UCA

UROLOGY CENTERS OF ALABAMA

A Growing Problem for Men…BPH

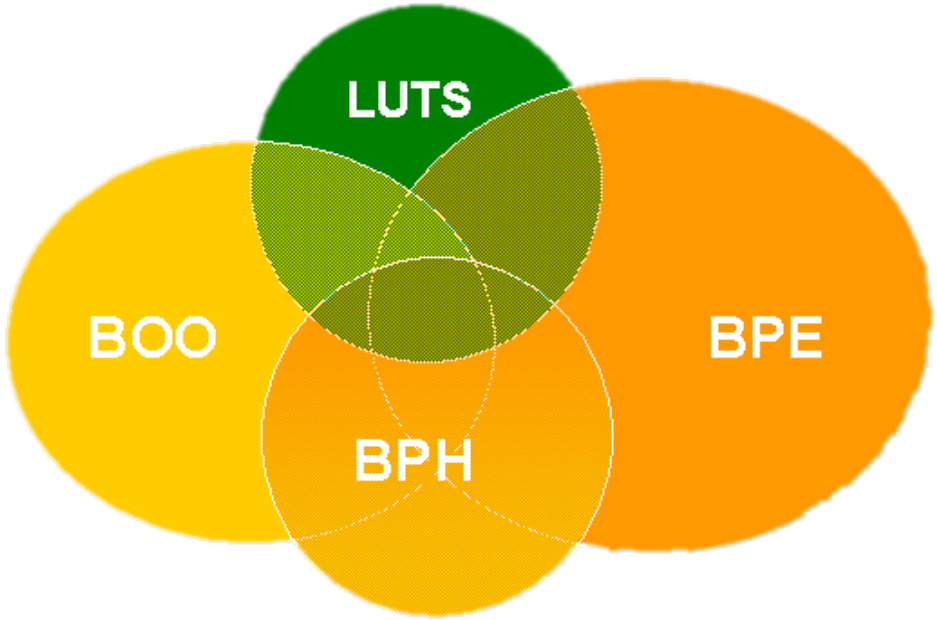
Mark DeGeunther, *MD*

- Prostatism
- BPH
- BOO
- LUTS

Pathophysiology of BPH and LUTS

Lower Urinary Tract Symptoms
(clinical diagnosis)

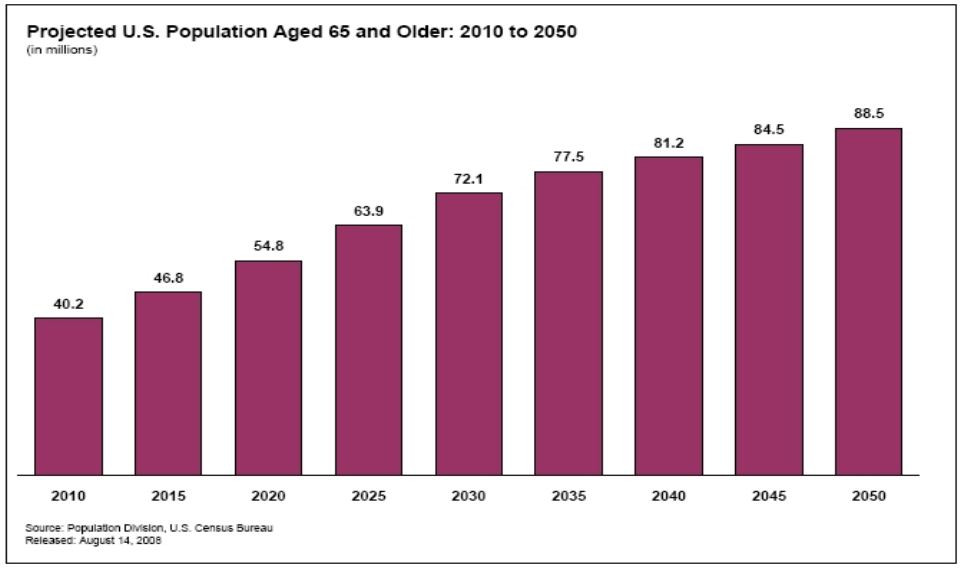
Bladder Outlet Obstruction (urodynamics diagnosis)

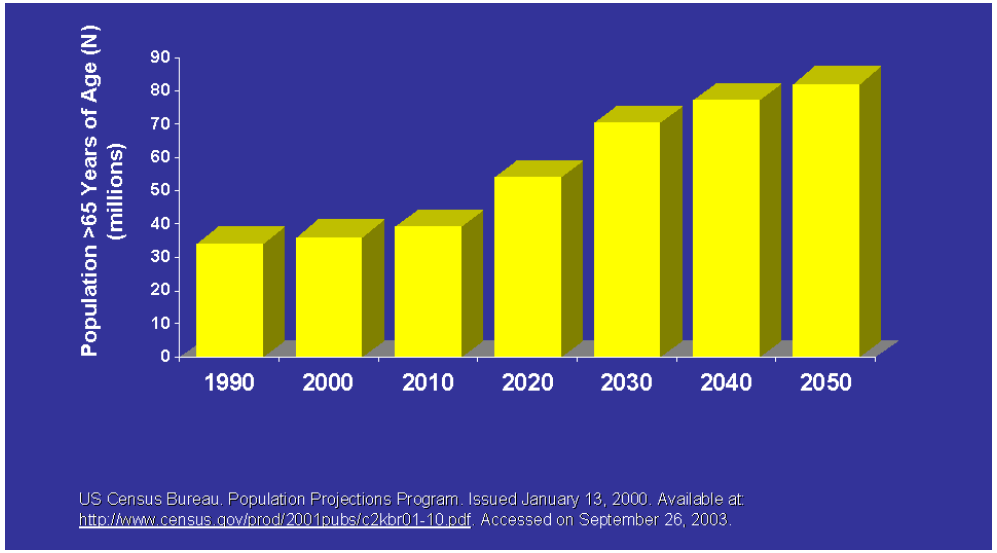


Benign Prostatic Enlargement (anatomical diagnosis)

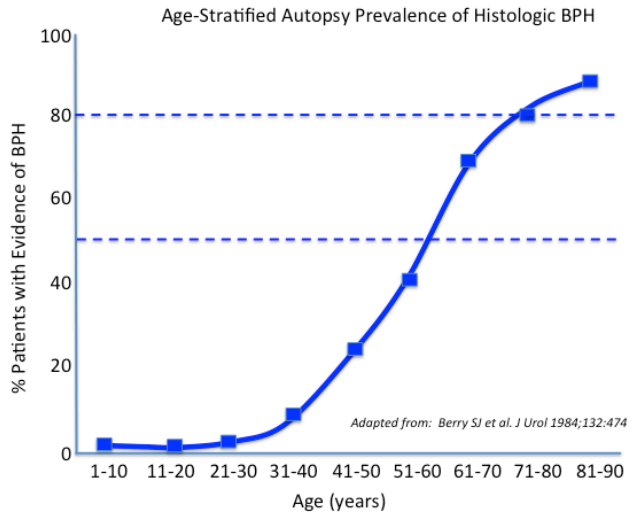
Microscopic Benign Prostatic Hyperplasia
(histologic diagnosis)

