10 Years of Transobturator Male Slings: Lessons Learned

Aaron C. Lentz, MD, FACS
Associate Professor of Surgery
Duke University Division of Urologic Surgery
Physician Disclosure

- Consultant, speaker, preceptor
  - Coloplast
  - Boston Scientific (AMS)
Technology milestones in 2006…..

- The first “tweet” is sent
- Facebook opens its social network
- Blu-ray discs launch
- PlayStation 3
- 1 billionth song sells on iTunes
- Wal-Mart officially stops selling VHS

iPhone released in 2007
2006 Surgical Options for Male SUI?

- Urethral bulking agents
- Bone-Anchored InVance Sling
- Artificial Urinary Sphincter

Wilson LC et al. BJUI 2011;107:7-10
These guys had an idea..

What if it’s more than just a compression problem?

Supporting Structures

- **Anterior**
  - Puboprostatic ligament
  - Pubovesical ligament

- **Posterior**
  - Denonvillier’s fascia
  - Rectourethralis
  - Perineal body
  - Levator ani complex
Membranous Urethral Length

Continence Stratified by Preoperative MUL

Continence Stratified by % Change in MUL

Red line: Pts with preop MUL ≤ 14 mm
Blue line: Pts with preop MUL ≥ 14 mm

Red line: % change in MUL ≤ 6%
Blue line: % change in MUL ≥ 6%

Urethral Bulb
(Corpus Spongiosum)

- Contraction of the BSM ↑ pressure in the urethral bulb
- Pressure is transmitted to the distal MU
- Phenomena seen with
  - Physical activity
  - Sexual intercourse
TORUS
Transobturator Retrourethral Slings

AdVance® Sling (2006)
TORUS

Transobturator Retrourethral Slings

Virtue® Sling

(2009)
Mechanism of Action

1. Elevation and support of the urethral bulb
2. Functional elongation of the MUL
3. Concentric luminal coaptation

Trends in Utilization

- Liu et al.
- 6 month ABU case logs (2003-2013)
- Academic Urologists 1.5x more likely to place AUS
- Median # of slings was 2 (32.7% slings exclusively)
- 3.4% of Uro’s accounted for 22% of all slings

Liu JS et al. Urology 2016;87:95-99
Trends in Utilization

Liu JS et al. Urology 2016;87:95-99
Trends in Utilization

- Santiago-Lastra et al.
- AMS sales data 2001-2013
  - InVance 2002
  - AdVance 2007
  - Virtue 2010
- No decline in AUS utilization was noted
- Sling utilization peaked in 2009
Trends in Utilization

Yearly Utilization Rate of Surgical Therapies for Post-Prostatectomy Incontinence (2001-2013)
Patient Evaluation

- History and Physical
- 24 hr pad weights/bladder diary
- Cystoscopy
- Urodynamics

Not all patients need every study!
Patient Evaluation

- History and Physical
  - Timing
  - Motivation
  - Manual dexterity
  - Body habitus
  - General health
  - Performance status
  - Mental capacity

Obesity and Sling Failure

- 290 patients, 2006-2012
- Adjusted for age, race, diabetes, HTN, immunosuppression, smoking status and XRT

Patients with a BMI > 30 kg/m2 were 1.5 times more likely to experience sling failure

## Patient Evaluation

### Severity of Incontinence

- **Pad Weights and 3-Day Bladder Diary**

### Incontinence Volume

<table>
<thead>
<tr>
<th>Incontinence</th>
<th>Volume</th>
<th>AdVance® Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>&lt;200 ml/d</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>200-500 ml/d</td>
<td>79.6%</td>
</tr>
<tr>
<td>Severe</td>
<td>&gt;500 ml/d</td>
<td>71.4%</td>
</tr>
</tbody>
</table>

Rehder P and Webster G. Eur Urol 2011; 11 (Suppl.):390-394
Patient Evaluation

- Cystoscopy and Dynamic Urethroscopy
- Appearance of sphincter at rest
  - Poor, normal, or intermediate?
- Appearance during pelvic floor contraction
  - Closes/coapts or fails to coapt?
- Presence of sphincter injury
  - Sector defect or cleft defect?

