

Update on the Treatment of BPH

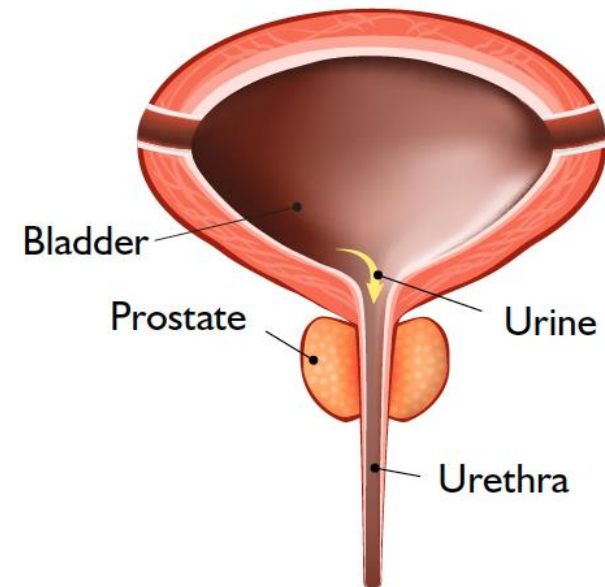
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CENTERS OF ALABAMA

Overview of the Prostate

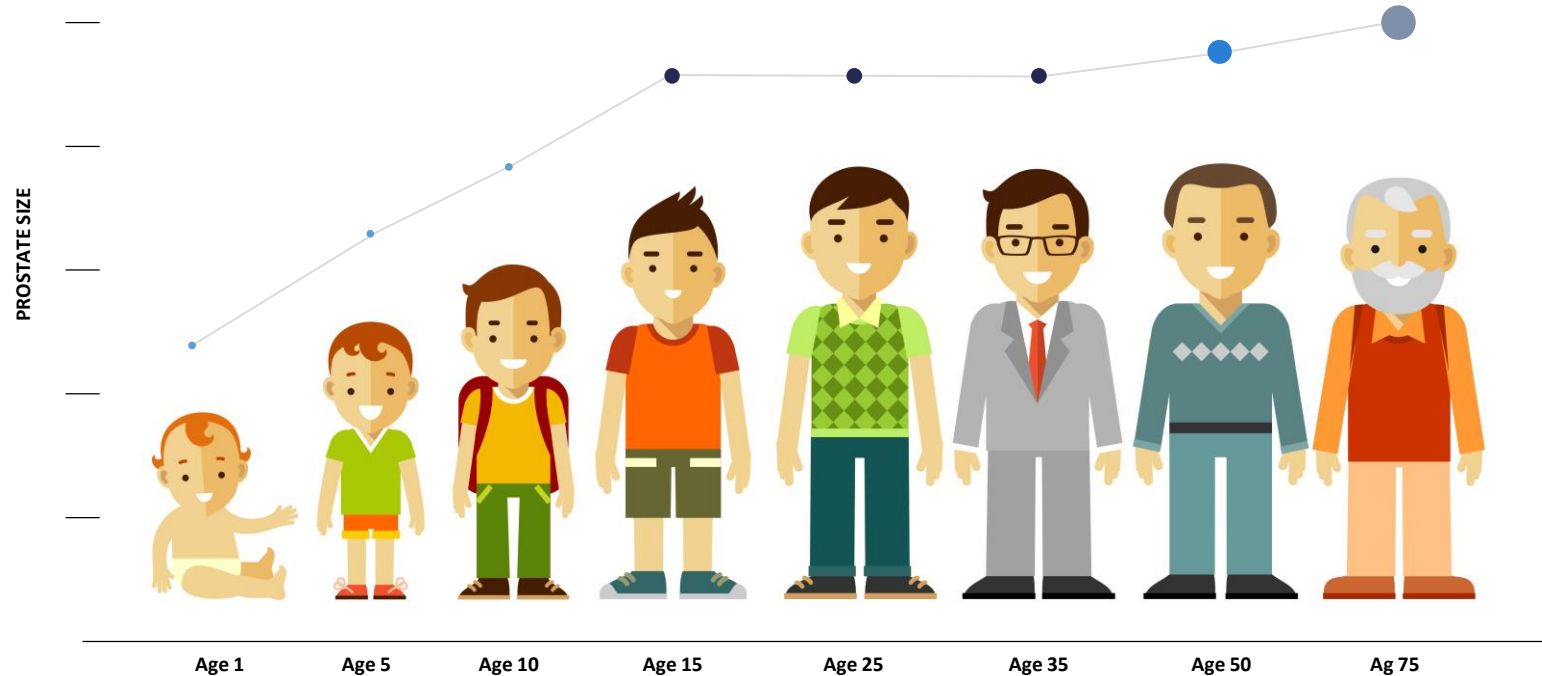
- Walnut-sized gland at base of the male bladder
- Surrounds the urethra
- Produces fluid that helps transport sperm during ejaculation

Normal Prostate



Anatomy of a Prostate Over Time

- There are two phases of prostate growth. The prostate grows to a normal size in teenage years, then continues to grow again later in life.



Prostate Conditions

Prostatitis	<ul style="list-style-type: none">• Swelling/inflammation of the prostate
Prostate Cancer	<ul style="list-style-type: none">• Very common cancer among men• Typically a slow growing cancer, but still important to screen appropriate age groups
Enlarged Prostate	<ul style="list-style-type: none">• Enlargement of the prostate gland

Each condition affects the prostate differently

*Having one condition does not mean
you will have another*

What is BPH?

- **Benign Prostatic Hyperplasia** (BPH) is the clinical term for enlarged prostate
- ***Non-cancerous*** enlargement of the prostate gland
 - BPH is not an indication or a predictor of cancer
 - PSA can rise with both BPH and prostate cancer, so PSA alone cannot tell you which is the issue

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.