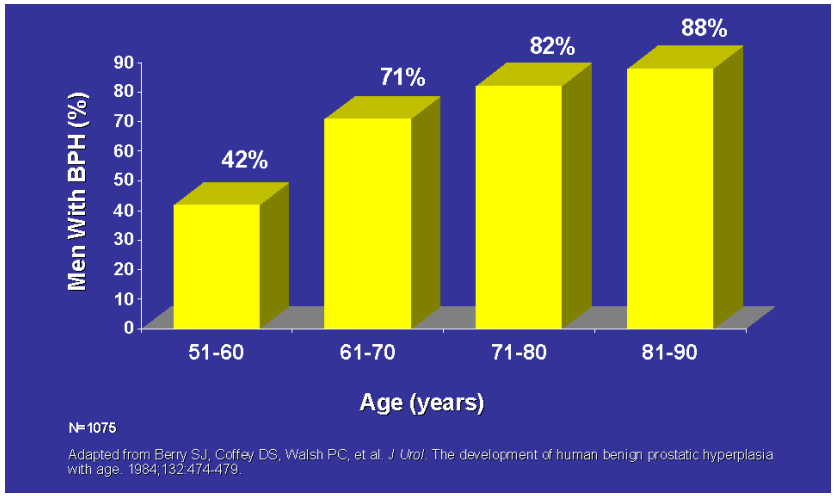
Aging of the US Population





Prevalence of BPH by Age





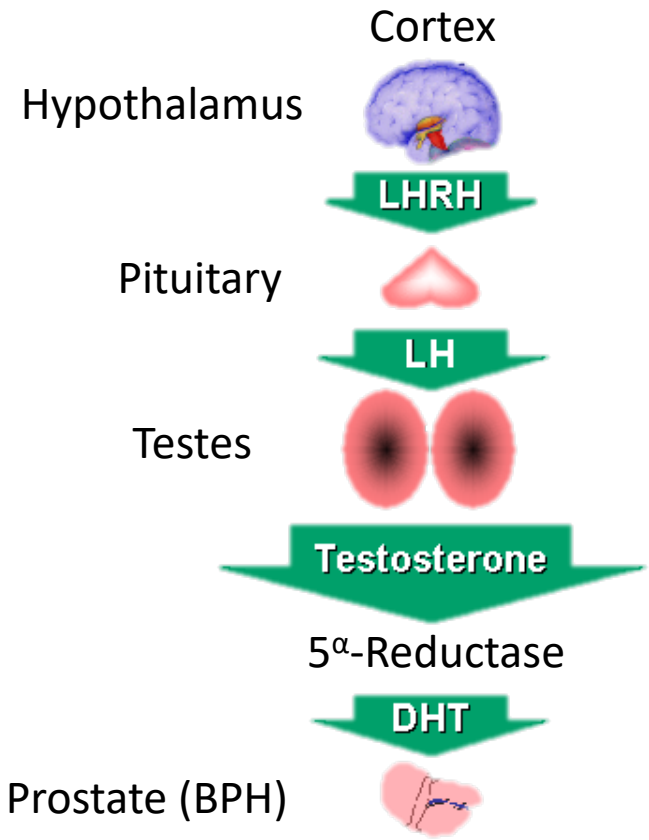
BPH is Important

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	Gastroesophogeal 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.