Rehder et al. BJU Int 2010;106:1668-72
Davies et al. Urology 2009;74:354-7
Patient Evaluation

- **Bladder Function (Urodynamics)**

- **Primary Goals**
  - Identifying detrusor overactivity
  - Poor bladder compliance
  - LPP as a measure of sphincter function
  - Confirming the absence of poor contractility

Rehder P. and Webster G. Eur Urol 2011; 11 (Suppl.):390-394
Detrusor Overactivity

- 290 patients, 2006-2012
- Evaluation
  - UDS
  - AUA sx score
  - 3-day bladder diary
- Results
  - DO on UDS more predictive of sling failure than functional capacity or urge sx

Ajay D. et al. 17-6788 AUA 2015
Cystometric Capacity

- Low maximum cystometric capacity (UDS) was associated with worse sling outcomes; HR = 0.995 (p<0.001)
  - e.g. a 10 mL decrease in max cystometric capacity leads to 5% increase in sling failure
  - Adjusting for pelvic radiation, 24 hour pad weights and pre-operative VLPP, HR of 0.996 (p=0.002)

- Low maximum voided volume (bladder diary) not associated with sling outcomes; HR = 0.999 (p=0.55)

Cystometric Capacity

- Patients with Urodynamic bladder capacity >300 cc fail at half the rate of those with capacity ≤300 cc.

Kaplan-Meier survival estimates
Urodynamics Cystometric Capacity

Proportion of Continent Patients

<table>
<thead>
<tr>
<th>Time (Months)</th>
<th>Bladder Capacity ≤300</th>
<th>Bladder Capacity &gt;300</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>151</td>
<td>89</td>
</tr>
<tr>
<td>20</td>
<td>32</td>
<td>19</td>
</tr>
<tr>
<td>40</td>
<td>14</td>
<td>6</td>
</tr>
<tr>
<td>60</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

HR 0.47 (95%CI 0.29-0.77)
Wilcoxon test p<0.001

Valsalva Leak Point

- Patients with a VLPP of > 70 cmH2O were 50% less likely to fail after TOS placement vs those with VLPP < 70 cm

- HR of 4 for VLPP > 100 compared to < 100

Ajay D et al. SUFU 2017, Annual SUFU Winter meeting, 2017 Feb 28- March 4
Banard J et al. BJU Int 2014; 114, Suppl 1, 34-37
Urodyanamics—What I Do

- Describe your pads and activity of daily living
- **Do you use a pad at night?**
- **Do you leak in the supine or recumbent position?**
- Do you leak due to urgency?
- Cysto (nearly) every PPI patient and leave full, stand and cough
- Study poor historians, mixed symptoms, and most radiated patients
Urodynamic Testing may help plan treatment in patients with confounding symptoms and a history of radiation therapy.

In most cases, even though the urodynamic testing reveals a deviation from “normal,” outcomes with treatment (male sling) tend to be good if highly selective.
Preoperative Counseling

- Transobturator slings have their place, but……..
  - Severe Incontinence
  - Minimal or absent sphincter function
  - Prior surgery for incontinence, urethral scaring, XRT

- Suboptimal Sling Candidates
  - Individual patients may be successful
  - Overall success rates tend to be lower

- Patients should **NOT** be promised a pad-free future!
Risk Factors for Failure

- Suboptimal patients
  - Poor coaptation
  - Bladder neck contracture
  - Prior radiation
  - Prior surgical procedures for SUI

<table>
<thead>
<tr>
<th></th>
<th>Success rate, %</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall success rate</td>
<td>86</td>
<td>-</td>
</tr>
<tr>
<td>Ideal candidates</td>
<td>90</td>
<td>-</td>
</tr>
<tr>
<td>One suboptimal factor</td>
<td>78</td>
<td>0.17</td>
</tr>
<tr>
<td>$\geq$ 2 suboptimal factors</td>
<td>67</td>
<td>0.15</td>
</tr>
</tbody>
</table>

Rapoport et al. J Urol 2009;181:619
Effect of Radiation

- **Cornu J-N et al, 2009**
  - 102 pts, median f/u 13 mo
  - Success with XRT 59%
  - Success without XRT 85% (p=0.039)

- **Bauer et al, 2011**
  - 24 pts, median f/u 18 mo
  - Success with XRT 50%

- **Reason?**

References:
- Bauer et al. Urology 2011; 77:474-9
Two reviewers independently selected studies for inclusion based on pre-specified criteria:

- Adult men with urinary incontinence due to RP and XRT
- Clinical trials and observational studies
- Jan 2006 and Jan 2015
- Alternate sling techniques and follow up less than 1 month were excluded

MEDLINE, Cochrane Controlled Trials Registry, Embase, Web of Science, Scopus and Urology meeting abstracts were searched with assistance from a medical librarian.
From this meta-analysis,

- Men with urinary incontinence secondary to RP/XRT treated with a transobturator sling have 26% (12-41) objective success rate.
- 50% (at best) report satisfaction with surgery.
- Complications include acute urinary retention and urethral erosions.

Ajay D et al. 111th Annual AUA conference, 2016 May 6-10
What if XRT is after the sling?

