Male Incontinence and Urethral Slings

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Outline

- Current understanding of the male sphincter
- Post prostatectomy incontinence
- Current male slings
  - Retropubic Bulbourethral slings: where it all started
  - Bone anchored bulbourethral slings
  - Male TOT
- Future designs
- Conclusions
Urinary Incontinence

- A result of
  - Bladder pathology
    - Detrusor overactivity
    - Poor compliance
  - Sphincter pathology

Male sphincter

- Understanding of the male sphincter complex has evolved over time
- Challenges
  - Based on small number of cadaveric studies
  - Anatomic findings in children/fetuses applied to adults
  - Terminology
  - Majority of work done in German
Male sphincter

- Traditionally:
  - Internal sphincter (Bladder neck)
  - Prostatic muscular stroma
  - Intrinsic sphincter
  - Extrinsic sphincter

“Two morphologically related, but functional unrelated components”
1: Bladder musculature
2: Proximal internal SM sphincter
3: Distal SM sphincter/urethra
4: Rhabdosphincter
5: Prostatic portion rhabdosphincter

Anatomic Concepts
- Tapering
- Completeness
- Atrophy
Male sphincter

- Smooth muscle provides passive continence
  - Normal: holds urine at BN
  - Post TURP: holds urine at resection limit, where SM intact
    - Above the main component of the rhabdosphincter
  - Post posterior urethroplasty: holds urine at BN
    - Ext rhabdosphincter is resected
  - Post RRP Incontinence: resect too distal, injure SM, ext rhabdosphincter intact
    - Still have increased MUCP in UDS
  - Continence is maintained after curare injection into rhabdosphincter, or pudendal nerve block

Male sphincter

- Smooth muscle sphincter is redundant
  - Circular muscle fibers create maximal closure of urethra at
    - Bladder neck
    - Membranous urethra
Male sphincter

- Rhabdosphincter
  - Provides active continence
  - Contraction moves anterior urethral wall against rigid posterior plate (denonvilliers and rectourethralis)
  - Mix of fast and slow twitch fibers
  - Prostatic rhabdosphincter
    - Side to side contraction, important for ejaculation

Male sphincter

- Correlation with UDS
  - Continence is a function of the smooth muscle sphincter
  - Intact rhabdosphincter does not guarantee continence
  - Deficient rhabdosphincter doesn’t produce incontinence with an intact SM sphincter
  - SM sphincter can be 1/2 its normal length and maintain continence (1.5cm)
## Post Prostatectomy Incontinence

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Pt num</th>
<th>Physician / Anon.</th>
<th>Subjective leak</th>
<th>Pad usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalona</td>
<td>1999</td>
<td>1328</td>
<td>Physician</td>
<td>N/A</td>
<td>8%</td>
</tr>
<tr>
<td>Zincke</td>
<td>1994</td>
<td>3170</td>
<td>Physician</td>
<td>N/A</td>
<td>5% (post-1998)</td>
</tr>
<tr>
<td>Stanford</td>
<td>2000</td>
<td>1291</td>
<td>Anonymous questionnaire</td>
<td>48%</td>
<td>21%</td>
</tr>
<tr>
<td>Kao</td>
<td>2000</td>
<td>1069</td>
<td>Anonymous questionnaire</td>
<td>66%</td>
<td>33%</td>
</tr>
</tbody>
</table>

8-12% of patients will have enough leakage after RRP to seek treatment for SUI.

Urinary incontinence has a significant detrimental effect on HRQOL.
Post Prostatectomy Incontinence

- Points of injury intraoperatively
  - Damage to NVB
  - SV dissection and damage to pelvic plexus
  - Injury to sphincter muscle/fascia tissues
    - Direct injury to sphincter fibers
    - Injury to sphincteric supports
    - Neuronal injury

Post Prostatectomy Incontinence

- Multifactorial
  - Destrusor instability 20-30%
  - Reduced bladder compliance
  - Reduced bladder sensation
  - Impaired bladder contractility
  - Intrinsic sphincter dysfunction
    - Reduced functional urethral length
    - Decreased MUCP
  - Bladder neck contracture
Post Prostatectomy Incontinence