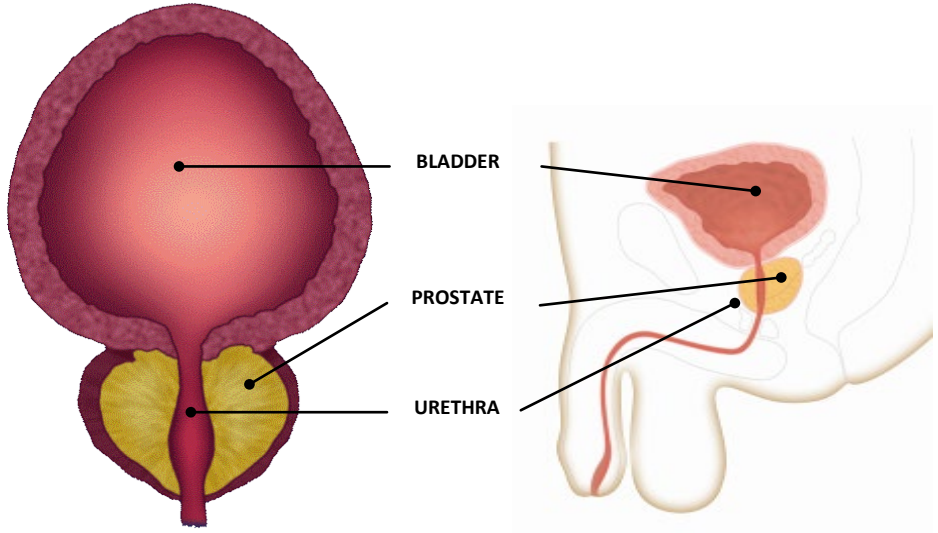
Hormonal Regulation of the Prostate



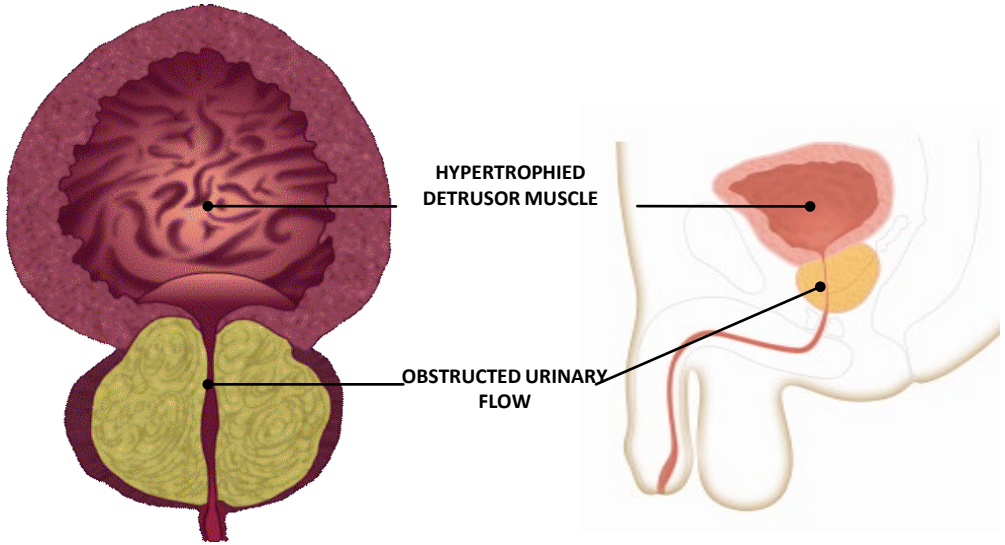
Normal vs. Enlarged Prostate

- 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

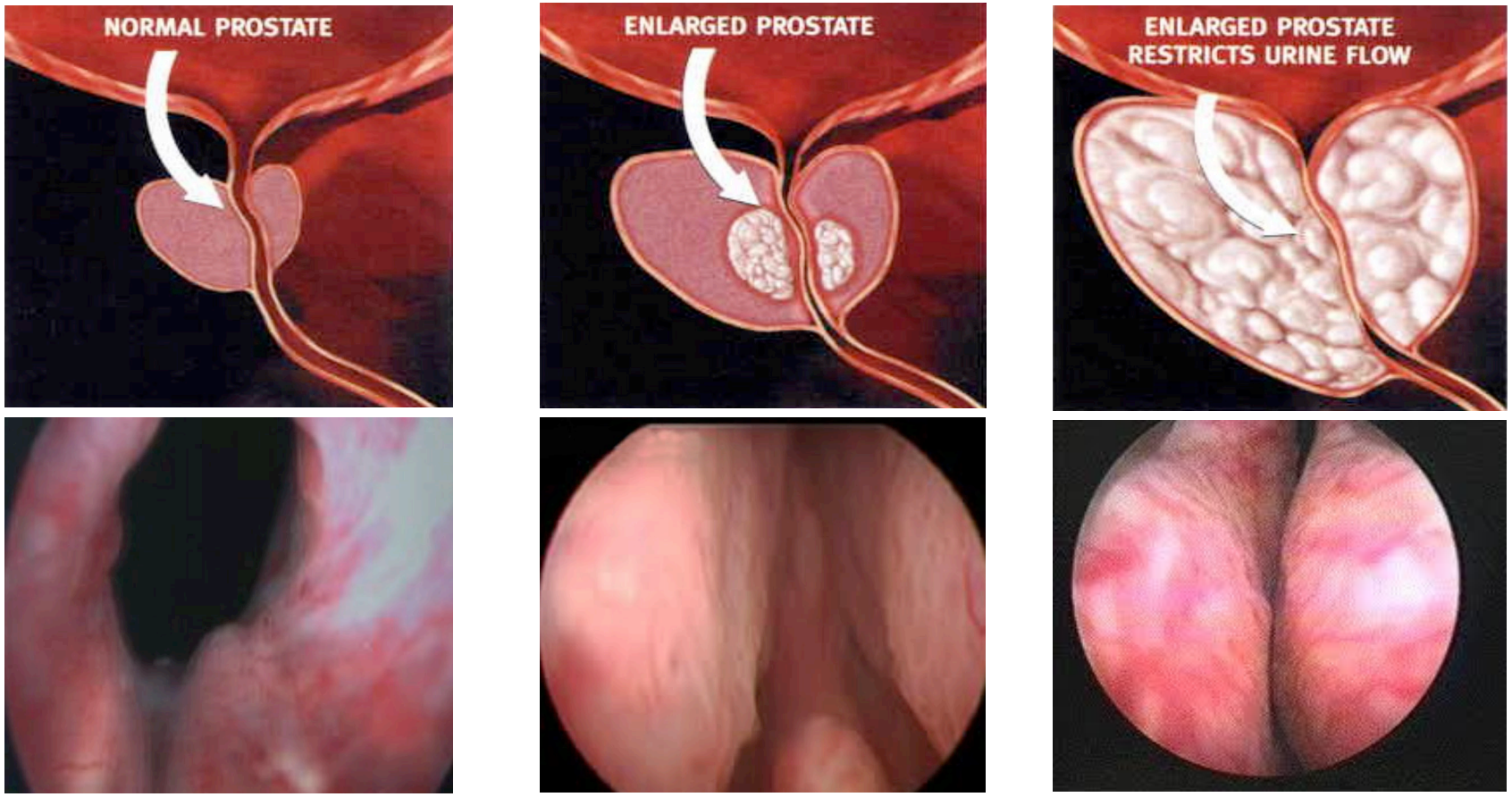


Enlarged Prostate (BPH) Anatomy



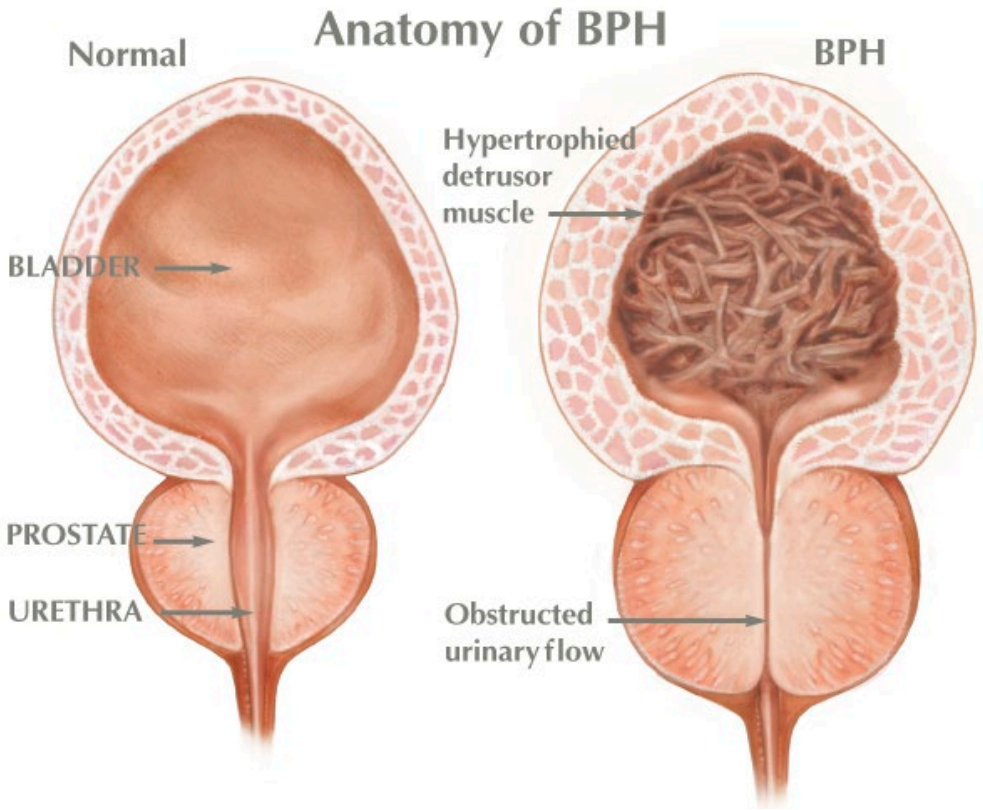
Roehrborn CG, McConnell JD. In: Walsh PC et al, eds. Campbell's Urology. 8th ed. Philadelphia, Pa: Saunders; 2002:1297-1336.

