

# ***UroLift for BPH***

## **FDUS, August 2019**



**Steven Gange MD FACS**  
**Director of Research and Education**



# My BPH Disclosures

## GSK (Avodart):

Investigator (REDUCE trial)

## Neotract/Teleflex (UroLift):

Investigator (first UroLift in North America, lead-enroller in RCT), Consultant, First CoE

## NxThera/Boston Sci (Rezūm):

Investigator (first Rezūm in North America, lead-enroller in RCT); Former Consultant

## Nymox (Fexapotide):

Investigator, Consultant

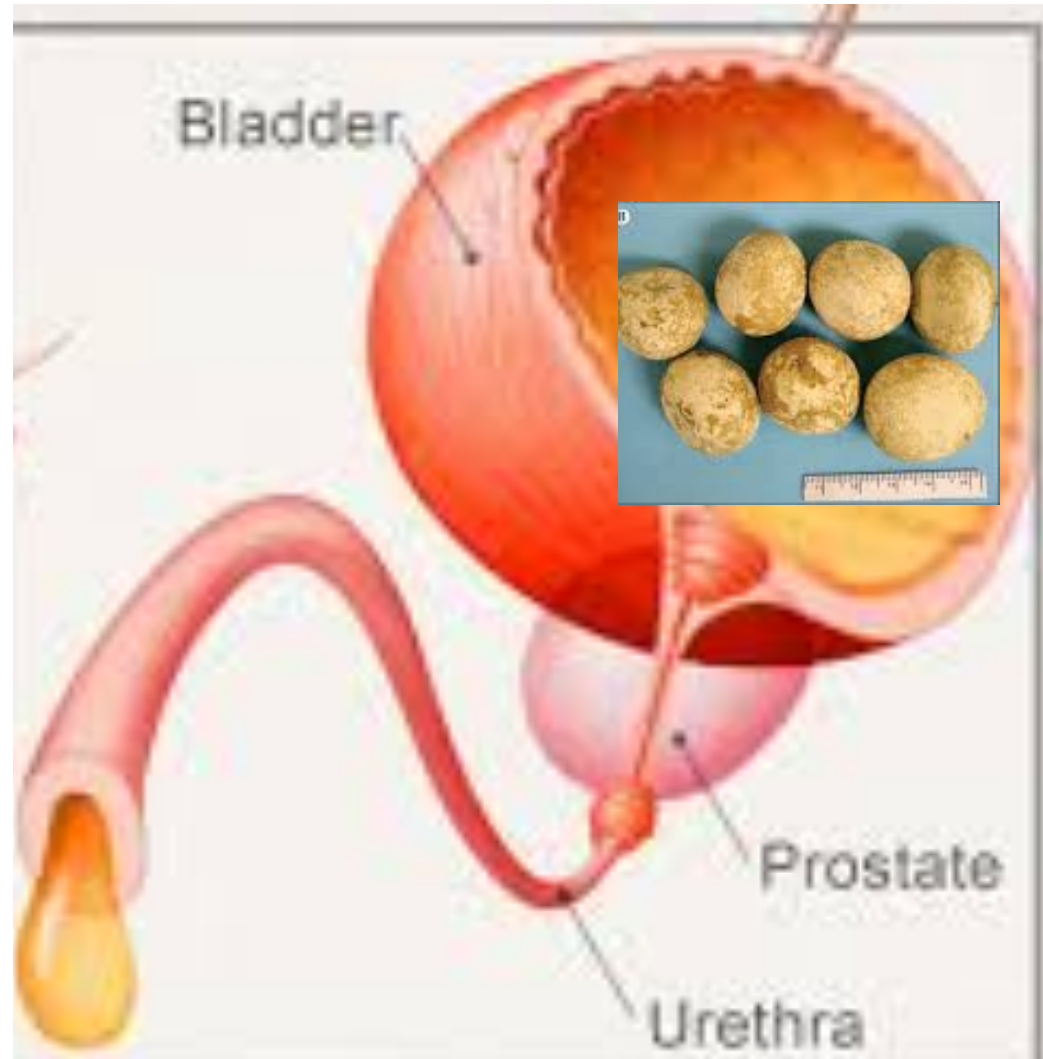
# My UroLift Experience

- First UroLift EVER under **Local Anesthesia** (3/2011)
- ~650 UroLift procedures, >90% in-office, most under strictly topical anesthesia:
  - 20cc 2% chilled intra-urethral lidocaine jelly, for 20 min
  - (plus, rarely, 0.5-2 mg of oral alprazolam)
  - Heavy reliance on Verbal Anesthesia<sup>1</sup>
  - In-office: no prostate blocks, IV sedation, or N2O
  - *I have aborted 3 office cases in 8 years*
- >40 OML cases



1. Gange,S, Baum,N JOJ Urology & Nephrology 4(5):1-6, Jan 2018

# The BPH-Doctor's Ultimate Goal: *Protect and Preserve!*





# History of “BPH Treatment”: Lithotomists



200 BC: Ammonius

“Lithotomus”, fragmented stones in situ transperineally

1<sup>st</sup> Century: Celcus and Susruta described perineal lithotomy

7<sup>th</sup> Century: Aegineta and Albucasis added drills and forceps

16<sup>th</sup> Century: Franco used suprapubic approach; ‘Frere Jacques’ Baulot (a “cloaked” Dominican Friar) used a lateral approach to vesicolithotomy

