Artificial Urinary Sphincter after 40 Years of Use: Indications, Techniques and Outcomes

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Learning Objectives

1. Identify indications and contraindications to AUS
2. Highlight information pertinent to patient evaluation prior to AUS
3. Summarize an approach to troubleshooting AUS
4. Discuss the use of AUS in special populations
Outline

• Background
• Indications and contraindications
• Patient evaluation
• Technique
• Outcomes
• Short and long-term complications
• Troubleshooting
• Special populations
• Conclusions

Artificial Urinary Sphincter (AUS)
History of AUS

<table>
<thead>
<tr>
<th>Year</th>
<th>Model</th>
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<tbody>
<tr>
<td>1972</td>
<td>AS721</td>
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<tr>
<td>1974</td>
<td>AS742</td>
</tr>
<tr>
<td>1976</td>
<td>AS761</td>
</tr>
<tr>
<td>1977</td>
<td>AS791</td>
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<tr>
<td>1982</td>
<td>AMS800</td>
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Since 1982:
Addition of fluoro silicone gel, a narrow-back cuff, kink resistant tubing, color coded tubing, Y tubing connectors and Inhibizone antibiotic coating

Demographics of AUS

- More than 150,000 patients worldwide have been implanted with an AUS device\(^1\). ~11,500 AUSs are placed annually\(^2\).

- In the US 13% of urologists perform AUS surgeries and only 4% of urologists are considered high volume for routinely placing AUS’s (>20 per year)\(^1\).

- In Ontario 2.8% of men who undergo radical prostatectomy had subsequently AUS device implantation\(^2\).

\(^1\)Van der Aa F. European Urol 2013 \(^2\)Wallis CJ. Can Urol Assoc 2014.
Indications for AUS

• Individuals with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency having failed conservative management

Before 1985:
1. Neurogenic disease (17-50%)
2. Post-urethral surgery (17%)
3. Trauma/post pelvic surgery (3-39%)

After 1985:
1. In men
   a. Post-radical prostatectomy incontinence (39-69%)
2. In women (<1%)
   a. Neurologically induced SUI (14-50%)
   b. Post- SUI surgery (0-50%)
Indications for AUS

– Post-radical prostatectomy incontinence
  • Incontinence refractory to pelvic floor physiotherapy (i.e. kegels) and other conservative management
  • At least 6 months post-radical prostatectomy\(^1,3,7\)

Contraindications for AUS

• Patient factors:
  – Patients deemed to be poor surgical candidates due to physical or mental conditions
  – Patients deemed to be poor anesthetic candidates
  – Patients with active urinary tract infection
  – Patients with a known allergy or sensitivity to rifampin, minocycline or other tetracyclines
  – Patients with systemic lupus erythematosus\(^10\)


http://www.amslabeling.com/assets/files/1004681r03_IFU_AMS800_MaleUSA.pdf
Contraindications for AUS

• Patient Anatomy:
  – Patients with urinary incontinence due to irreversibly obstructed lower urinary tract
  – Patients with irresolvable detrusor overactivity with urge incontinence, storage parameters creating a risk for upper tract deterioration
  – Patients with bladder neck or vesico-urethral anastomotic stricture

Patient Evaluation

• History (mandatory)
• Physical Exam (mandatory)
• Urinalysis (mandatory)
• Cystourethroscopy (strongly recommended)
• Urodynamics (optional)
Patient Evaluation

- History
- Physical Exam
- Urinalysis
- Cystourethroscopy
- Urodynamics

- Prior surgical procedures to lower GU tract
- History of pelvic radiation
- Neurologic symptoms
- Focused incontinence history*, voiding diary and pad test

- Abdomen, external genitalia, perineum and rectum
- Screening neurologic exam of the lower extremities
- Dexterity and confirmation of patient’s dominant hand
- Scrotal exam to rule out inguinal hernia, hydrocele, scrotal mass
Patient Evaluation

- History
- Physical Exam
- Urinalysis
- Cystourethroscopy
- Urodynamics

- Rule out active urinary tract infection

Patient Evaluation

- History
- Physical Exam
- Urinalysis
- Cystourethroscopy
- Urodynamics

- Rule out bladder neck contracture, urethral stricture, diverticulum, erosion of prior AUS
- Assessment of voluntary contraction of the external urethral sphincter and status of the bladder
Patient Evaluation

• History
• Physical Exam
• Urinalysis
• Cystourethroscopy
• Urodynamics

• Stratify by etiology of incontinence (Neurogenic vs. non-neurogenic) and clinical history

Counseling the patient

• Use a model to demonstrate AUS mechanics
• Deactivation of the device:

11/28/16

Counseling the patient

• Activation of the device:

• Outcomes: social continence and patient satisfaction
• Median lifespan of device 5-7 years\textsuperscript{11-13} and chance for future device revision\textsuperscript{14}
• Complications: erosion, cuff atrophy and mechanical malfunction
Technique

• Pre-operative
  – Position/Perineal approach
  – Ensure low bacterial counts

• Operative
  – Pressure regulated balloon placed under the abdominal wall fascia
  – Pump should be placed in the scrotum
  – Cuff placed around urethra
  – Post placement cystourethroscopy


Technique

• Post-operative
  – Immediate:
    • Prescriptions: analgesic, stool softener, no antibiotic*
    • Limit physical activity and lifting more than 6kg for 6 weeks
  – Long-term:
    • Follow-up visit 4-6 weeks for device activation
    • Monitor bladder and upper urinary tracts
    • Ensure patient understands he/she must fore-warn healthcare professionals in the event that catheterization is planned
Short-term complications

- Urinary retention (1-31%)
- Cellulitis (1%)
- Acute device infection (2%)
- Acute urethral erosion (2%)

Long-term complications

- Mechanical failure (2-13.8%)
- Urethral erosion (2%)
- AUS infection (<2%)
- Sub-urethral atrophy (2-7.9%)
Outcomes

• Social continence 79%
• Satisfaction 80-90%
• Median lifespan of device 5-7 years\textsuperscript{11-13} and chance for future device revision\textsuperscript{14}
• Most common reasons for failure:
  – Mechanical failure (2-13.8%)
  – Urethral erosion (2%)
  – AUS infection (<2%)
  – Sub-urethral atrophy (2-7.9%)

Troubleshooting

AUS troubleshooting

Recurrent or persistent incontinence
AUS infections
Obstructive symptoms
Recurrent or persistent incontinence

- **Assessment:**
  - History and physical, voiding diary, pad test
  - Pad test > 1 pad/day → cystourethroscopy, pelvic x-ray +/- video urodynamics

Urethral erosion (2%)

- **Assessment:**
  - Other signs: urethral spotting of blood, frank hematuria, dysuria or recurrent infection

- **Management:**
  - Removal of the cuff exclusively or the device entirely will mainly depend on time since AUS implantation
  - Eroded cuffs should be replaced at different urethral locations (proximal better)
Sub-urethral atrophy (2-7.9%)

• Assessment:
  – History: time to develop ~ almost 3 years
  – Cystourethroscopy

• Management:
  – Options include measuring and downsizing the cuff at the same cuff location, implantation of a tandem cuff, proximal repositioning of the cuff or transcorporal cuff placement

AUS infections (<2%)

• Assessment:
  – History and physical
    • Severity
  – Cystourethroscopy

• Management:
  – Antibiotics
  – If urethral erosion, severe or persistent infection entire device should be explanted
Mechanical failure (2-13.8%)

• Definitive diagnosis
• Management:
  – Whole system replacement or not dependent on timing and site of failure

Obstructive symptoms

• Assessment:
  – Cystourethroscopy

Obstructive symptoms

- Urethral erosion
- Stricture remote from cuff site
- Sub-cuff stenosis

1http://milamurology.com/surgical_procedures/surgical_procedures_to_improve_continence_in_men
Troubleshooting

- AUS troubleshooting
  - Recurrent or persistent incontinence
    - Mechanical failure
    - Sub-urethral atrophy
    - Loose cuff
    - Urethral erosion
  - AUS infections
    - Urethral erosion
    - Stress erosion from cuff site
    - Sub-cuff erosion
  - Obstructive symptoms

Special populations-Radiation

- Debate as to whether implanted AUS is associated with increased risk of cuff erosion and re-operation in post-radical prostatectomy post-radiation patients\(^\text{25,26}\)
- Proposed mechanism:
  - Radiation leads to urethral atrophy due to reduced blood supply\(^\text{25}\) and detrusor overactivity
- Despite these risks AUS implantation performed in irradiated patients has satisfactory continence outcomes\(^\text{26}\)
- Management:
  - Transcorporal cuff placement, lower pressured PRB (51-60cmH2O) and delayed activation at 6 weeks\(^\text{27}\)
  - 3.5cm AUS associated with increased (21%) risk of cuff erosion\(^\text{28}\)

Special populations - Neurogenic incontinence

• Acceptable outcomes have been observed in both males and females.\(^{31-32}\)
  • In males 84.2% continence rate after 8 years follow-up; annual revision rate was 0.2 revisions per patient; 2/19 patients developed upper tract dilatation.\(^{33}\)
  • In females 57.7% continence rate; 90% device survival rate after 5 years follow-up.\(^{8}\)
• AUS erosion is the major cause of AUS removal with a rate reported to go from 6% to 31%\(^{34,35}\)
• AUS infection rate is higher (as high as 8%)\(^{36}\)