- Are these changes a consequence of surgery, or due to:
  - Long term BOO
  - Age related changes
  - Often these changes are asymptomatic and only detected on UDS

Post Prostatectomy Incontinence

<table>
<thead>
<tr>
<th>Authors, year [ref]</th>
<th>Type of study</th>
<th>No. of patients</th>
<th>Follow-up (mo)</th>
<th>DO No (%)</th>
<th>RBC No (%)</th>
<th>Impaired detrusor contractility No (%)</th>
<th>BOO No (%)</th>
<th>GSI No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holbrom et al, 1989 [22]</td>
<td>Prospective</td>
<td>24</td>
<td>6</td>
<td>—</td>
<td>19 (100)</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<tr>
<td>Leach and Yuan, 1992 [27]</td>
<td>Retrospective</td>
<td>71</td>
<td>40</td>
<td>6 (25)</td>
<td>5 (7)</td>
<td>—</td>
<td>—</td>
<td>25 (35)</td>
</tr>
<tr>
<td>Kleinman et al, 1999 [23]</td>
<td>Retrospective</td>
<td>25</td>
<td>12</td>
<td>—</td>
<td>5 (20)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Gacanzan et al, 2004 [56]</td>
<td>Prospective</td>
<td>25</td>
<td>12</td>
<td>—</td>
<td>5 (20)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Hooker et al, 2005 [26]</td>
<td>Prospective</td>
<td>25</td>
<td>12</td>
<td>—</td>
<td>5 (20)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Khed and Clemens, 2005 [36]</td>
<td>Retrospective</td>
<td>25</td>
<td>12</td>
<td>—</td>
<td>5 (20)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Majors et al, 2005 [26]</td>
<td>Prospective</td>
<td>25</td>
<td>12</td>
<td>—</td>
<td>5 (20)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

Ref = reference; DO = detrusor overactivity; RBC = reduced bladder compliance; BOO = bladder outlet obstruction; GSI = genuine stress incontinence; — = not reported.

2-77%  10-20%  8-70%
Post Prostatectomy Incontinence

- Bladder compliance
  - Perivesical inflammation/fibrosis
  - Alteration of bladder wall geometry
  - Disruption of detrusor innervation

Post Prostatectomy Incontinence

- Detrusor Overactivity
  - Vesicourethral reflex
  - Post surgical change to bladder
  - Recruitment of new spinal circuits in patients with BOO
Post Prostatectomy Incontinence

- Some evidence UDS can predict post RRP incontinence
- 1/3 patients had pre existing deficit
- These patients had 39% SUI postop (vs 3%)

Aboseif Urol Int 1994
Post Prostatectomy Incontinence

- **UDS Conclusions**
  - Detrusor dysfunctional rarely the sole diagnosis
    - DO as a new finding variable, 2-75%
    - Impaired compliance 8-39% (de novo 50%)
    - Impaired contractility in 30-40% (de novo 50%)
  - ISD usually present, but is the sole diagnosis in only 25-50%
  - In select cases preop UDS may help predict etiology and those at high risk of postop urinary complications

- **Who gets treatment?**
  - SUI that is persistently bothersome despite 12mon of active conservative treatment
- **Conservative treatment**
  - Fluid restriction
  - Medical management (DO)
  - Pelvic floor exercises
  - Periurethral bulking agents
Leaky treatment option #1

Geezer Squeezer Klip
$19.95

Leaky Treatment option #2
Leaky Treatment option #2

- High level of success across all levels of incontinence for 30yrs
  - Success rates 75-90%
  - Long term followup available
- Revision rate of 15-20% at 5yrs
  - Mechanical failure 8%/lifetime
  - Infection rate 3%
  - Erosion 0-13%

Comiter, Nat Cl Prat Urol 2007

Option #3
Male sling: Introduction

- Goal
  - Apply sufficient urethral occlusive pressure to prevent leakage, but to allow normal voiding with detrusor contraction
Male sling: Introduction

- Designed with hope to overcome some of the disadvantages of the AUS
  - Infection
  - Urethral erosion
  - Need for device manipulation
  - Expense
  - Physiological voiding
  - Need for future surgery