1727: Cheselden open vesical lithotomy in 1 minute

1830: Civiale’s transurethral lithotripsy

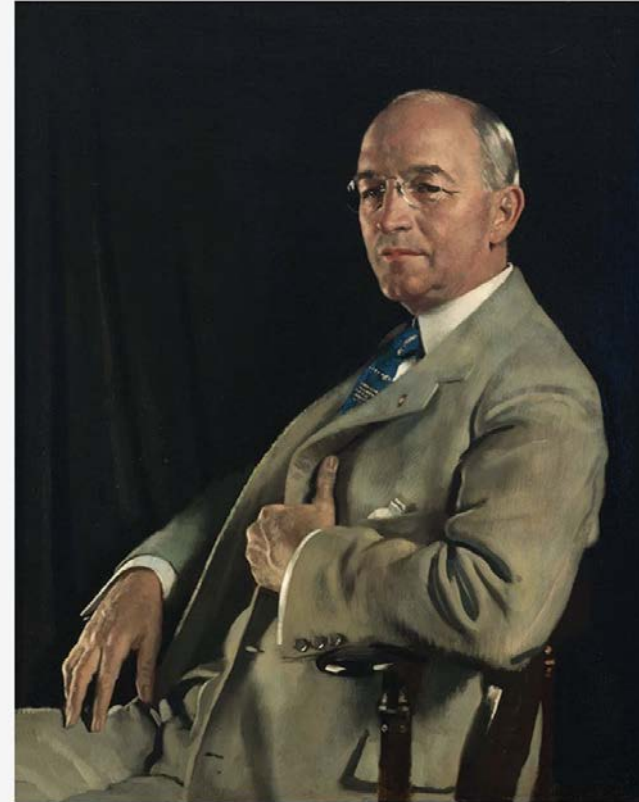
*I will not cut for stone...I will leave this to practitioners*  
~ Oath of Hippocrates

# Hugh Hampton Young, MD

## Founding Father of Modern Urology

- **First simple perineal prostatectomy for BPH in 1903**
- **Founding Chair of the Brady Urological Institute at Johns Hopkins**
- **Published his *Practice of Urology* in 1926**

Hugh H. Young

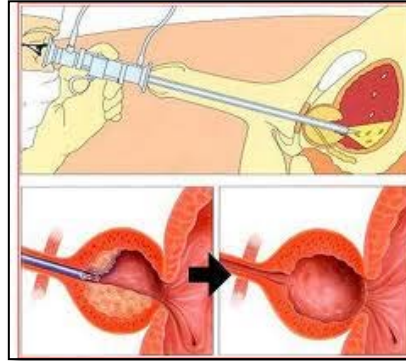


# Modern BPH Surgery: Also No Panacea

Monopolar TURP (Stern & McCarthy, c.1935)

Much later Lasers (Vaporization, Enucleation)

*TURP= #1 surgery in  
USA in 1960s-70s, and  
defined our specialty*



## Advantages

- Maximizes flow and symptom relief
- No more TUR-syndrome (now Bipolar)
- Removes prostate tissue (pathology)

*Urologists, Patients,  
and their PCPs  
have long sought alternatives*

## Disadvantages

- Requires full anesthesia, in OR
- Possible hospital stay
- Catheter for 1-3 days
- 4-6 weeks restricted activity

TURP Complications: bleeding,  
stricture/BNC, incontinence,  
>60% loss of ejaculation, 10% ED

# BPH Drug Therapy Milestones

## The 1990s Ushered In The BPH Med Era



**Later. Lesser?  
Now “Generic”**



Lepor H et al J Urol 1992;148:1467-1474  
Gormley GJ, et al N Engl J Med 1992;327:1185-1191  
Kirby RS, Roehrborn CG et al Urology 2003;61:119-126

***To my knowledge NO BPH DRUGS are in development***



# But Many Drug Patients Are Not Satisfied

**2/3 of drug patients are not satisfied and are interested in an alternative to BPH meds**

**Nearly half of these patients do not even have a clinically significant improvement (MCID): <4 pt IPSS improvement**

**Well-known side-effects may include headaches, dizziness, asthenia, nasal congestion, ejaculatory dysfunction, loss of libido, erectile dysfunction**

***Up to 70% drug discontinuation rate in 1 year***

Prostate Research Study, Harris Interactive Group 2007;  
Data on file – Urinary Symptoms Satisfaction Survey;  
Wei, et al, J Urol April 2010; 183(4): e197 AUA 2010 abstract;  
Pearson, Am Fam Physician 2014; 90(11): 769-774;  
Cindolo, Eur Urol 2015 Sep; 68(3): 418-25;  
AUA Guidelines 2010

# Bladder Health Summary

- BPH is a common, progressive condition that causes bothersome LUTS and reduces quality of life
- BOO initiates structural and functional changes to the bladder
- The data suggest that BOO results in irreversible bladder damage if left untreated...
- While medical therapy may alleviate and slow the progression of symptoms, BPH drugs do little to address BOO and bladder deterioration
- *Earlier disobstruction may be justified to prevent bladder damage and to optimize outcomes*