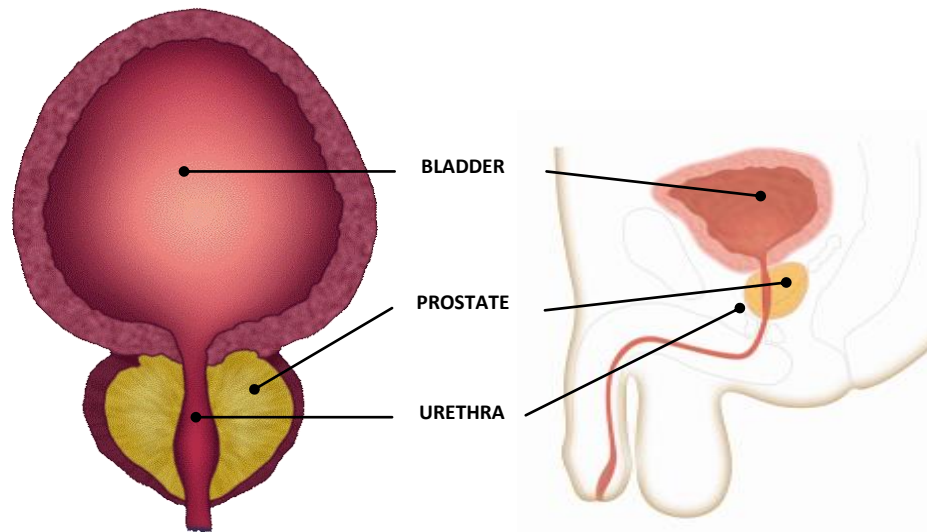
BPH Affects Quality of Life

- Many men who suffer from BPH experience a reduction in quality of life
 - Avoiding travel
 - Interruption of leisure activities
 - Using the bathroom stalls instead of urinals
 - Disruption of sleep patterns

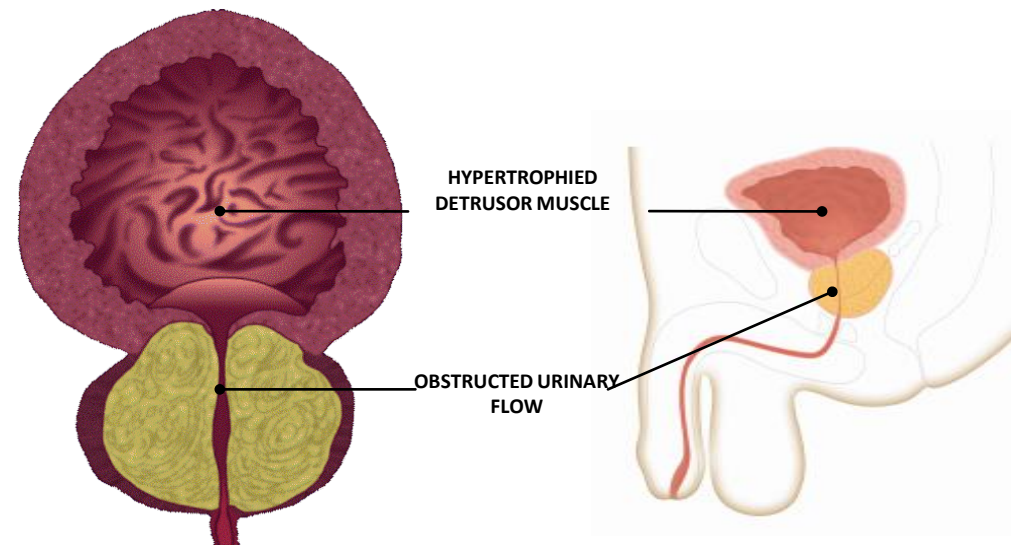
Normal vs. Enlarged Prostate

- 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

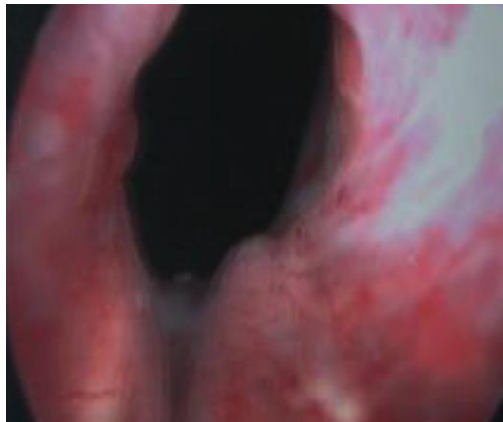
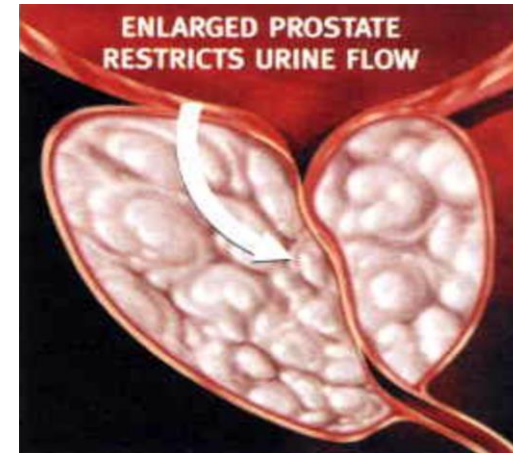
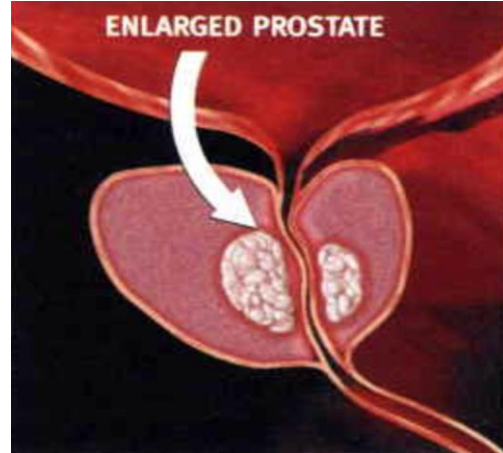
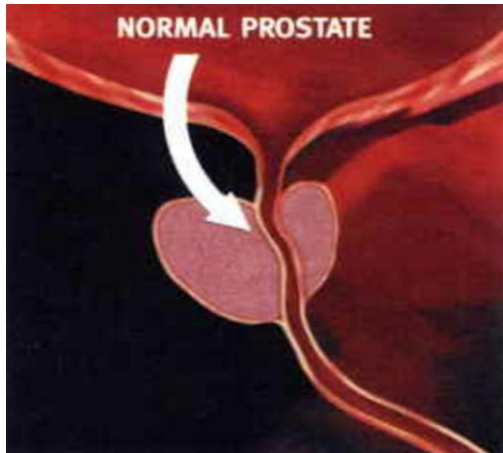
Normal Prostate Anatomy