Male sling: Introduction

- Principles
  - Adequate tension
  - Well designed synthetic materials
  - Adequate sling fixation
  - SUI treated by increasing urethral resistance
Male sling: Introduction

- Patient selection
  - Mild to moderate SUI
  - No periurethral fibrosis
  - Appropriate detrusor voiding pressures
  - Not dependent on manual dexterity

Original Male sling

- Conceptualised in 1960-70’s
  - Kaufmann III
    - Silicone gel filled hemispherical prosthesis with two polyurethane straps used to compress urethra
  - Kishev
    - Prosthetic under bulbar urethra tensioned with sutures through rectus fascia
- Recent slings are based on the original concept of urethral compression
- Initial slings used allograft/xenograft, which did not maintain long term tension
Retropubic Bulbourethral Sling

- Mesh/autologous fascia suspended with sutures over rectus fascia
- Studied with multiple etiologies and degrees of SUI
Retropubic Bulbourethral Sling

Xu, Eur Urol 2006

Retropubic Bulbourethral Sling

John, JU 2004
Retropubic Bulbourethral Sling

- Current principles of a successful Bulbourethral sling
  - Synthetic graft (necessary for long term tension)
  - Wide area of urethral compression (prevent erosion)
  - Appropriate tension (via urethral filling P, VLPP under spinal, with an early adjustment)

- Complications
  - Perineal pain/numbness
  - Erosion
  - Failure

Retropubic Bulbourethral Sling

- Medium term results
  - Schaeffer’s bolster technique
  - 95 men with PPI (5-10 pads/day)
  - 4yr mean followup

Stern, JU, 2005
Bone Anchored Bulbourethral Sling

- Bulbourethral sling with bone anchoring (InVance, AMS)
  - Marketed 2001
  - Minimally invasive, perineal procedure
  - 6 screws with battery powered drill attached to prolene suture
  - Silicone coated polyester mesh

Bone Anchored Bulbourethral Sling

- Bone anchored male sling is indicated for mild-moderate SUI (1-3pad/day)
- Contraindicated in
  - Immunocompromise
  - Renal failure
  - UTI
  - Osteomyelitis
- Others:
  - Risk of TCC
  - Urethral stricture
  - DO, detrusor hypocontractility, reduced capacity
  - Stone disease requiring repeat endoscopic treatments
Bone Anchored Bulbourethral Sling

- 48 patients, primarily with PPI
- Inclusion criteria
  - Detrusor voiding pressures >60cmH20
  - Normal voiding time
  - Absence of BOO
  - Normal cysto
- Treated with InVance, tensioned to 60cmH20

Comiter, Neuro Urodyn 2005

Bone Anchored Bulbourethral Sling

- Median F/U 4yrs
- Complications
  - 1 infection (erosion)
  - 7 scrotal pain/numbness (gone at 3mon)
  - 2 screw dislodgements
Bone Anchored Bulbourethral Sling

<table>
<thead>
<tr>
<th>Series</th>
<th>Year</th>
<th>Patients</th>
<th>F/U (mon)</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Madjar</td>
<td>2001</td>
<td>14</td>
<td>12</td>
<td>86% dry, 14% improved</td>
</tr>
<tr>
<td>Fassi-Fehri</td>
<td>2004</td>
<td>22</td>
<td>3</td>
<td>50% dry, 23% improved</td>
</tr>
<tr>
<td>Cerqueira</td>
<td>2005</td>
<td>10</td>
<td>9</td>
<td>80% dry, 20% improved</td>
</tr>
<tr>
<td>Rajpurkar</td>
<td>2005</td>
<td>46</td>
<td>24</td>
<td>37% dry, 37% improved</td>
</tr>
<tr>
<td>Castle</td>
<td>2005</td>
<td>42</td>
<td>18</td>
<td>16% dry</td>
</tr>
<tr>
<td>Gallagher</td>
<td>2007</td>
<td>31</td>
<td>15</td>
<td>75% dry</td>
</tr>
<tr>
<td>Guimaraes</td>
<td>2008</td>
<td>62</td>
<td>28</td>
<td>65% dry, 23% improved</td>
</tr>
<tr>
<td>Giberti</td>
<td>2008</td>
<td>42</td>
<td>41</td>
<td>62% dry, 8% improved</td>
</tr>
</tbody>
</table>

