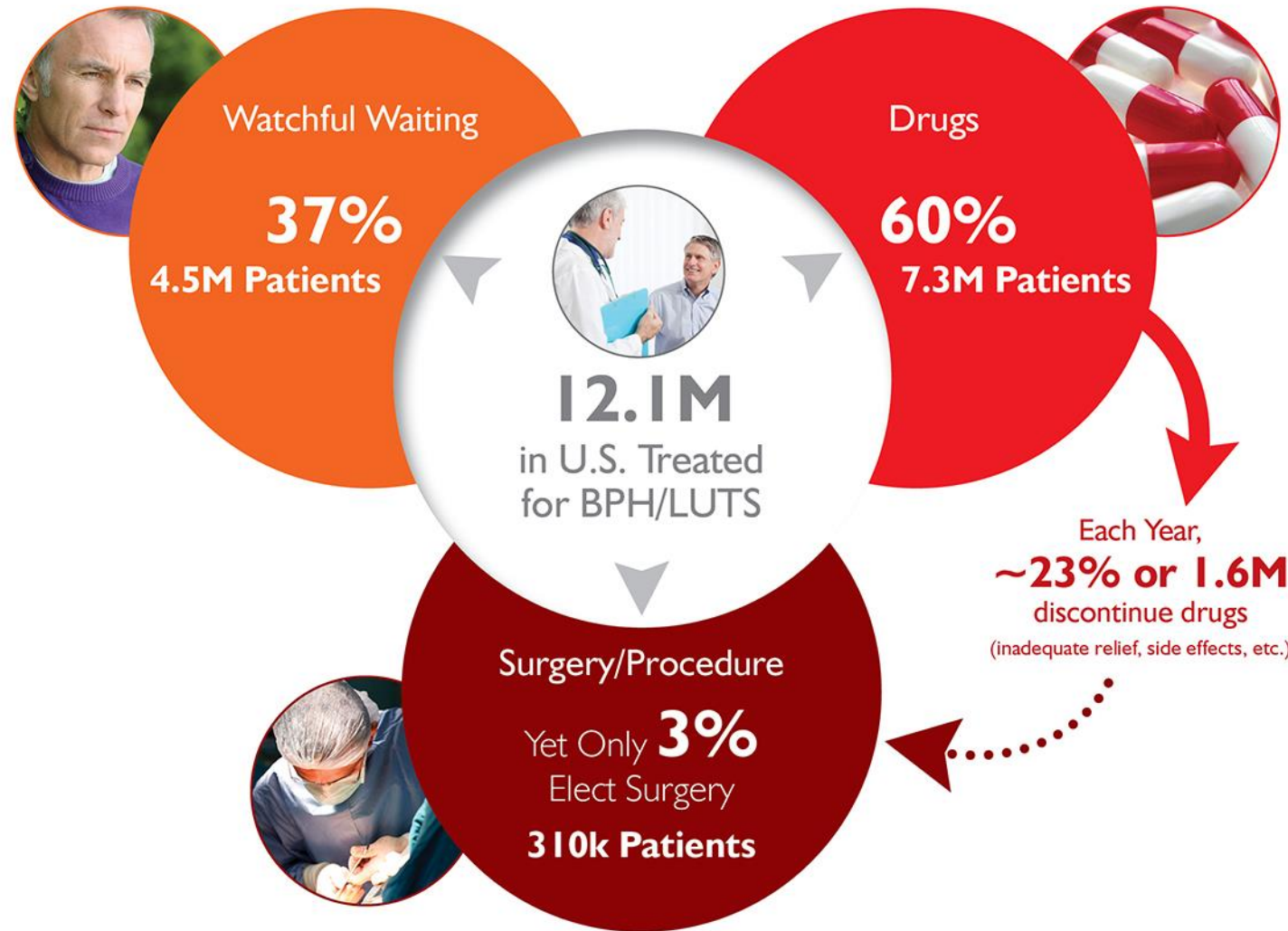
- 65% were interested in a new treatment alternative to medication
- These patients had more severe symptoms and lower quality of life compared to the average
- The survey results help urologists see the potential for UroLift® in their practices. Some patients are frustrated with their urinary symptoms, dissatisfied with medications and are interested in a new option

Interested in Hearing About A New Treatment Option?



	All Patients	Patients Interested in New Option
Average Age:	67.1	66.9
Average IPSS Score:	12.2	14.0
Average QOL Score:	2.9	3.3