Enlarged Prostate (BPH) Anatomy

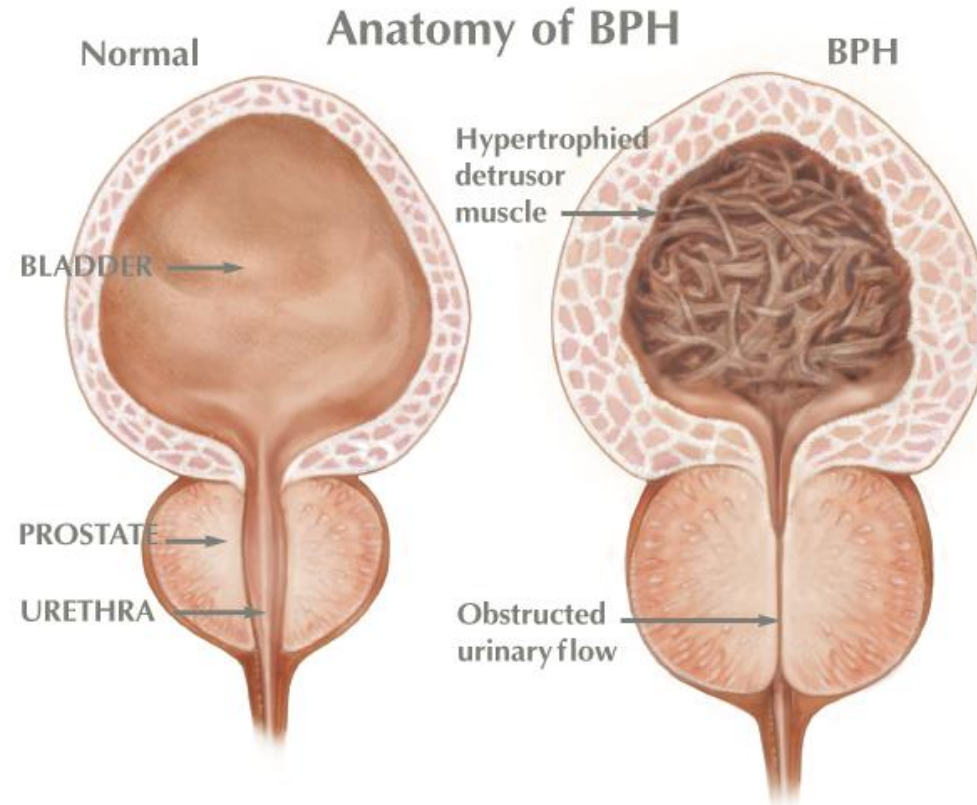


BPH Disease Progression



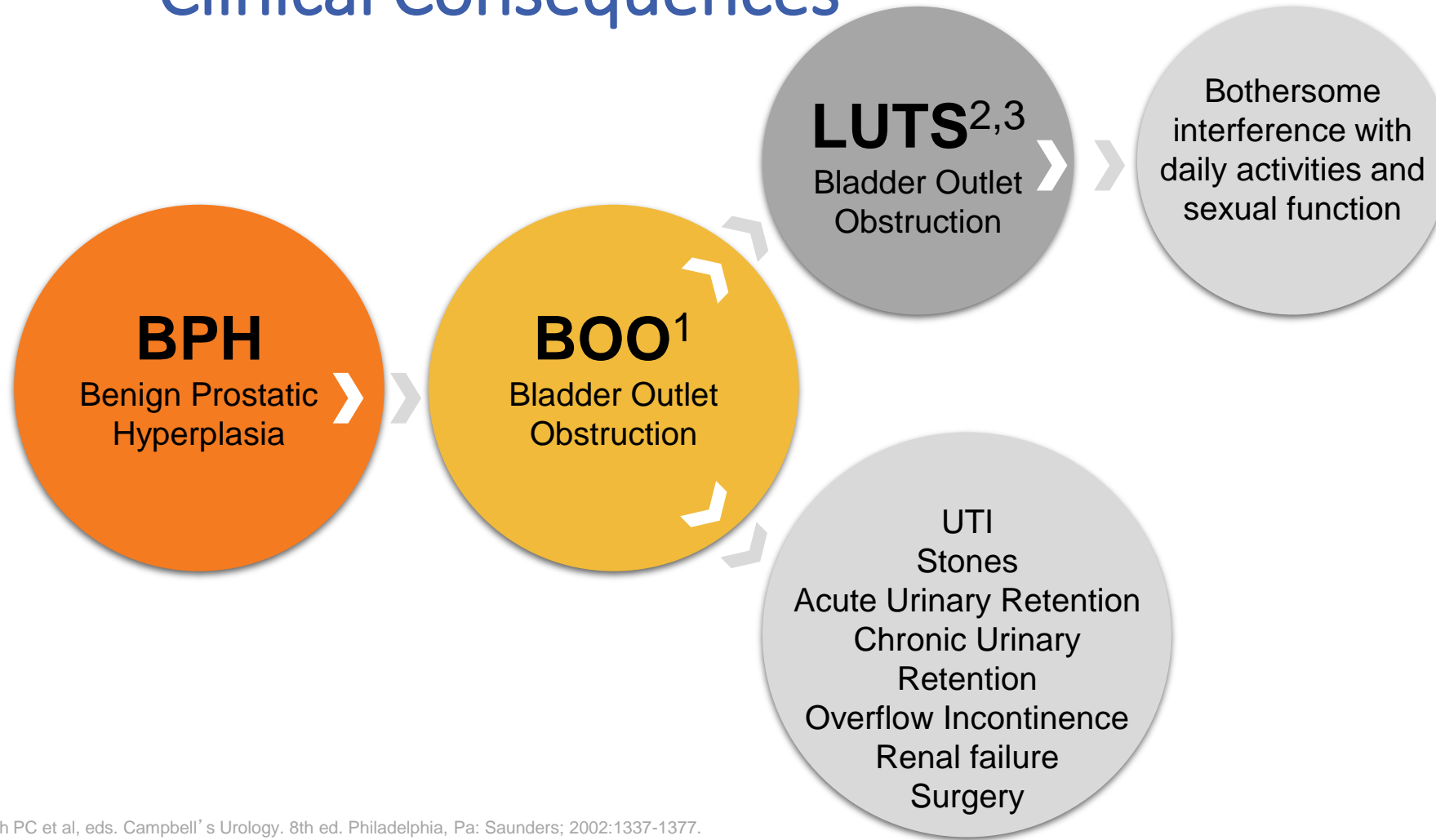
Images courtesy Dr. Steven Gange

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.

How is an Enlarged Prostate Diagnosed?

- Medical history
- Physical exam
- Bladder scan (Ultrasound)
 - Residual urine assessment
- Digital Rectal Exam (DRE)
 - Approximate prostate size
 - Texture and symmetry
- Symptoms – **International Prostate Symptom Score (IPSS)**
- How much of a bother is it to you?

INTERNATIONAL PROSTATE SYMPTOM SCORE SHEET

Dr Name: _____ Address: _____
 Patient Name: _____ Address: _____
 Date: _____

Age Group: 60-69 50-59
 60-69 70+

	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always	Your score
1. INCOMPLETE EMPTYING Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5	
2. FREQUENCY Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
3. INTERMITTENCY Over the past month, how often have you found you stopped and started several times when you urinated?	0	1	2	3	4	5	
4. URGENCY Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5. WEAK STREAM Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
6. STRAINING Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	
7. NOCTURIA Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	None 0	1 time 1	2 times 2	3 times 3	4 times 4	5 or more times 5	

Which of the above do you regard as most troublesome (1-7) _____
 TOTAL PROSTATE SYMPTOM SCORE _____

	Delighted	Pleased	Mostly satisfied	Mixed - satisfied and dissatisfied	Mostly dissatisfied	Unhappy	Terrible
QUALITY OF LIFE DUE TO URINARY SYMPTOMS If you were to spend the rest of your life with your urinary condition just the way it is now, how would	0	1	2	3	4	5	6

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

How is an Enlarged Prostate Diagnosed?