Complications
- Hematoma
- Retention
- Sling infection
- Erosion
- Initial/prolonged perineal pain
- Bone screw dislodgement
- De novo detrusor overactivity
Bone Anchored Bulbourethral Sling

- Will long term compression of the urethra cause altered bladder compliance and detrusor function?
  - Evidence from Schaeffer’s series 66 men
    - Unobstructed voiding on VUDS
    - Increased VLPP
  - Evidence from Comiter’s series 22 men
    - RLPP increased from 20 to 60cmH2O
    - Flow rate 18 vs 19mL/s postop
    - Detrusor pressure 40 vs 46cmH2O
    - No de novo UI, BOO
    - 4 patients de novo DO (asymptomatic)

Bone Anchored Bulbourethral Sling

- Consider alternative treatment in patients with
  - Radiation
  - BN contracture
  - Previous incontinence treatment
- Likely will decrease pad use, but will not cure
Bone Anchored Bulbourethral Sling

- Does a failed bone anchored sling prevent successful AUS?
  - 11 patients, failed sling
    - RT
    - Absorbable sling
    - Severe incontinence
    - Prior failed AUS

Surgical approach
- NonRT patients
  - Perineal incision
  - Divided sling
  - Placed cuff
- RT patients/infection
  - Transverse perineal incision
  - Urethral cuff placed distal

Fisher, Urol 2007

<table>
<thead>
<tr>
<th>Table 2. Outcomes of AUS after failed male sling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of incontinence after AUS (n)</td>
</tr>
<tr>
<td>Dry (0 pads)</td>
</tr>
<tr>
<td>Mild (1 to 2 pads/day)</td>
</tr>
<tr>
<td>Moderate (3-5 pads/day)</td>
</tr>
<tr>
<td>Severe (&gt;5 pads/day)</td>
</tr>
<tr>
<td>Mean UCLA/RAND scores (incontinence section)</td>
</tr>
<tr>
<td>Patient satisfaction (%)</td>
</tr>
<tr>
<td>Infections requiring removal</td>
</tr>
<tr>
<td>Revisions</td>
</tr>
</tbody>
</table>

Abbreviations as in Table 1.
Bone Anchored Bulbourethral Sling

- Patient satisfaction
  - Pad use decreases (3.7 to 1.3)
  - 37-38% pad free
  - Significant improvement in
    - MUDI and MUSIQ scores
    - UCLA/RAND questionnaire
  - 70-75% patients satisfied with procedure using validated QOL measures at 15mon

Gallagher, Urol 2007
Rajpurkar, Eur Urol 2005

Male TOT Sling

- The male TOT (AdVance, AMS)
  - Marketed in 2006
  - Indicated for mild to moderate SUI secondary to RRP/TURP
  - Contraindicated
    - UTI
    - Coagulopathy
    - Immunocompromise
    - Renal failure/BOO
Male TOT Sling

- Different paradigm: suspension vs compression
  - Damage to posterior urethra/supporting structures
  - Residual sphincter function implies urethral prolapse and dorsal sphincteric urethral descent
  - Dorsal surface of the proximal bulb is rotated proximally utilizing a broad surface on the bulb
  - Prolapsed dorsal surface of the sphincteric urethra is indirectly supported without direct compression
  - “Augments residual function”

Gozzi & Rehder, Abstract at the SIU, 2005

Male TOT Sling

- Force vectors differ
  - Limited force perpendicular to sling
Male TOT Sling

- **Technical points**
  - Preop cysto demonstrating coaptation of bulb with perineal pressure predicts success
  - Position: low lithotomy position
  - Bulbospongiosus muscle should be divided
  - Urethral bulb should be mobilised until proximal movement is possible
  - Mesh should be fixed to bulb
  - Tensioning: in cadaveric studies bulbar urethra elevated 3-4cm without obstruction
  - Tape ends fixed in sub cut tissue
  - Postop limit leg spreading/lifting