- 11 pts received XRT after sling (median 18 mo)
- 8/11 were dry prior to salvage XRT
- 7/8 report sling failure after XRT!

---

Procedural Details

- **Position**
  - Low lithotomy ("Social Lithotomy")

- **Pre-op Antibiotics (AUA Guidelines)**
  - Aminoglycoside + 1st/2nd Gen. Cephalosporin or Vancomycin

- **Prep**
  - Chlorhexidine-Alcohol prep

- **Approach**
  - Perineal

References:
- http://www.auanet.org/content/media/antimicroprop08.pdf
Urethral Dissection

1-2 cm below the adductor longus
Just lateral to the ischiopubic ramus

Trocar Passage
Mesh Attachment

Sling Tension

- Remove Foley
- Pull!
  - 2-4 cm of movement
- Cystoscopy
- Place 12F Foley
- Close BS muscle
- Tunnel mesh*
- Other procedures

Post-Procedure

- **Post-Op**
  - D/C home
  - Foley for 1-3 days (catheter removal at home)
  - No lifting, squatting, or climbing x 6 weeks
  - RTC 6 weeks

- **Follow-Up**
  - 3 months, then PRN
Post-op Urinary Retention (POUR)

- 290 patients, 2006-2012
- 34/290 (11.7%) failed post-op TOV
- 23/34 (67.6%) taught CIC
- 10/34 (29%) had indwelling Foley
- 85% resolved in 1-7 days, the rest within 30d
- POUR predicted better long-term outcomes

Ajay D et al. AUA 2016
Post-op Urinary Retention (POUR)

Algorithm

Kaplan-Meier survival estimates

Figure 1: Sling failure over time in patients with and without post-operative urinary retention

Ajay D et al. AUA 2016
Sling Failure

**Causes**
- Inappropriate indication
- Poor technique
- Sling slippage
- Prior XRT (urethral mobility)

**Options**
- Secondary sling
- AUS
Secondary Slings

**Bauer et al, 2010**
- 35 pts, median f/u 16.6 mo
- 21/29 patients dry
- 90% of pts self-reported as “success”

**Recommendations**
- Don’t remove first sling
- Non-absorbable suture
- Consider tunneling sling arms

Bauer et al. Eur Urol 2010;58:767-772
Does a previous TOS sling affect the outcome of a subsequent AUS?

Are operative complications higher?

Is infection/malfunction more likely?

Is continence equivalent?
<table>
<thead>
<tr>
<th></th>
<th>Primary AUS</th>
<th>Sling + AUS</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. Patients</td>
<td>136</td>
<td>29</td>
<td>n/a</td>
</tr>
<tr>
<td>Operative time (min)</td>
<td>79.8 ± 14.4</td>
<td>75.5 ± 15.6</td>
<td>0.089</td>
</tr>
<tr>
<td>EBL (mL)</td>
<td>22 ± 28.8</td>
<td>20.7 ± 27.1</td>
<td>0.863</td>
</tr>
<tr>
<td>Urethral injury</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Follow-up (mo.)</td>
<td>37.2 ± 19.7</td>
<td>20.7 ± 12.7</td>
<td>&lt;0.005</td>
</tr>
<tr>
<td>Time to revision (mo.)</td>
<td>5.1 ± 3.3</td>
<td>7.2 ± 5.8</td>
<td>0.66</td>
</tr>
<tr>
<td>Mechanical Complications</td>
<td>4 (2.9%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Non-mech. Complications</td>
<td>8 (5.9%)</td>
<td>2 (6.9%)</td>
<td>0.69</td>
</tr>
<tr>
<td>Infections</td>
<td>3 (2.2%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Total No. Revisions</td>
<td>12 (8.8%)</td>
<td>2 (6.9%)</td>
<td>1.00</td>
</tr>
</tbody>
</table>
Salvage AUS

- Functional Outcomes
  - 28/29 patients used ≤ 1 pad at 3-month f/u

- Conclusions
  - Safe and effective option for persistent SUI
  - Technical challenge is no greater

61 men with sling failure

- 32 received an AUS
- 29 received a secondary sling

Overall treatment failure

- 16/29 (55%) of repeat slings
- 2/32 (6%) with an AUS
Final Thoughts

- Slings are a great option for select men with PPI
- Patient selection is critical
- Mechanism of action is not obstruction
- Prior radiation increases the risk of failure
- Don’t promise a pad-free future
- Patients with sling failure can be salvaged!

Questions?

Aaron C. Lentz, MD, FACS
Reconstructive Surgery, Male Sexual Health, and Urologic Trauma
Duke University Medical Center/Duke Urology of Raleigh
3480 Wake Forest Rd., Suite 506, Raleigh, NC 27609
Tel: 919.862.5600