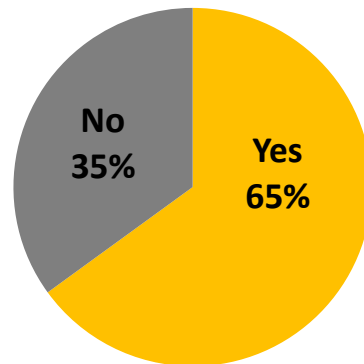
Optional studies

- Uroflow
- Pressure flow studies
- Transrectal Ultrasound (TRUS)
 - With or without biopsy depending on PSA levels
- Cystoscopy

● Patient Urinary Symptoms Satisfaction Survey

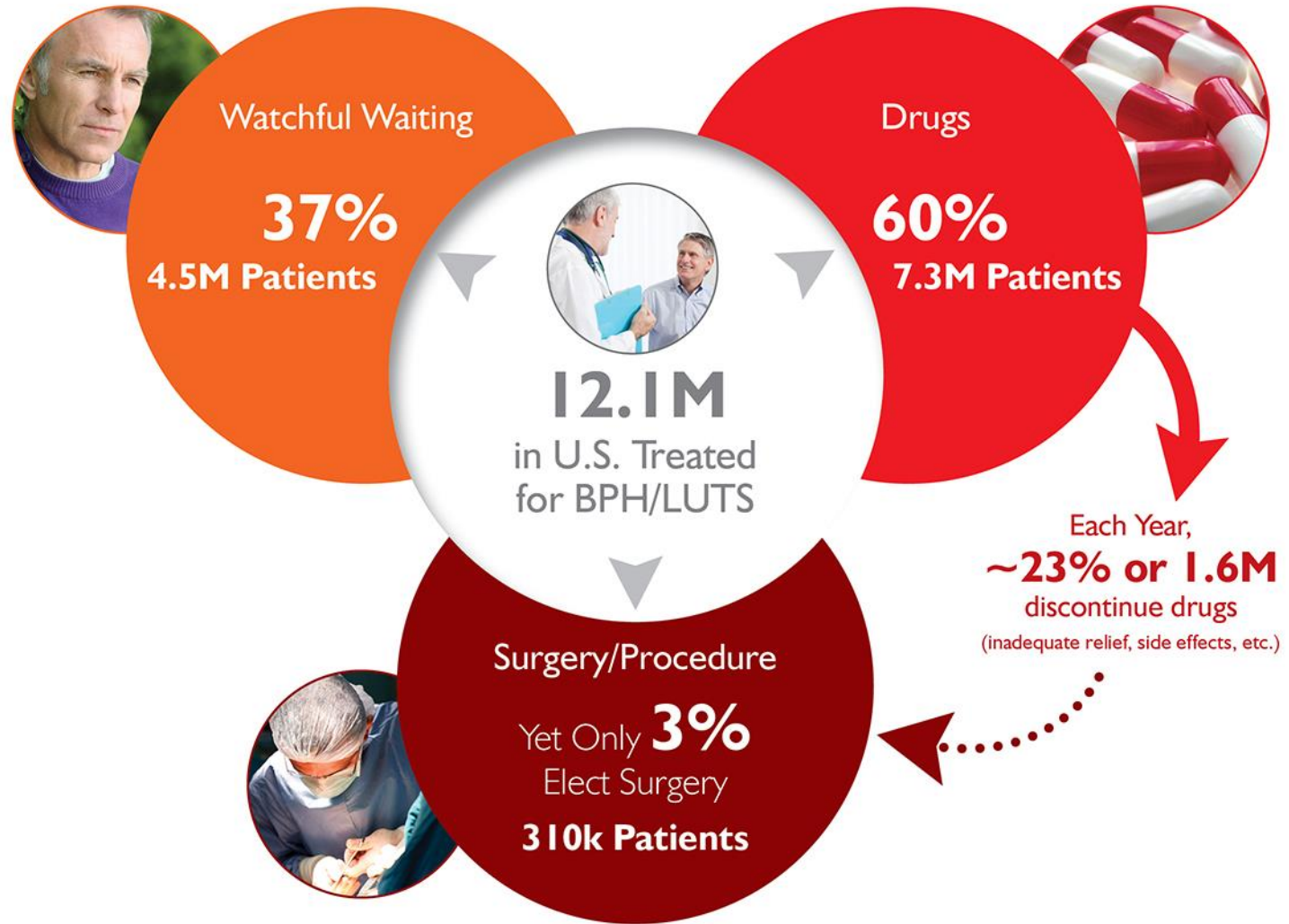
- 65% were interested in a new treatment alternative to medication
- These patients had more severe symptoms and lower quality of life compared to the average
- The survey results help urologists see the potential for improving patient QOL in their practices. Some patients are frustrated with their urinary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

Interested in Hearing About A New Treatment Option?



	<u>All Patients</u>	<u>Patients Interested in New Option</u>
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



Treatment Options for Enlarged Prostate



Different treatments are appropriate for different patients

Treatment Options for Enlarged Prostate

- Watchful Waiting
- Medications/Herbal remedies
 - Alpha blockers (Flomax, Uroxatral, Rapaflo, Hytrin, Cardura)
 - 5 alpha reductase inhibitors (Proscar, Avodart)
 - Saw palmetto
- Office Based/Minimally Invasive Treatments
 - Urolift
 - Heat based (TUMT, TUNA, Rezum)
- Surgical
 - Bipolar TURP/TUVP
 - Robotic subtotal prostatectomy

Watchful Waiting



Advantages

- No surgery
- Cheaper than drugs
- No side effects

Disadvantages

- May require lifestyle change
- May not have symptom improvement
- Risk that symptoms will worsen

Medications/Herbal Remedies



Medication *Flomax, Uroxatral, Rapaflo, Proscar, Avodart, Cialis*

Advantages

- No surgery
- May provide enough symptom relief

Disadvantages¹

- Must be taken daily, from now on
- Potential side effects**
 - Lowered sexual drive, erection problems, ejaculation problems, dizziness, lack of energy
- High out-of pocket cost²
- Loses effectiveness over time

Herbal Remedies- Saw Palmetto

Advantages

- No surgery
- No drugs
- No side effects

Disadvantages*

- May not have symptom improvement – none have shown benefit in clinical trials
- Risk that symptoms will worsen
- Potential down stream issues³
 - Bladder stones; bladder health, kidney function
- Future treatments may be less effective

*Herbal remedies have not been evaluated by the Food and Drug Administration. These are not intended to diagnose, treat, cure, or prevent any disease..

