W3: Surgical Management of Male Incontinence – Advanced

Workshop Chair: Wilhelm Hübner, Austria

23 October 2024 08:30 - 10:00

Start	End	Topic	Speakers
08:30	08:35	introduction	Wilhelm Hübner
08:35	08:45	AUS in Males, specific Tipps, Tricks for primary implantation	Craig Comiter
08:45	08:55	Specific aspects in Females	Emmanuel Chartier-Kastler
08:55	09:05	Fixed slings, challenges and criteria for success	Ralf Anding
09:05	09:10	Adjustable slings, challenges criteria for success	Wilhelm Hübner
09:10	09:15	Discussion	Wilhelm Hübner Ralf Anding Emmanuel Chartier-Kastler Craig Comiter
09:15	09:25	Trouble shooting and revisions for late failures	Craig Comiter
09:25	09:30	Challenging technical situations and their management	Wilhelm Hübner
09:30	09:40	Discussion	Wilhelm Hübner Ralf Anding Emmanuel Chartier-Kastler Craig Comiter
09:40	09:50	adjustable hydraulic sphincters	Ralf Anding
09:50	09:55	electronic sphincter, future aspects	Emmanuel Chartier-Kastler
09:55	10:00	closing remarks, evaluation form	Wilhelm Hübner

Description

Successful continence surgery significantly adds to the quality of life of patients, however, complex cases may be a strategic as well as technical challenge. This panel has means to provide answers to any complex challenge in surgical management of surgical treatment of incontinence. we want this ICS WS to be the appointment, where interested delegates find the answers to their most complex questions concerning male incontinence, in fact also female AUS topics can be covered by this panel. As key learning points we will provide the delegates with expert information on surgical techniques of both standard and challenging cases. Techniques for males sling and sphincter surgeries (transobturator/retropubic slings, balloons, transscrotal, tandem etc.) are described. for AUS Implantation urethral preparation using a 18Fr of foley and possibly leaving an atrophic bulbocavernosus muscle on the urethra is mentioned. transcavernousal approach, “open cuff” concept and "tunica flap" may be used for fragile urethras or in certain cases of intraoperative urethral lesions. Management of late difficulties such as subcuff atropy, urethral erosion, bladder neck obstruction (particularly in irradiated patients), mechanical failure, system leak search and others can be managed by specific means such as tandem cuff, stress cuff, cuff removal with urethral reconstruction, recurrent blunt bladder neck rubbing and/or change of components. Concerning slings and balloons potential and limits will be covered focussing on patient s characteristics and specific surgical techniques. Concerning fixed slings mobilizing of the bulb is crucial, with adjustable slings - both transobturator or retropubic - a snug contact to the urethra with correct leak point pressure guaranties best results. AUS implantation after failed previous other surgeries may be hampered, but in the vast majority not significantly. Upcoming new developments like AUS with remotely controlled electrical pump are on the way, however not yet commercially available. Key learning points (abridgment) and take home messages: Skills for optimal implantation of AUS and other implants: Urethral preparation using a 18Fr of foley and possibly leaving an atrophic bulbocavernosus muscle on the urethra Fragile urethra: Consider transcavernousal approach, maybe use tunica flap, ev. low pressure balloon handeling upcoming intraoperative difficulties: Consider open cuff plus transcavernousal approach for intraoperative urethral lesion Management of late complications: As described in the literature Long term supervision of complex cases: Counsel as " mutual journey" over years with possible revisions at start References: • Boswell TC, Elliott DS, Rangel LJ, Linder BJ. Long-term device survival and quality of life outcomes following artificial urinary sphincter placement. Transl Androl Urol. 2020 Feb;9(1):56-61. doi: 10.21037/tau.2019.08.02. PMID: 32055467; PMCID: PMC6995928. • El-Akri M, Bentellis I, Tricard T, Brierre T, Cousin T, Dupuis H, Hermieu N, Gaillard V, Poussot B, Robin D, Pitout A, Beraud F, Bertrand-Leon P, Chevallier D, Bruyere F, Biardeau X, Monsaint H, Corbel L, Saussine C, Hermieu JF, Lecoanet P, Capon G, Cornu JN, Game X, Ruffion A, Peyronnet B. Transcorporal vs. bulbar artificial urinary sphincter implantation in male patients with fragile urethra. World J Urol. 2021 Dec;39(12):4449-4457. doi: 10.1007/s00345-021-03783-6. Epub 2021 Jul 17. PMID: 34272596. • Hüsch T, Kretschmer A, Thomsen F, Kronlachner D, Kurosch M, Obaje A, Anding R, Pottek T, Rose A, Olianas R, Friedl A, Hübner W, Homberg R, Pfitzenmaier J, Grein U, Queissert F, Naumann CM, Schweiger J, Wotzka C, Nyarangi-Dix J, Hofmann T, Ulm K, Bauer RM, Haferkamp A; Debates on Male Incontinence (DOMINO)-Project. Risk Factors for Failure of Male Slings and Artificial Urinary Sphincters: Results from a Large Middle European Cohort Study. Urol Int. 2017;99(1):14-21. doi: 10.1159/000449232. Epub 2016 Sep 3. PMID: 27598774. • Khouri RK Jr, Ortiz NM, Dropkin BM, Joice GA, Baumgarten AS, Morey AF, Hudak SJ. Artificial Urinary Sphincter Complications: Risk Factors, Workup, and Clinical Approach. Curr Urol Rep. 2021 Mar 29;22(5):30. doi: 10.1007/s11934-021-01045-x. PMID: 33779844. • Moses RA, Keihani S, Craig JR, Basilius J, Hotaling JM, Lenherr SM, Brant WO, Myers JB. Efficacy of Pressure Regulating Balloon Exchange in Men With Post Artificial Urinary Sphincter Persistent or Recurrent Stress Urinary Incontinence. Urology. 2019 Jan;123:252-257. doi: 10.1016/j.urology.2018.07.052. Epub 2018 Sep 7. PMID: 30201300.

Aims of Workshop

Techniques for males sling and sphicter surgeries (transobturator/retropubic slings, balloons, transscrotal, tandem etc.) are described. we cover questions of AUS Implantation such as tricks for urethral preparation (size of foley, transcavernousal approach, “open cuff” concept, "tunica flap, leak search, etc.) as well as management of late difficulties (subcuff atropy, leak search, bladder neck obstruction - particularly in irradiated patients), mechanical failure and others. Concerning slings and ballons potential and limits will be covered focussing on patient s characteristics . AUS implantation after previous other surgeries will be discussed. In this WS we want to provide skills that can be recalled in complex cases in the future.

Educational Objectives

this workshop has been held in Toronto and was extremely successful. the discussion after excellent presentation on the topic was absolutely intriguing. We will adapt a few aspects to the latest literature and findings and we will change the assignment of presenters an put more focus on the latest developments in electronic sphincters.
we hope that again this workshop will be to the appointment, where interested delegates find the answers to their most complex questions concerning male incontinence.

Learning Objectives

1. 1. -Provide expert knowledge on AUS implantation technique and trouble shooting
2. 2. -Provide expert knowledge on sling and ballon implantation technique and trouble shooting
3. 3. -answer questions from delegates

Target Audience

Urology

Advanced/Basic

Advanced

Suggested Learning before Workshop Attendance

• Boswell TC, Elliott DS, Rangel LJ, Linder BJ. Long-term device survival and quality of life outcomes following artificial urinary sphincter placement. Transl Androl Urol. 2020 Feb;9(1):56-61. doi: 10.21037/tau.2019.08.02. PMID: 32055467; PMCID: PMC6995928. • El-Akri M, Bentellis I, Tricard T, Brierre T, Cousin T, Dupuis H, Hermieu N, Gaillard V, Poussot B, Robin D, Pitout A, Beraud F, Bertrand-Leon P, Chevallier D, Bruyere F, Biardeau X, Monsaint H, Corbel L, Saussine C, Hermieu JF, Lecoanet P, Capon G, Cornu JN, Game X, Ruffion A, Peyronnet B. Transcorporal vs. bulbar artificial urinary sphincter implantation in male patients with fragile urethra. World J Urol. 2021 Dec;39(12):4449-4457. doi: 10.1007/s00345-021-03783-6. Epub 2021 Jul 17. PMID: 34272596. • Hüsch T, Kretschmer A, Thomsen F, Kronlachner D, Kurosch M, Obaje A, Anding R, Pottek T, Rose A, Olianas R, Friedl A, Hübner W, Homberg R, Pfitzenmaier J, Grein U, Queissert F, Naumann CM, Schweiger J, Wotzka C, Nyarangi-Dix J, Hofmann T, Ulm K, Bauer RM, Haferkamp A; Debates on Male Incontinence (DOMINO)-Project. Risk Factors for Failure of Male Slings and Artificial Urinary Sphincters: Results from a Large Middle European Cohort Study. Urol Int. 2017;99(1):14-21. doi: 10.1159/000449232. Epub 2016 Sep 3. PMID: 27598774. • Khouri RK Jr, Ortiz NM, Dropkin BM, Joice GA, Baumgarten AS, Morey AF, Hudak SJ. Artificial Urinary Sphincter Complications: Risk Factors, Workup, and Clinical Approach. Curr Urol Rep. 2021 Mar 29;22(5):30. doi: 10.1007/s11934-021-01045-x. PMID: 33779844. • Moses RA, Keihani S, Craig JR, Basilius J, Hotaling JM, Lenherr SM, Brant WO, Myers JB. Efficacy of Pressure Regulating Balloon Exchange in Men With Post Artificial Urinary Sphincter Persistent or Recurrent Stress Urinary Incontinence. Urology. 2019 Jan;123:252-257. doi: 10.1016/j.urology.2018.07.052. Epub 2018 Sep 7. PMID: 30201300.

The Artificial Urinary Sphincter

Craig V. Comiter, M.D.

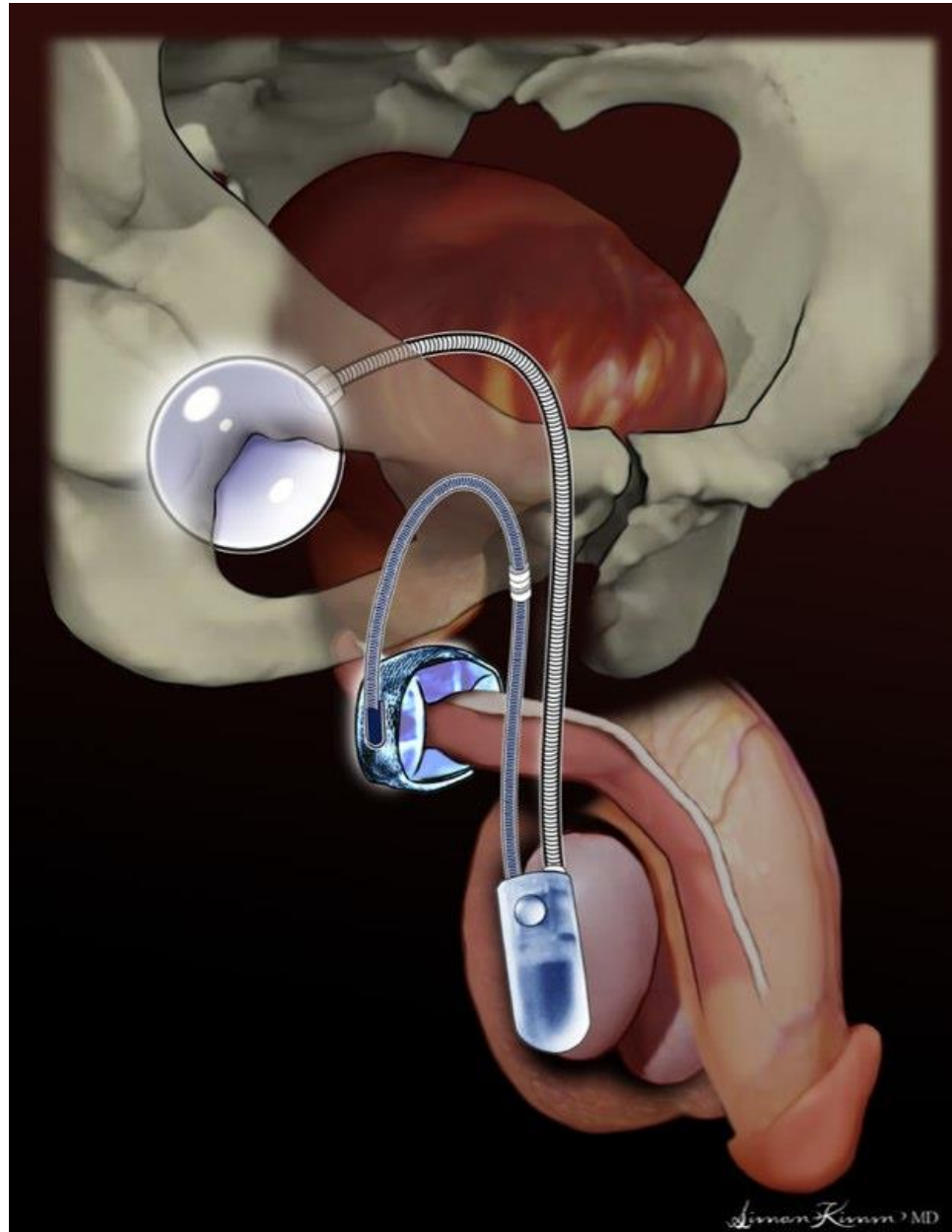
Professor, Department of Urology

Professor, Department of Obstetrics and Gynecology

Stanford University School of Medicine

Artificial Urinary Sphincter

- The AUS is the most predictably reliable treatment for SUI for men with all degrees of incontinence
    - Speed JM, Comiter CV, Up to Date, 2021
- The AUS is composed of a circumferential urethral cuff, a pressure-regulating balloon reservoir, and a scrotal pump
- Placed via a two-incision technique, using a perineal incision for cuff placement and an inguinal incision for balloon reservoir and scrotal pump placement
- The cuff opens after manual compression of the scrotal pump and automatically closes after a period of two to three minutes.



AUS Guidelines

- Artificial urinary sphincter should be considered for patients with bothersome stress urinary incontinence after prostate treatment. (Strong Recommendation; Evidence Level: Grade B)

- Prior to implantation of artificial urinary sphincter, clinicians should ensure that patients have adequate physical and cognitive abilities to operate the device. (Clinical Principle)

- In the patient who selects artificial urinary sphincter, a single cuff perineal approach is preferred. (Moderate Recommendation; Evidence Level: Grade C)

Indications for AUS (rather than male sling)

- In men with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, artificial urinary sphincter is preferred over male slings or adjustable balloons. (Moderate Recommendation; Evidence Level: Grade C)

- In patients with persistent or recurrent stress urinary incontinence after sling, an artificial urinary sphincter is recommended. (Moderate Recommendation; Evidence Level: Grade C)

- In patients with persistent or recurrent stress urinary incontinence after artificial urinary sphincter, revision should be considered. (Strong Recommendation; Evidence Level: Grade B)

- In men with severe stress urinary incontinence
  - Male slings should be considered as treatment options for mild to moderate stress urinary incontinence after prostate treatment. (Moderate Recommendation; Evidence Level: Grade B)

- In men with detrusor underactivity and moderate to severe stress urinary incontinence

Do Urodynamics Matter?