BPH Disease Progression



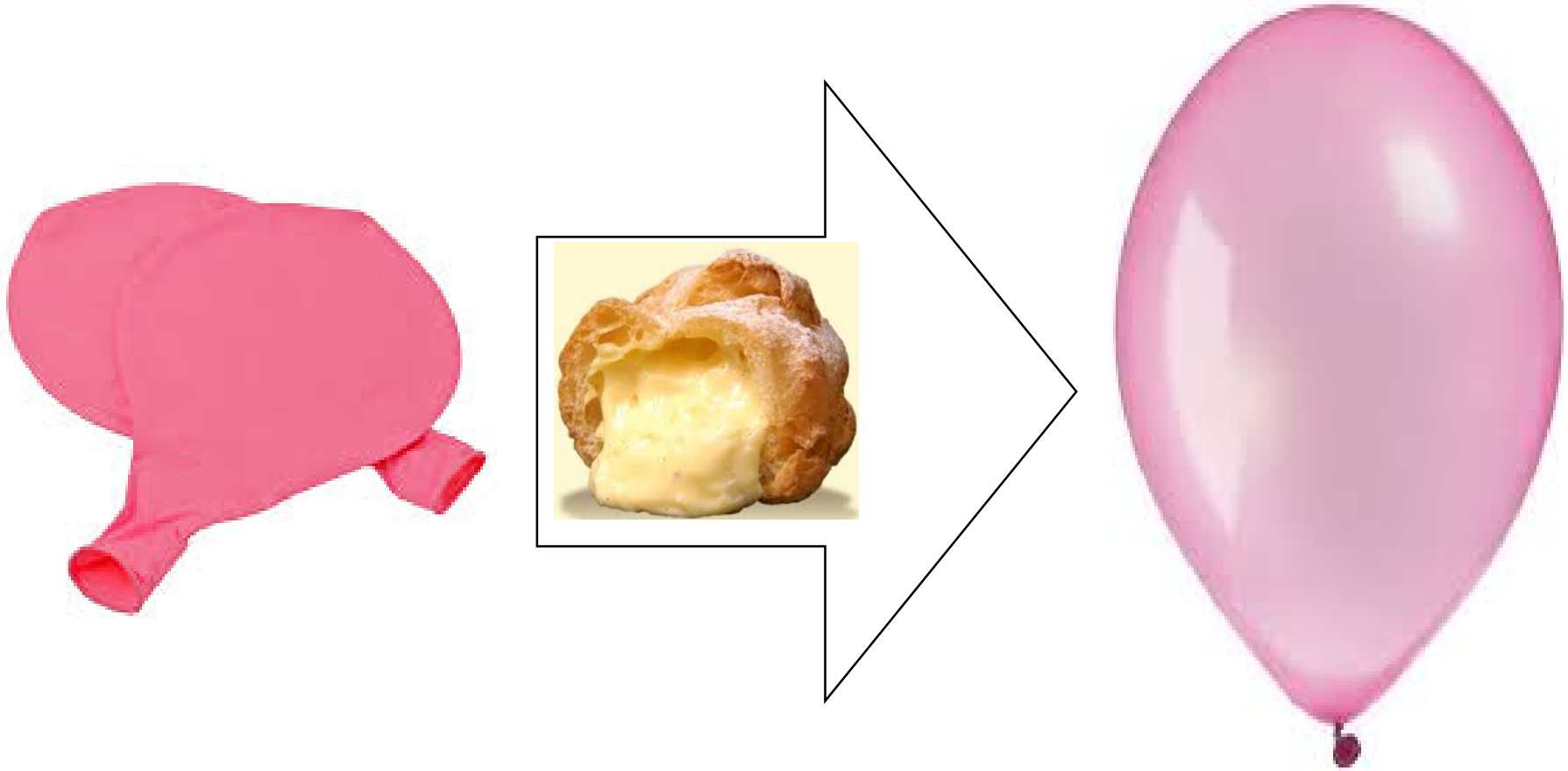
Images courtesy Dr. Steven Gange

What Happens if BPH is Not Treated?

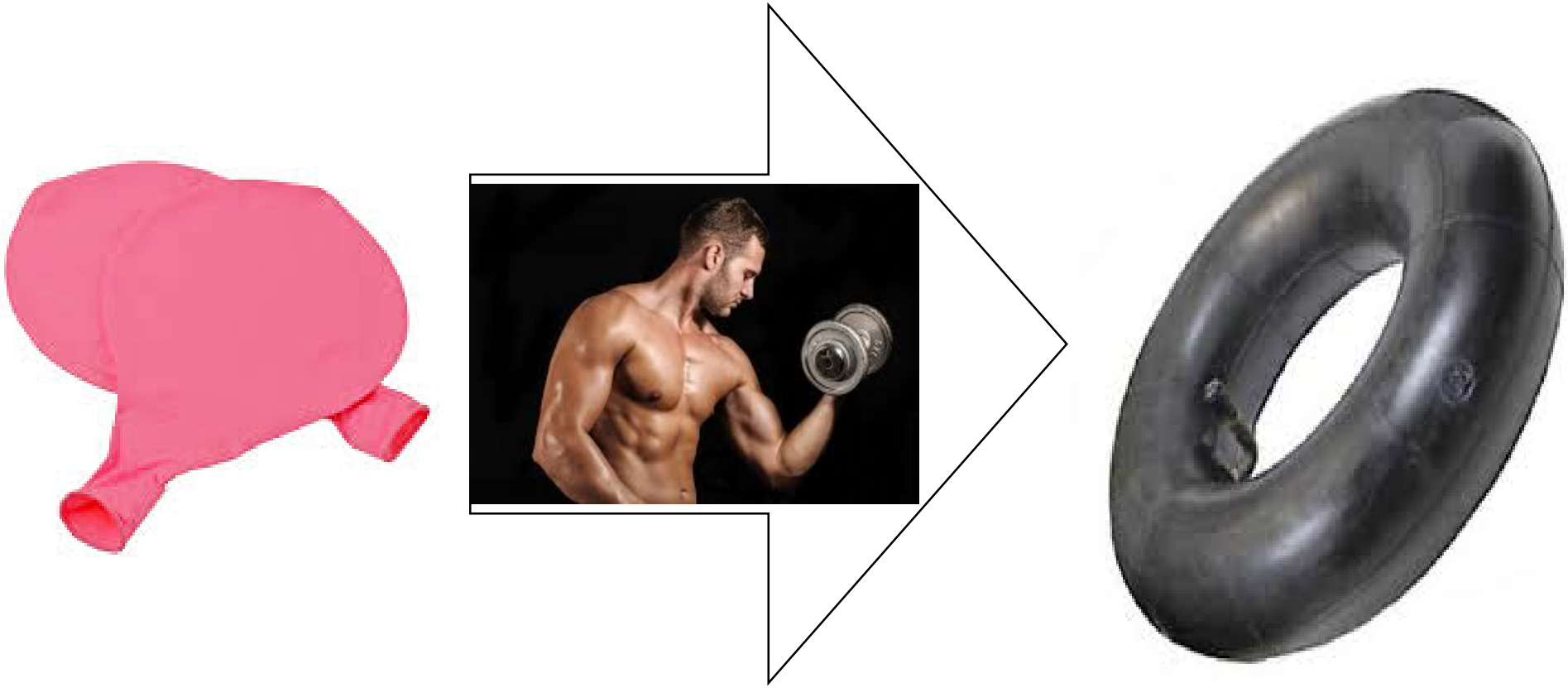


Not treating enlarged prostate can lead to bladder deterioration

Pathophysiology: Your Bladder Should Be Like



But If Your Bladder Works Too Hard:



Symptoms of BPH

Obstructive symptoms

- Hesitancy
- Weak urine stream
- Intermittency
- Dribbling at the end of urination
- Sensation of incomplete emptying of bladder

Irritative symptoms

- Nocturia
- Frequency
- Urgency

Distinguishing BPH From Other Causes of LUTS

BPH must be distinguished from

- Prostate cancer[1]
- Prostatitis[2]
- Urinary tract infection[1]
- Renal insufficiency[1]
- Urethral stricture[1]
- Bladder dysfunction[1]
- Bladder stones[1]
- Overactive bladder[3]
- Bladder Cancer[1]

1. AUA Practice Guidelines Committee. J Urol. 2003; 170:530-547
2. Krieger JN et al. Urology. 1996:48: 715-722
3. Mostwin JL. Urology. 2002(suppl 5A): 22-27

Confounding Co-Morbities

- Parkinson's Disease
- Dementia
- CVA
- Multiple Sclerosis
- Diabetic Neuropathy
- Spinal Cord Injury
- Advanced age

Complications Associated with BPH

- Urinary retention
- Renal insufficiency
- Urinary tract infection
- Gross hematuria
- Bladder stones

Patient Evaluation

- Medical history
  - Review of patient complaints
  - Patient self-administered questionnaire
    - Use of AUA-SI/IPSS
- Focused physical examination
  - General physical examination, including DRE
  - Neurologic examination
- Laboratory studies
  - Urinalysis
  - PSA assay in appropriate men
  - Urine cystology when appropriate
    - Multiple risk factors
    - Irritative symptoms predominate

AUA Symptom Index Score

	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
1. 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. 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. Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
4. Over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
5. Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5
6. Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
	None	1 time	2 times	3 times	4 times	5 or more times
7. 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?	0	1	2	3	4	5

Total Symptom Score

Adapted from AUA Practice Guidelines Committee. *J Urol*. 2003;170:530-547.

The Most Important Question

How much do your urinary symptoms bother you?

- Enough to take daily medicine?
- Enough to consider surgery?