Special populations - Females

• AUS implantation is a salvage technique in bothered patients after mid-urethral sling failure in the absence of urethral mobility.\(^{9}\)
• Overall rate of success after 1\(^{st}\) revision 60-70%, 2\(^{nd}\) revision 50%, 3\(^{rd}\) revision 25%
• In women with non-neurogenic UI with revision AUS after 8.47 years follow-up 73.5% continent, 79% satisfied, redo rate 15.3% and 7% were explanted. Prior Burch or pelvic radiation increases chance of failure.\(^{37}\)
• Retropubic approach is recommended over vaginal approach to reduce infection rate.\(^{38}\)
Special populations- Inflated Penile Prosthesis (IPP)

• Simultaneous AUS/IPP is associated with higher urethral erosion rates (11.6%) than AUS alone (4.3%)\textsuperscript{39}

Conclusions

• Indications for AUS: individuals with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency having failed conservative management

• Contraindications: patient factors and patient anatomy

• Initial evaluation of all AUS candidates requires a detailed history, physical exam, urinalysis and cystourethroscopy
Conclusions

• Approach to troubleshooting AUS

<table>
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<tr>
<th>Complication</th>
<th>Signs and Symptoms</th>
<th>Repair</th>
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<tbody>
<tr>
<td>Mechanical failure (2-13.8%)</td>
<td>Rapid onset device malfunction with no evidence of erosion, atrophy or infection.</td>
<td>Removal of entire device or use of ohmmeter to identify defective part to be replaced.</td>
</tr>
<tr>
<td>Urethral erosion (2%)</td>
<td>Recurrent incontinence, urethral spotting of blood, frank hematuria, dysuria or recurrent infection; often preceded by catheterization</td>
<td>Removal of all components of the AUS.</td>
</tr>
<tr>
<td>AUS infection (&lt;2%)</td>
<td>Scrotal erythema and induration at the site of the pump.</td>
<td>Removal of all components of the AUS and antibiotics to cover Staph, MRSA and gram negatives.</td>
</tr>
<tr>
<td>Sub-urethral atrophy (2-7.9%)</td>
<td>Recurrent incontinence (gradual)</td>
<td>Measure and downsize the cuff at the same cuff location, implantation of a tandem cuff, proximal repositioning of the cuff or transcorporal cuff placement.</td>
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</tbody>
</table>
Conclusions

- Special populations
  - Radiation and neurogenic: acceptable continence outcomes but more complications
  - AUS offers a good second line option for women with refractory SUI
  - Simultaneous AUS/IPP insertion associated with higher erosion rates

Questions

1. The most significant contraindication to AUS for sphincteric incontinence is:
   a. Impaired cognitive function
   b. Pad weight test result >1000mg/24hrs
   c. Prior pelvic radiation
   d. Organic erectile dysfunction
Questions

1. The most significant contraindication to AUS for sphincteric incontinence is:
   a. Impaired cognitive function
   b. Pad weight test result >1000mg/24hrs
   c. Prior pelvic radiation
   d. Organic erectile dysfunction

Questions

2. The most likely cause of gradual return of urinary incontinence 2 years after AUS is:
   a. Mechanical failure
   b. Sub-urethral atrophy
   c. Pressure-regulating balloon aneurysm
   d. New onset detrusor overactivity
   e. Tubing kink
Questions

2. The most likely cause of gradual return of urinary incontinence 2 years after AUS is:
   a. Mechanical failure
   b. Sub-urethral atrophy
   c. Pressure-regulating balloon aneurysm
   d. New onset detrusor overactivity
   e. Tubing kink

Questions

3. In a man with a history of recurrent noninvasive bladder cancer and sphincteric urinary incontinence following TURP with a pad weight of 230g for 24 hrs and leak-point pressure of 80cm H₂O, the best solution for the incontinence is:
   a. Bulbar AUS
   b. Bladder neck AUS
   c. Cunningham clamp
   d. Transobturator male sling
   e. Cystectomy with urinary diversion
Questions

3. In a man with a history of recurrent noninvasive bladder cancer and sphincteric urinary incontinence following TURP with a pad weight of 230g for 24 hrs and leak-point pressure of 80cm H₂O, the best solution for the incontinence is:
   a. Bulbar AUS
   b. Bladder neck AUS
   c. Cunningham clamp
   d. **Transobturator male sling**
   e. Cystectomy with urinary diversion

Questions

4. During urethral dissection for implantation of a bulbar AUS, a urethrotomy is made with the scissors. After repairing the urethral defect, the next step is:
   a. Catheter drainage for 7 days with delayed re plantation
   b. Placement of the cuff at a more distal location
   c. Transobturator sling
   d. Irrigation with antibiotic solution and transcorporal cuff placement
   e. Tunica vaginalis flap coverage and bulbar cuff placement
Questions