Flanigan, J Urol 1998 July; 150: 12-17

Tubaro, J Urol 2001 July; 166: 172-176

Tubaro, Drugs Aging 2003; 20 (3): 185-195

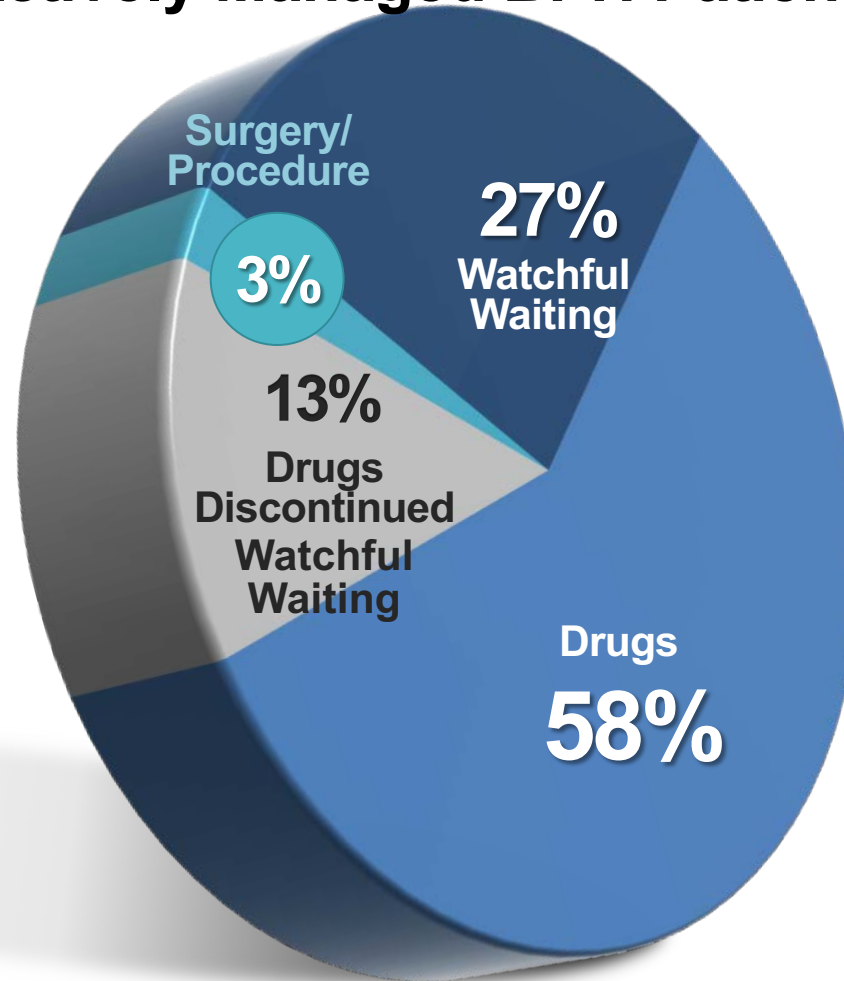
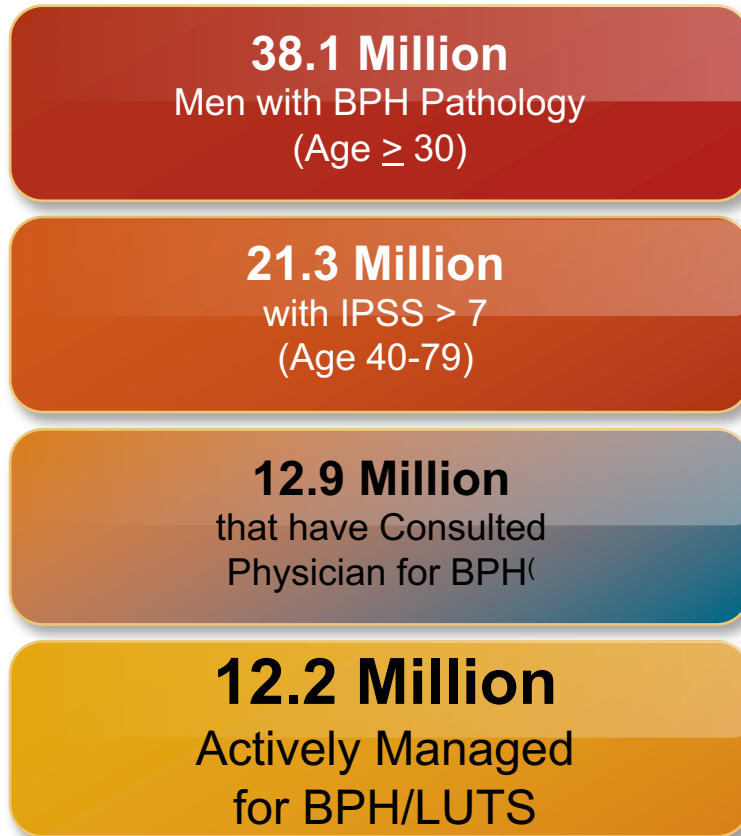
De Nunzio, J Urol 2003 Feb; 169: 535-539

# US BPH Paradigm

## 12 million

### Population Breakdown

### Actively Managed BPH Patients



*>50% of BPH pts are managed by PCPs and they write 75% of  $\alpha$ B for BPH*

# *They might just see us...*



American  
Urological  
Association

## What Sets Us Apart?

- We are THE Men's Health- and the only real BPH-Doctors
- N40.1 is #1
- Breadth of BPH Understanding
- Bladder Health Focus
- Fewer Distracting Co-Morbidities
- Diagnostic Tools That Enhance Our Accuracy
- Evidence-Based Treatment Algorithms

...Our Responsibility: *Stay Current and Do BPH Well*



# More Reasons to Consider Alternatives to BPH Drug Therapy

More recent and potentially serious side effect concerns:

$\alpha$ B:

➤ Intraoperative Floppy Iris Syndrome (IFIS):

*77% complication rate for cataract surgery*

➤ Ischemic Strokes:

*Double the risk in first 3 wks*

➤ Dementia!