**Side effects may vary depending on medication type

1. AUA Guidelines 2018, 2010, 2003

2. Consumer Reports Best Buy Drugs

3. Campbell-Walsh Urology

UroLift® System Treatment



Advantages

- Can be done in office/outpatient center
- Preservation of sexual function*^{1,2}
- Rapid symptom relief and recovery^{2,3}
 - Typically return to normal activity within 5-9 days
- Typically no catheter afterward³
- Provides durable results/10% retreatment rate^{4/}

Disadvantages

- May experience some discomfort during and after the procedure
- Potential for some blood in urine
- Potential for increased urgency
- Most symptoms resolved within two to four weeks after the procedure²
- Prostate needs to be 80gm or less

*No instances of new, sustained erectile or ejaculatory dysfunction

1. McVary, J Sex Med 2014

2. Roehrborn, J Urology 2013 LIFT Study

3. Shore, Can J Urol 2014 Local Study

4. Roehrborn, Can J Urol 2015

Heat & Steam-Based Therapies

TUMT – Microwave; TUNA – Radiofrequency; Rezum



Advantages¹

- In office procedure
- Fewer permanent side effects than surgery

Disadvantages¹

- Some discomfort
- Potential for blood in urine
- Increased urgency after procedure
- Typically catheter for several days
- 4-6 weeks until symptom relief
- Potential for sexual dysfunction
- Higher retreatment rates

Surgery *TURP – Resection; Greenlight – Laser Vaporization, Robotic subtotal prostatectomy*



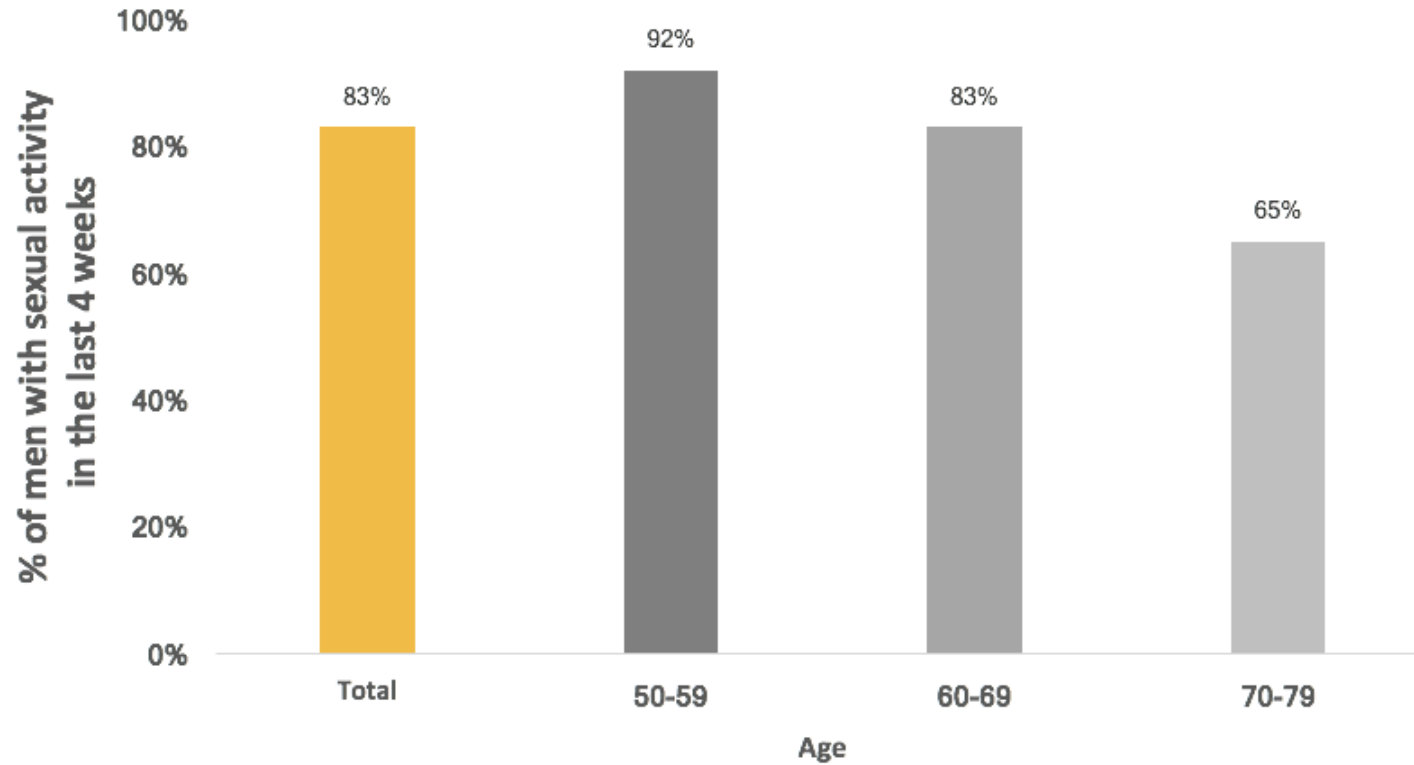
Advantages¹

- Maximizes flow and symptom relief
- Removes prostate tissue
- Durable
- Low retreatment rate

Disadvantages¹

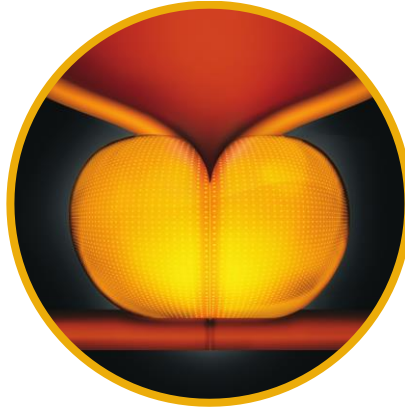
- Hospital procedure with general or regional anesthesia
- Can require hospitalization
 - Laser typically not overnight hospital stay
- Catheter for 1-7 days
- 4-6 weeks restricted activity
- 10% have erectile problems
- 40%-65% lose ejaculation
- 3% incontinence
- 7% strictures

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.