● How Patients are Treated for BPH

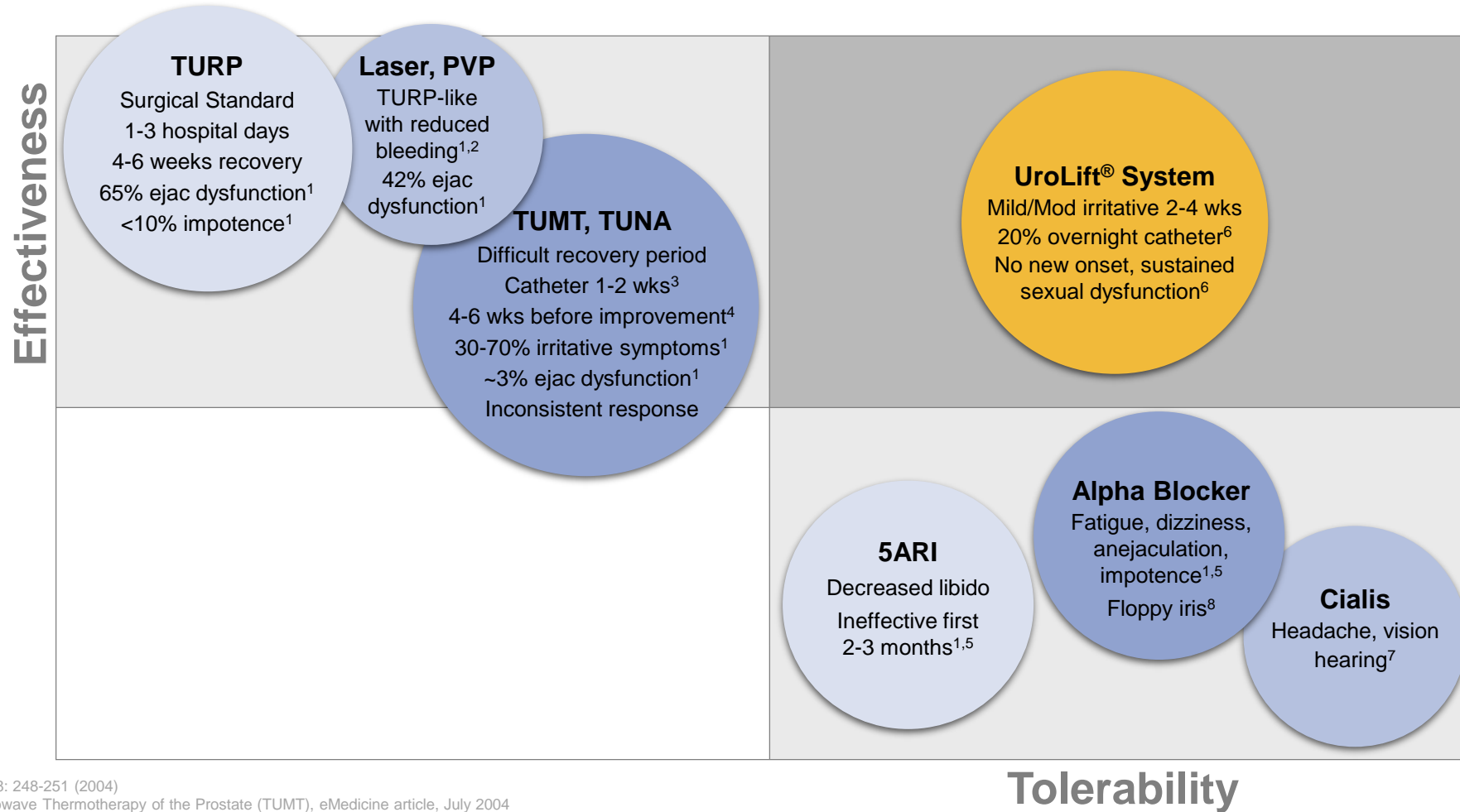


NeoTract US Market Model estimates for 2017 based on IMS Health Drug and Procedure data