4. During urethral dissection for implantation of a bulbar AUS, a urethrotomy is made with the scissors. After repairing the urethral defect, the next step is:
   a. **Catheter drainage for 7 days with delayed re plantation**
   b. Placement of the cuff at a more distal location
   c. Transobturator sling
   d. Irrigation with antibiotic solution and transcorporal cuff placement
   e. Tunica vaginalis flap coverage and bulbar cuff placement

Questions

5. A 43 year old man with myelomeningocele has persistent incontinence after placement of a 4 cm bulbar AUS. UDS shows normal bladder capacity. The next step is:
   a. Downsize the cuff to 3.5 cm
   b. Addition of tandem cuff
   c. Reposition cuff at the bladder neck
   d. Increase PRB to 71 to 80cm H₂O
   e. Close bladder neck and create Mitrofanoff
Questions

5. A 43 year old man with myelomeningocele has persistent incontinence after placement of a 4 cm bulbar AUS. UDS shows normal bladder capacity. The next step is:
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   b. Addition of tandem cuff
   c. Reposition cuff at the bladder neck
   d. Increase PRB to 71 to 80 cm H₂O
   e. Close bladder neck and create Mitrofanoff

Acknowledgements

• Dr. Alex Kavanagh
• Dr. Mark Nigro
• Dr. Danny Rapoport
Extra slides

Troubleshooting activation of AUS

– Pump is too hard and will not allow depression: push deactivation button several times
– There is a large dimple and activation is not possible: Refill the pump
Urodynamics

Safe bladder parameters: maximum cystometric capacity > 200ml; bladder compliance > 12 cm H$_2$O/ml; and demonstrated ability to maintain storage detrusor pressures below 40 cm H$_2$O.

Urodynamics

• Post-radical prostatectomy
  – if associated with DO, Detrusor underactivity and even mild loss of bladder compliance this has no impact on outcome of AUS placement. Not compromised bladder contractility is a relative contraindication to male sling surgery but not AUS.
• TURP
  – wherein intrinsic sphincter deficiency induced by resection or scar, detrusor overactivity, persistent obstruction or impaired compliance can be seen in isolation or in combination. Baseline results can help guide patient expectations.
Future directions

• The “ideal” AUS:
  – Easily manipulated and inactivated
  – Modify cuff pressure after implantation
  – Adapt occlusive cuff pressure in a real-time manner
  – Simple and robust design
  – Safely implanted and minimally invasive procedure
  – Cost effective

New inventions

• FlowSecure- adjustable AUS with additional stress relieving balloon and comes as one piece device
• Periurethral constrictor-has an adjustable hydraulic system in the abdomen where it can be activated
• Zephyr- hydraulic base system is implanted as a single unit
• Tape mechanical occlusive device- spring loaded mechanism to apply circumferential pressure around the urethra

Strictures

AUS versus sling

<table>
<thead>
<tr>
<th>Variable</th>
<th>AUS</th>
<th>Sling</th>
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<tbody>
<tr>
<td>Dry rates</td>
<td>73-90%</td>
<td>65%</td>
</tr>
<tr>
<td>5-year device</td>
<td>80%</td>
<td>?</td>
</tr>
<tr>
<td>survival rate</td>
<td></td>
<td>?</td>
</tr>
<tr>
<td>Lifetime</td>
<td>5-7 years</td>
<td>? Less parts to malfunction</td>
</tr>
</tbody>
</table>

- Slings are best suited for men with lesser degrees of incontinence
- Absolute contraindication to sling is prior radiation
InhibiZone

- AUS covered in rifampicin and minocycline coating (cuff and pump only)
- InhibiZone penile implants are associated with reduced infection rate as compared to other antibiotic coatings
- However, no difference in infection rates noted in AUS devices and associated with higher cost (total of approximately $276,000 more for 213 coated devices)

Single versus double cuff

- First proposed by Dr. Mulcahy with the guidelines that pad usage >5 per day should have double cuff
- Controversial if rates of social continence and less persistent UI are better
- 5.7-fold higher risk of devices explantation during late follow up and significantly shorter explantation-free survival associated with double cuff
Transcorporal cuff

- Usually reserved for complex/high risk cases
  - prior radiation therapy, urethroplasty, multiple treatments for bladder neck contracture or urethral stricture, urethral stent placement or a history of erosion or infection in a previous AUS
- Indicated when urethra is difficult to dissect
- Contraindicated with IPP
- 18.9% explantation rate
- 69.7% social continence rate
- 88% satisfaction rate