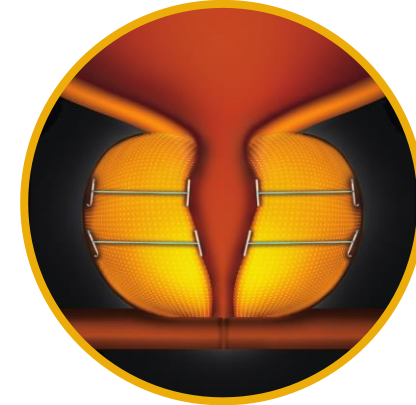
How the UroLift[®] System Works



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

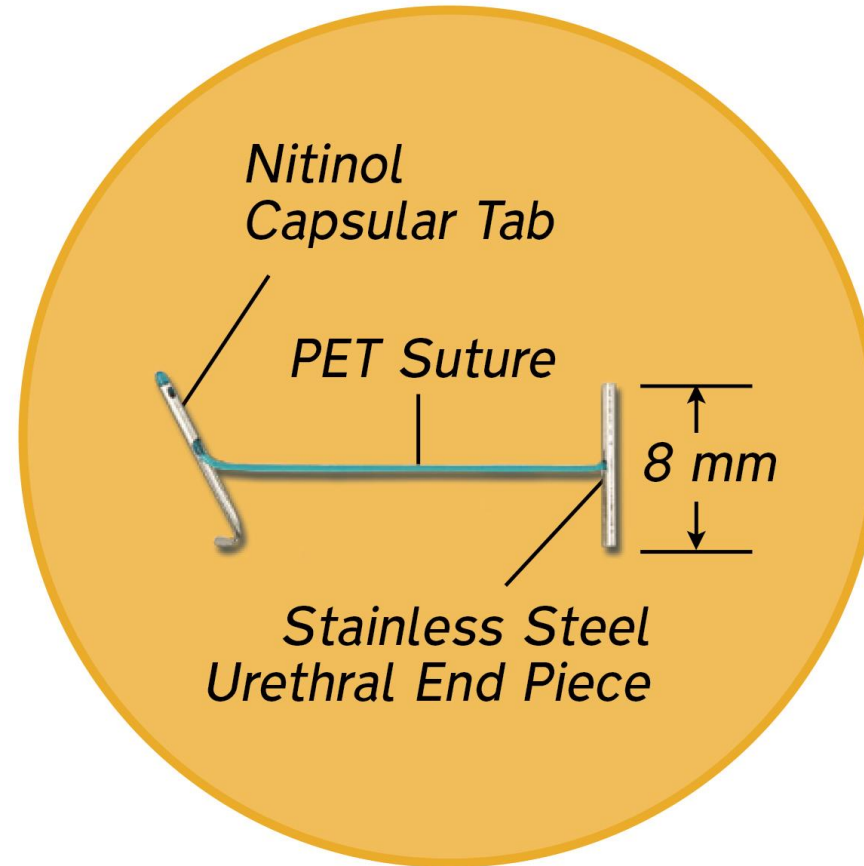


UroLift Implants are placed through a needle that comes out of the delivery device to lift the enlarged prostate tissue out of the way.



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

UroLift[®] Permanent Implant



UroLift[®] Animation

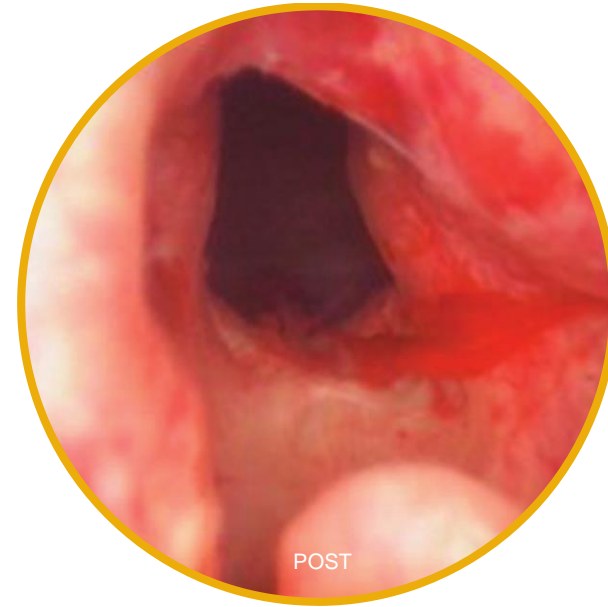


UroLift[®] Treatment Images

Before Treatment:
Obstructed Channel



After Treatment:
Open Channel



Post-Treatment Expectations

- Symptom improvement typically starts within a few days, may continue to improve up to 3-6 months
- Some irritation such as pain upon urinating, small amount of blood in urine, pelvic discomfort or urgency for 2-7 days 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

UroLift® vs TURP:

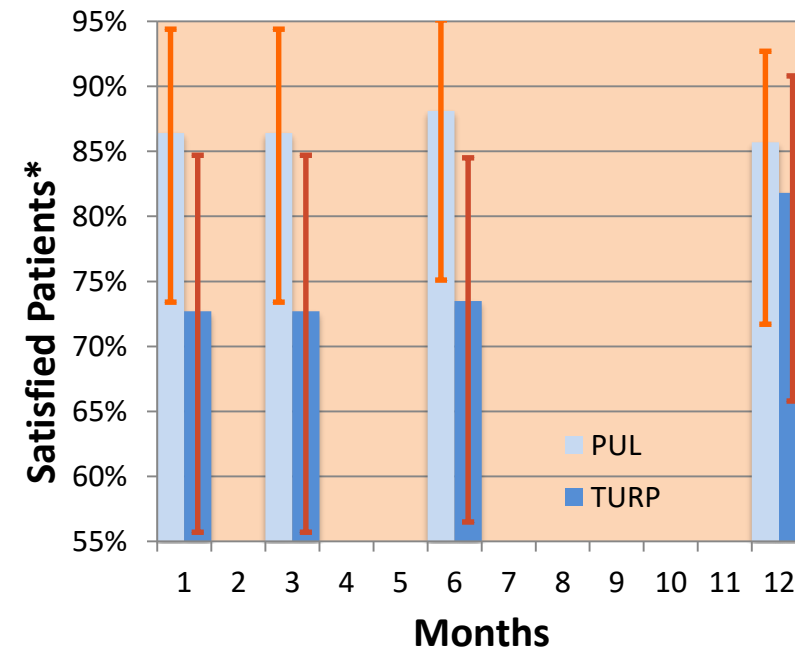
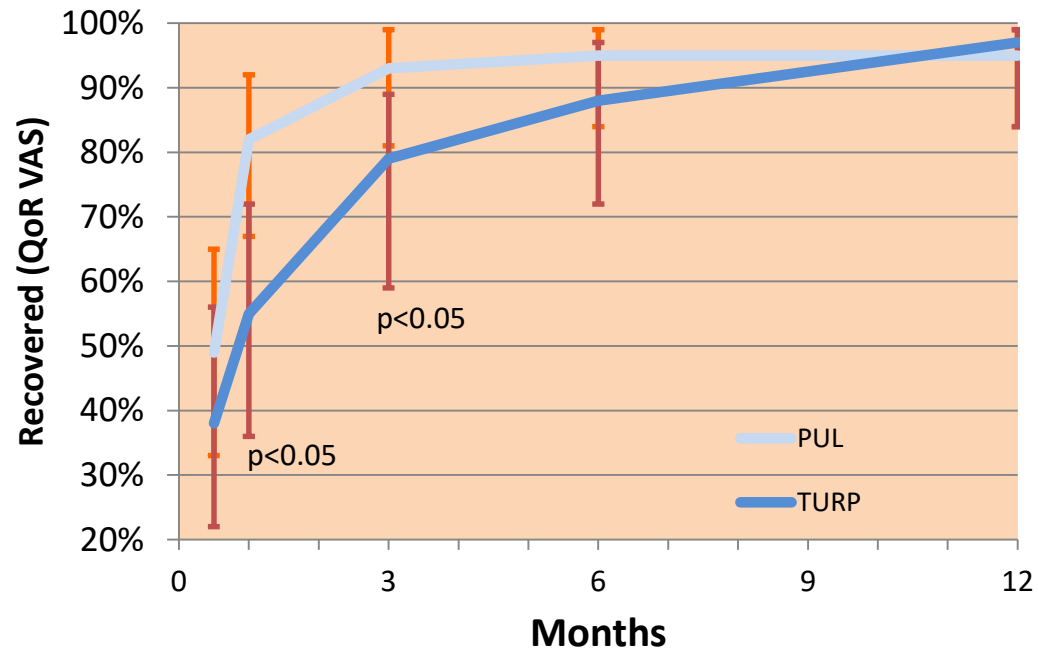
No Difference in Quality of Life