Treatment Options for Enlarged Prostate



Trade-Offs Must Be Weighed



1 AUA Guidelines 2003, 2010

2 Varkarakis et al, The Prostate 58: 248-251 (2004)

3 Rubenstein J, Transurethral Microwave Thermotherapy of the Prostate (TUMT), eMedicine article, July 2004

4 Muruve, N, Transurethral Needle Ablation of the Prostate (TUNA), eMedicine article, June 2005

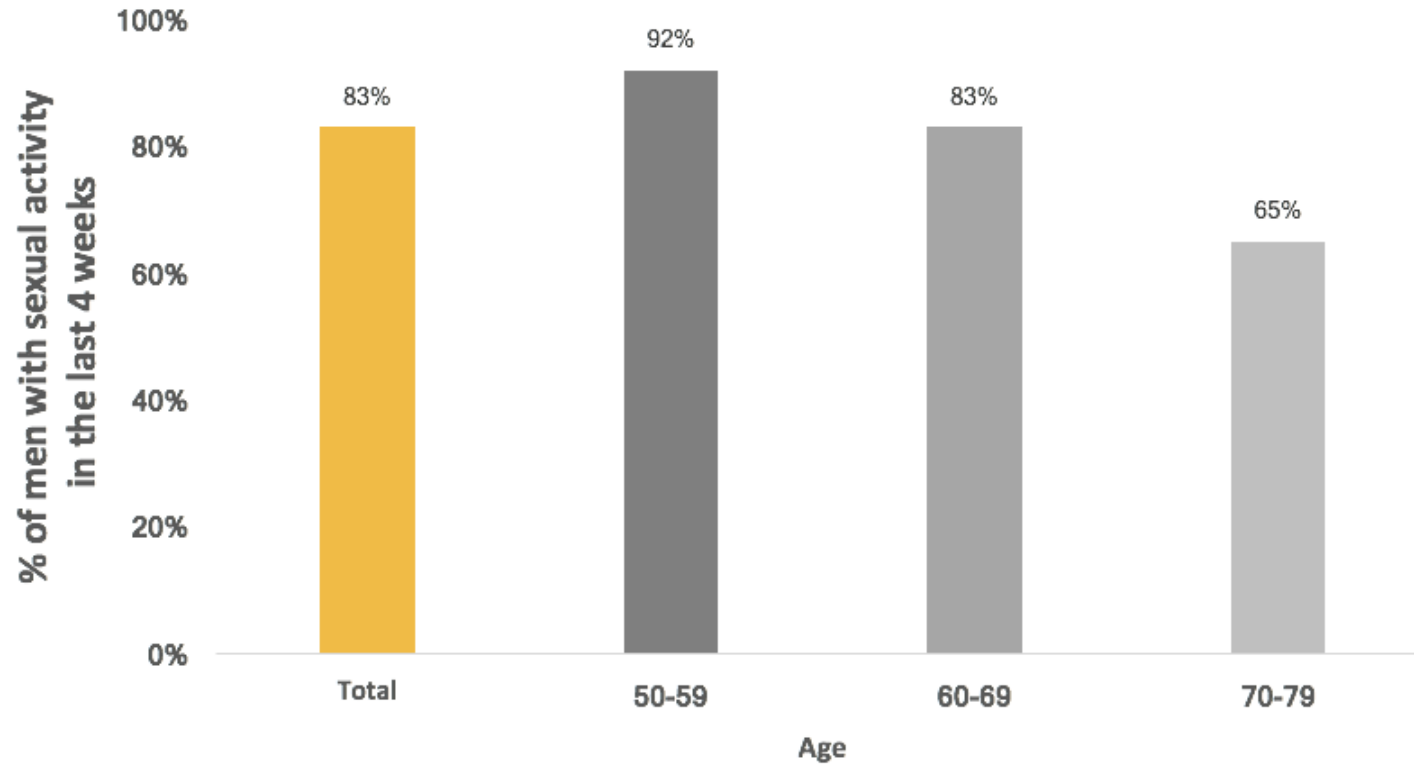
5 AUA: Urologyhealth.org

6. Roehrborn 2013 LIFT Study

7. Cialis Safety Information

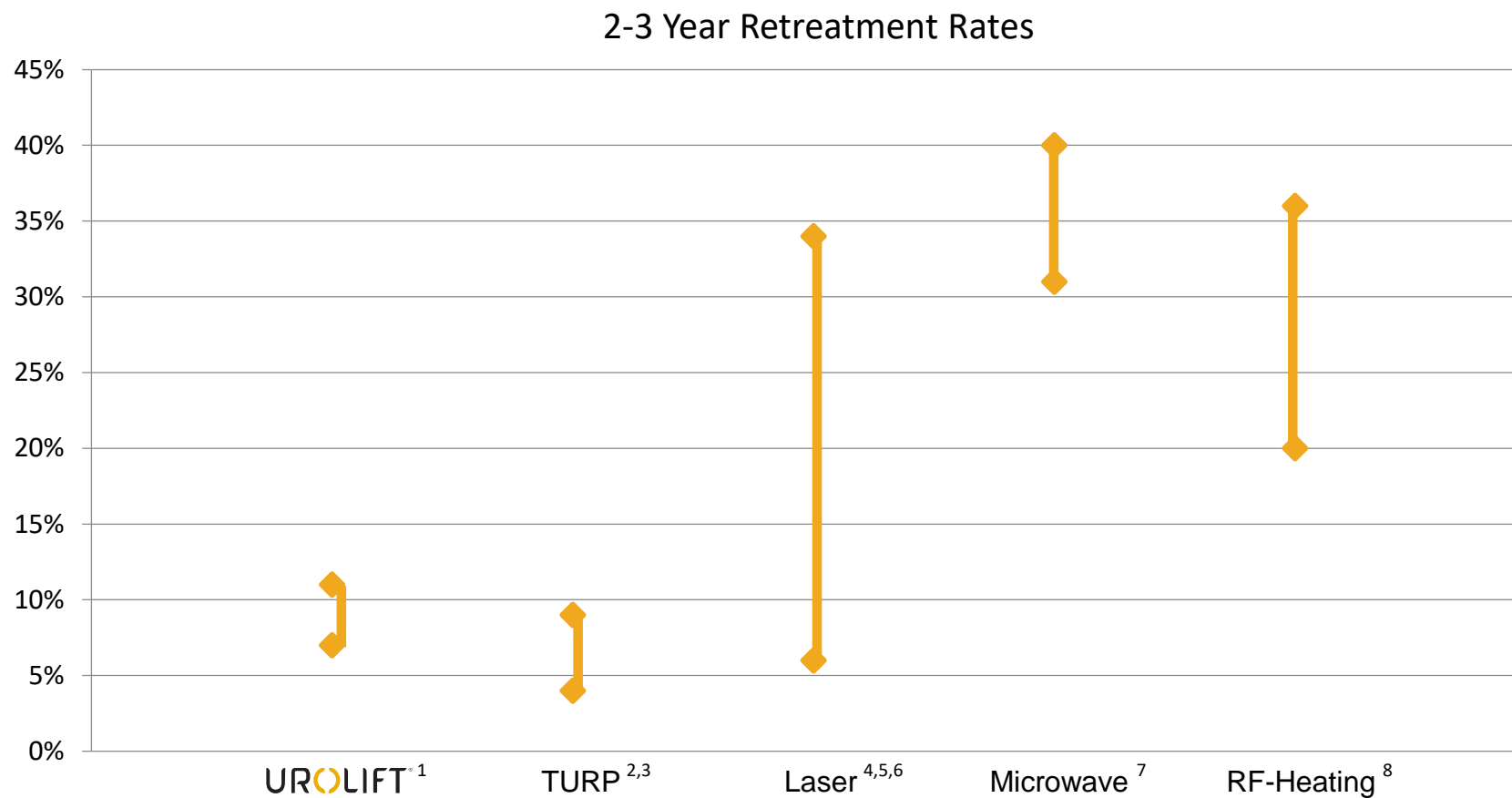
8. Flowmax Prescribing Information

Older Men are Still Sexually Active



Rosen R. Multinational Survey of the Aging Male (MSAM-7). Presented at the Annual Meeting of the American Urological Association; May 26, 2002; Orlando, Fla.

Retreatment: What Should Be the Goal?



1. Roehrborn et al. Can J Urol 2015 3-Year LIFT Study
2. Madersbacher S et al: Eur Urol 2005; 47: 499.
3. Mamoulakis C et al: Eur Urol 2013; 63: 667.
4. Hai MA: Urology 2009; 73: 807.

5. Al-Ansari A et al: Eur Urol 2010; 58: 349.
6. Broggi E et al: Urol Int, Epub ahead of print March 12, 2014.
7. Hoffman RM et al: Cochrane Database Syst Rev 2012; 9: CD004135.
8. Bouza C et al: BMC Urol 2006; 6:14.

UroLift® System Treatment

Advantages

In-office procedure/ASC

Preserves sexual function

No new and lasting problem with erections or ejaculation

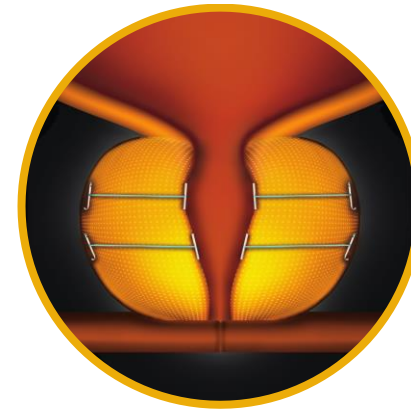
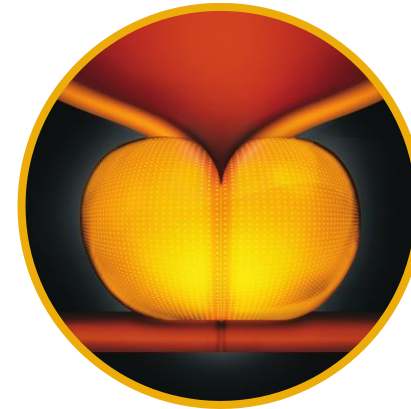
Rapid, durable relief

Typically return to normal within 5-9 days

Typically no catheter (80-85%)

Disadvantages

Some discomfort, small amount of blood in urine and increased urgency after procedure (as with any transurethral procedure)



Roehrborn Urology Clinics 2016. McVary et al. J Sex Med 2013. Shore et al. Can J Urology 2014.

