New Technologies in BPH/LUTS Treatment

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BPH Disclosures

**NeoTract**: Investigator, Consultant, Faculty, Proctor, first UroLift® Center of Excellence designee

**NxThera**: Investigator (formerly Consultant, Proctor)

**Nymox**: Investigator

**Zenflow**: Investigator
Existing BPH/LUTS Treatment Options

• Watchful waiting
• Pharmacologic therapy
  – $\alpha_1$-adrenergic blockers
  – 5-ARIs
  – PDE-5 inhibitor
  – Antimuscarinics, $\beta$-3 agonist
  – Combinations
• Surgery
  – TURP (including bipolar)
  – TUIP
  – Laser vaporization & enucleation
  – Open/robotic surgery
• Thermotherapy (TUMT/CTT® and TUNA/Prostiva RF® Urologix)
• “New” FDA-cleared therapies
  – PUL (UroLift® NeoTract)
  – WAVE (Rezum® NxThera)

United States:
Over 12 M Treated

- Drugs 58%
- 40%
- Watchful Waiting
- Surgery & Thermotherapy 2-3%
2016 BPH Procedure Outlook
(excluding TURP/bipolar/laser/open/robotic)

- **Heat:**
  - TUMT/Cooled ThermoTherapy® & TUNA/Prostiva® *(Urologix)*
  - Water Vapor: Rezūm® *(NxThera)*

- **Mechanical:**
  - Prostatic Urethral Lift: UroLift® *(NeoTract)*

- **Investigational (local anesthesia):**
  - Injectable: topsalysin *(Sophirus)*; fexapotide *(Nymox)*; EtOH/TEAP; Botox® *(Allergan)*

- **Investigational (IV sedation/GA):**
  - Prostatic Artery Embolization/PAE
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Prostatic Artery Embolization

- Useful for uncontrollable prostatic hemorrhage; no clear size restriction reduces gland volume by 30%
- Introduced 2008 for BPH/LUTS, numerous reports but just one published RCT (v TURP, which outperformed PAE)
- Described as “technically difficult” w risk of “unintended in-field embolization” (eg, bladder or rectal necrosis)
- *Probably being offered by your hospital’s IR Department*

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Aquablation/AquaBeam®

- Real-time image (TRUS) guided heat-free water pressure-induced resection (yields chips)
- FIM now published: n=15, 1/3 with middle lobes, 8 min ablation time, 48 min case time (need for post-ablation hemostasis); no major complications
- 6 month data: IPSS -17, Qmax +10cc/sec
- Phase 3 underway in US

Gilling et al, BJU Int 2016 Jun; 117(6) 923-9
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Temporary Implantable Nitinol Device

- Geometrical 50x33mm basket-like device placed under ‘light sedation” via 22 FR rigid scope
- TEMPORARY: removed cystoscopically 5 days later
- \textit{Radial force reshares urethra and bladder neck though ischemic necrosis}
- Phase 3 RCT (v Foley) underway in US

Porpiglia et al, BJU Int 2015; 116:278-87
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Transurethral Split of the Prostate

- Single arm study reported recently, from China: n=565 over 9 yrs (FIM reported 2015, n=113)
- Novel double (proximal and distal) “columnar” polyurethane balloon catheter, designed to expand the bladder neck and prostatic urethra
- Placement under epidural anesthesia
- Balloon catheter “left in situ 6-7 days”
- IPSS -14; f/u 38-99 months

Huang, et al, Medicine Oct 2016 95 (40): e4657
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Spring®

- FIM/feasibility ongoing (New Zealand, P Gilling)
- US trial projected Q4 2017
- Permanent nitinol “spring”; radial force precludes migration and a distal button allows for easier removal than its predecessors

Zenflow; personal communication
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PUL: The UroLift® Implant Procedure

- 20F rigid sheath
- Compress and deliver UroLift® implants
- Typically ~4 implants delivered per case
- Well-tolerated in-office under local
The UroLift® Implant

Permanent Trans-prostatic Tissue Retractor
• Implant sized *in situ* to prostate lobe

Delivery Device
Immediate Visual Impact of UroLift®

- Mechanically opens the prostatic fossa
- Goal: create an anterior channel plainly visible from veru to bladder neck
- Implants are positioned anterolaterally, away from the dorsal venous complex and NV bundles
UroLift® System Milestones

• Pivotal Sham-Controlled L.I.F.T. Trial
  – 206 subjects, standard BPH inclusions and exclusions (no middle lobes, <80cc); all local anesthesia (+diazepam):
    IPSS -11.1, Qmax +4.4 ml/sec, no ED/EjD
  – 4 year data: durable IPSS impact, 13.6% retreatment

• Approvals
  – FDA cleared 9/2013
  – CMS (2014): first-ever 0-day global period
  – Unique CPT codes: 52441, 52442
  – EAU 2016 BPH Guidelines: Oxford 1a Level of Evidence

• Several more studies incl BPH6 (randomized v TURP) and MedLift (ongoing); 18 peer-reviewed publications

• >>15,000 treatments worldwide

Roehrborn, Urol Clin N Am. 43 (2016) 357-68
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WAVE: Water Vapor Energy
Rezūm® General Principle

**Outside the Body**

- Radiofrequency Energy
- Sterile Water
- Vapor

**Inside the Body**

- Convective Water Vapor Heat
- Energy*

*Convective Water Vapor Heat
Rezūm® System

Delivery Device

Generator

Technique: Local plus sedation, 2-8 vapor shots (9 sec each), middle lobe ok, Foley
Rezūm® Pivotal Trial

- 196 subjects, RCT (v sham cysto)
- <80cc, median lobe ok (31%)
- Results:
  - All local (intravesical and intraurethral), plus oral [benzo+narcotic]**+ketorolac; >20% blocks, 10% IV sedation; VAS post-vapor pain 6.4/10
  - 90.4% Foley (mean 3.4 days, up to 21 days)
  - Typical AEs, plus >6% EjD (no ED)
  - IPSS -11.3 pts and Qmax +6.2 cc/sec
  - Maximal impact 6 months

FDA cleared 10/2015; AUA suggested **CPT 53852 (TUNA)

**FDA boxed warning for this combo 9/2016

Rezūm® vs UroLift®

NO COMPARATIVE DATA (first-hand perspective)

- Similar indications, but middle lobes ok with Rezūm®
- Both in-office; Rezūm® is easier for MD, harder for patient:
  - essentially always requires a Foley, longer recovery
- No substantial sexual side effects for either procedure
- 1 year (2 yr in press) vs published 4 year data for UroLift®
- 90-day vs 0-day global period
- Reimbursement Trends:
  - UroLift® has unique codes: 100% Medicare, increasing private-payer coverage
  - Rezūm® started with all payers (using TUNA code), but now beginning to decrease:

  *Anthem, Aetna, Humana, and Palmetto CMS: can no longer use 53852, not covered*
Advantages of BPH Procedures In-Office Under Local

• **Patient**
  - Lower copay and overall cost
  - Less anxiety (familiar surroundings)
  - Fewer hassles: no NPO, labs, IV, paperwork, etc
  - More voiding trial successes

• **Urologist**
  - Easier to launch
  - Enhanced efficiency
  - Office staff buy-in
  - Economical advantages
BPH/LUTS Challenges For All of Us

- Our patients may not actually be “fine”, and they may need our help to realize this
- Watchful Waiting may result in progressive detrusor decompensation
- Medications have limited value, many side effects, and reasons men would rather not take them
- Minimally invasive options have improved, and are still evolving; patients typically prefer these

- TURP as “gold-standard” is being challenged—we can potentially do better for our patients!