Rehder, Int Braz J Urol. 2007

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Male TOT Sling

- 20 men with SUI, and a degree of residual sphincter function
- **UDS**
  - Membraneous urethral length increased from 3 to 17mm
  - MUCP increased from 13 to 86
  - Qmax unchanged
- **MRI**
  - Ventral urethral bulb moved proximally into pelvis

Rehder, Eur Urol 2007
Male TOT Sling

- 2 patients with perineal discomfort
- 1/20 reported dissatisfaction with procedure
- TOT sling “gave way” with activity in one patient
- Pad usage at 6 wk followup (stable in 18/20 patients)

<table>
<thead>
<tr>
<th>Daily pad usage</th>
<th>No. of patients (%) reporting pad use at baseline</th>
<th>No. of patients reporting pad use post-operatively</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>–</td>
<td>8 (40%)</td>
</tr>
<tr>
<td>1-2</td>
<td>2 (10%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>3-4</td>
<td>5 (25%)</td>
<td>6 (30%)</td>
</tr>
<tr>
<td>5-6</td>
<td>9 (45%)</td>
<td>–</td>
</tr>
<tr>
<td>7-8</td>
<td>3 (15%)</td>
<td>–</td>
</tr>
<tr>
<td>9-10</td>
<td>1 (5%)</td>
<td>–</td>
</tr>
</tbody>
</table>

Male TOT Sling

- Theoretical advantages
  - Less urethral pressure to prevent erosion
  - Perineal procedure, avoids scarred retropubic space
  - Easier to place than the InVance, avoid potential complications of bone screws
  - TO pathway safe in cadaveric models, well established in females
Other Male Sling Designs

- Adjustable bulbourethral sling (Argus, Promedon SA)

Other Male Sling Designs

- Perineal sling with tissue expander
Other Male Sling Designs

- Ventral Urethral Elevation + (Levera, Caldera Medical)
  - Combines elevation and compression of urethra

Conclusions

- Male incontinence is a significant problem
  - 10% patients after RRP seek treatment
  - RT, TURP, Orthotopic neobladder, neurogenics
- Revived interest in the male sling due to success in females and development of reliable synthetics
- Consider in patients
  - Failed conservative therapy for >12mon
  - Significant bother from mild-mod SUI (1-5 pad/d)
  - UDS: Adequate detrusor pressure, without BOO, no DO
  - Minimal periurethral fibrosis (RT, perineal Sx)
  - Inability to manipulate AUS
  - Can’t afford AUS
  - Unable to tolerate possible revision of AUS
Conclusions

• For workup consider
  • UDS
    • Detrusor function
    • Capacity
    • DO (make sure it is treatable first)
  • Cysto
    • R/O BN contracture, stricture
    • Ensure coaptable urethra
    • Ensure some sphincter function

Conclusions

• Retropubic bulbourethral suspensions
  • Urethral compression with synthetic
  • Studied in mild to severe PPI
  • Risk of urethral erosion, perineal pain, bladder perforation
  • Medium term outcomes
    • 4yrs 81% cured/improved
Conclusions

- Bone anchored bulbourethral sling
  - Urethral compression with fixation to pubic bone
  - Perineal procedure, “minimal invasive”
  - Studied in mild to moderate PPI
  - Risk of erosion, bone complications, generally short term perineal pain
  - Mostly short term F/U, small series, some medium term FU
    - 4yrs about 60% “dry”
    - 70-75% are satisfied, have improved QOL
    - Does not preclude AUS placement with failure

- Male TOT sling
  - Urethral elevation and compression
  - Perineal procedure, easier than placing bone screws, familiar to urologists
  - Studied in mild to mod PPI
  - Risk of erosion theoretically less, risk of pain theoretically less, no bone complications
  - New technique, with few published series
    - Safe and effective with short term followup
Future directions

- Many procedures performed, few series published!
  - 18,000 InVance (2001)
  - 10,000 AdVance (2006)
- RCT
  - 1-3pad leakage in motivated patient
  - Randomised to AUS vs sling
  - 5yr followup
- Future directions
  - Other populations: neurogenics, orthotopic neobladders
  - Long term followup and better understanding of long term efficacy and risks