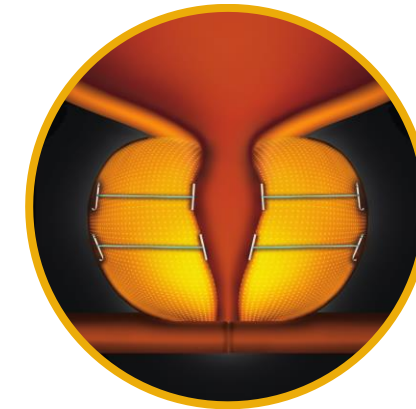
● How the UroLift® System Works



The UroLift delivery device is placed through the urethra to access the enlarged prostate.

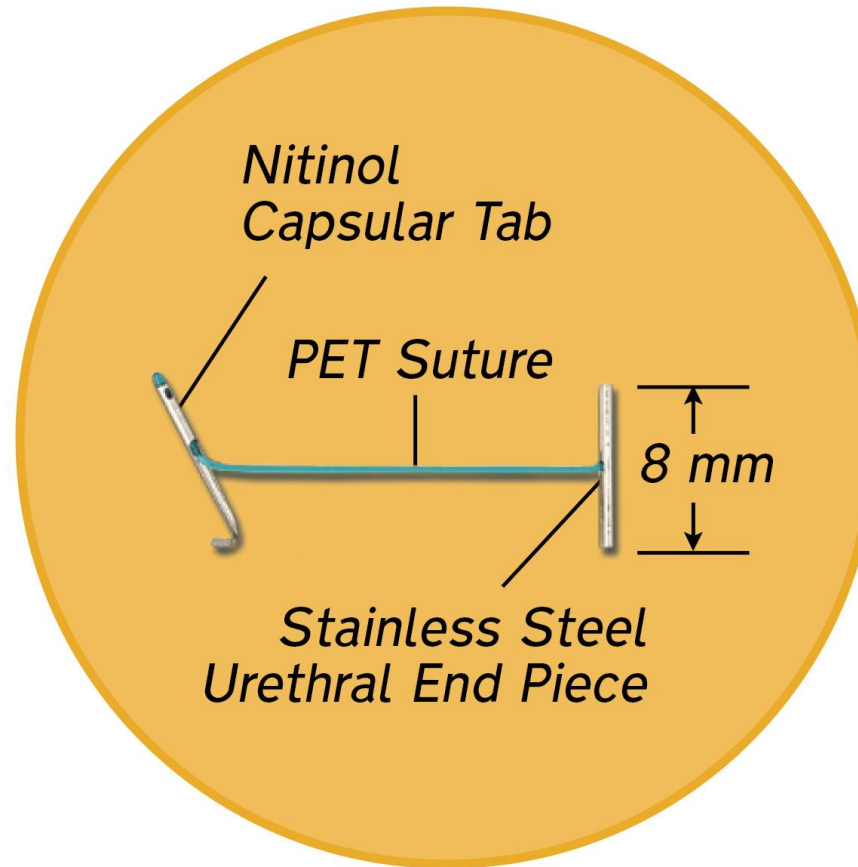


UroLift Implants are placed through a needle that comes out of the delivery device to lift the enlarged prostate tissue out of the way.

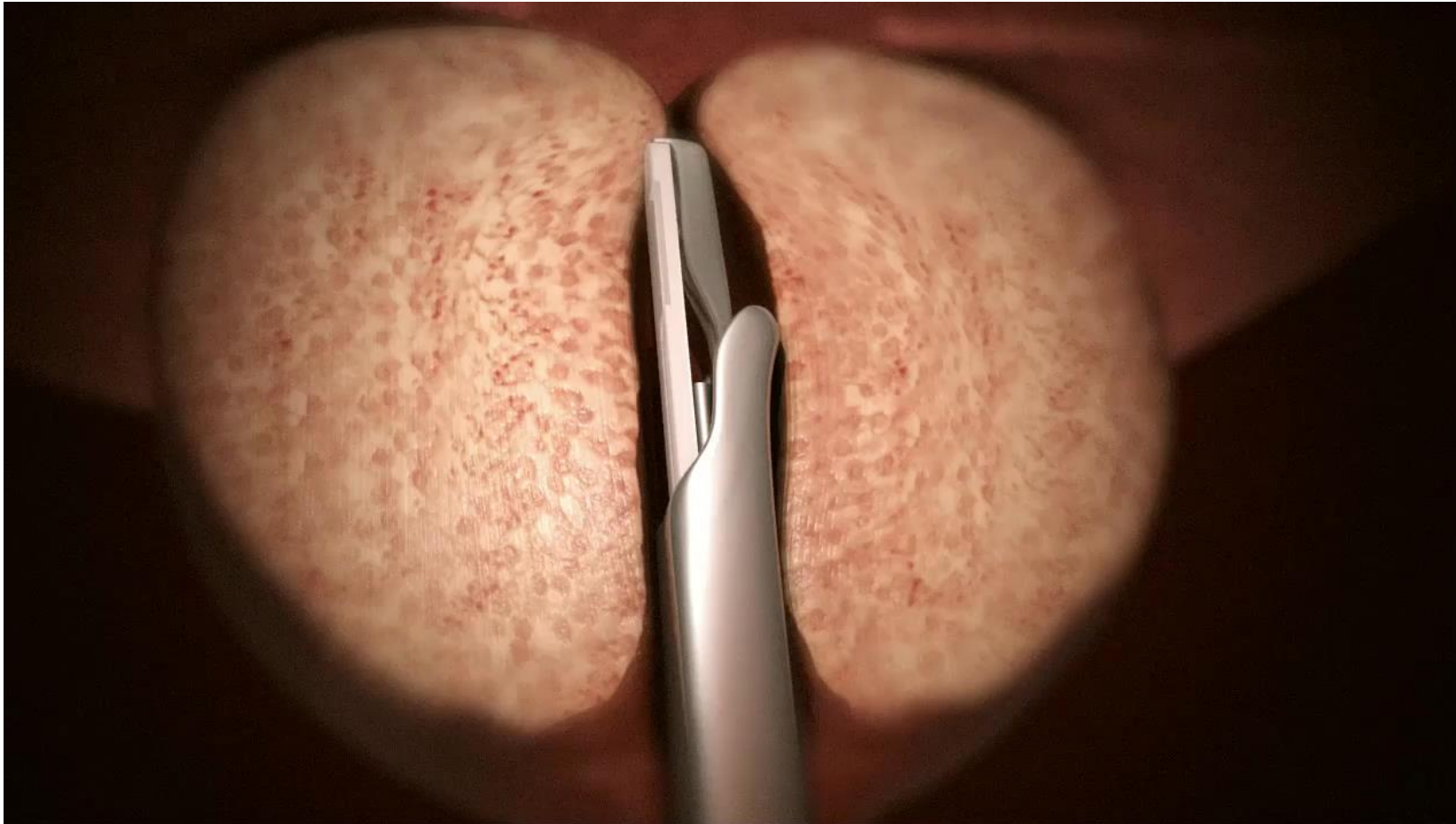


The UroLift delivery device is removed, leaving a more open urethra.