- Only if there is low volume detrusor overactivity or poor compliance
  - Typically evident by symptoms and history of Neurogenic Bladder or Radiation Treatment

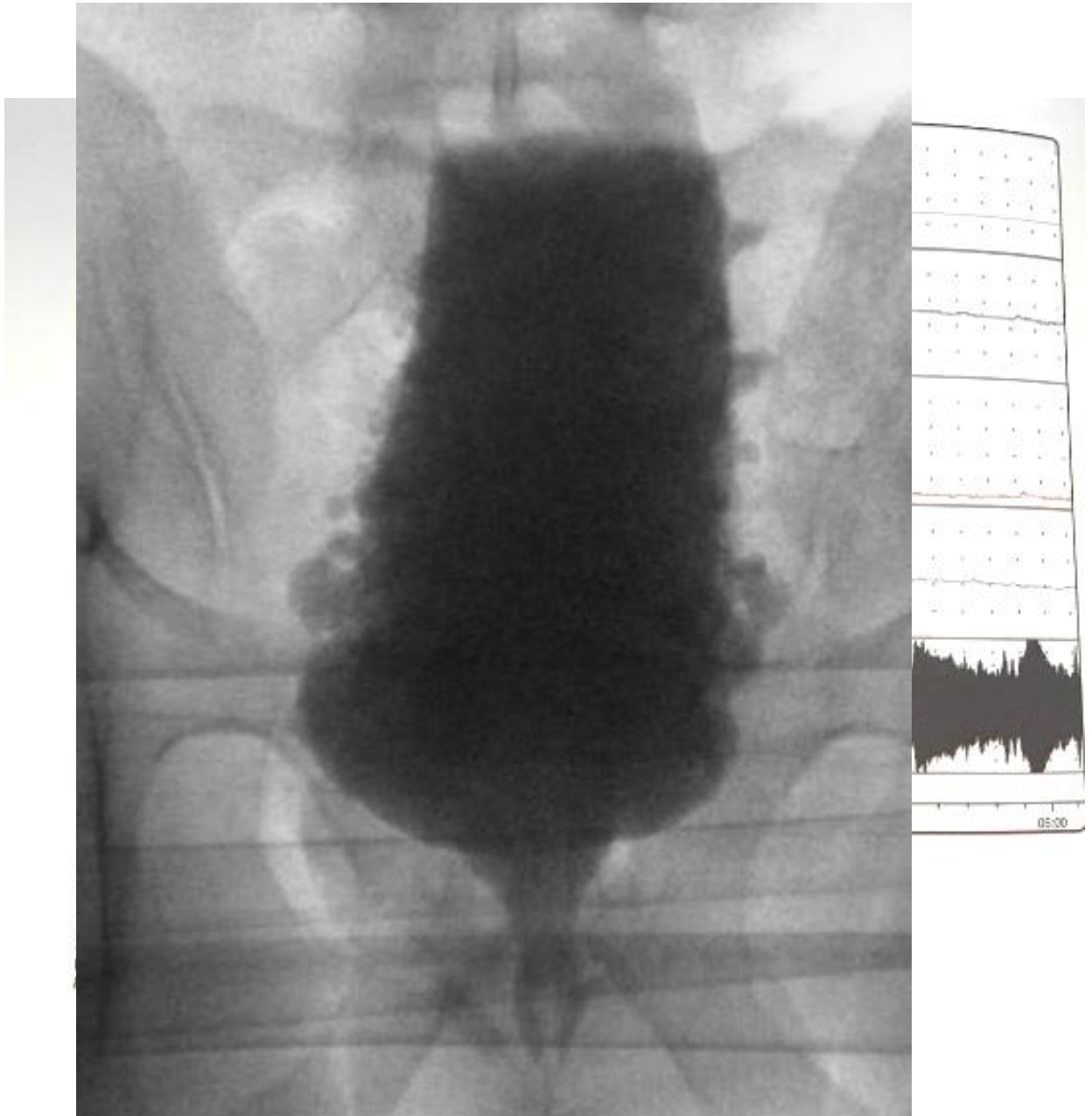
- Detrusor underactivity
  - Device is cycled open, so Valsalva voiding can achieve complete emptying
  - Prospective trial of 40 patients with 4.5 year follow-up: preop DUA did not affect surgical outcome
    - Trigo Rocha F, et al, Urology, 2008
  - Even pure Valsalva voiding does not affect outcome.
    - Lai HH et al, J Urol, 2007

- Detrusor overactivity
  - Typically improves after AUS, does not affect resolution of SUI
  - DO decreased from 50% to 25% after AUS implantation
    - Afraa TA et al, Can J Urol, 2011
  - Persistent OAB should be treated with typical OAB algorithm
    - Lai HH et al, Urology 2009

Do Urodynamics Matter?

- Diminished vesical compliance
  - Rare (5%) if no XRT, may be **urodynamic artifact from chronically empty bladder being filled at supra-physiologic rate**
    - Ficazzola MA, Nitti VW, J Urol, 1998
  - Typically improves postop if no XRT
    - Affraa, 2011

- The “hostile” bladder
  - In radiated patients, not safe to assume impaired compliance resolves after resumption of normal bladder filling
  - More likely component of intrinsic bladder wall fibrosis
    - Sung DJ, Sung CK, Uroradiology, 2012.
  - Must monitor for development of hydronephrosis, and repeat UDS as necessary
    - Ghoniem GM et al, World J Urol, 1994



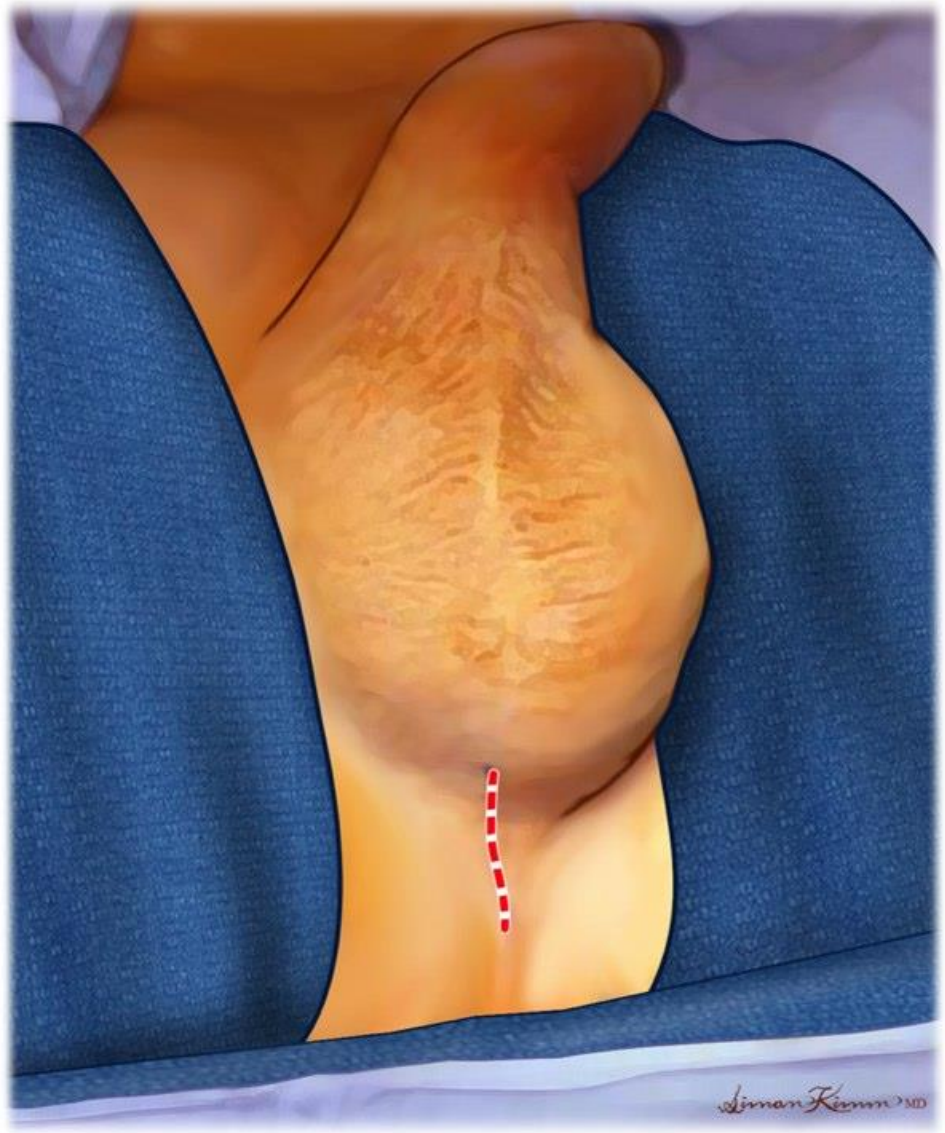
AUS has track record of proven efficacy

- Literature is replete with studies demonstrating the efficacy of the AUS in both the short and long term
    - Mottet, Urol Int, 1998; Sacomani, Int Braz J Urol, 2018; Walsh, BJU Int, 2002; Gomha, J Urol, 2002; Guillaumier Urol Ann, 2017; Kuznetsoy Urology, 2000; Gousse, J Urol 2001; Santos, Int Braz J Urol, 2017; Lai, J Urol, 2007

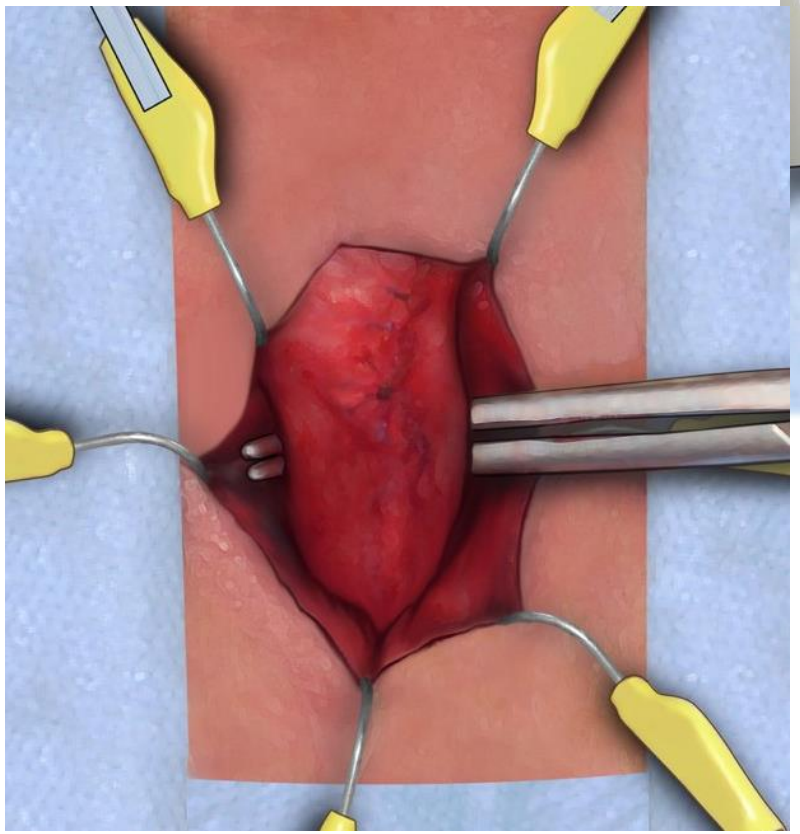
- Satisfaction at two years exceeds 90%
    - 20% never leaked
    - 55% reported leakage of a few drops daily
    - 22% leaked less than a teaspoon daily
        - Litwiller SE, et al: J Urol, 1996

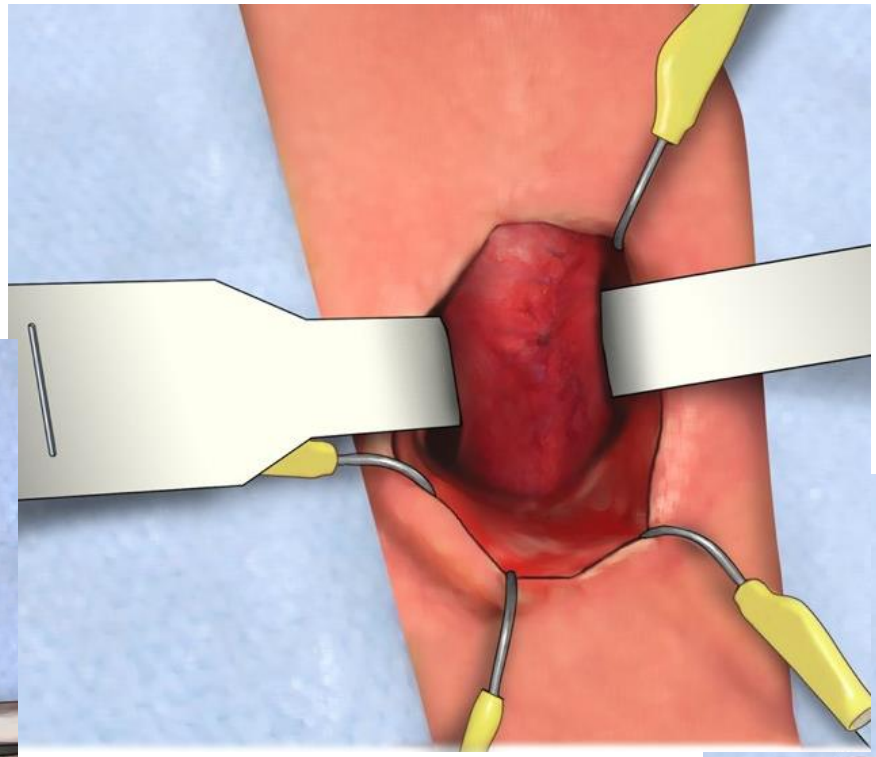
- Large cohort with up to 11 year follow-up
    - Mean pad use declined 85 percent
    - 4.0 to 0.6 pads per day
        - Trigo Rocha F, et al: Urology, 2008