- 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

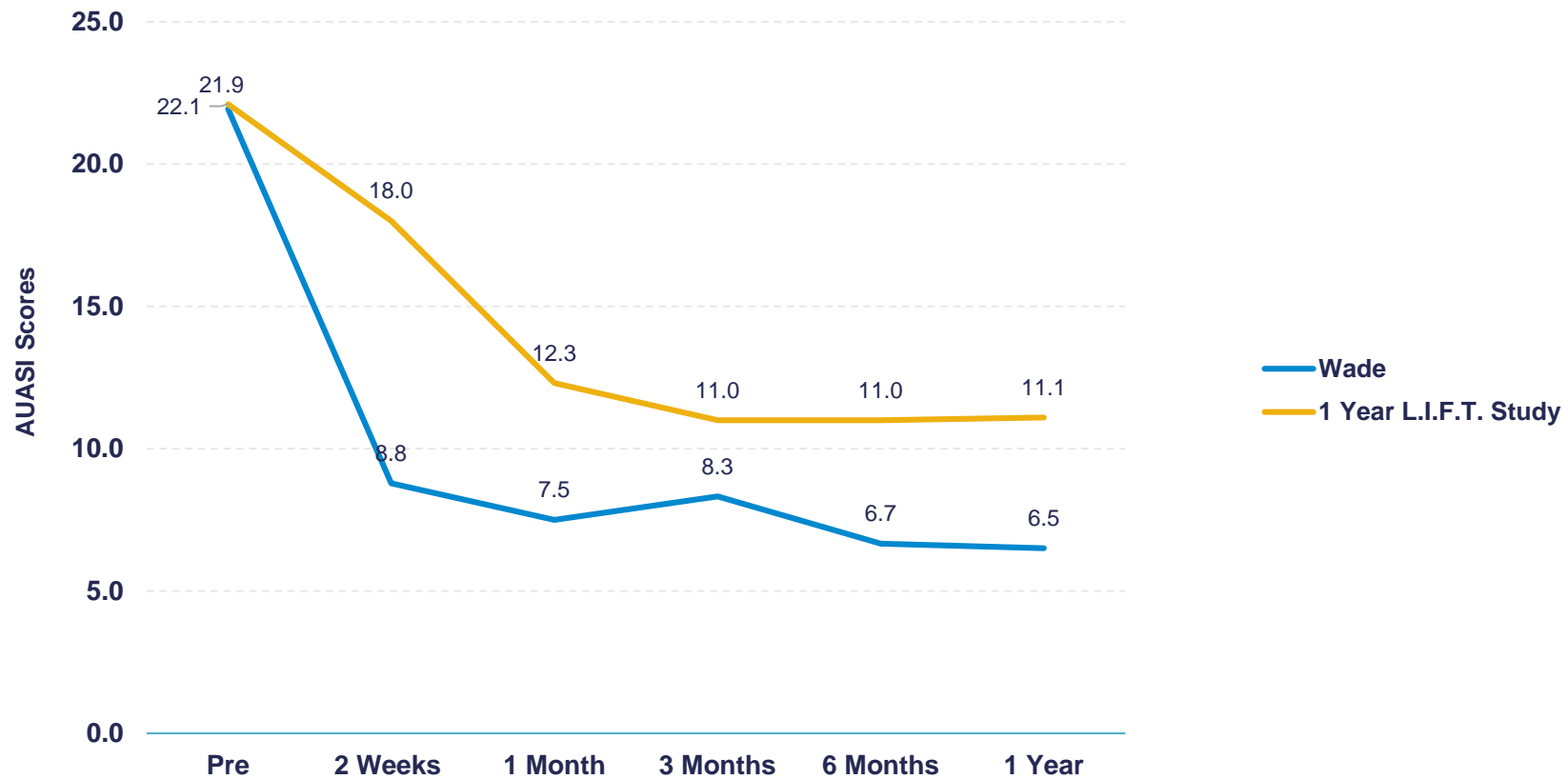
- UroLift[®] patients recover more quickly
 - TURP catches up between 6 to 12 months
- UroLift patients satisfied sooner and to greater extent