UroLift® Permanent Implant

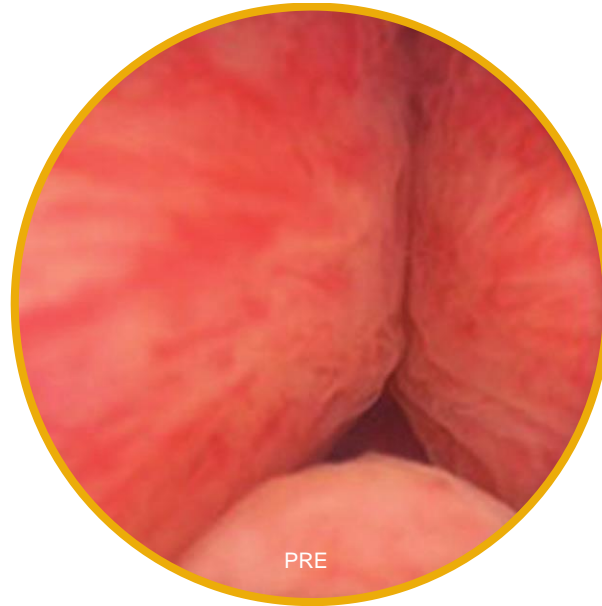


● UroLift® Animation

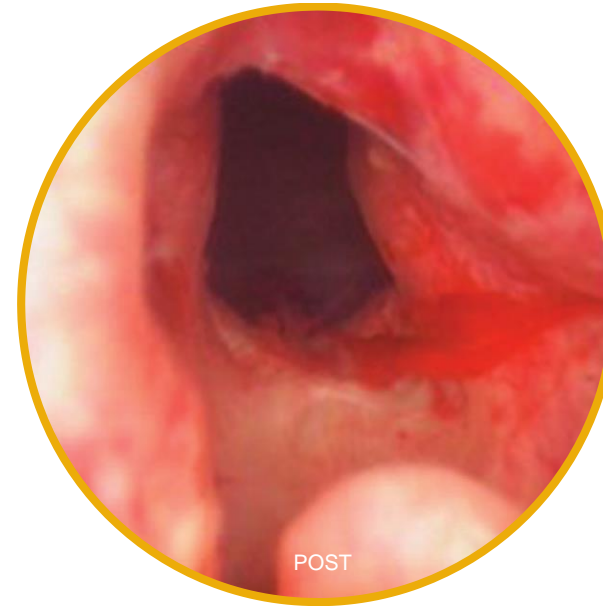


UroLift® Treatment Images

Before Treatment:
Obstructed Channel



After Treatment:
Open Channel



Images courtesy of Dr. Peter Chin, Wollongong, NSW, Australia

● Post-Treatment Expectations

- Symptom improvement may start within 2 weeks, may continue to improve up to 3 months
- Some irritation such as pain upon urinating, small amount of blood in urine, pelvic discomfort or urgency for some time after the procedure
- Typically return to preoperative activity level within 5-9 days
- Symptom relief may last for 5 years or longer
 - That doesn't mean the implants only last 5 years
 - 5 years is the maximum length of published clinical follow-up thus far

Rapid Return to Work and Pre-Op Activities: L.O.C.A.L. Study Results

- 86% achieved high quality recovery¹ within 1 month
- Satisfaction (via Patient General Impression Index):
 - 90% reported improvement in their condition

Perioperative Assessments	Mean	SD
Return to work (days)	2.8	3.7
Return to preoperative activity* (days)	5.1	5.8
Work Productivity at 1 Month		
Work missed	0%	0%
Overall work impairment	3%	9%
Impairment in activity	8%	19%

¹High quality recovery defined as ≥ 80 on the Quality of Recovery VAS

Shore et al. Can J Urol 2014; 21(1): 7094-7101.