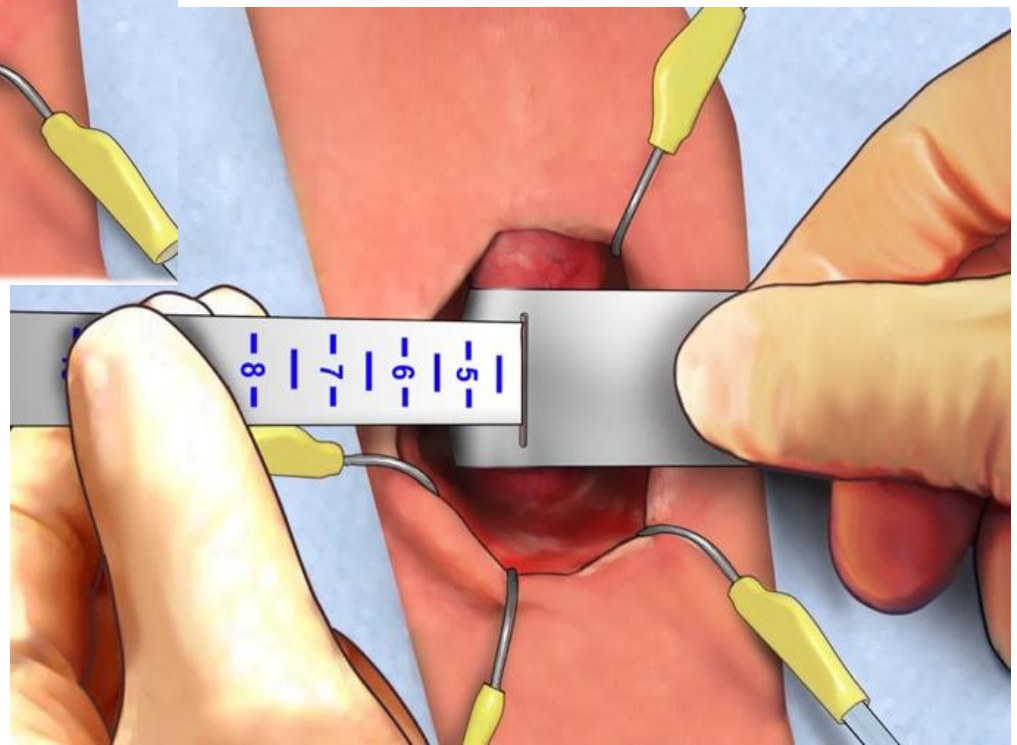
Single Incision, Perineal Approach



Dissect Circumferentially, Measure with Ruler





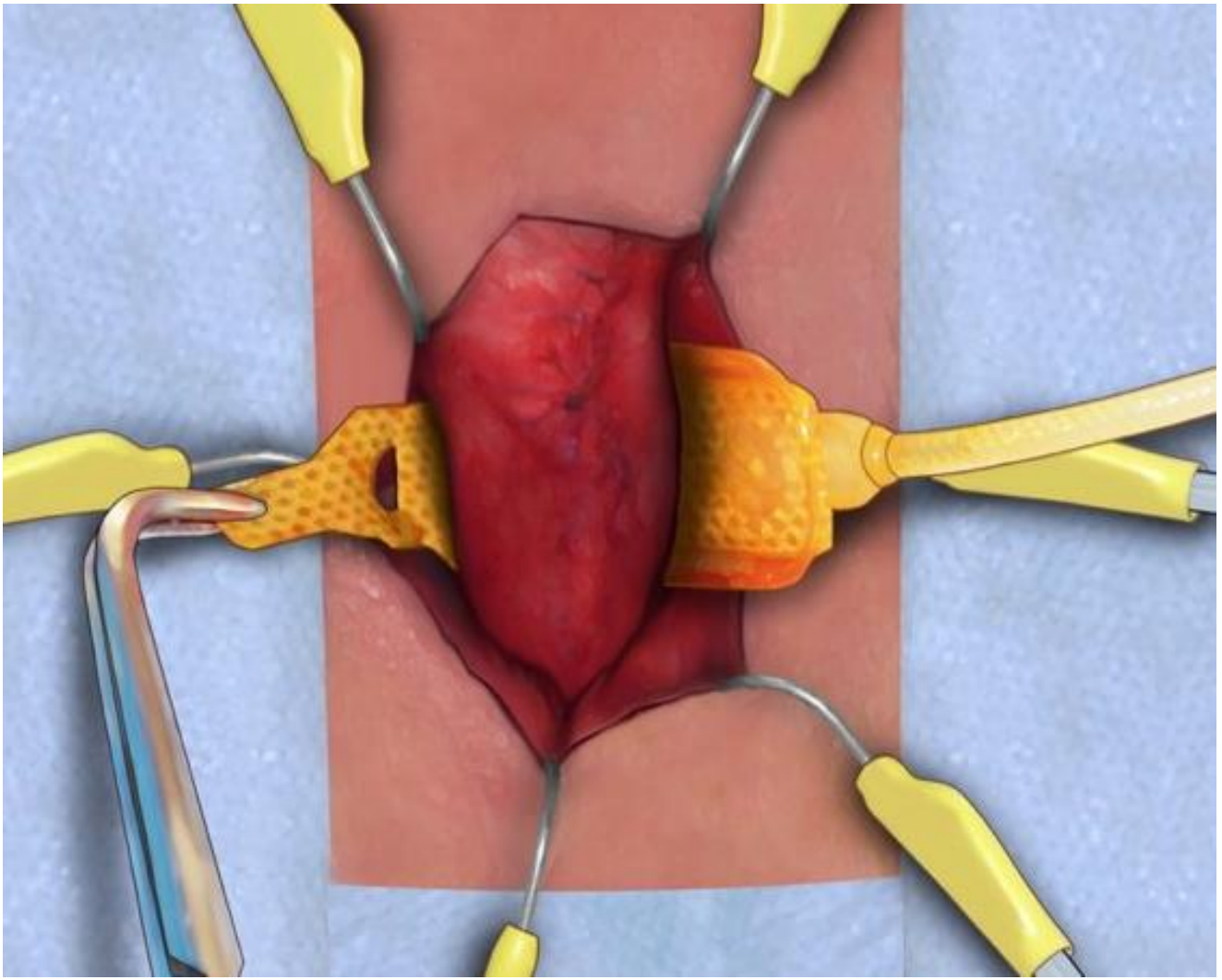


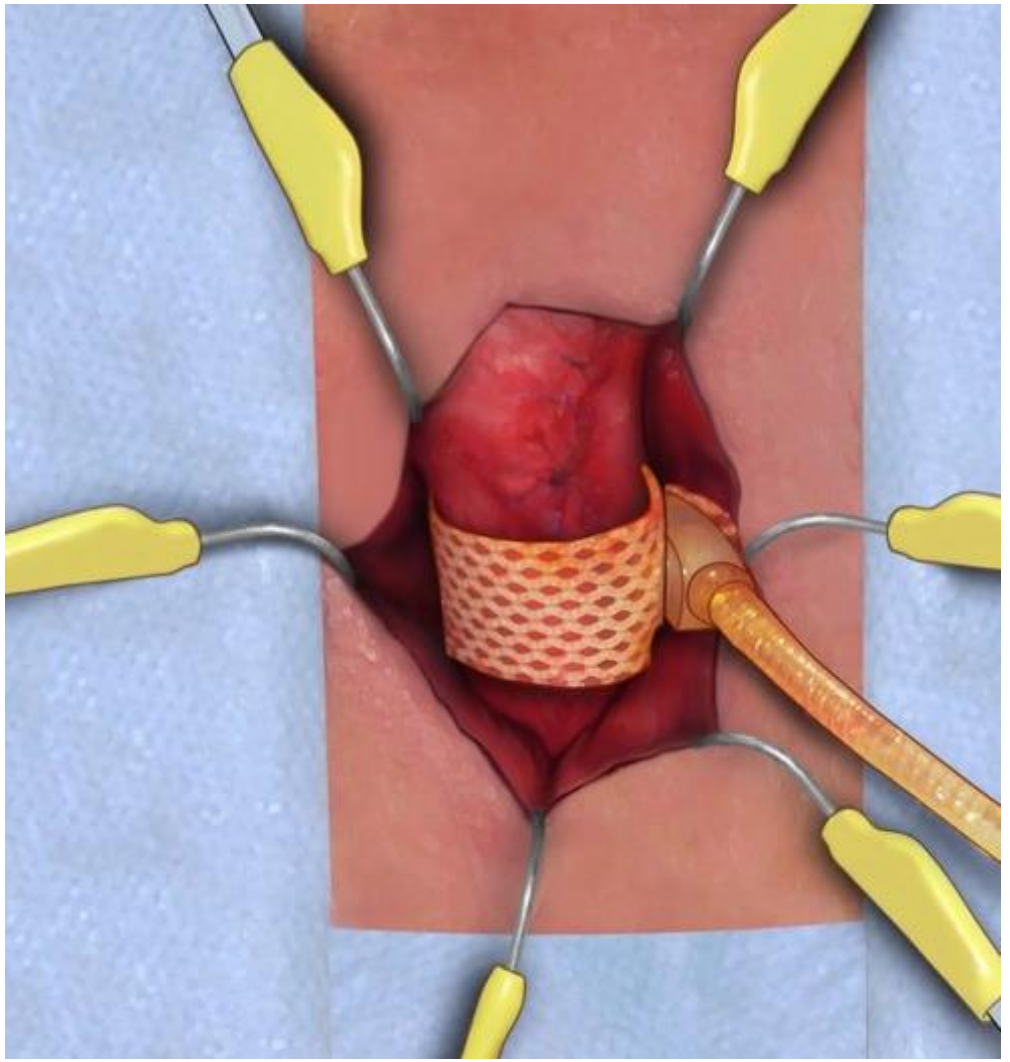
What Size is Best

- 2 schools of thought
  - Measure it, and then go up one size (0.5 cm)
  - Use best fit
- In general, AUS works almost always in the short term
- Looser cuff decreases risk/fear of erosion/atrophy
- Tighter cuff has better continence

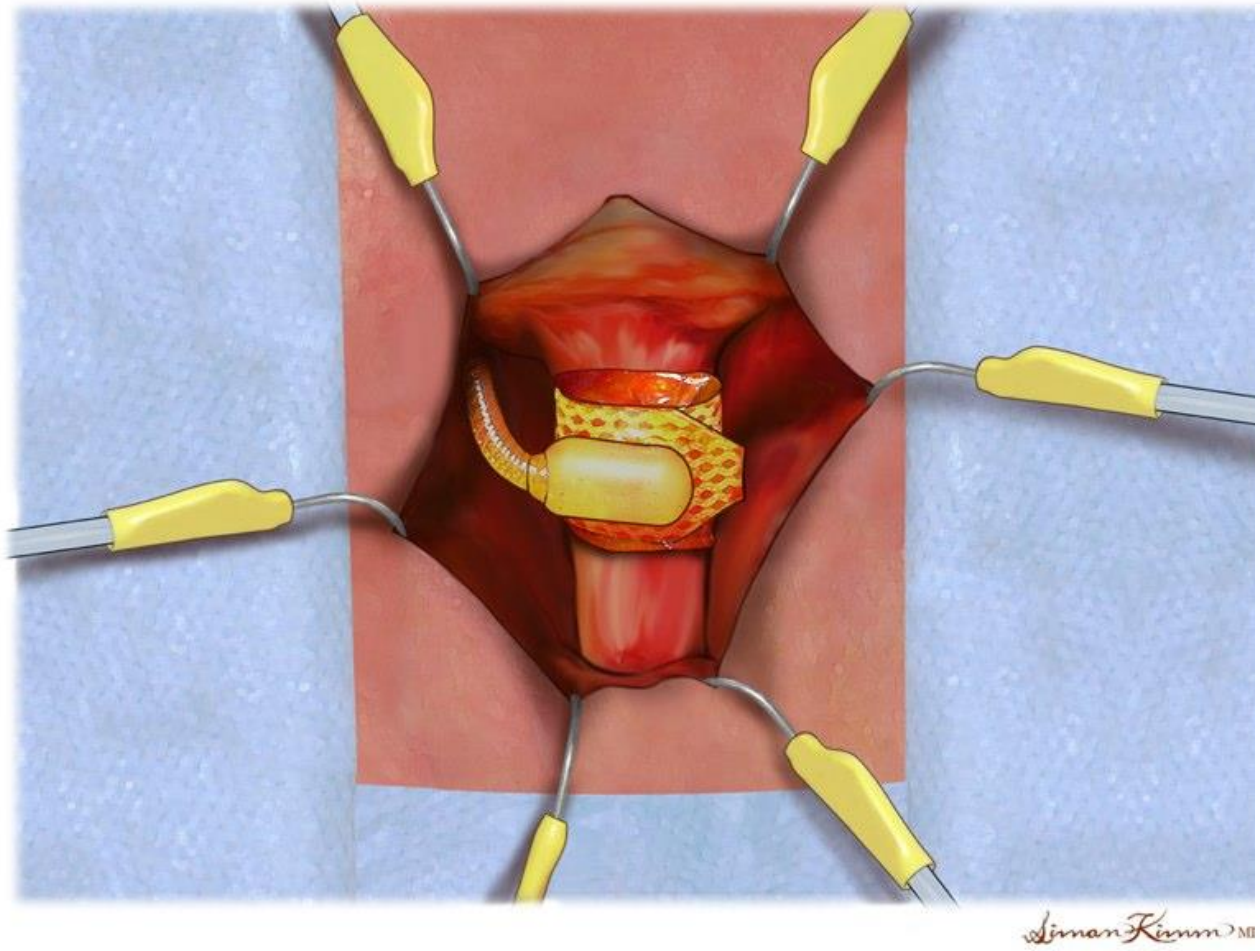
- Retention should be a “never” event
  - High risk of infection/erosion with foley, or even suprapubic tube
  - Consider immediate upsizing if not voiding within 3 days