When to Refer to a Urologist

- DRE reveals palpable nodules or irregularities[1]
- PSA level 2.5ng/mL or yearly increase >0.4ng/mL in PSA level over a 3-year period[1]
  - Higher PSA cutoff point (4.0ng/mL) may be justified in older (<70 years)
- Inadequate response to medication/Intolerable side effects
- Refractory LUTS
- Complications[2]
  - Renal failure
  - Bladder or urethral stones
  - UTI
  - Hematuria
  - Urinary retention

1. Barry MJ e al. In: *Primary Care Medicine*. 4th ed. *Philadelphia, PA: Lippincott Willimas & Wilkins; 200: 742-747*
2..Clinical Practice Guideline Number 8: Benign prostatic hyeprlasia: diagnosis and treatment. Rockville, Md: US DHHS: 1994. AHCRP Publication NO. 94-0582

The Urologist's Evaluation

- History/Physical
- UA +/- PSA
- Uroflowmetry
- Post-void residual volume (PVR)
- Cystoscopy
- TRUS measurement of prostate volume

Treatment Options for BPH

- Watchful waiting/Observation
- Pharmacologic therapy
  - Alpha blockers
  - 5AR Inhibitors
  - Herbals (saw palmetto)
- Surgical intervention
  - In office, non-heat based tx (Urolift)
  - In office, heat based tx (Rezum)
  - VLAP (laser TURP)
  - TURP
  - TUVP (“Button” procedure)
  - Robotic subtotal prostatectomy

Pharmacologic Approaches to BPH Treatment

- Phyto therapy (Saw palmetto)
  - Herbal product available OTC
  - Approximately 60% subjective response
  - Main problem is potency of the purchased product since the FDA classifies as a “food product”
  - Takes 2 months to work
  - $6-20 per month
- Alpha-adrenergic blockade
  - Relaxes smooth muscle of prostate/bladder neck
  - Rapidly improves urinary flow and symptoms
  - No long-term issues with medication but about 33% of patients develop significantly decreased effectiveness within several years

Pharmacologic Approaches to BPH Treatment

- 5-alpha reductase inhibitors
  - Reduces prostate size over 5-6 months
  - More gradual symptom improvement
  - Only works in large prostates
  - Lowers serum PSA levels by 40-50%
    - This is often helpful diagnostically in patients with elevated PSA's and prior negative biopsies. If PSA does not fall 40-50%, the rise is likely NOT due to BPH

“Combination Therapy” Alpha blocker + 5 AR Inhibitor

MTOPS (Medical Therapy of Prostatic Symptoms) Study[1] (finasteride vs doxazosin vs combination vs placebo

Results

- 1 year: doxazosin = combo > finasteride > placebo
- 3 year: combo > doxazosin or finasteride > placebo
- Finasteride and combo decreased risk of invasive tx by 64% and 67%, doxazosin did not
- Finasteride and combo both worked much better with larger prostates (>30g)

1. McConnell JD et al. (2003) The long-term effect of doxazosin, finasteride, and combination therapy on the clinical progression of benign prostatic hyperplasia. N Engl J Med 349: 2387–2398

Surgical Treatment

- Minimally Invasive
- Heat based therapies
  - Rezum - Steam injection
- Non-heat based therapies
  - Urolift

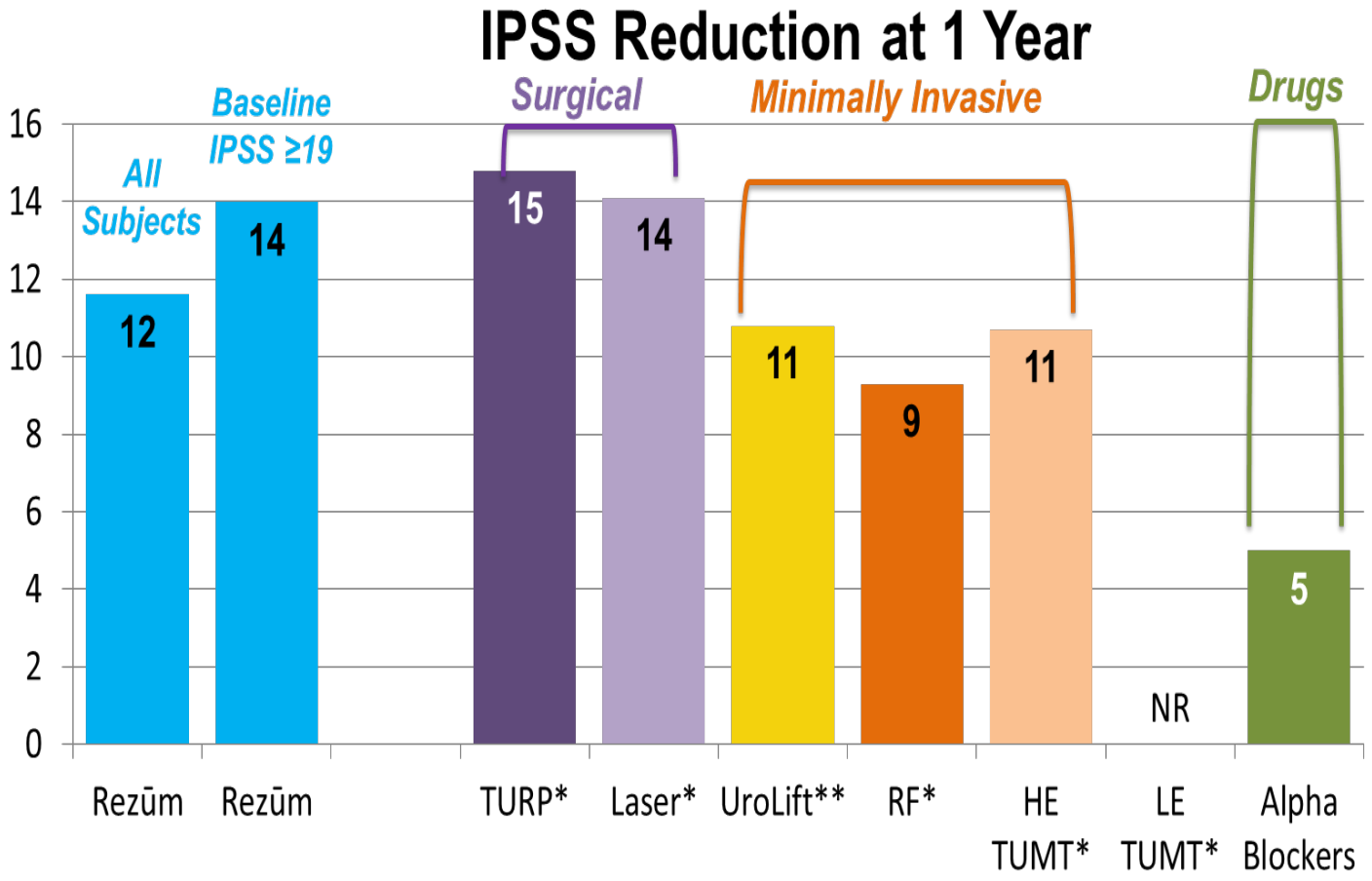
- Invasive
  - VLAP - Visual Laser Ablation of the Prostate (Laser TURP)
  - TUVP – TransUrethral Vaporization of the Prostate
  - TURP – TransUrethral Resection of the Prostate
  - Robotic subtotal prostatectomy