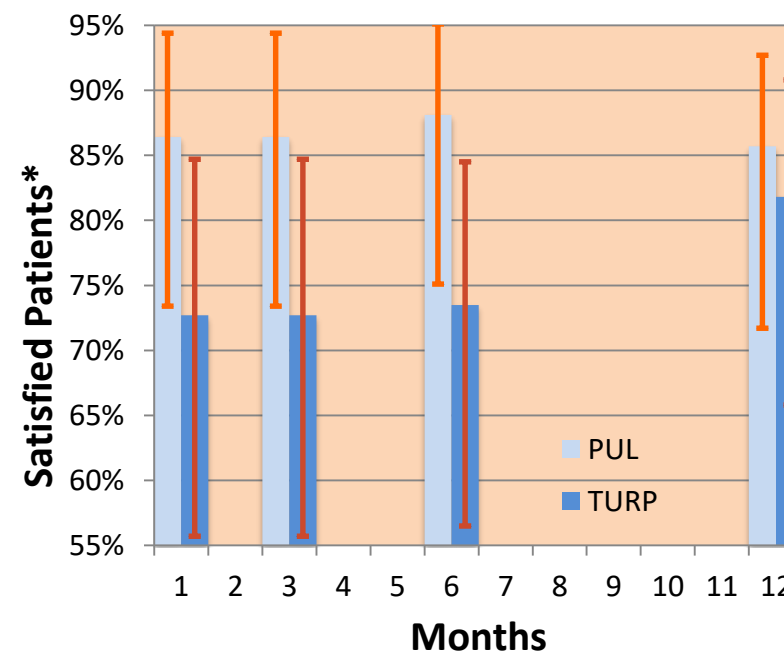
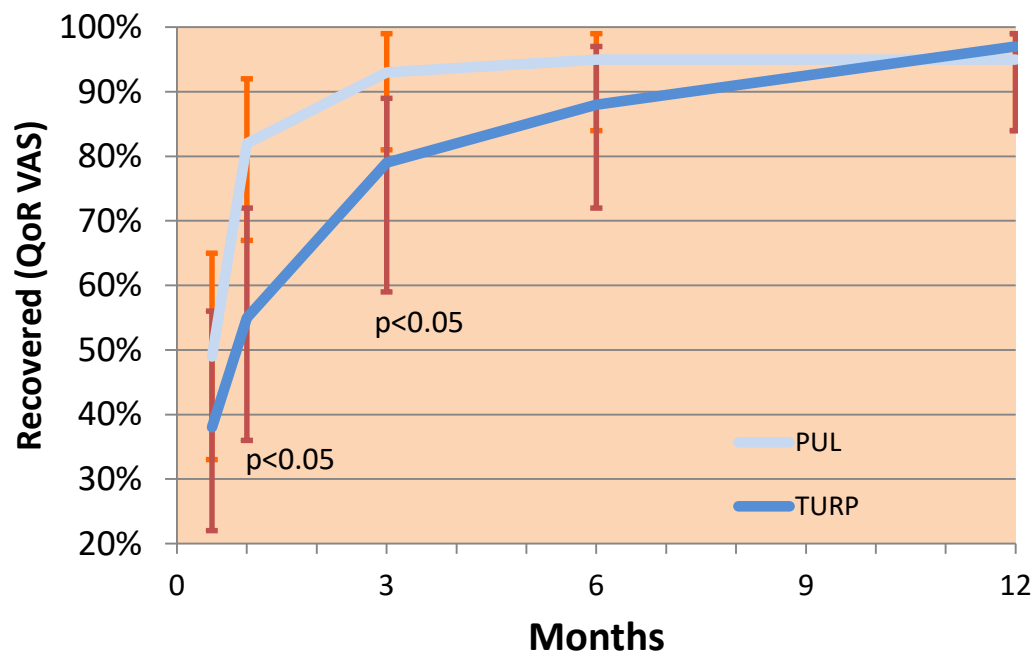
UroLift® vs TURP: No Difference in Quality of Life

- Despite predicted differences in IPSS and Qmax, improvement in quality of life was not different.
- Important to evaluate with patients risks vs returns for each treatment option.

	Change at 1 year		Difference p-value
	PUL	TURP	
IPSS	-11.4	-15.4	0.02
Qmax [mL/sec]	+4.0	+13.7	<0.001
QoL	-2.8	-3.1	0.4 Not Significant

● Patient Recovery and Satisfaction

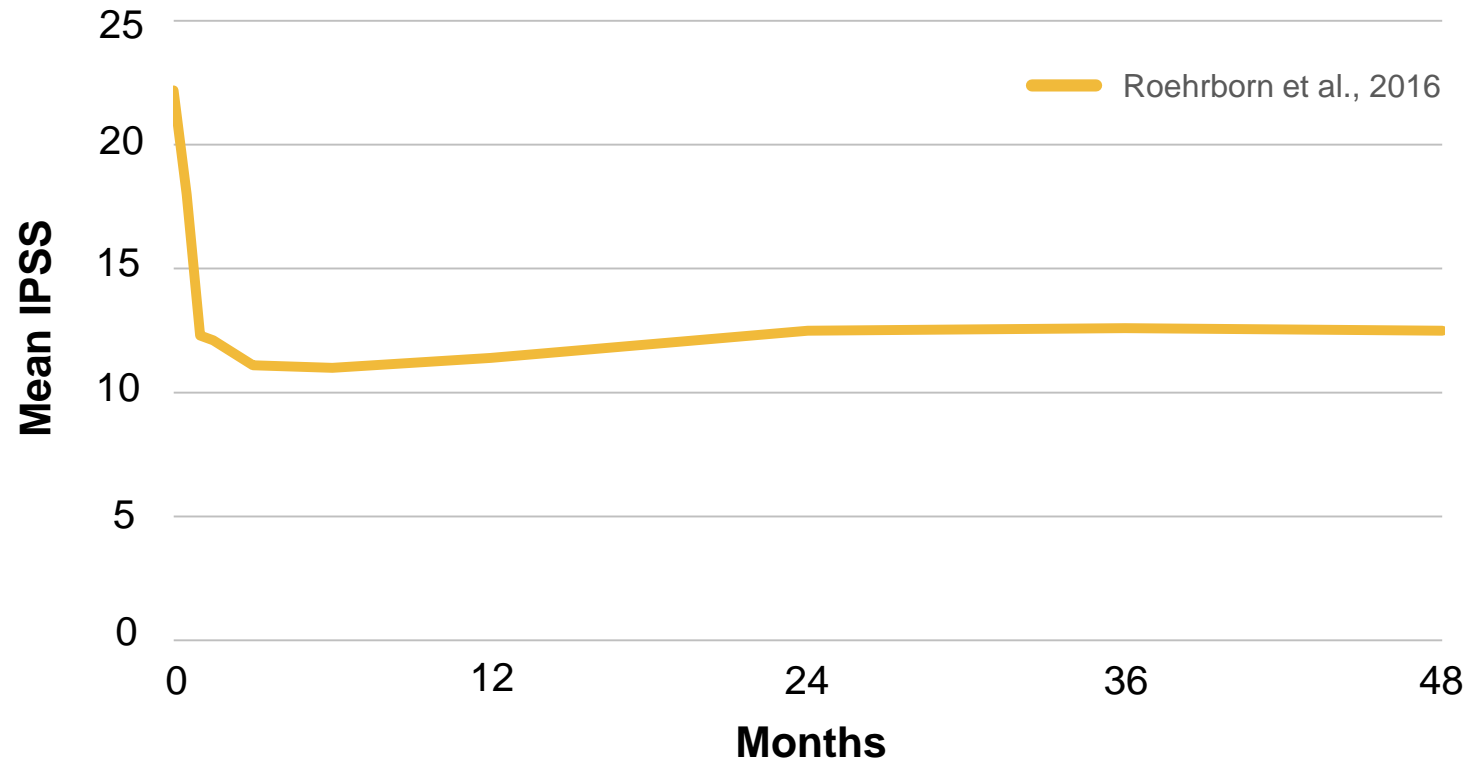
- UroLift[®] patients recover more quickly
 - TURP catches up only between 6 to 12 months
- UroLift patients satisfied sooner and to greater extent



*would recommend procedure

Sonksen et al. Eur Urol 2015; Barber N. AUA2015.