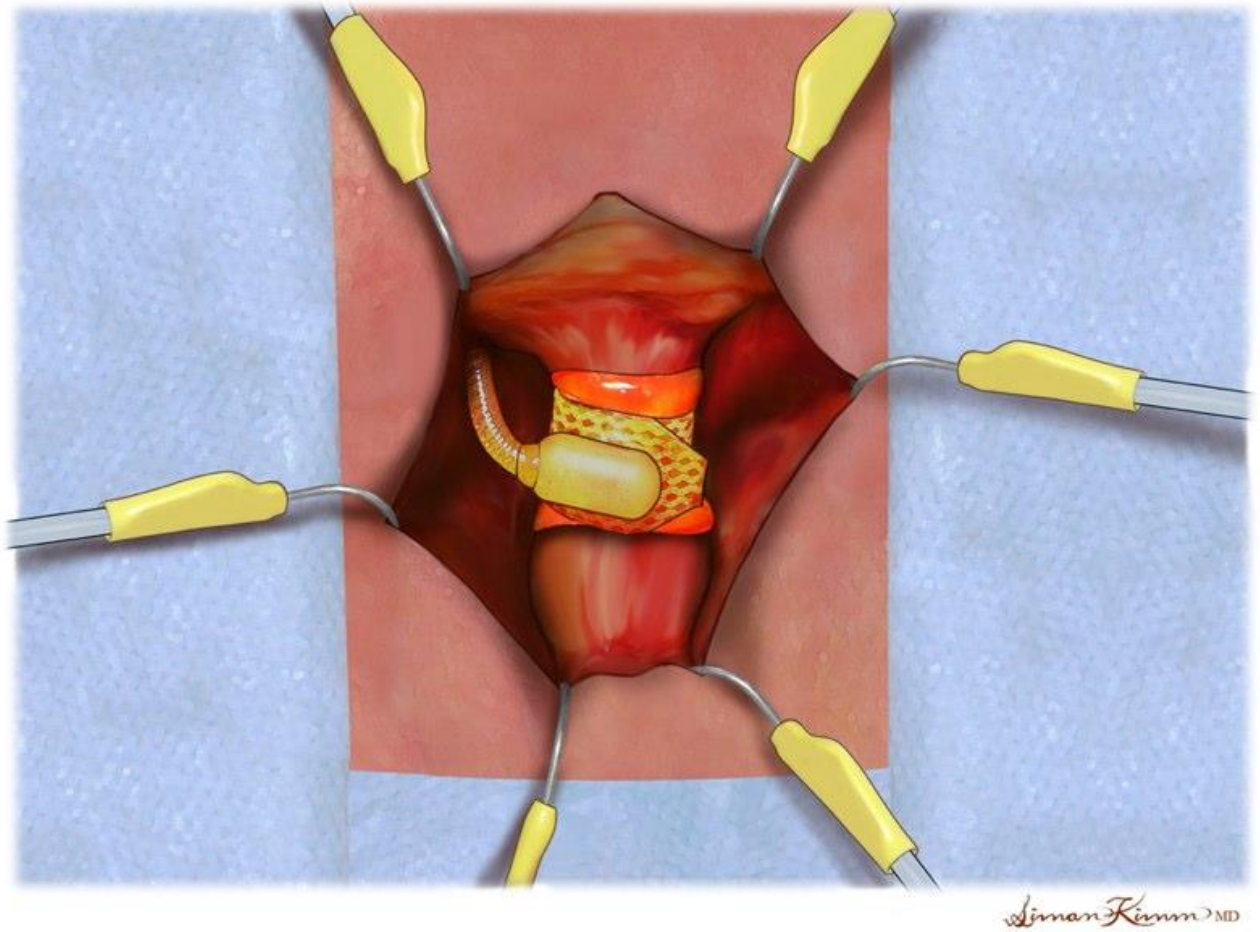
Cuff Fits Around Urethra, Can Easily Rotate





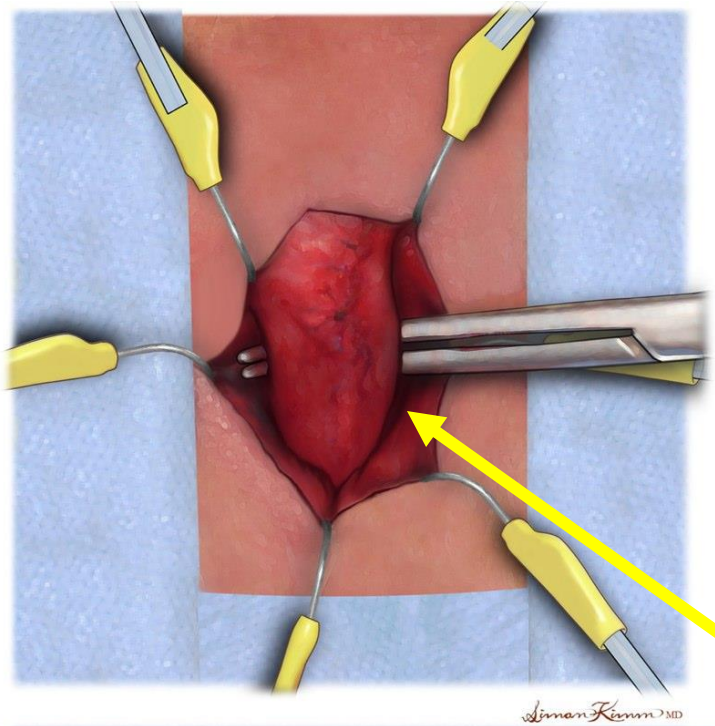
Cycle Intraoperatively, Obvious Filling and Emptying

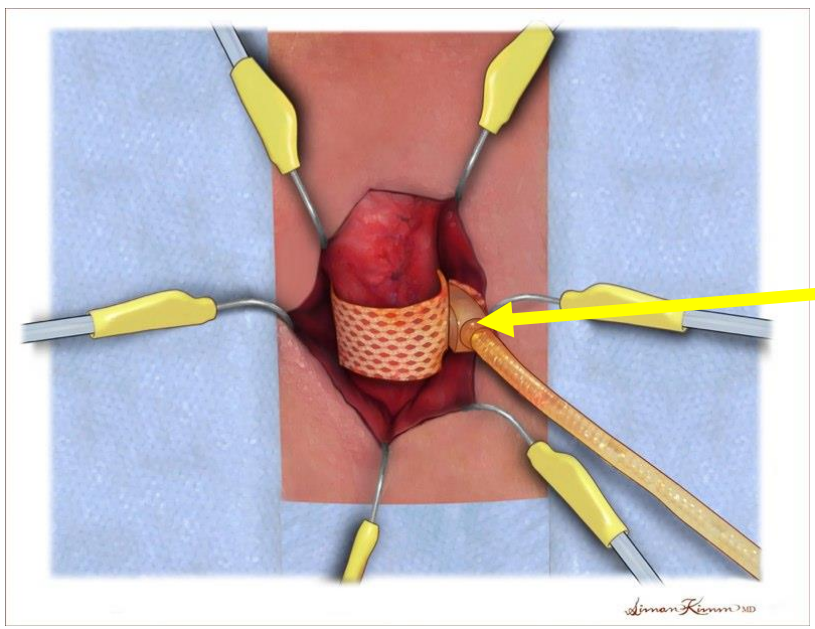


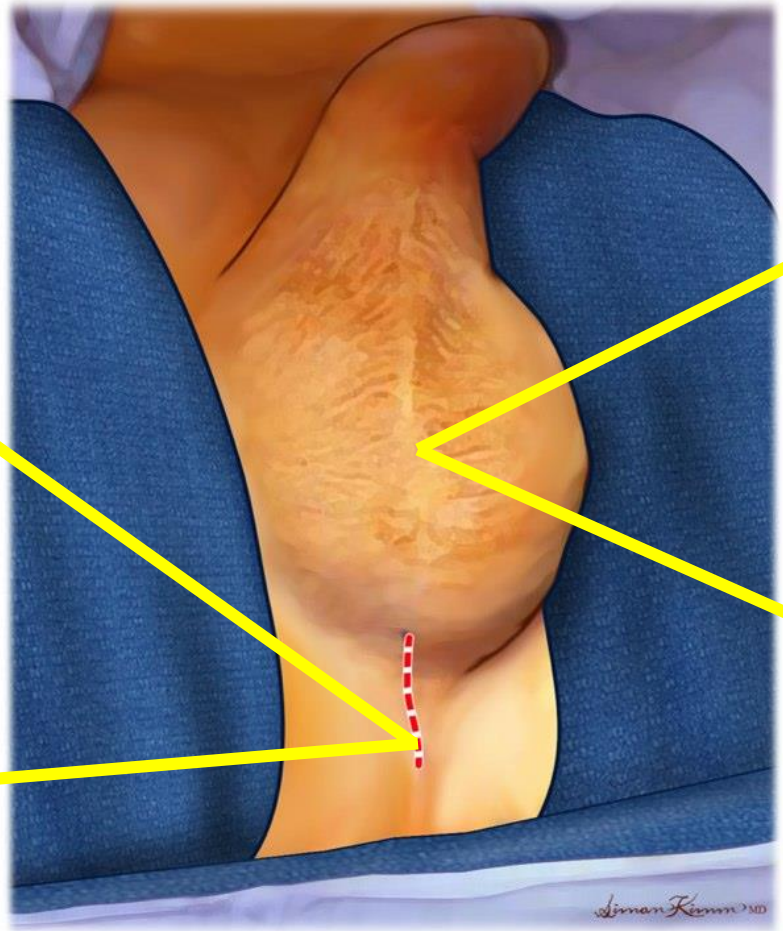


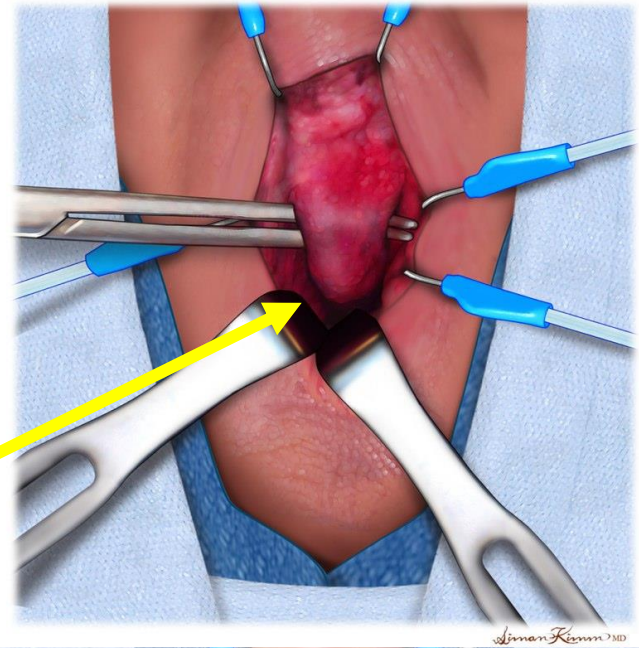
Perineal vs Trans-scrotal Approach

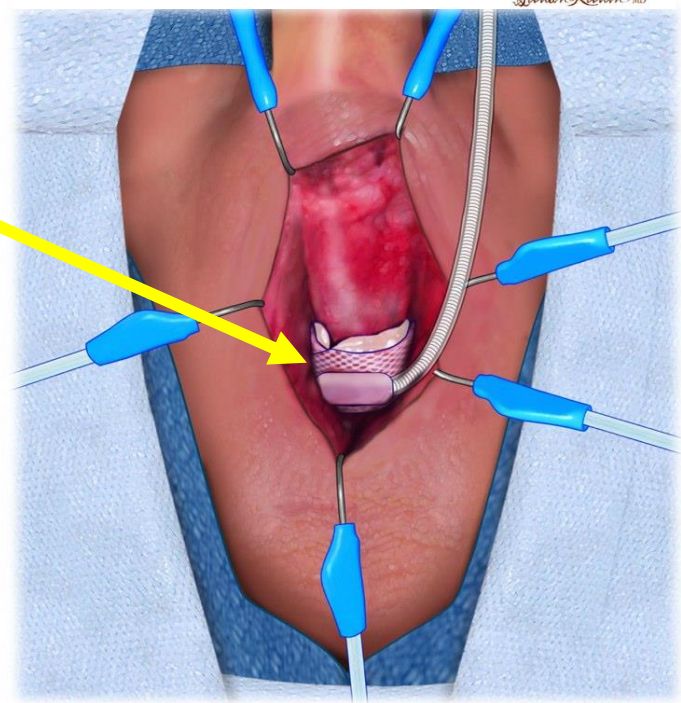
- AUS placement is feasible via a transverse scrotal incision
  - Wilson S, et al: J Urol, 2003
- However, it did not gain traction and was quickly abandoned as comparative studies indicate inferior outcomes.
- Increased complication rate/short-term explantation
  - 9% perineal versus 19% transverse scrotal
    - Kretschmer A. et al: Urol Int 2016.
- Transverse scrotal approach has decreased completely dry rates, and socially continent rates (< 1 pad per day)
  - Higher revision surgery due to continued incontinence.
    - Henry GD, et al: J Urol 2009.
- Failure of transverse scrotal approach likely due to a more distal cuff placement, along with an increase in complications and need for revision surgery.