The Rezūm System

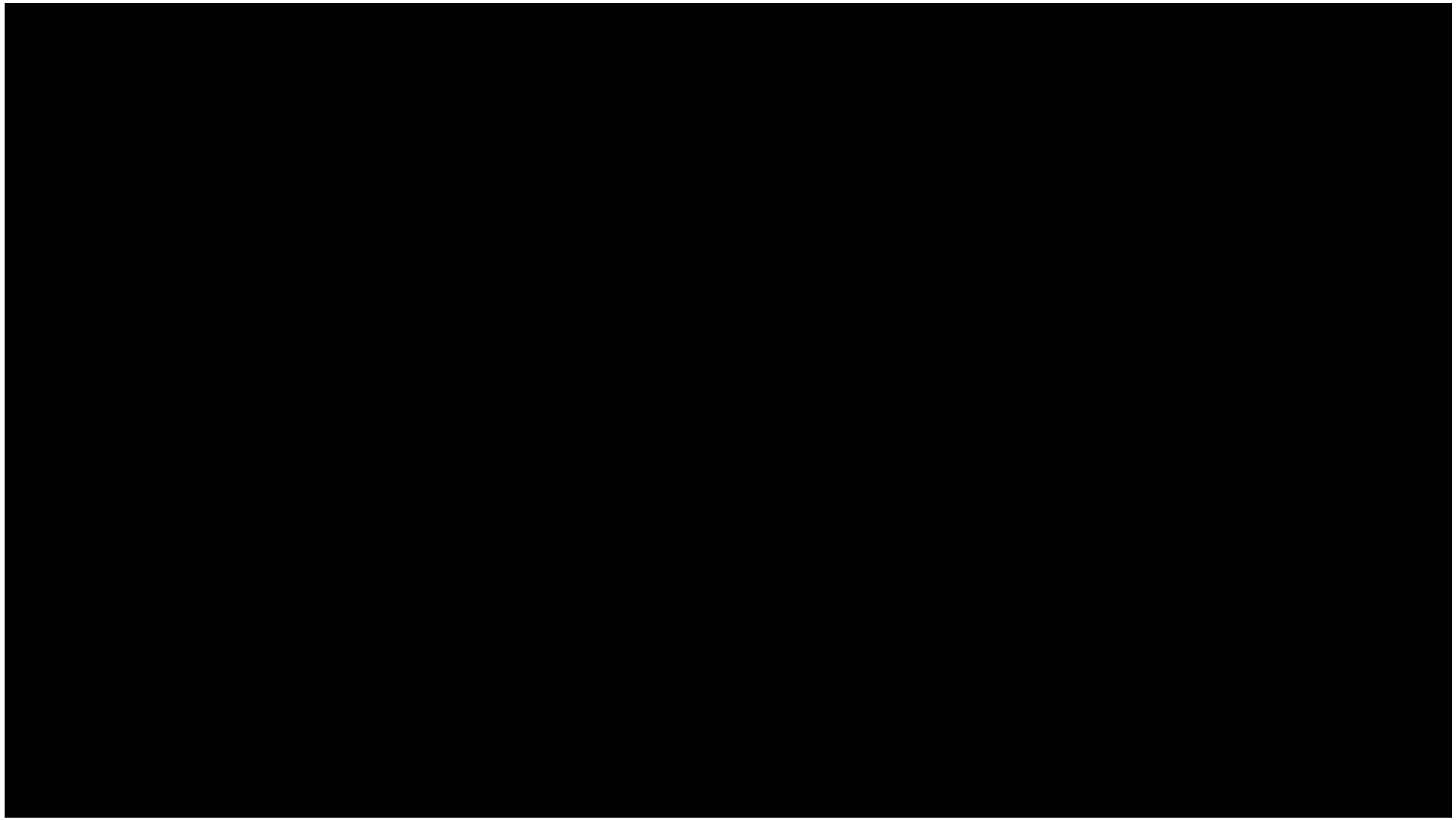
The Rezūm System consists of a hand held delivery device and generator

Rezūm II Pivotal Study

IPSS Symptom Improvement Comparable to Surgical Procedures



Rezūm Animation



Rezūm Video

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.

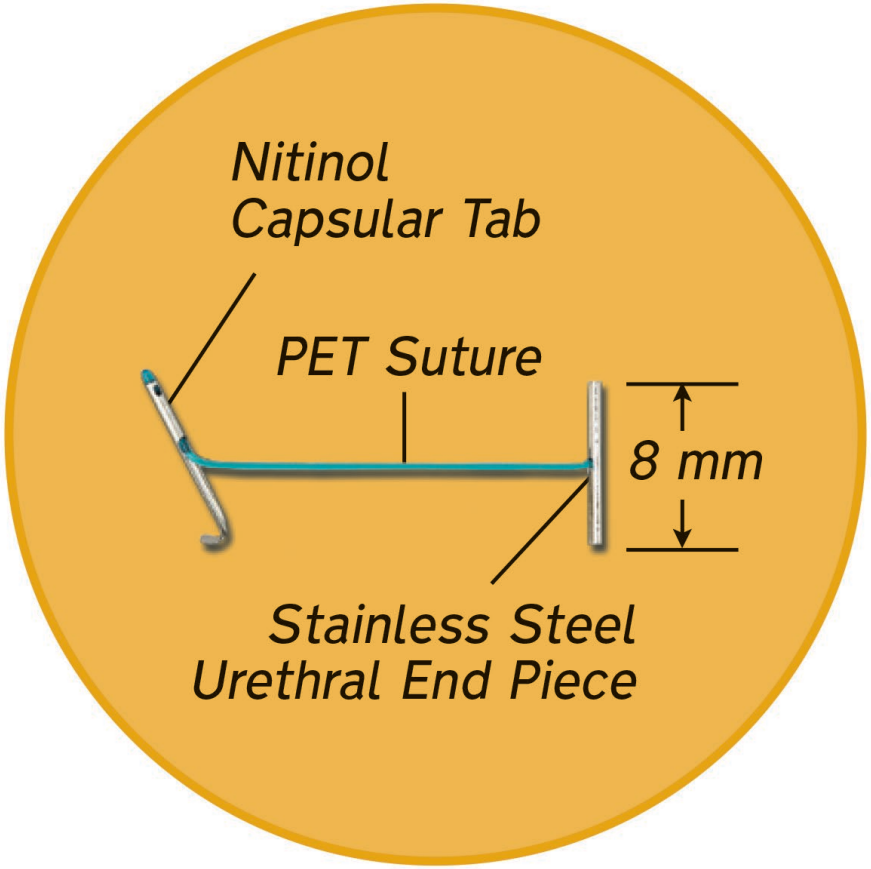
How the UroLift® System Works

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

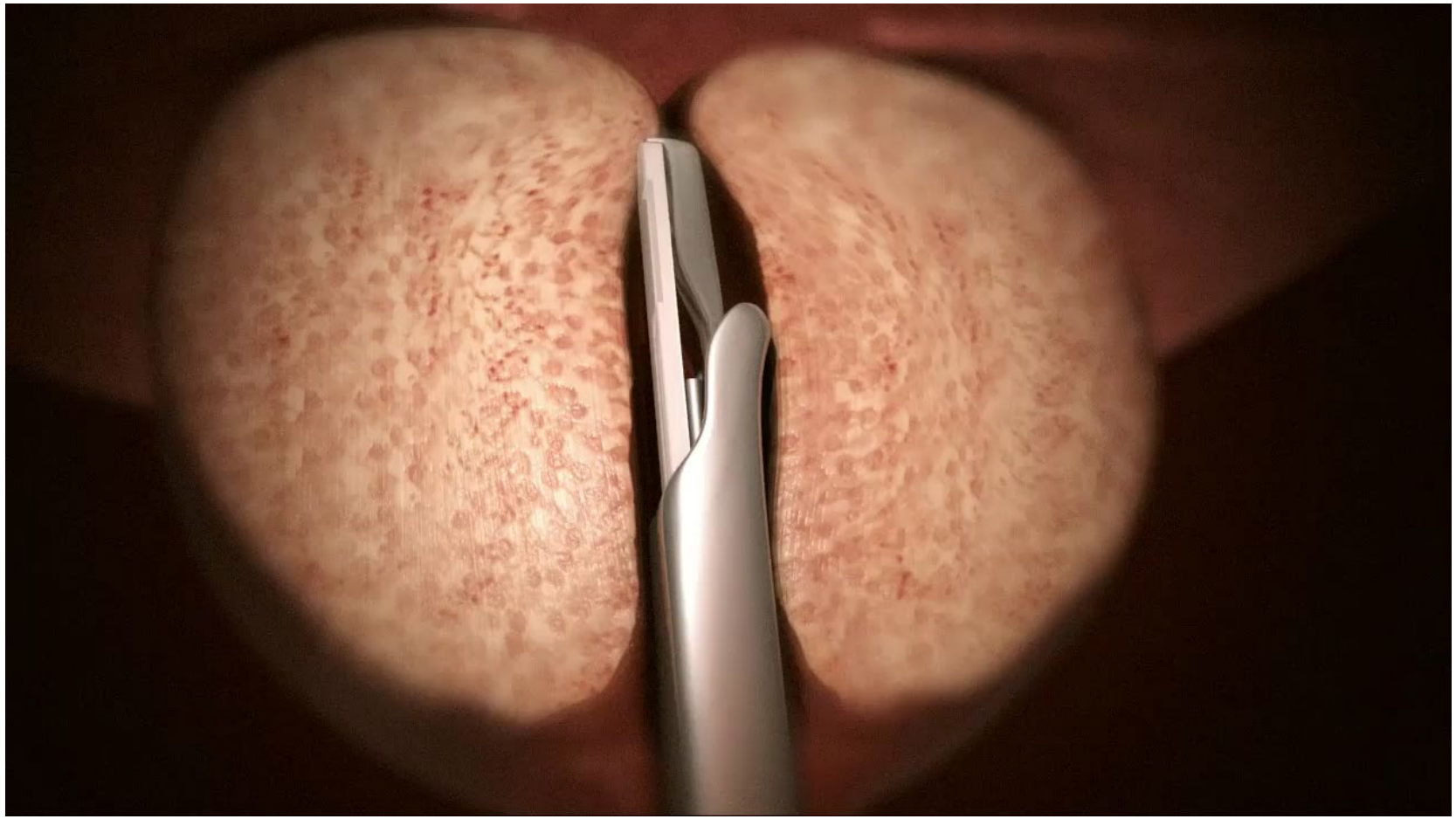
UroLift Implants are placed through a needle that comes out of the delivery device to lift the enlarged prostate tissue out of the way.