*17% increased risk*

Chang, D et al JCRS 31:664-67

Lai, CL et al CMAJ March 2016 188(4):255-260

Duan, Y et al Phamaco Drug Safety Jan 2018, 301-313

# A Few More Reasons to Consider Alternatives to BPH Drug Therapy

More recent and potentially serious side effect concerns:

## 5ARIs:

- Persistence of sexual side effects after discontinuation (post-finasteride syndrome)
- Lipid metabolism issues
- Depression
- Type 2 DM
  - *finasteride=dutasteride: HR=1.3-1.5*
- Impact on prostate cancer: (VA study)
  - *39% increased 5ARI CaP risk*
  - *2 year delay in diagnosis;10% increase in mortality*

Baas, W et al Urology 120:143-149, 2018

Welk B, et al. JAMA Intern Med May 2017

Traish A, et al. Horm Mol Biol Clin Investig. June 2017

Wei L, et al. BMJ April 2019, 365:l1204

Sarker RR et al JAMA Int Med May 6, 2019

# Plus, Unknown Effects of Polypharmacy



**Z79.899**



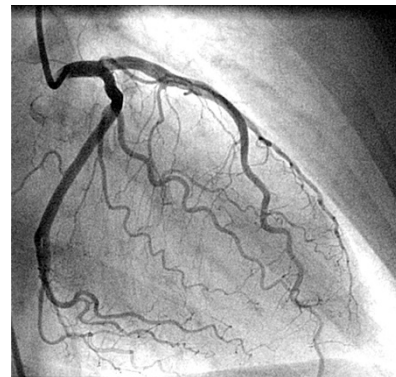
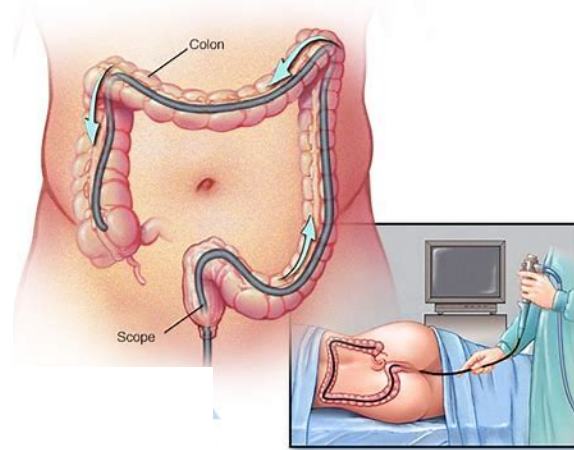


# Imaging Enhances Treatment Decisions and is Recommended in 2018 AUA Guidelines

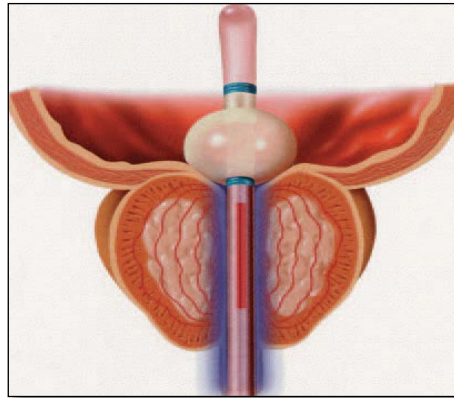
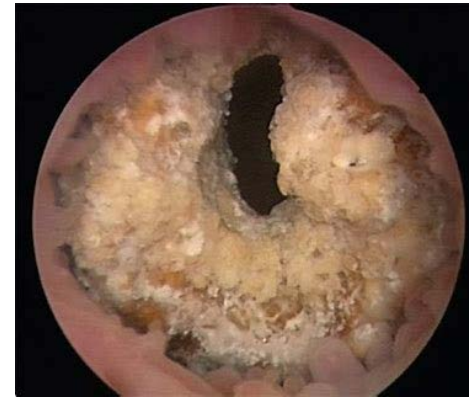
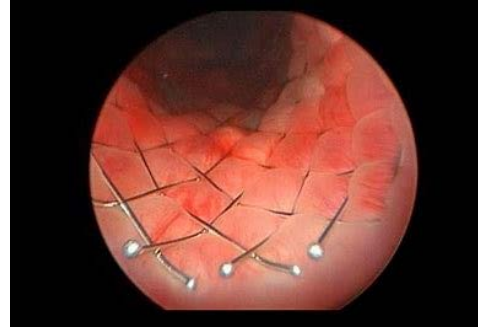
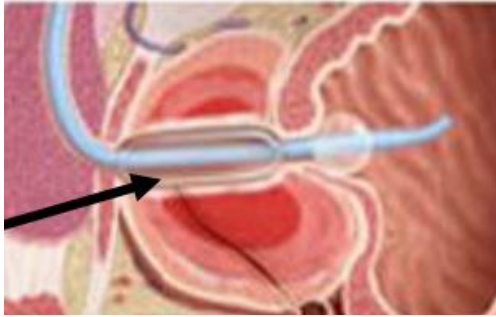
**Timing Consideration: *Early is Justifiable***