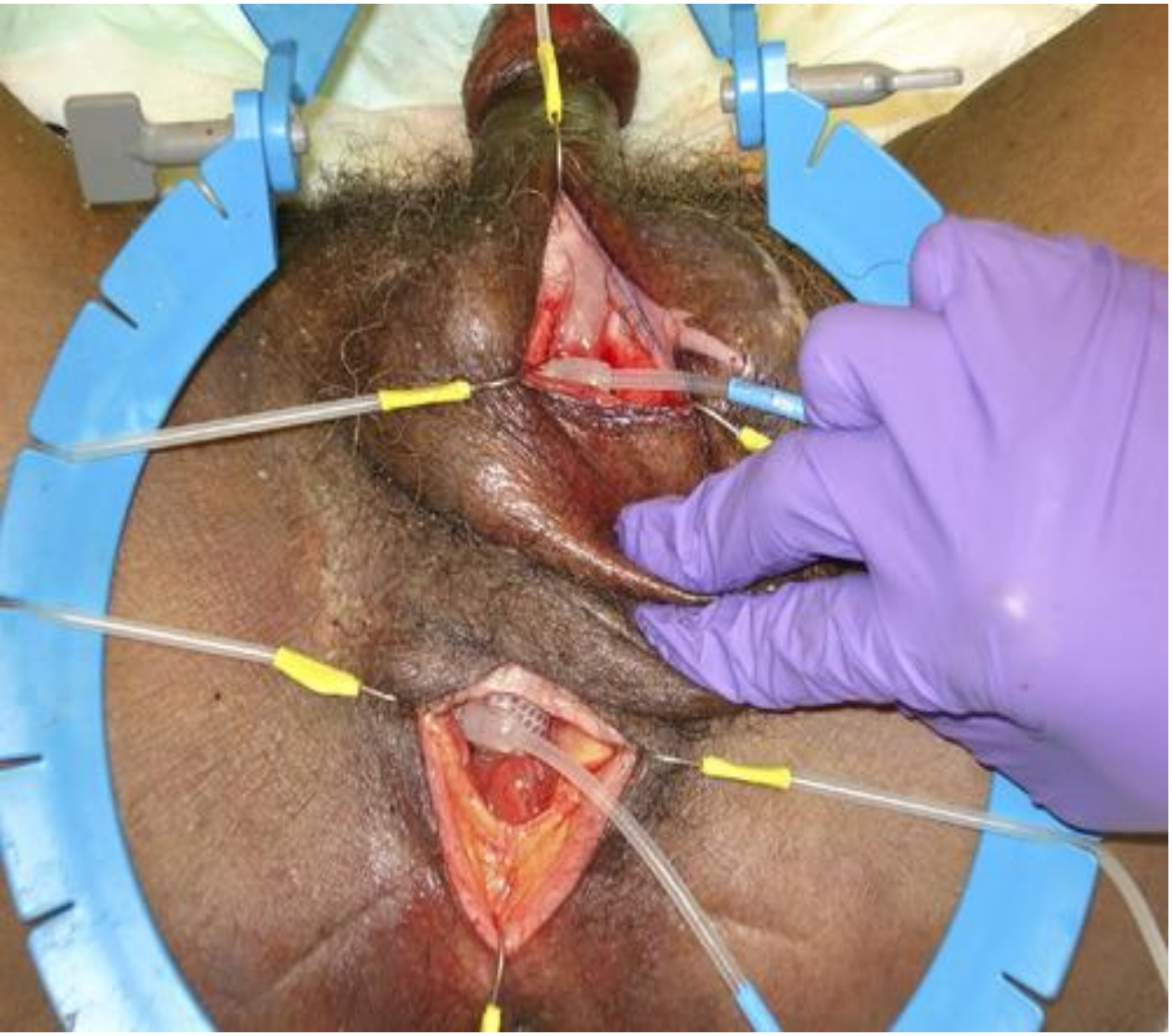








Cadaver Study

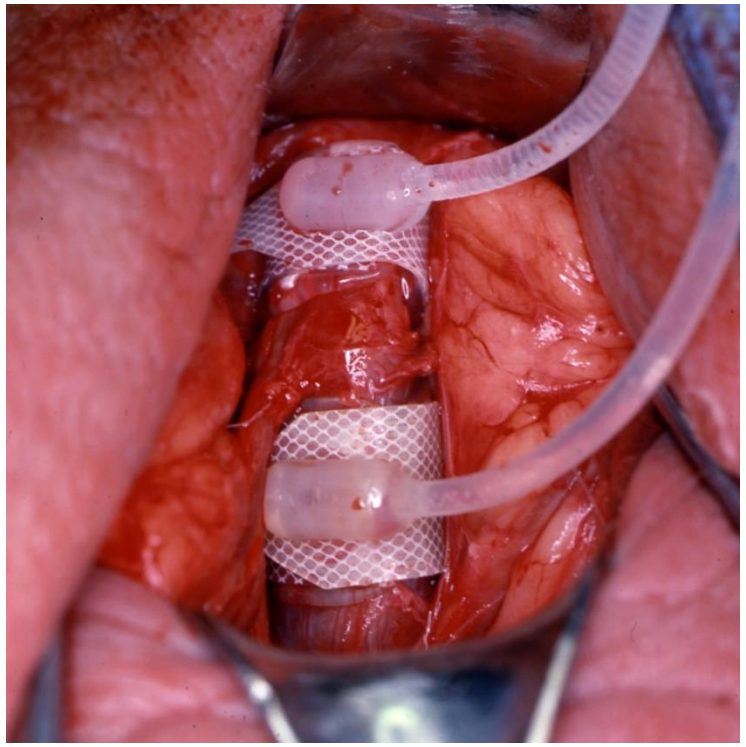


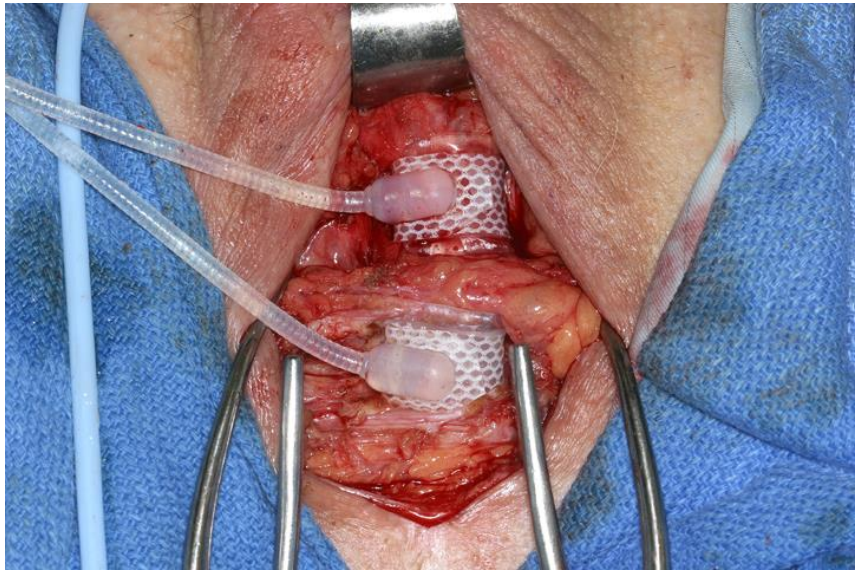
- Trans-perineal Approach
  - Mean circumference 5.38 cm
  - Mean RLPP 90.1 cm H2O
    - P<0.0001
- Trans-scrotal Approach
  - Mean circumference 3.81 cm
  - Mean RLPP 64.9 cm H2O
    - P=0.0002

    - Anusionwu I, et al: J Urol, 2012

Single versus Double Cuff

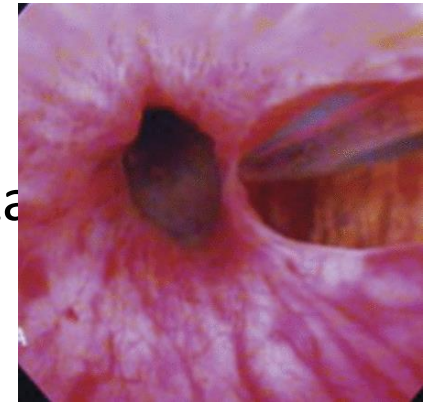
- Equivalent continence outcomes
- Increased risk of complications in the tandem cuff group.
    - Ahyai SA, et al. BJU Int 2016.
    - O'Connor RC, et al. 2008
- 124 tandem cuff vs 57 single cuff patients
    - Equal pad weight
    - Equal daily pad use
    - 17% risk of explant at 48 months in tandem cuff group
    - 4% risk of explant at 48 months in single cuff group.
        - Ahyai SA, et al, BJU Int 2016
- In another cohort, overall dry rate and daily pad use between the two groups was similar
    - Tandem cuff group had 12 additional surgeries related to complications versus 7 in the single cuff group.
        - O'Connor RC, et al, 2008
- **Single cuff via perineal approach is the standard technique for initial implantation**





Infection and Erosion

- Infection and erosion are the most common indications for early device explantation.
  - Infection rates are generally less than 5 percent, and urethral cuff erosion occurs at rates between 1 and 10 percent
    - Lai HH, et al: J Urol, 2007; Raj GC et al: J Urolk, 2005
- Early erosions likely related to unrecognized urethral injury during surgery
- Late erosions often due to subsequent urethral instrumentation/catheteriza
- Cuff erosion presentation: dysuria and hematuria.
  - Diagnosis is made cystoscopically
    - Kowalczyk JJ, et al, Urology, 1996; Motley RC, Barrett DM, Urology, 1990



- While the urethral defect typically heals with urethral catheterization, repair of the eroded urethra diminishes subsequent urethral stricture rates
    - Rozanski AT, et al, J Urol, 2014
- Following AUS erosion/infection, the entire device should be removed, followed by a waiting period of three to six months prior to reimplantation.
- Washout combined with immediate device replacement is not reliably effective
    - Bryan DE, et al J Urol, 2002.

Where do Erosions Occur – Ortiz J Urol 2020

- Ventral in 66.7% of TC and 79.5% of ST erosions.
- Lateral erosions in 33.3% of TC and 20.5% of ST erosions.
- Dorsal erosions in 20% of TC and 5.1% of ST)
- Comparison of the frequency of cuff erosion location between ST and TC AUS revealed no significant difference between the 2 groups (p=0.1).

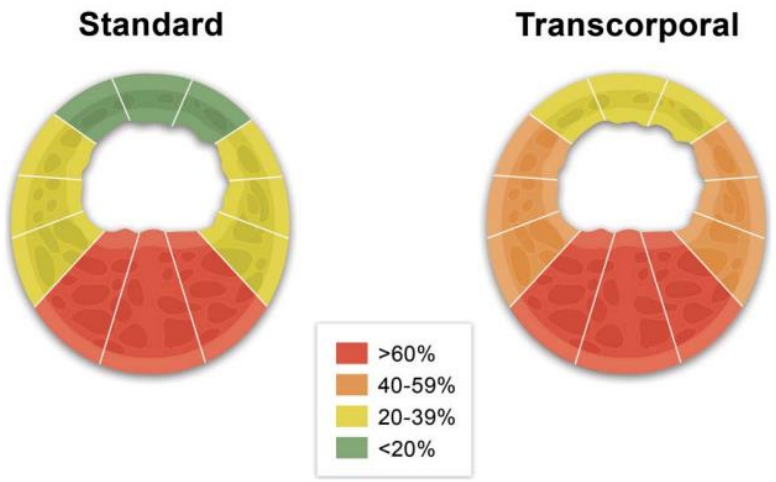


Figure 2. Distribution of urethral erosions among patients with ST and TC cuff placement.

Table 3. *Cox regression analysis of risk factors for AUS cuff erosion*

	HR	95% CI	p Value
Placement (ST vs TC)	1.6	0.8–3.1	0.1
Prior urethral surgery	6.0	3.1–11.5	<0.05
Prior AUS erosion	0.5	0.2–1.1	0.1
History of radiation	3.5	1.9–6.5	<0.05
Cuff size (3.5 cm vs others)	1.3	0.7–2.5	0.3
Diabetes	0.9	0.4–1.8	0.7
Coronary artery disease	3.7	2.1–6.4	<0.05
Hypertension	0.9	0.5–1.7	0.9

Why do Cuffs Erode?

- AUS cuff erosion is likely a multifactorial process.
- Risk factors include previous urethral surgery, radiation and hypogonadism.
    - Hofer, Urology, 217
- Unlikely from iatrogenic injury:
    - erosions occur predominantly in the ventral area of the urethra, whereas it is believed the dorsal urethra is most at risk during difficult dissection
- Ventral urethral has the thickest cross-sectional area of spongiosum.
    - Ventral surface is directly exposed to frequent and significant external perineal pressure, such as prolonged sitting on hard surfaces.
    - External perineal pressure may exacerbate ischemia and subsequent tissue atrophy. Previous and ongoing disease processes and treatments, such as radiotherapy, may compound this process.

My observations over a quarter century

- Several days of pre-op antibiotics, prolonged post-op antibiotics, Inhibizone have not been shown to help, so please save my planet and be judicious with antibiotics…
- Infection should be very rare
  - Respect sterility
  - Irrigate copiously
  - Keep your fingers out of my wound!
  - Go faster – 2 teams -- 1 for abdominal balloon placement and other for perineal cuff
  - Do not put in the cuff, then go prep the balloon, and start inguinaly, leaving the cuff to get infected. Balloon should already be in place!
- Erosion in a non-radiated, virgin surgery, eugonadal man, cuff $\geq$ 4.0 cm is almost never
  - But I do not get to do many AUS placements in these men anymore….
- Erosions in radiation, revision, 3.5 cm cuff, urethroplasty, hypogonadal patient are not rare
  - So my erosion rate has gone up over time, as the male sling has stolen my easy AUS implantations
- So just do the best you can….

Handout WS 3, 2024 - Anding

FIXED SLINGS, CHALLENGES AND CRITERIA FOR SUCCESS

Male slings are supposed to reestablish the baseline continence provided by the smooth muscle system as well as supporting the external urethral sphincter during straining. The sling is placed under the bulbar urethra and passed through the obturator foramen. The surgery includes transection of the central tendon and mobilisation of the bulbous urethra. The sling ends are bilaterally guided through the obturator foramen in a typical outside-in fashion. The urethral bulb is fixed to the central part of the sling and then lifted upwards, however compression of the urethra must be avoided. In theory, sphincteric function can be restored by repositioning and anchoring of the proximal urethra.

The most critical factor of success in male slings is a thoroughly established indication. As a generally accepted classification of male incontinence is still lacking, a threshold of >200 g of urine loss/24h should be regarded as severe incontinence because of less favorable results of fixed slings that are suitable for cases of mild to moderate incontinence. A simple pad count is a poor measure of urinary incontinence severity because of the poor correlation with actual urine loss. Also, little changes in daily activity have a significant impact on 24h pad weight.

A crucial step for a good indication is the endoscopic urethral repositioning test with critical evaluation of urethral tissue quality, anastomotic width, sphincteric length, and mobility of the bulbar urethra. In the ideal patient, with parallel elevation of the perineum to the urethral axis a concentric closure of the external sphincter and a lengthening of the active sphincter zone can be observed.

Age at surgery does not seem to be a prognostic factor for (AdVance-XP) male sling efficacy, as presented with 7 years data by the Munich group.

A substantial difference in continence rates can be observed after previous radiotherapy. The risk for failure of male slings is significantly higher with a history of pelvic irradiation. In cases of local prostate cancer recurrence, incontinence surgery should be accomplished before radiation therapy. The decision for surgery should then not be determined by the status of cure as quality of life matters equally in a palliative setting. Also, psychological aspects in decision-making must be considered. When the decision is in the balance, the majority of patients favors a non-mechanical device like a fixed sling. Only a small minority desired the more definitive procedure (AUS) with a proven track record. Due to a recent study 20% of patients with male SUI reported decisional regret, shared decision-making was associated with less regret.

ADJUSTABLE HYDRAULIC SPHINCTERS

In the last decades the artificial urinary sphincter has been regarded as the definitive management for urinary incontinence in men, particularly after radical prostatectomy. In the majority of cases even high patient expectations can be realized. The AMS 800 sphincter prosthesis is still a mainstay of treatment for moderate to severe stress incontinence in men.

However, other hydraulic systems like the Zephyr™, Victo™, and ContiReflex™ seem to offer similar qualities adding the possibility of postoperative adjustment.

The ZSI 375 (Zephyr™) consists only of a preconnected (one-piece) cuff and pump that facilitates implantation. The regulation unit covers both the function of a pressure regulating reservoir as well as the opening pump mechanism. It involves two hydraulic compartments, one to fill the cuff and a second one regulating the pressure in the

system. Implantation can be performed through a single perineal approach or via two incisions (perineal and inguinal). The ZSI 375 provides adjustability by percutaneous filling at any time after implantation. A success rate of 72-78% is reported, associated with a revision rate of 8% at 7 years after implantation. Kretschmer et al found less favourable results in a small multi-center study.
The Victo sphincter is also one-piece implant that consists of a cuff, a pump, a balloon, and optionally an additional intraabdominal balloon for conditional pressure increase (Victo plus). Therefore, sudden pressure rises are transferred from the intraabdominal stress-balloon to the cuff. This allows for decreasing the resting pressure in the cuff to a minimum. The pressure within the system can be adjusted at any time after implantation by puncture of a self-sealing port within the pump. Implantation is performed through a perineal and inguinal incision. At 12 months, a success rate of 76.4% is reported with no significant difference between the Victo and Victo plus that is hardly being used anymore.
The new Rigicon™ AUS device ContiReflex also contains an extra stress relief balloon to provide a safeguard on the urethral cuff against a sudden increase in intra-abdominal pressure. Better adjustability is realized with a greater range of cuff sizes with 0.25 cm diameter increments compared to the 0.5 cm steps with the AMS 800. Preliminary data show a survival rate of 93.2% at 12 months and a revision rate of 6.9%, with three (of 116) cases of fluid loss. No success rates are reported, yet.
Differences and limitations of all established and novel devices will be discussed in order to avoid failures and poor results. Highly experienced urologists will discuss the current options for an optimal counseling and a special focus on contraindications.