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

UroLift® Permanent Implant

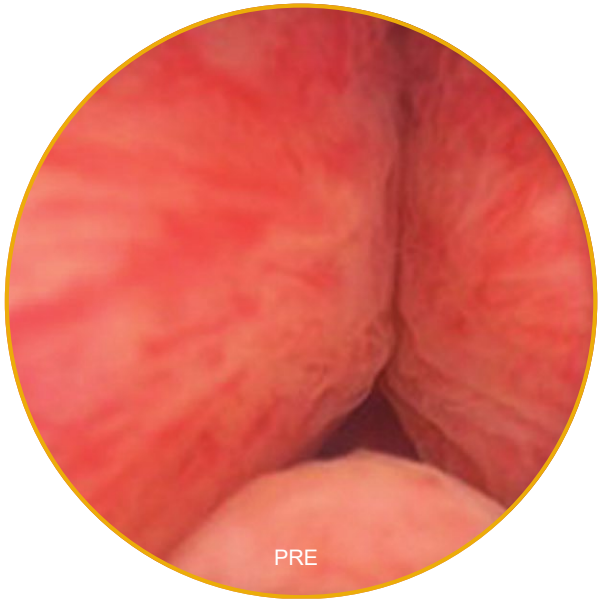


UroLift® Animation

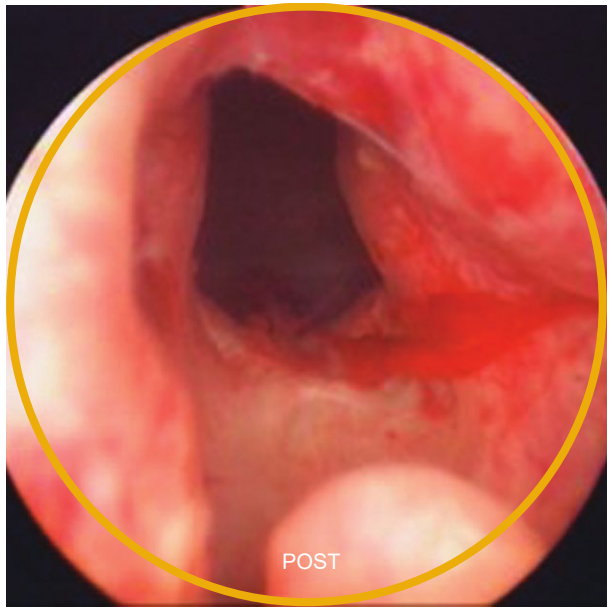


UroLift® Treatment Images

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

Roehrborn Urology Clinics 2016. Chin et al. Urology 2012.
Shore et al. Can J Urology 2014.

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

- 86% achieved high quality recovery[1] 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%

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

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

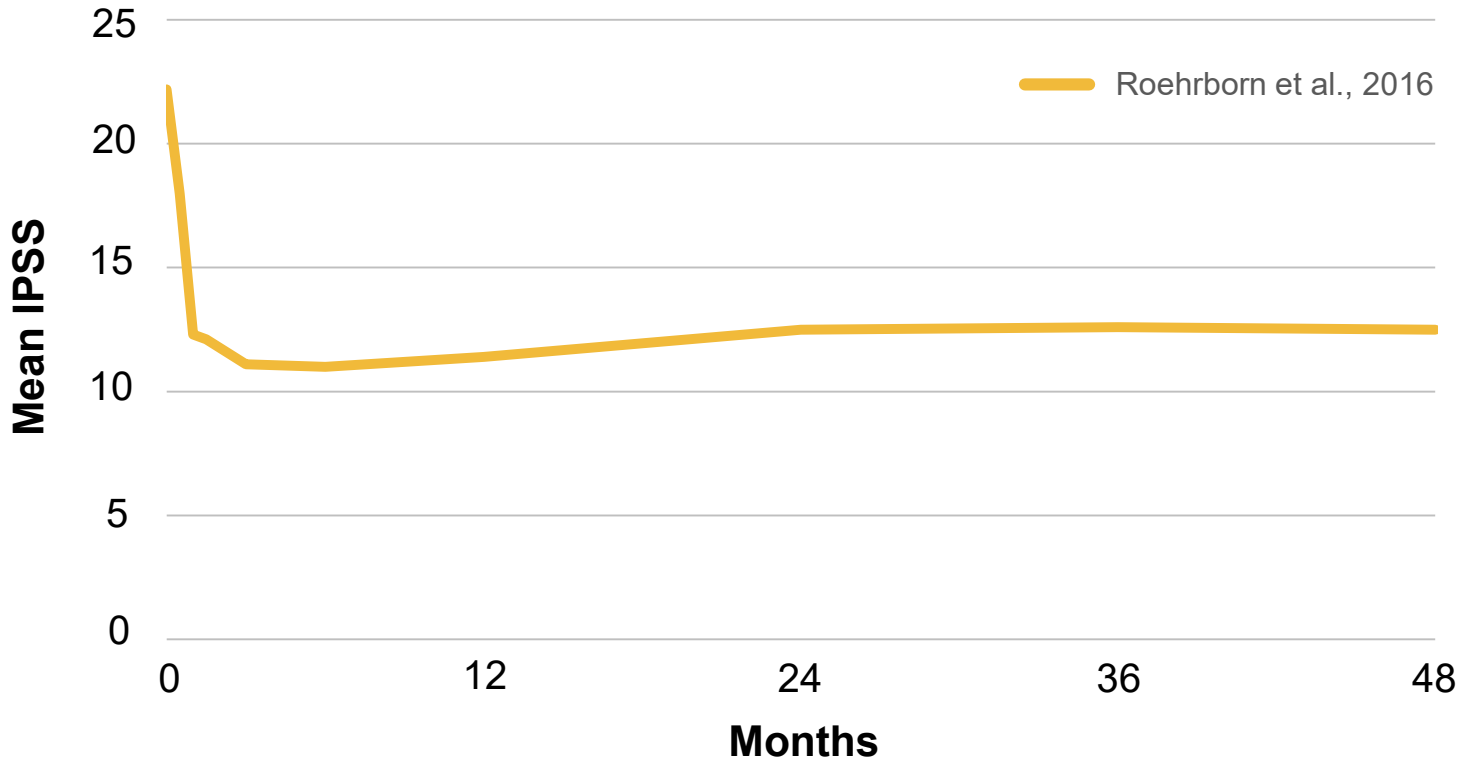
UroLift® vs TURP: No Difference in Quality of Life