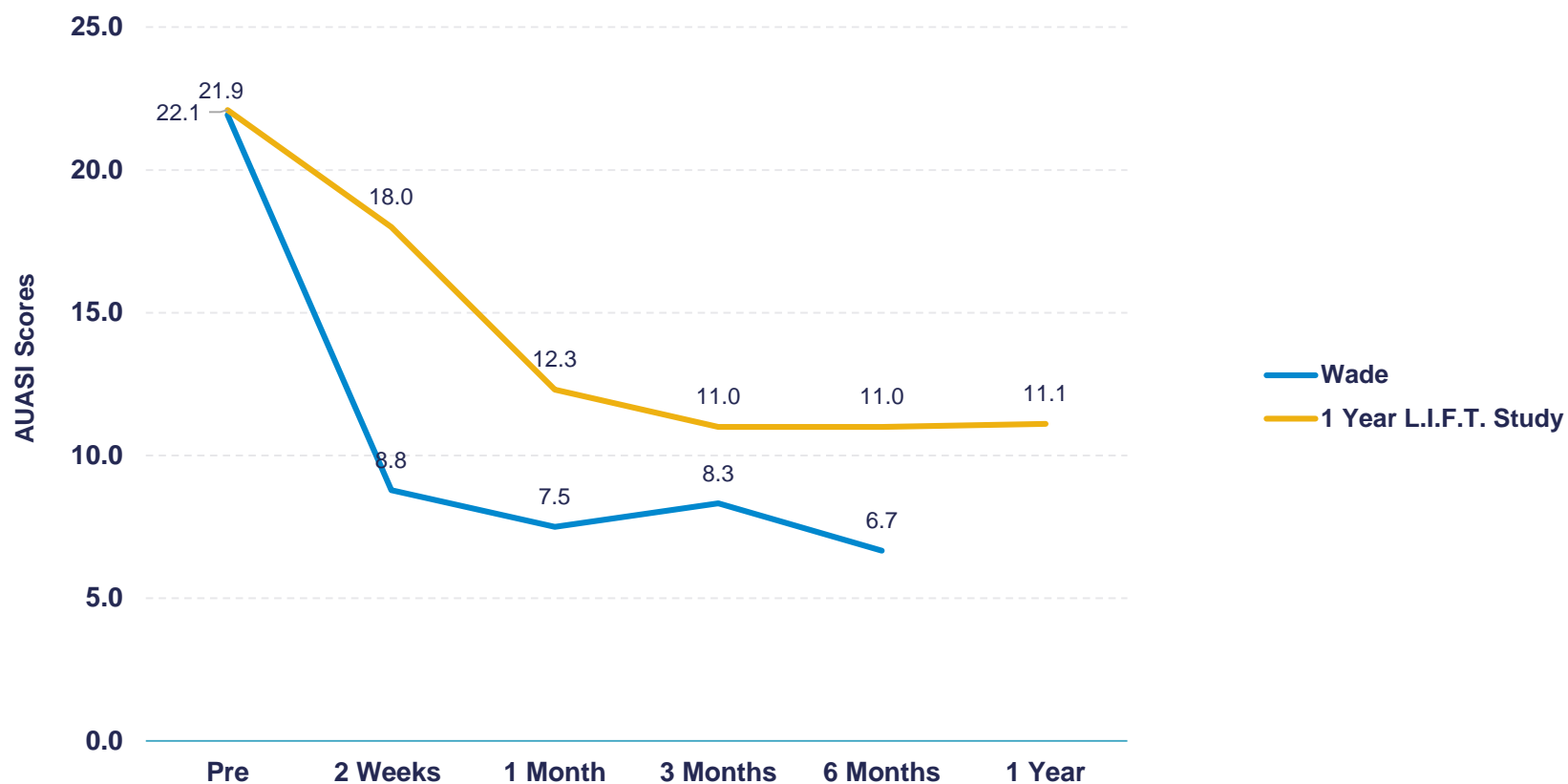
L.I.F.T. Study Results



Roehrborn Urol Clin N Am 2016

Our Outcomes vs 1-Year L.I.F.T. Study

Date chart created: 4/4/2019



Roehrborn, J Urology 2013 LIFT Study

Disclaimer: The physician outcomes in this graph were provided by the practice/physician and have not been independently reviewed or verified by NeoTract, Inc., including scores and treatment or recording dates. This graph is solely intended to be used as a tool to track AUASI scores against the L.I.F.T. Study and is not an endorsement of the practice/physician or their knowledge of or experience with the UroLift System procedure.