Troubleshooting the Failed Artificial Urinary Sphincter

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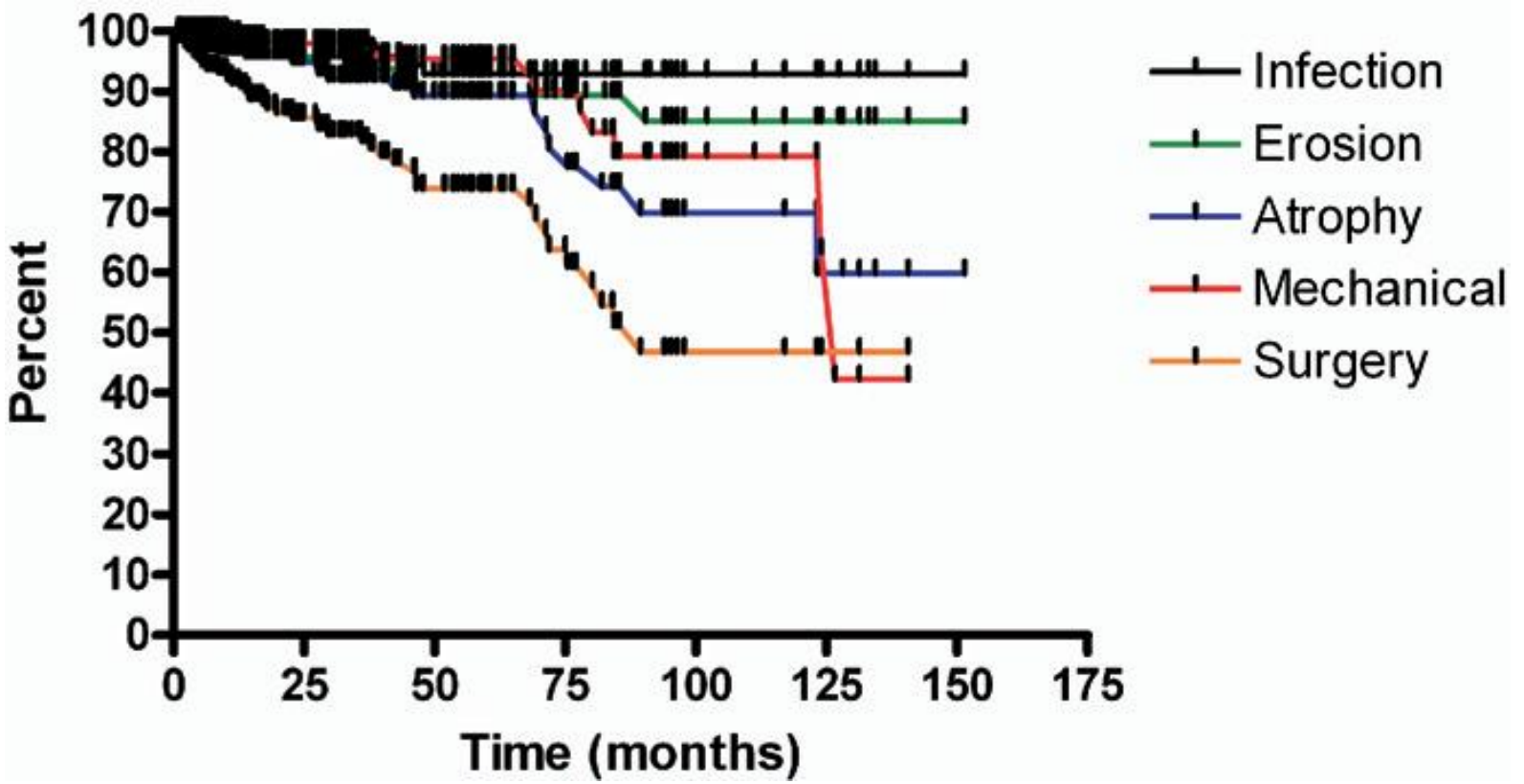
Rates of AUS Failure

- Baylor series
- 13 years
- 218 patients
- Mean f/u of 13 years
  - 6% infection
  - 6% cuff erosion
  - 6% mechanical failure
  - 10% urethral atrophy
- Revision surgery
  - 25% at 5 years
  - 5% at 10 year



Lai HH et al. J Urol 2007 177: 1021-1025

SO…..

IF YOU ARE PLACING ARTIFICIAL SPHINCTERS,

FAILURES WILL OCCUR

Causes of AUS failure stratified by timing

Early AUS failure - persistent incontinence after device activation

Cuff size is too large

Insufficient reservoir pressure

System leak

Detrusor overactivity

Overflow incontinence / Urinary retention

Inadvertent device deactivation

Early cuff erosion

Late AUS failure – recurrent incontinence

Inadvertent device deactivation

Device malfunction – fluid leak

Urethral atrophy

Urethral erosion

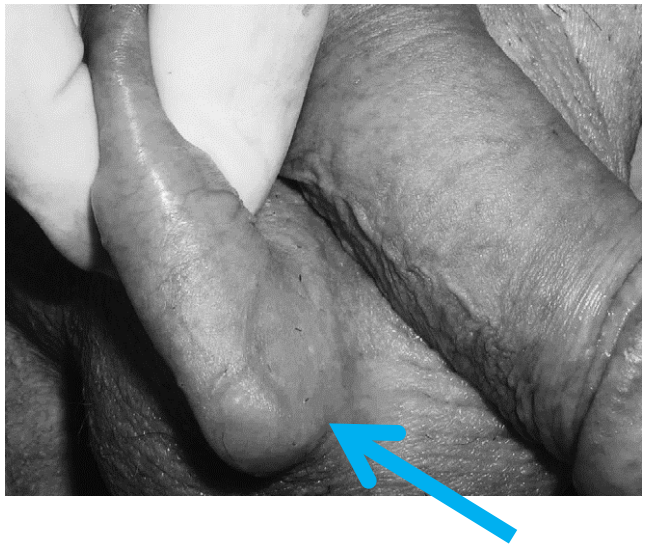
De novo detrusor overactivity / decreased bladder compliance

Steps to Identify the Cause

- History
  - Did the device ever work – if so how well ?
  - What is the current degree of incontinence ?
  - Did incontinence return suddenly or slowly ?
    - Sudden – device failure
    - Slow - atrophy
  - Any signs of UTI ?
  - Is the incontinence due to stress maneuvers (vs urge) ?

  - Did anything happen just prior to incontinence ?
    - Foley placement
    - Trauma of some form

Physical Exam

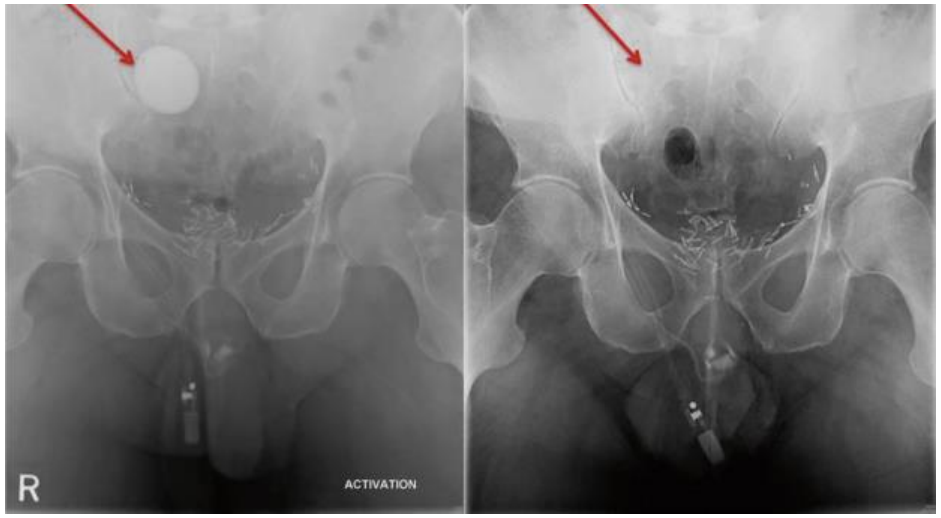


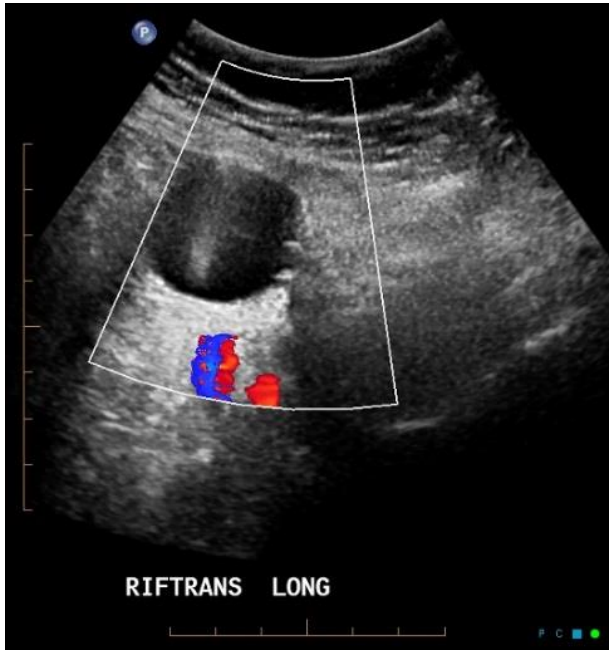
- Examine the pump
  - If under-filled (dimpled) this is the problem
    - Deactivated or leak
- Note the number of squeezes to open the cuff
  - If this is excessive it can indicate atrophy [1]
    - Pt history can aid with this diagnosis
      - “Over time having to pump more and more to open”
- Post-void residual
  - Should be close to zero

Webster GD et al. Curr Opin Urol 2005 15: 386-390

Recurrent Incontinence – Fluid Loss

- Device should be cycled by the urologist to assess functionality.
- Imaging to verify the presence of fluid in the reservoir to rule out a leak.
  - However only 2cc of leak can lead to malfunction (HARD TO SEE)
- During exploration, if a leak is confined to one part of the device, the remaining components may be left *in situ* if they were placed within the prior two years
    - Lai HH, et al, J Urol, 2007; Maillet F, et al, Eur Urol, 2004; Peterson AC, Webster GD, Urol Clin North Am, 2011





Urodynamics

- Performed if the diagnosis is unclear
  - Detrusor overactivity versus inadequate coaptation (ISD) as the cause
- Filling cystometrogram
  - DO or poor compliance
- Assessment of Sphincteric Integrity
  - Abdominal Leak Point Pressure
  - Retrograde Leak Point Pressure / Perfusion Sphincterometry [1]
  - Urethral Pressure Profilometry
    - All three with system open and closed
- Voiding Phase

Comiter CV, Sullivan MP, Yalla SV: Urology, 1997

Leak Point Pressure

- MUCP
- ALPP
- RLPP

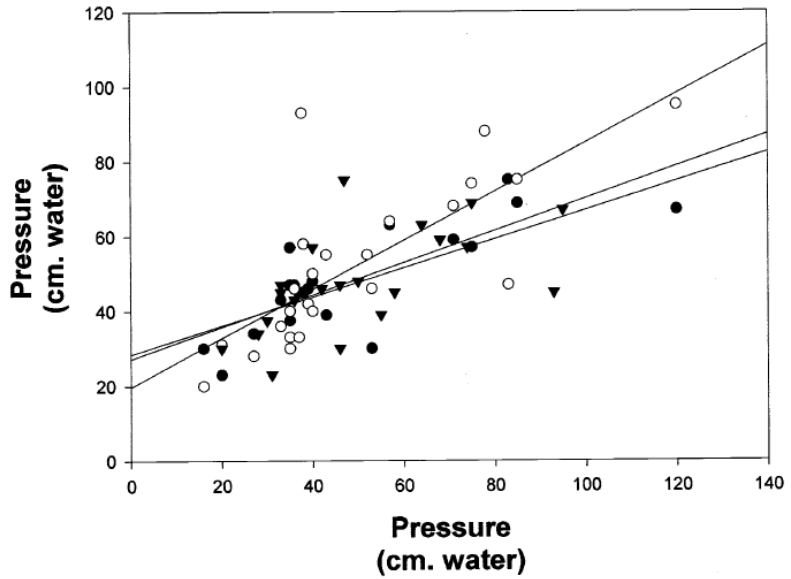
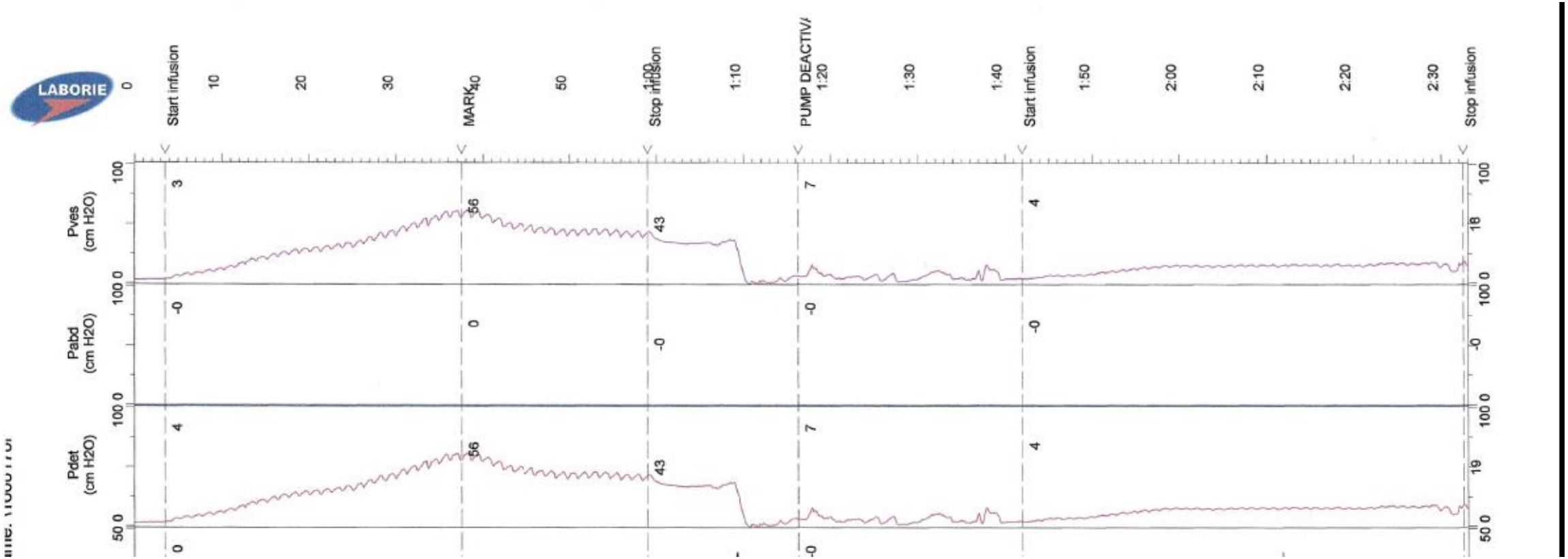


FIGURE 2. *Correlation among leak point pressures. Filled circle, ALPP vs. RLPP (r = 0.79, P <0.001); open circle, ALPP vs. MUCP (r = 0.75, P <0.0001); triangle, MUCP vs. RLPP (r = 0.59, P <0.005).*

MUCP, ALPP and RLPP are highly correlated in men with PPI and can be used interchangably