# Our Colleagues Don't Hesitate to Investigate *Prior to Treatment*



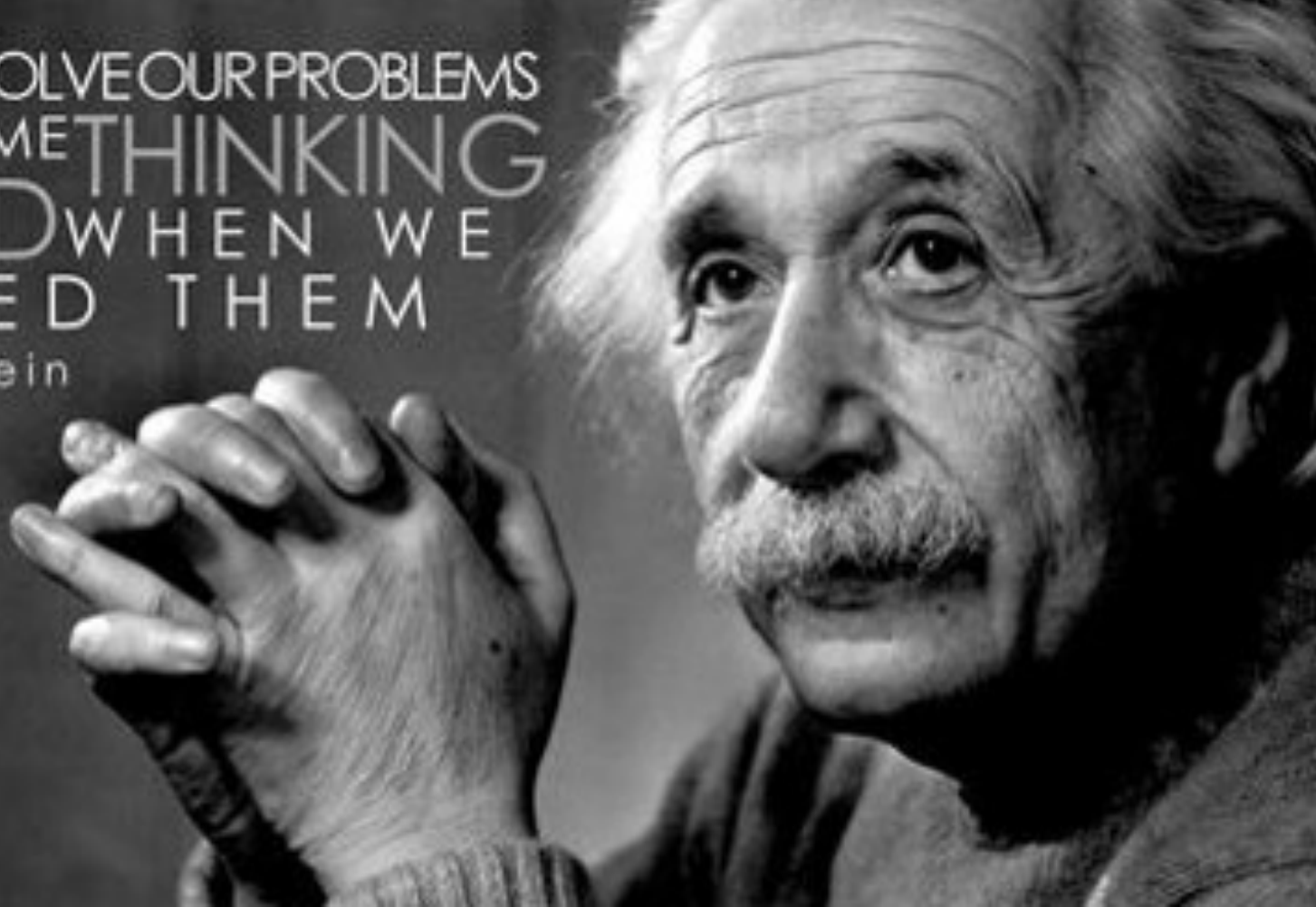
# 1990s-Early 2000s: The BPH MIST “Dark-Ages”