- 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

Sonksen et al. Eur Urol 2015

L.I.F.T. Study Results



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Transurethral Resection of the Prostate TURP

- TURP = The “Gold Standard”
- Requires general or spinal anesthesia
- Must be off anti-coag/anti-platelet meds
- 1-2 night hospitalization with catheter
- 90% overall success
- Tissue is available for pathologic examination

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Transurethral Vaporization of the Prostate TUVP

- Requires general or spinal anesthesia
- Must be off anti-coag/anti-platelet meds
- Similar to a TURP in rapidity of effectiveness and overall success (>90%)
- Less bleeding, quicker recovery, less pain, typically overnight stay
- Tissue not available for pathologic examination

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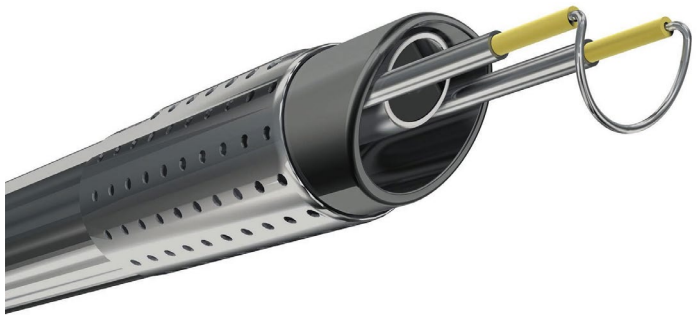
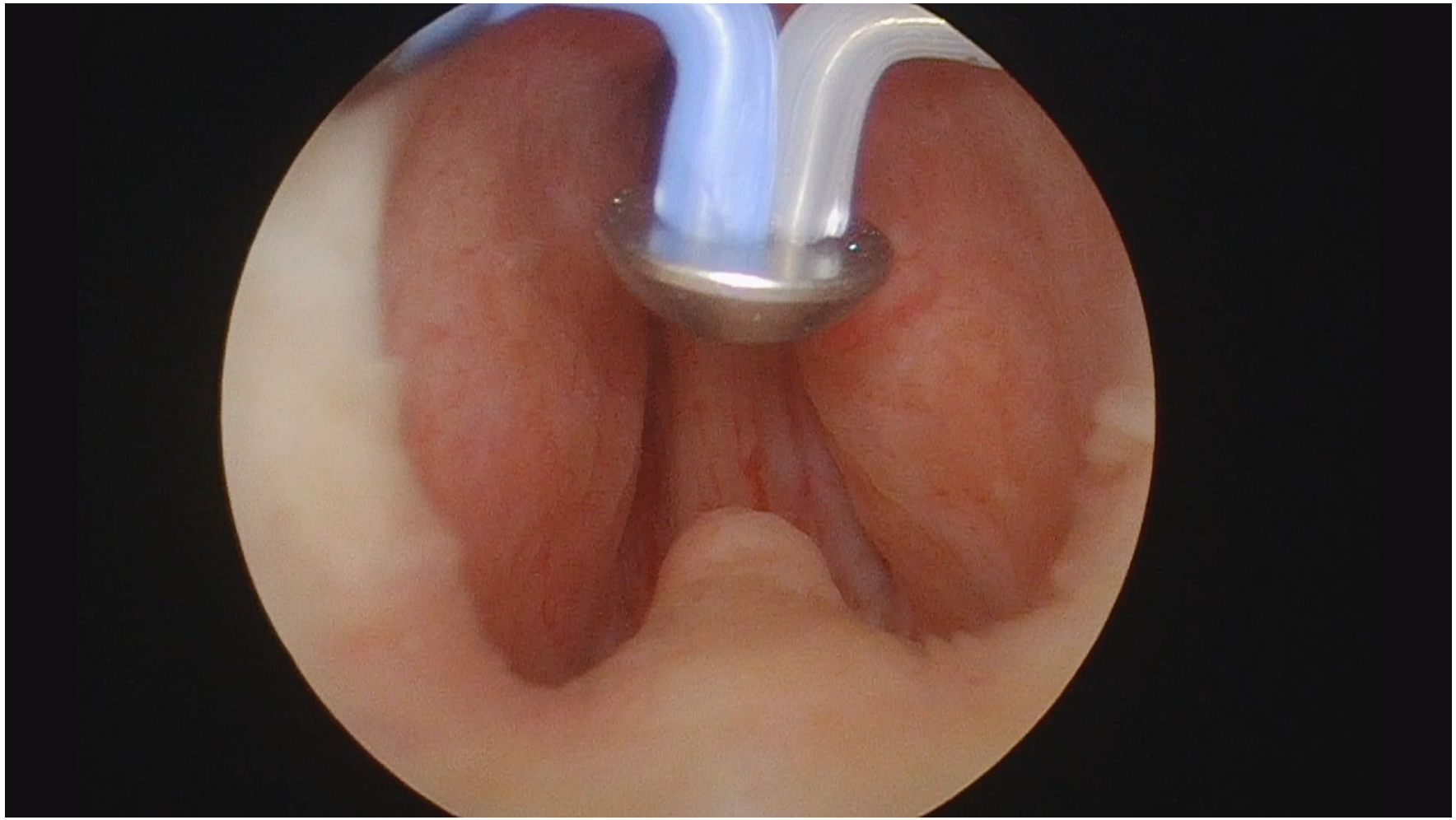
Resectoscopes

TURP Loop



TUVP Button

TUVP



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BPH Surgery Shared Decision Making

	TURP TransUrethral Resection of the Prostate	TUVP TransUrethral Vaporization of the Prostate	VLAP Visual Laser Ablation of the Prostate	Rezum	UroLift
Description	Cuts prostate tissue out through scope in urethra	Melts prostate tissue away through scope in urethra using electrical energy	Melts prostate tissue away through scope in urethra using laser energy	Steam injected into prostate via a scope in urethra to kill cells that will be reabsorbed by the body	Sutures placed via a scope through prostate to hold the urethra open
Anesthesia needed	General or spinal	General or spinal	General or spinal	Sedation and nerve block	Sedation and nerve block
Location performed	Hospital Operating Room	Hospital Operating Room	Hospital Operating Room	Office	Office or OR
Hospital stay	1-2 nights	0-1 night	0-1 night	None	None
Catheter needed	1-2 days	1 day	1 day	3 days	None usually
Improvement seen when	Better flow often immediate, relief in other symptoms (frequency, urgency, nighttime voiding) 6-12 weeks	Better flow often immediate, relief in other symptoms (frequency, urgency, nighttime voiding) 6-12 weeks	Better flow often immediate, relief in other symptoms (frequency, urgency, nighttime voiding) 6-12 weeks	No real improvement for 6-12 weeks	Better flow often immediate, relief in other symptoms (frequency, urgency, nighttime voiding) 2-3 weeks
Retrograde Ejaculation	75%	75%	75%	10%	<1%
Stricture/scarring risk	3%	3%	3%	<1%	<1%
Overall Success	90%	90%	90%	80%	80%
Years in clinical use	1950's	2013	2008	2014	2013
Also known as	Roto-rooter	Plasma Button by Olympus	Greenlight or Holmium laser	Water vapor or steam therapy	Prostatic Urethral Lift (PUL)
Length of procedure	45-60 min	45-60 min	45-60 min	10 min	10 min
Return to work	3-5 days	2-3 days	2-3 days	1 day (if can work with catheter)	1 day
Activity restrictions	No lifting over 25 lbs for 2 weeks, no bouncing like horseback riding for 2 weeks	No lifting over 25 lbs for 2 weeks, no bouncing like horseback riding for 2 weeks	No lifting over 25 lbs for 2 weeks, no bouncing like horseback riding for 2 weeks	None except as limited by catheter	None
Google Search terms	TURP	Button procedure by Olympus	Laser TURP or VLAP	Rezum	Urolift

THANK YOU

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