Comiter CV et al. Urol 2003 62: 75-78

Retrograde Leak Point Pressure



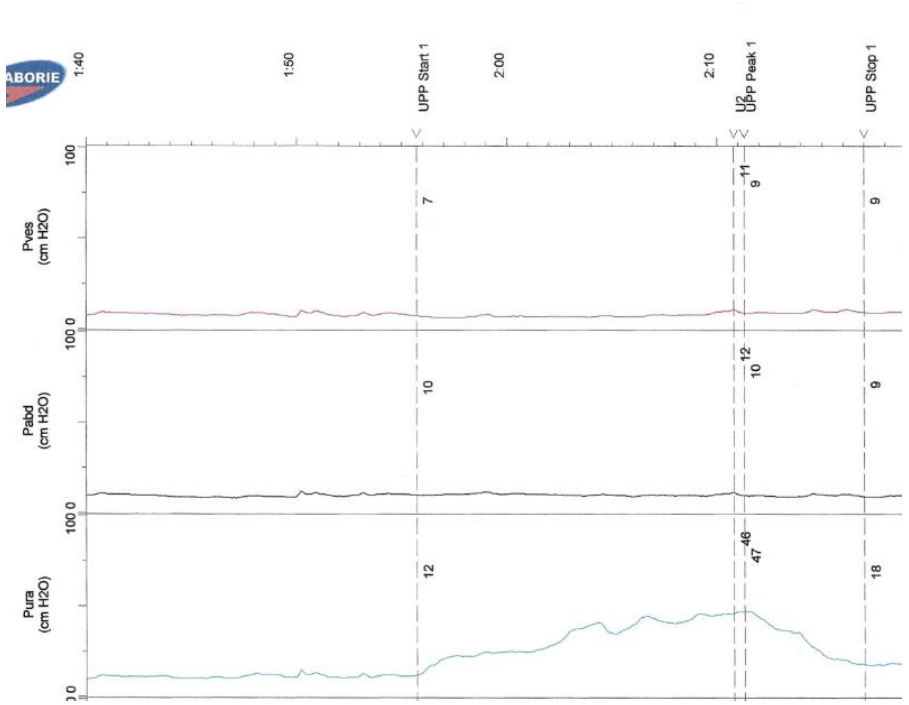
AUS ON

RLPP = 53

AUS OFF

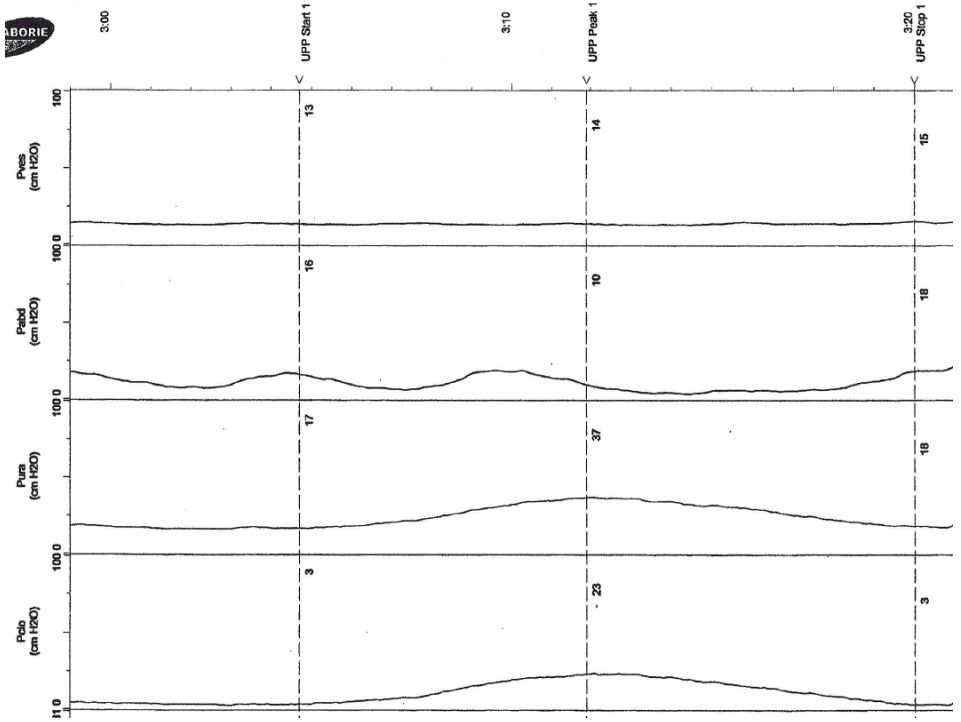
RLPP = 12

UPP (Cuff Atrophy)

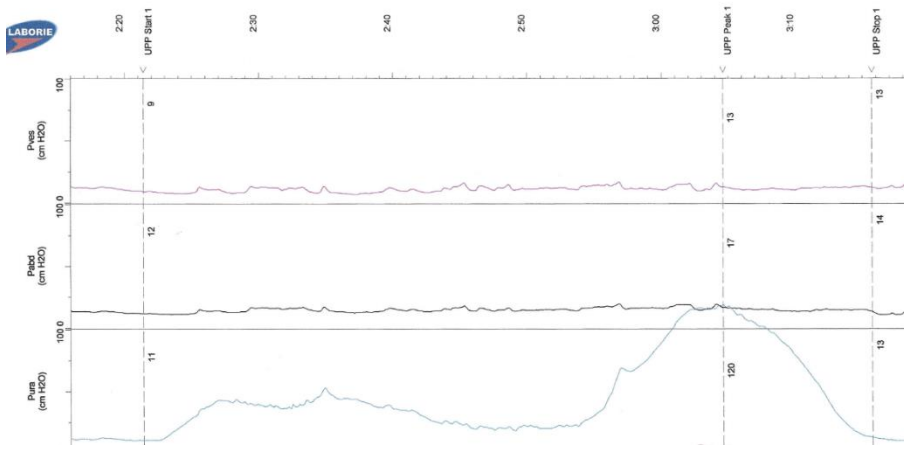


AUS On MUCP = 35

Pressure Differential of < 40 suggests cuff atrophy



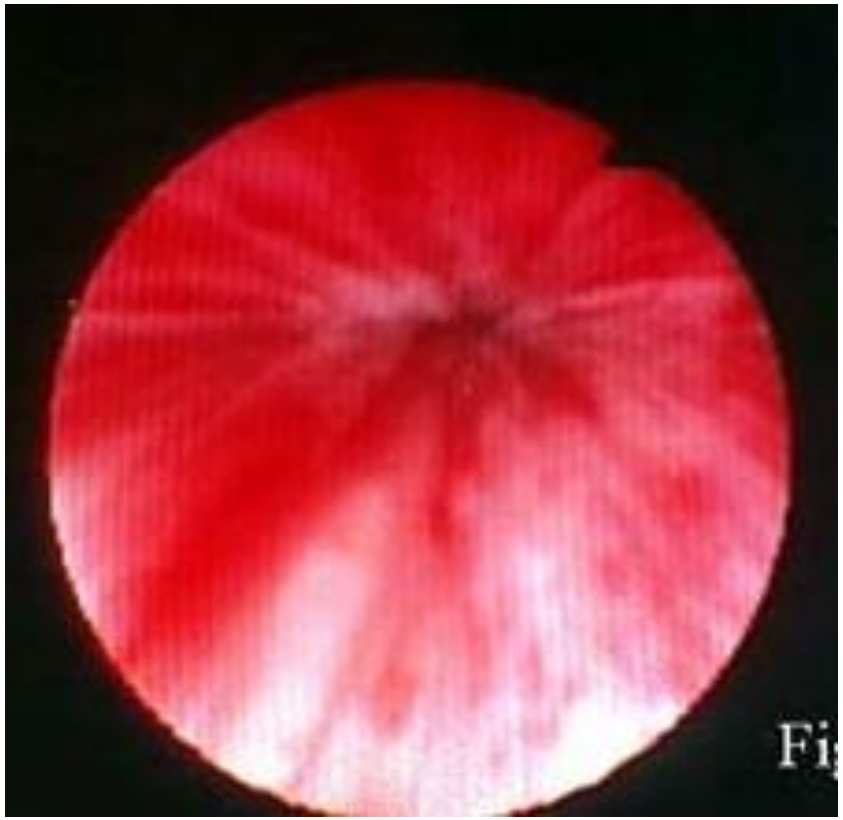
AUS Off MUCP = 20



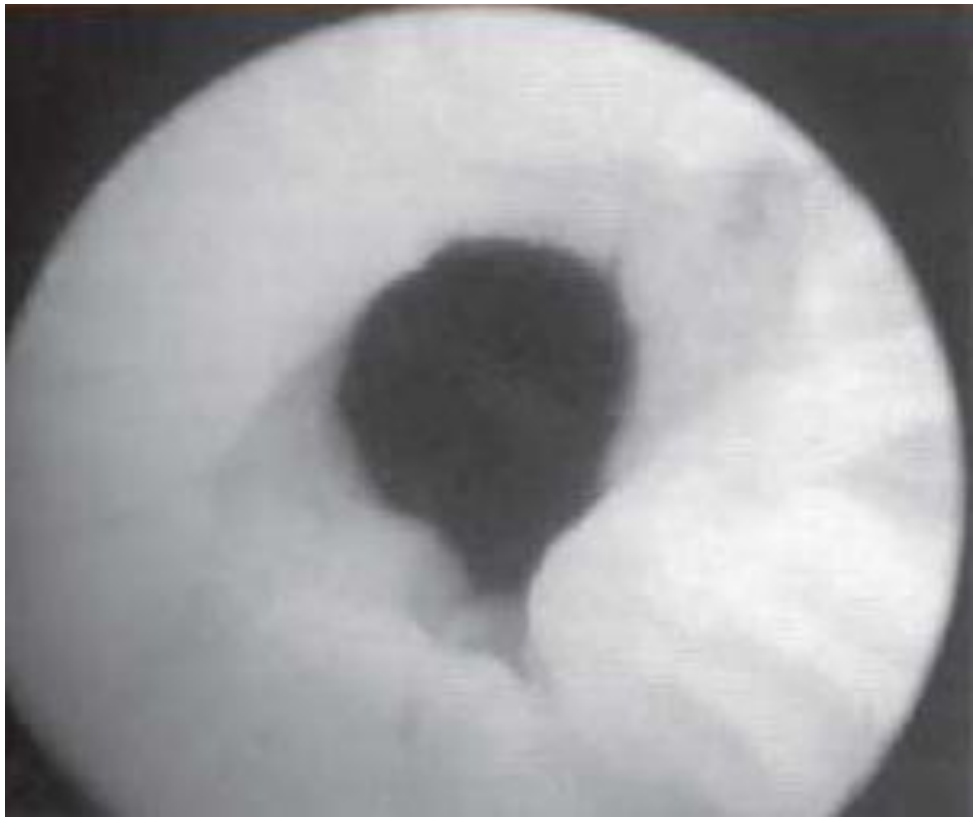
AUS On MUCP high (functions well)

Cystoscopy

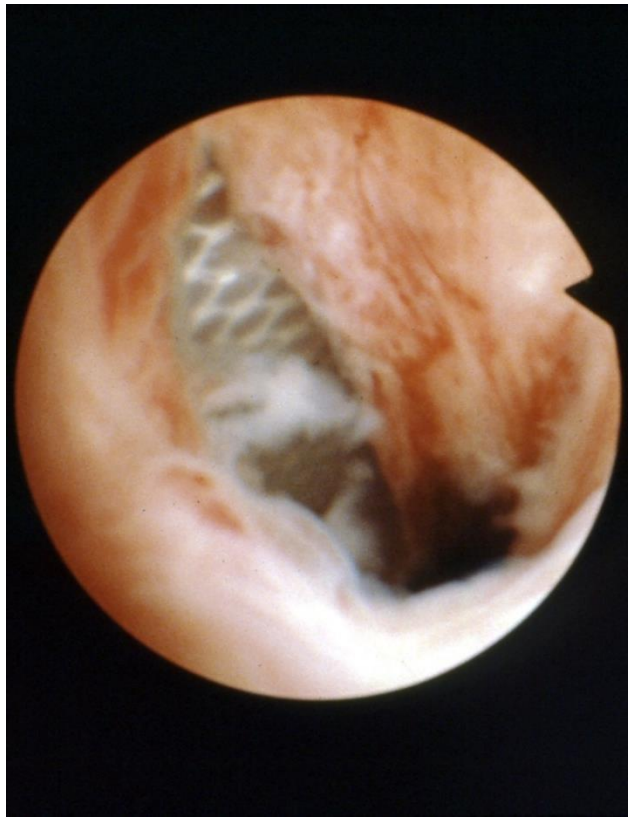
- Performed with the sphincter both opened and closed