WE CANNOT SOLVE OUR PROBLEMS  
WITH THE SAME THINKING  
WE USED WHEN WE  
CREATED THEM

- Albert Einstein



***Ted Lamson***



***Joe Catanese***



***Josh Makower***

UROLIFT

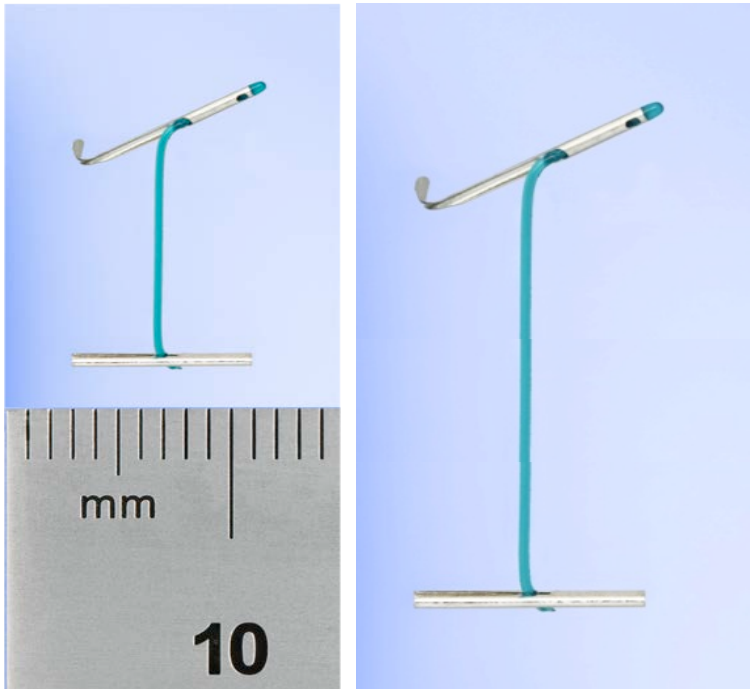
***NeoTract, c. 2004***



# The UroLift® Implant

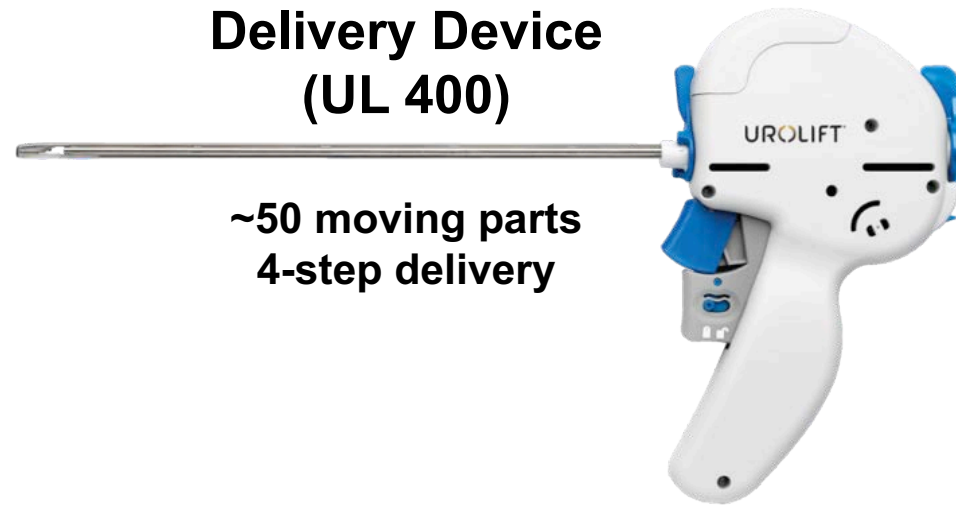
## Permanent Trans-prostatic Tissue Retractor

- Nitinol, PET suture, Stainless Steel
- Suture length is *sized in-situ*



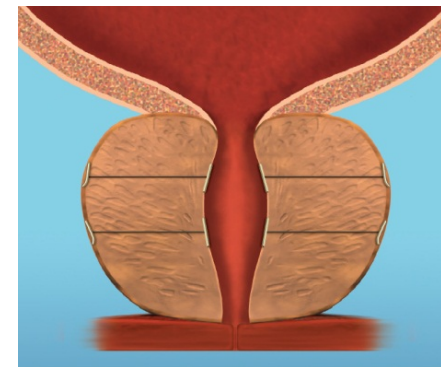
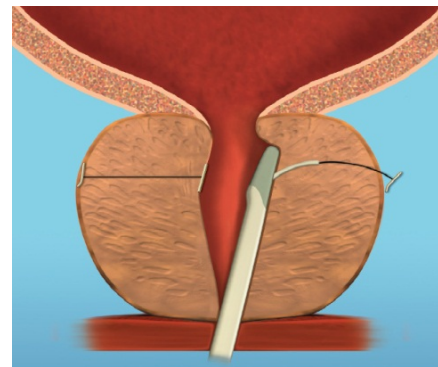
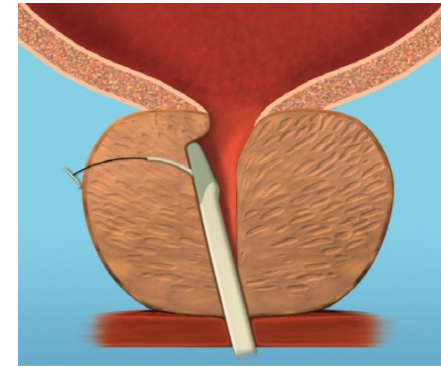
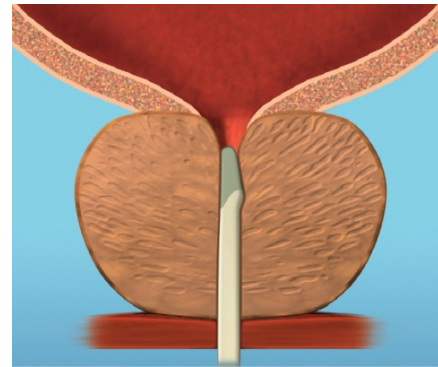
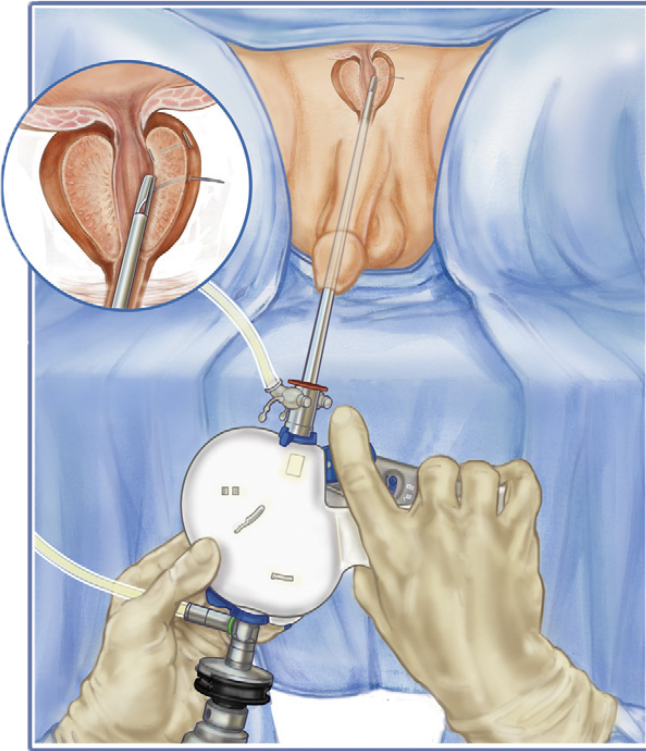
Delivery Device  
(UL 400)