MAC00809-01 Rev A

Your Outcomes vs 1-Year L.I.F.T. Study

Date chart created: 4/4/2019

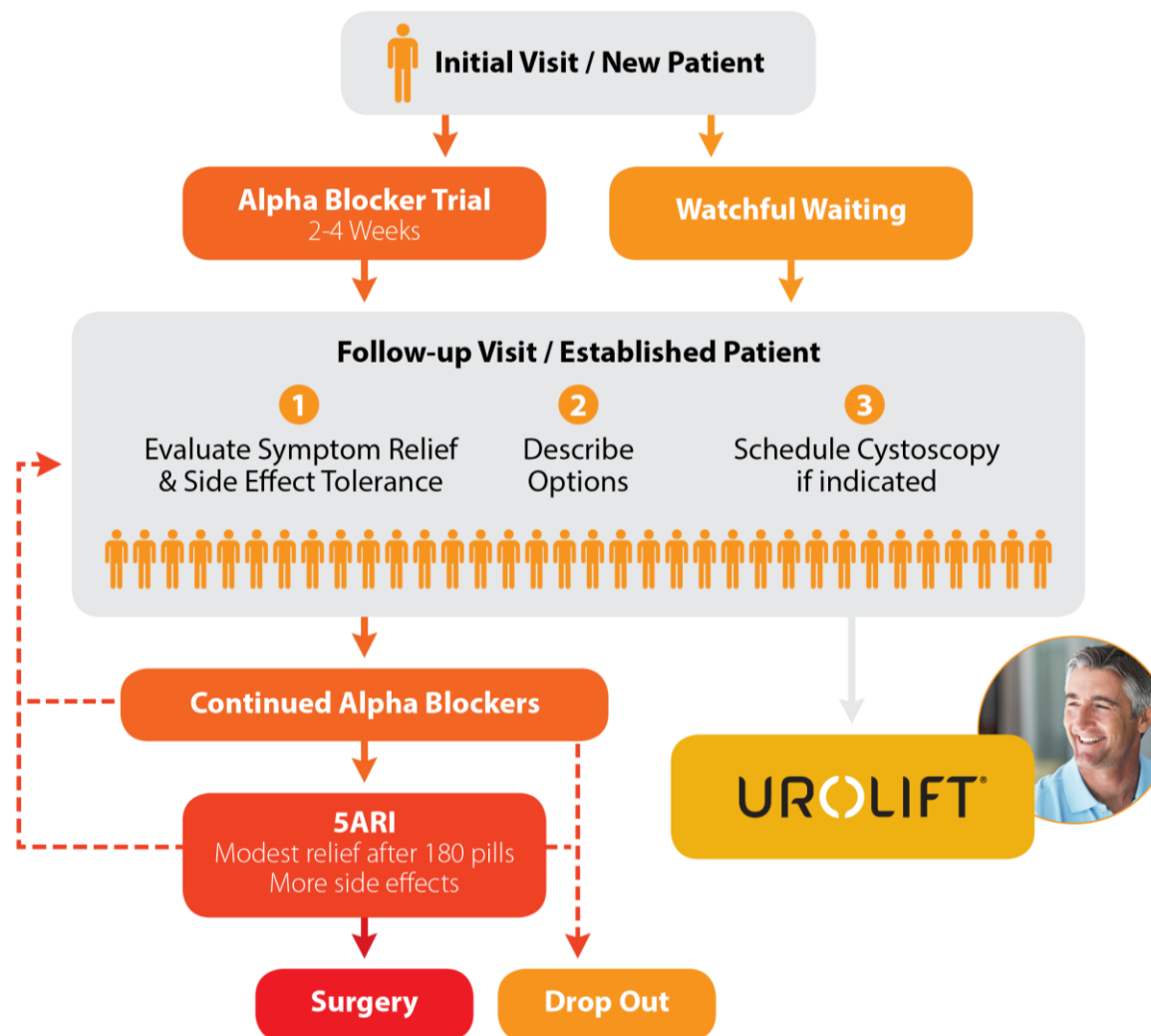


Roehrborn, J Urology 2013 LIFT Study

Disclaimer: The physician outcomes in this graph were provided by the practice/physician and have not been independently reviewed or verified by NeoTract, Inc., including scores and treatment or recording dates. This graph is solely intended to be used as a tool to track AUASI scores against the L.I.F.T. Study and is not an endorsement of the practice/physician or their knowledge of or experience with the UroLift System procedure.

MAC00809-01 Rev A

Where Does UroLift® Fit?



● All BPH/LUTS Patients Should be Considered!

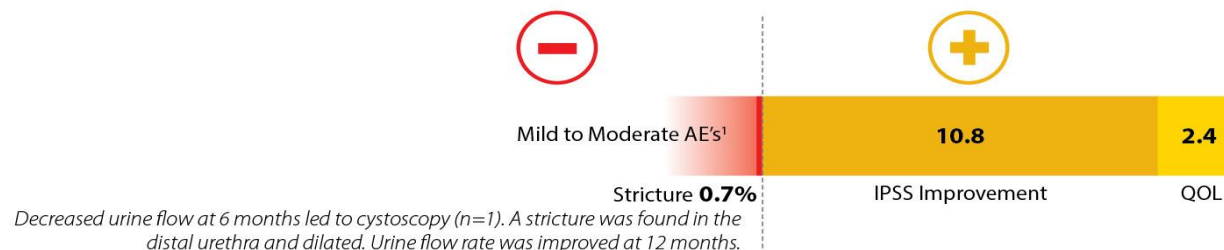


Men Who:

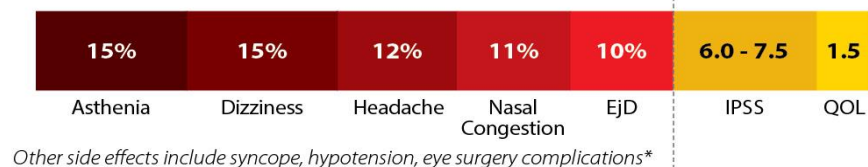
- Are frustrated by side-effects or daily hassle of medication
- Have modest symptomatic relief from medications
- Previously declined surgery
- Want to preserve their sexual function

Improvement Without Significant Downsides

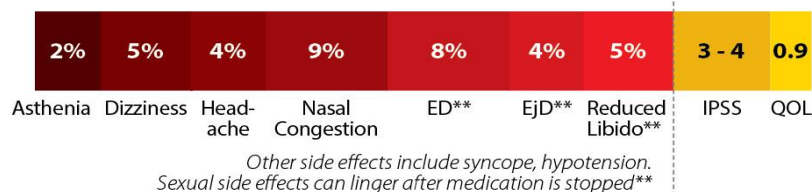
UROLIFT¹



Alpha Blockers



5ARI



Laser/TURP²



Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure.¹

1. L.I.F.T. IDE Study. Roehrborn. J Urology 2013; 2. AUA BPH Guidelines 2003, 2010; 3. Naspro, Eur Urol 2009; 4. Montorsi, J Urol 2008

*Bell et. Al. **Irwig & Kolukila JSM, 2001 <http://www.ncbi.nlm.nih.gov/pubmed/21418145>



Summary

Indication

The UroLift® System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men 45 years of age or older.

Contraindications

- Prostate volume of >80 cc
- No active UTI or prostatitis

Patient Selection

Candidates for TURP or Laser Who...

- Are concerned about complications
- Want to preserve sexual function
- Want a more rapid return to daily life

Men Unhappy With BPH Drugs Who...

- Are concerned about surgery
- Are seeking a less invasive solution
- Want to preserve sexual function

THANK YOU

Brain Wade, M.D. Jason Burrus, M.D.
bwade@urologyal.com jburrus@urologyal.com