*would recommend procedure

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

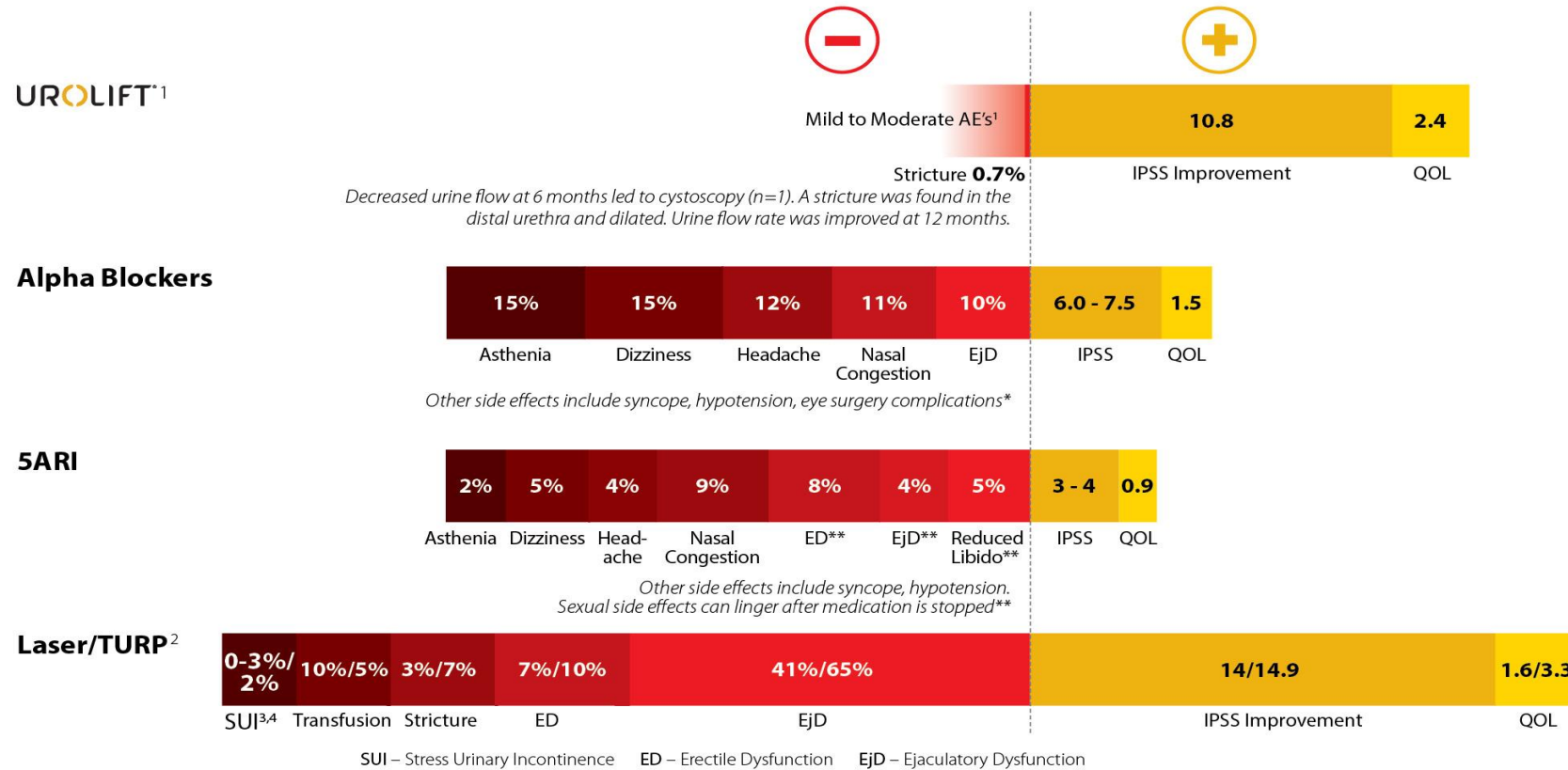
Date chart created: 8/9/2019



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.

Improvement without Significant Downsides



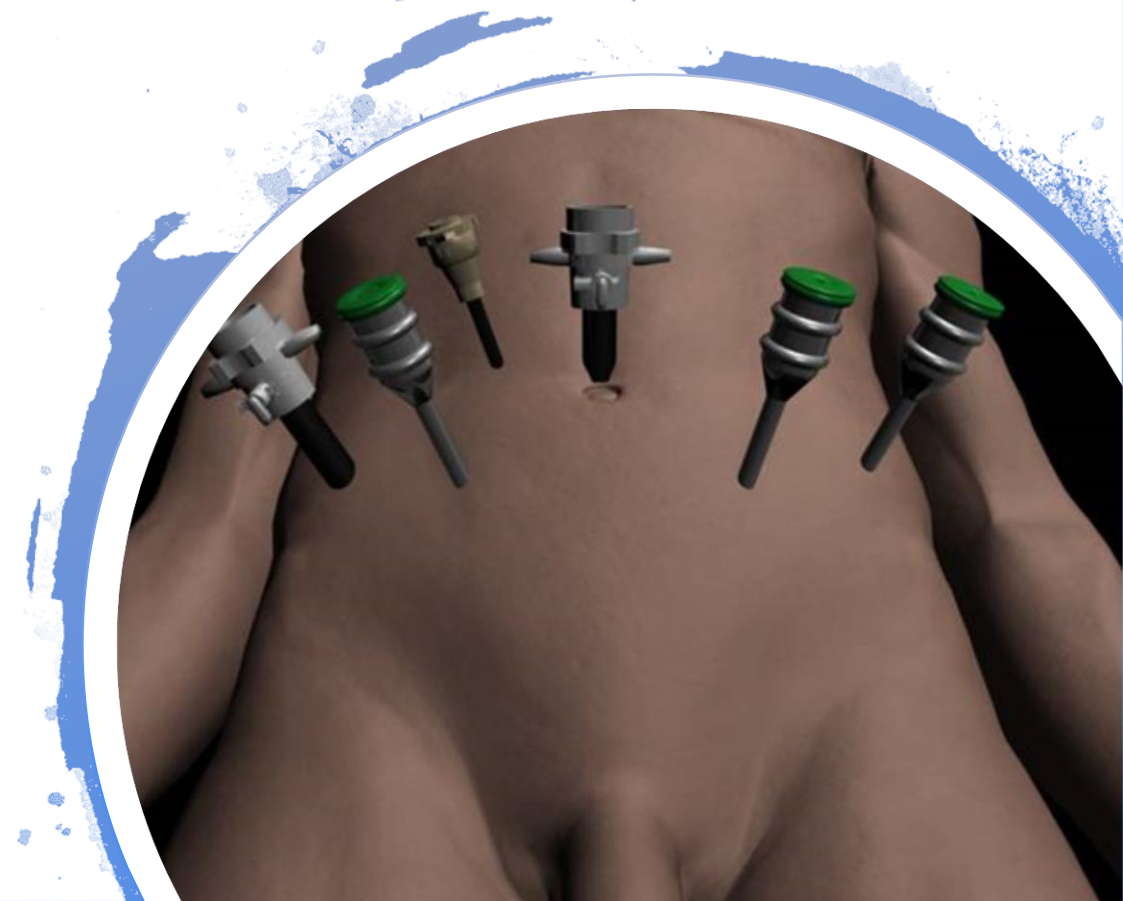
Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure.¹

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>

Robotic Subtotal Prostatectomy

- Used for very large >100gm prostates
- Has essentially replaced the open technique
- Has resulted in shorter hospital stays (1.3 days vs 2.6 days) and less blood loss (200cc vs 600cc)



Summary

- Many great options for men which continue to evolve
- Patients will have different levels of symptoms and different levels of bother from these symptoms which will tailor how we treat them
- We are seeing a shift in the paradigm on treating BPH as more minimally invasive treatments show rapid and durable relief
- Allowing patients to avoid or stop taking medications, which are not as “benign” as we once thought
- Not all options are good for every patient depending on their evaluation, but most will have several good options to consider

THANK YOU

Questions?

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