~50 moving parts  
4-step delivery

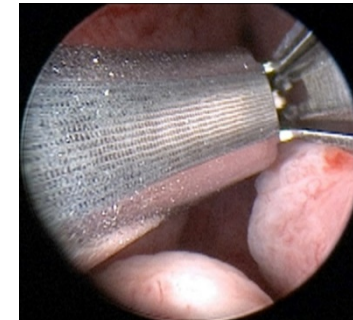


*A Mechanical Solution for  
A Mechanical Problem*

# The UroLift System<sup>®</sup> Implant Procedure



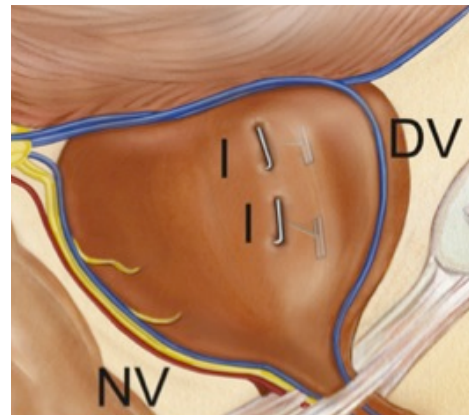
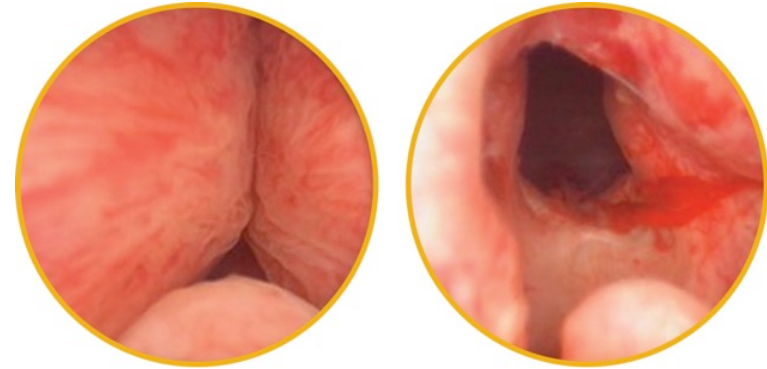
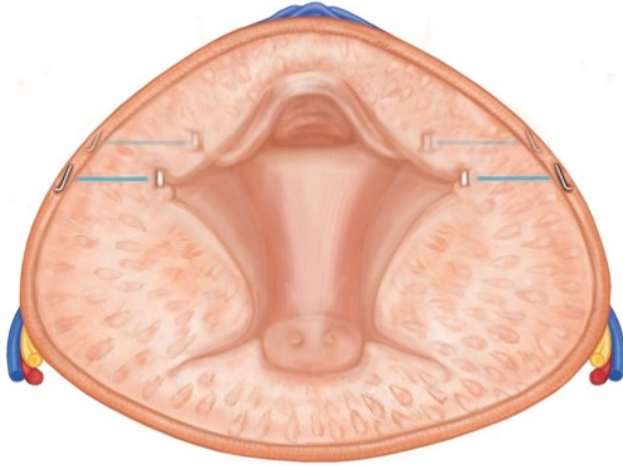
**Implants are placed cystoscopically (0°)**  
**Compress lobes then deliver implants**  
**Suture tension ensures invagination**



# Immediate Visual Impact

**Goal:** INSIST on an anterior channel plainly visible  
veru to bladder neck, achieved by **sculpting**

**Safety:** deploy *horizontally* and positioned antero-  
laterally, away from the DVC and NVBs



# Exceptional Clinical Results

## *Introducing a New Technology the Right Way*

### A \$40MM investment

- **5-year data** and 2 randomized trials
- FDA cleared and NICE guidance
- **+ 2018 AUA BPH Guidelines**
- >130,000 patients treated
- All major payers now covering

### Dramatically improved outcomes

- Tolerable under **topical anesthesia**
- Up to 84% catheter freedom
- Significant improvement at 2 weeks
- Return to normal in days
- Remarkable reproducibility
- **100% preservation of sexual function**

### >25 clinical papers







**Application in Day to Day Practice**

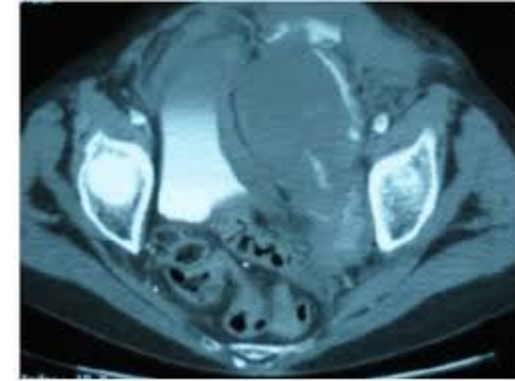
# Who Is *Not* A UroLift Candidate in 2019?

## Unable to safely stop anticoagulants

- Confer with Cardiology or Neurology

## FDA Contraindications:

- <45 yo (was <50 yo)
- Prostate volume >80cc (no lower limit)
- Urethral stricture or BNC
- UTI
- Active hematuria
- Nickel allergy
- (Note: obstructive middle lobes are no longer contraindicated)



## Unstudied--*NOT* Contraindicated

- Retention (UK: PULSAR, AUA 2019)
- Prostate cancer (US/AUS: RWS)
- Pre/Post Radiation (RWS)
- Wide glands (RWS)

# UroLift Anesthesia Options

**Hospital or ASC:** general/spinal/epidural/MAC:

Hospital contracting, RVU-based reimbursement, and ASC ownership may all factor in

**In-Office:** MAC, Conscious Sedation, Oral Sedation,  
or **Strict Topical:** “*Why would I want to do that??*”

➤ Vasectomy, Fusion and TP Prostate Biopsy, Botox, SpaceOAR, Interstim Stg 1, TURBT<5mm, Fiducials...

- All are considered “quick and tolerable”
- LOCAL Trial: VAS scores cysto=3/10, UroLift=5/10
- Safer and cheaper for patients
- Better voiding trial success

**When Under Local:** *Setting Expectations is KEY:*

~ *some discomfort, mostly urgency*

~ *<10 min + Music and Blinding Screen*

~ *Verbal Anesthesia*

# UroLift Complications

## Hematuria:

- ~25% in LIFT, no SAEs
- Typically managed with 18F Coude overnight
- I've only ever done 2 clot evacuations (OR)
- <1/10,000 pelvic/retroperitoneal hematomas

## UTI:

- 3% in LIFT (no abscess or sepsis)
- I've had 1 simple UTI

## De novo, sustained ED/EjD:

- 0%

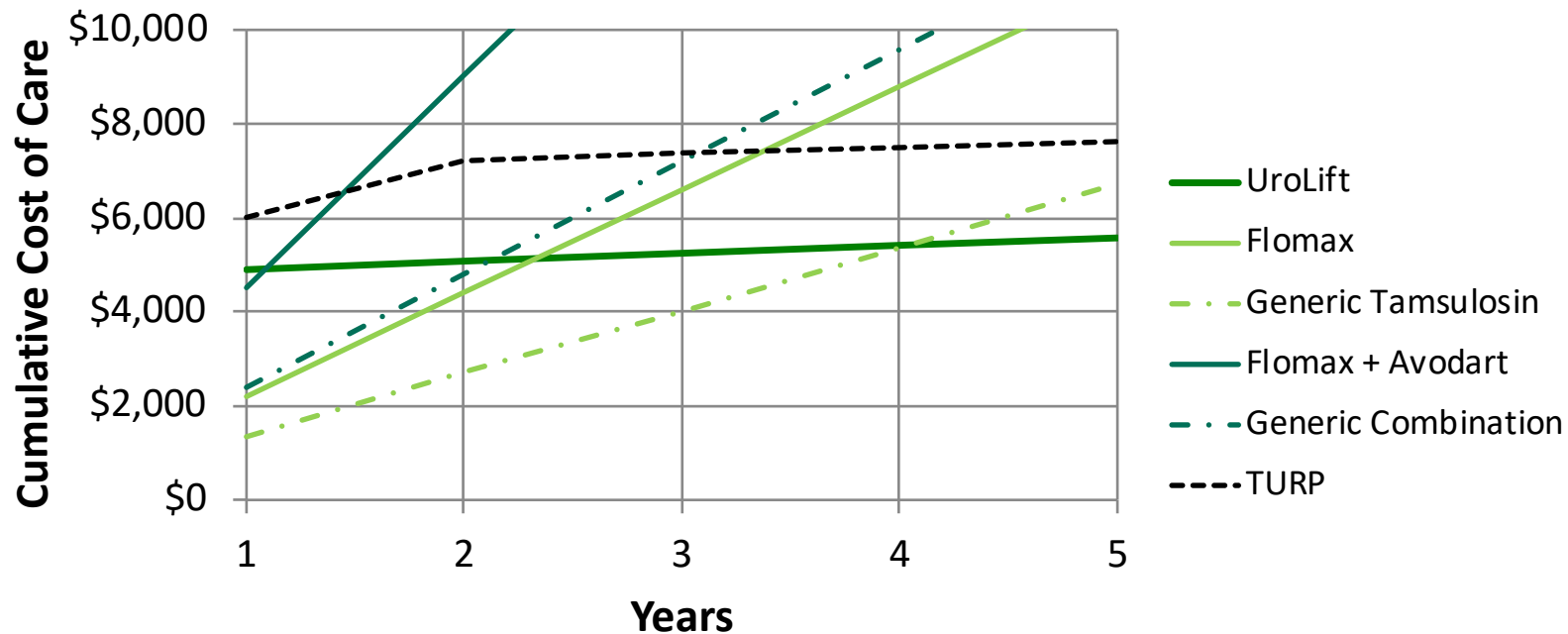
## And:

- 0% meatal stenosis, stricture, or BNC in my series

# Health Economics Analysis

## UroLift Compares Favorably to BPH Medications:

Cost crossover in 1-4 years, depending on drug <sup>1,2</sup>



1 Medicare SAF Database Study conducted by Medical Technology Partners, in publication draft

2 Evaluating Prescription Drugs Used to Treat: Enlarged Prostate • Consumer Reports Best Buy Drugs

# UroLift vs Rezūm

***Are These Really Competitors?***



# Rezūm® System

Delivery Device

Generator



# Rezūm Overview: My Perspective

## *NO COMPARATIVE DATA*

### PROS

Convective heat is more precise than Conductive

Efficient, in-office

Favorable 4-year outcomes

Proposed potential for focal Prostate Cancer therapy



### CONS

Acquisition cost of generator

Relatively painful

Catheter required, prolonged irritative recovery follows

Coding debacle...

*NO clinical scenario where Rezūm makes more sense to me than UroLift*

# For Me: Its All About *The Patient Experience*



# Other Minimally Invasive BPH Surgical Therapies (MIST) in Development

## Beyond Phase III

Medi Tate



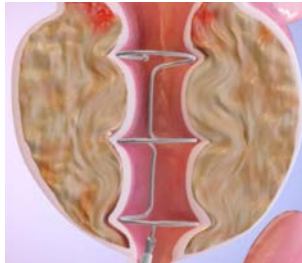
Allium Medical



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## In Development

zenflow



Butterfly Medical



ProVerum





# Take Aways



# BPH/LUTS Challenges For All of Us

It's time **we all** critically assess the **RISK:BENEFIT** of BPH drugs  
**TURP** as **Gold-Standard** is being challenged —

- *we can do better for our patients*
- this requires changes in long-held beliefs and biases, including prompting more timely referral from PCPs, and utilizing anatomical assessment tools early on

## What About Minimally Invasive Options?

- **UroLift**® is the most rigorously studied and extensively published, and offers a straightforward and predictable patient experience with 5 year durability LIFT data and favorable inclusion in 2018 AUA Guidelines
- Patients care about the procedural experience and their early recovery
- Some urologists choose **Rezum**® and in so doing seem to focus on ease of learning, efficiency of application, and acceptance of deferred patient satisfaction (often buffered by APPs)



**Thank You!**