Coapting



Noncoapting



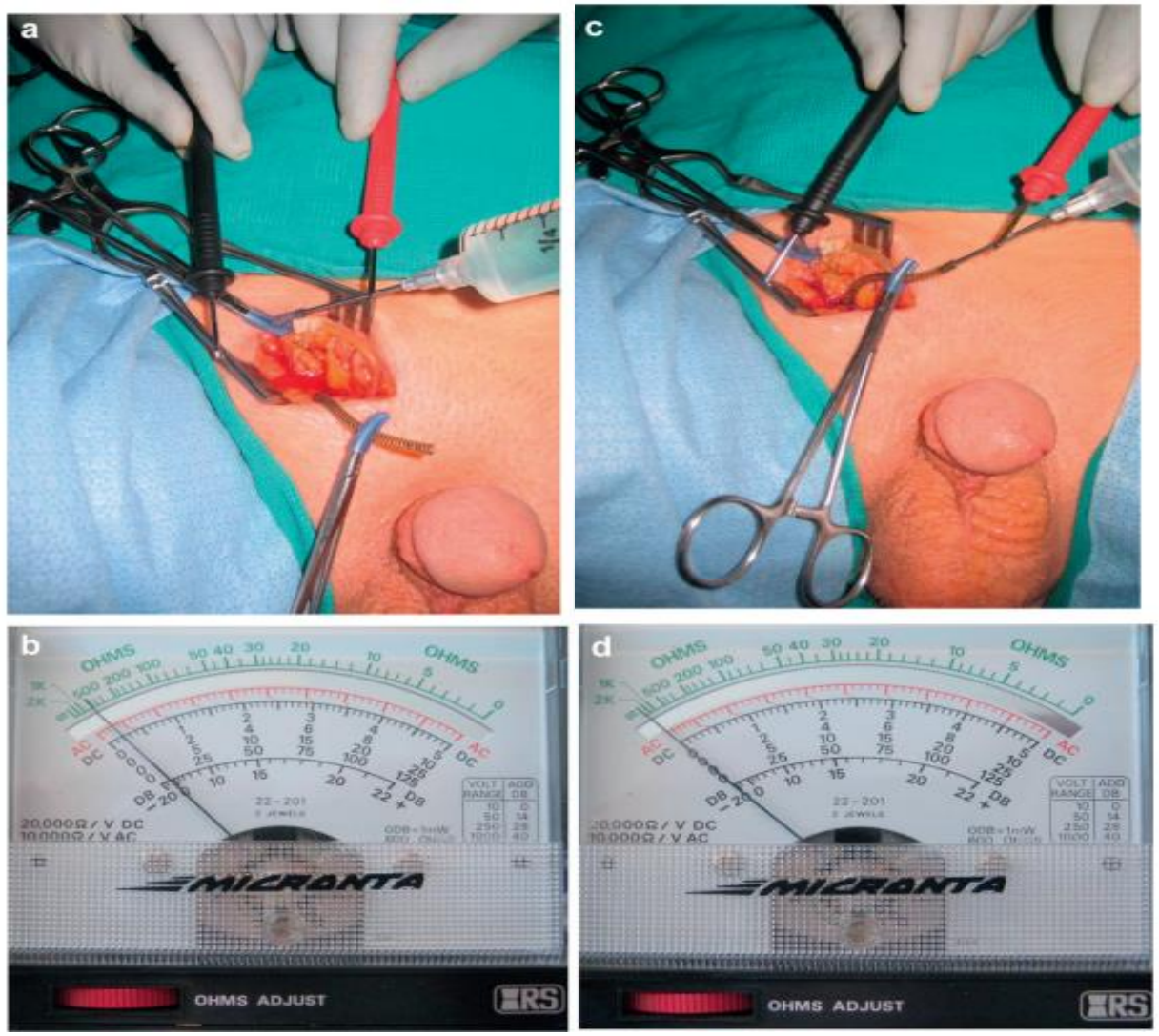
Eroded

Infection and Erosion

- Infection and erosion are the most common indications for early device explantation.
  - Infection rates are generally less than 5 percent, and urethral cuff erosion occurs at rates between 1 and 10 percent
    - Lai HH, et al: J Urol, 2007; Raj GC et al: J Urol, 2005
- Early erosions likely related to unrecognized urethral injury during surgery
- Late erosions due to subsequent urethral instrumentation/catheterization.
- Cuff erosion presentation: dysuria and hematuria.
  - Diagnosis is made cystoscopically
    - Kowalczyk JJ, et al, Urology, 1996; Motley RC, Barrett DM, Urology, 1990
- While the urethral defect typically heals with urethral catheterization, repair of the eroded urethra diminishes subsequent urethral stricture rates
    - Rozanski AT, et al, J Urol, 2014
- Following AUS erosion/infection, the entire device should be removed, followed by a waiting period of three to six months prior to reimplantation.
- Washout combined with immediate device replacement is **not** reliably effective
    - Bryan DE, et al J Urol, 2002.

How to use the Ohmmeter

- Inguinal incision to expose the tubing connection sites
- Clamp tubing from PRB to pump and from pump to cuff (shodded)
- 1 electrode grounded on patient, other on needle passed into tubing
- ANY deflection of needle signifies a leak in the component

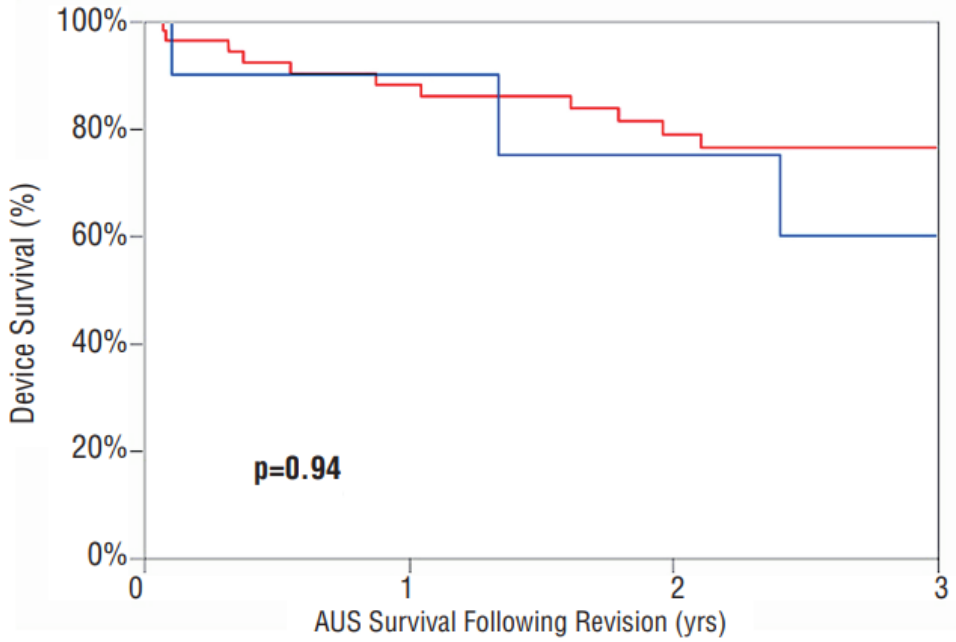


Urethral Atrophy

- Proximal relocation or downsizing of the cuff
- Tandem cuff placement
- Trans-corporal cuff placement to improve urethral coaptation, especially in the setting of prior radiation and/or erosion.
  - Urethral cuff is tunneled through the erectile bodies, whereby the tunica albuginea protects the dorsal aspect of the urethra.
- Balloon reservoir replacement
    - Moses RA, et al, Urology, 2019
  - PRB pressure declined by more than 10 cm H2O n 66.7% of patients with recurrent SUI
    - Pearlman AM, et al, Investig Clin Urol, 2018
  - But with device > 2 years old, while balloon failure may be primary cause, it is recommended to replace all 3 components due to wear and tear
- Efficacy and durability after secondary AUS placement for device failure appear to be similar to that after primary AUS placement
  - Slightly higher rate of cuff erosion
    - Raj GV, et al J Urol, 2005; Linder BJ, et al, J Urol, 2014; Lai HH, et al, J Urol, 2012
- Patient satisfaction relates more to continence than to number of reoperations
    - Gousse AE et al, J Urol, 2001; Viers BR, J Urol, 2016

Single Cuff Downsizing vs Tandem Cuff Placement

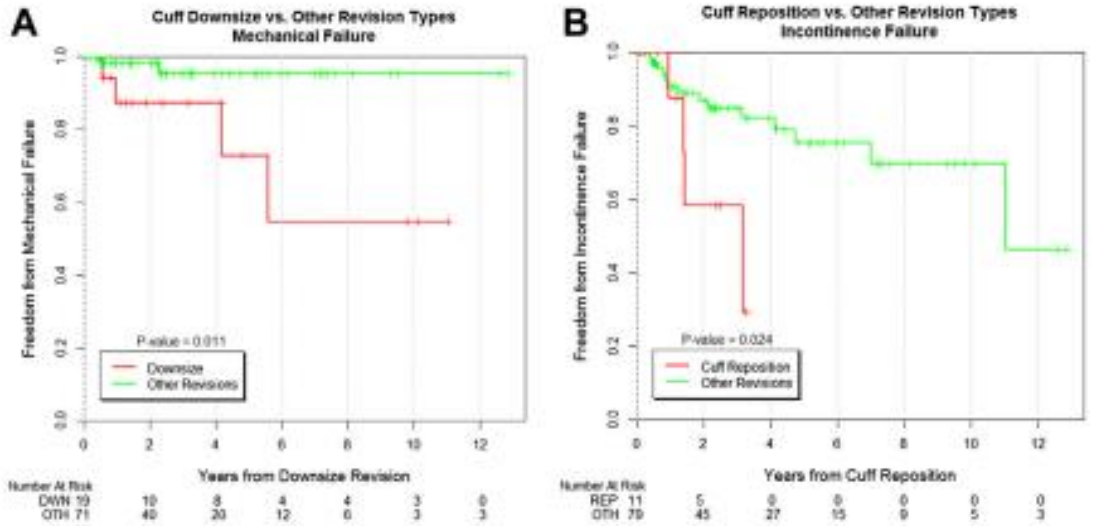
- 1778 surgeries over 24 years
  - 406 revisions, 69 for atrophy
  - 56 tandem cuffs vs 13 single cuff downsizing/relocation
- Similar age, BMI, XRT, follow-up
- NO DIFFERENCE in 3year overall device survival
  - 60% vs 76%, p=0.94
- NO DIFFERENCE for risk of tertiary surgery, urethral erosion, infection
    - Linder IBJU, 2017



	% Survival (No. at Risk)		
	0 years	**1 years**	**3 years**
--- Tandem	100% (56)	88% (43)	76% (28)
--- Downsize	100% (12)	90% (8)	60% (5)

Cuff Reposition, Downsizing, Tandem. PRB Revision

- 19 years, 90 revisions
  - 18 PRB, 11 cuff reposition, 42 tandem cuff, 19 cuff downsizing
- Median time to revision 29 months
- 34 months follow-up



- Cuff downsizing had higher rate of mechanical failure (P=0.01)
- Cuff repositioning higher rate of incontinence failure (P=0.02)
- Tandem cuff had lower rate of incontinence failure (P=0.02)

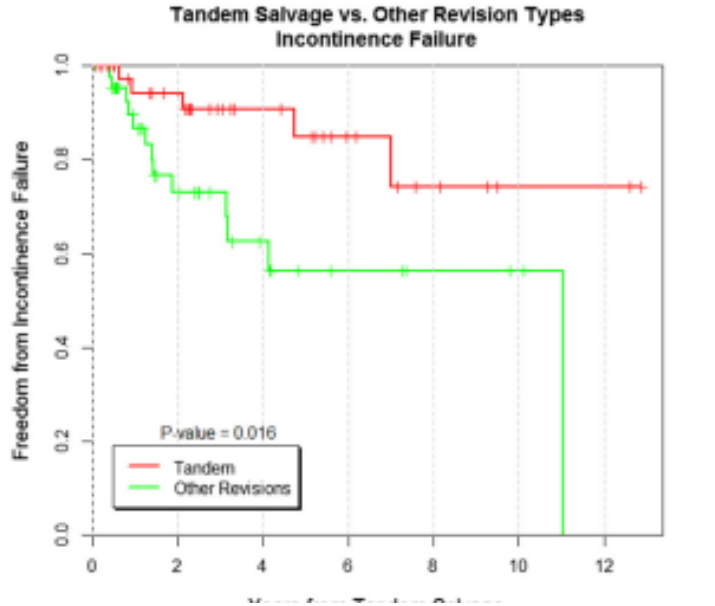


Table 2. Multivariable Cox proportional hazards model for AUS failure

	Overall Failure		Erosion Failure		Incontinence Failure		Mechanical Failure	
Revision Technique	HR	*P* Value	HR	*P* Value	HR	*P* Value	HR	*P* Value
Downsize	1.76	.141	0.22	.161	3.47	.034**	Model cannot be fit because no failures occurred for PRB and resite groups*	
PRB	1.19	.732	0.78	.751	1.69	.535		
Resite	2.21	.132	0.79	.828	6.03	.010**		

AUS, artificial urinary sphincter; HR, hazard ratio; other abbreviation as in Table 1.
* Tandem cuff used as reference.
** Statistically significant.

Eswara Urology 215

3.5 cm Cuff vs Transcorporal Cuff

- 12 years
- 625 AUS implants, 59 (9%) with TC, 168 (27%) 3.5 cm cuff
- 49 months follow
  - men with atrophy were treated with 3.5 cm cuff
  - men with prior erosion or urethroplasty were treated with TC cuff
- 28 (47%) TC with erosion vs 15 (15%) 3.5 cm cuff erosions
- TC cuff increased odds of erosion (OR 6.65, 95% CI 3.214.4, < 0.0001

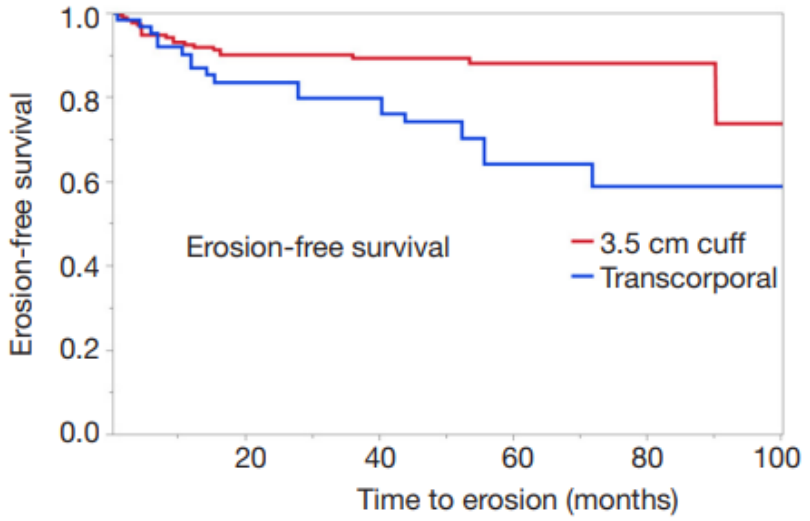
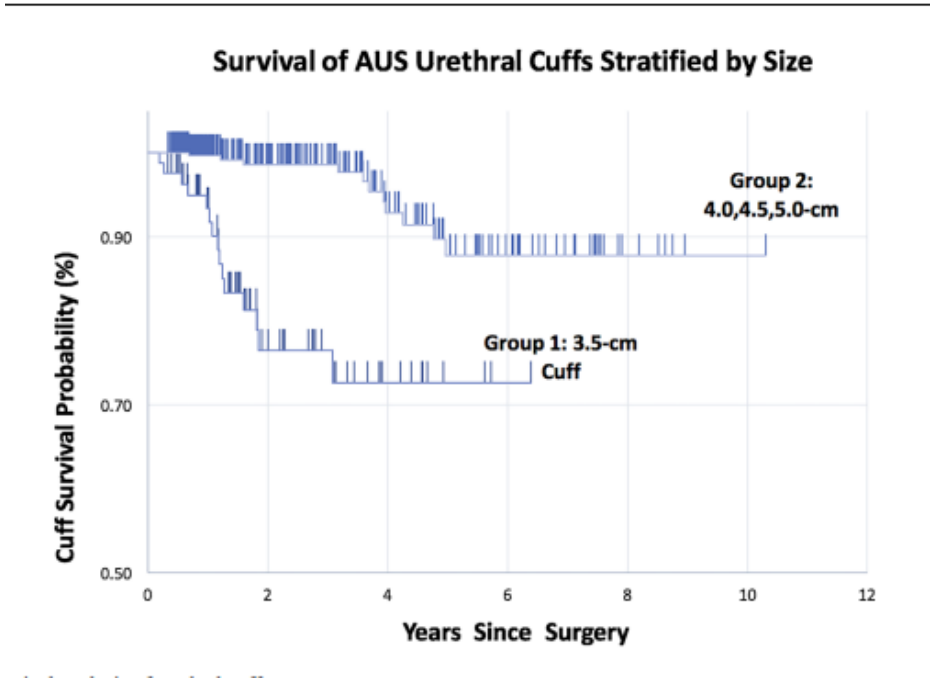


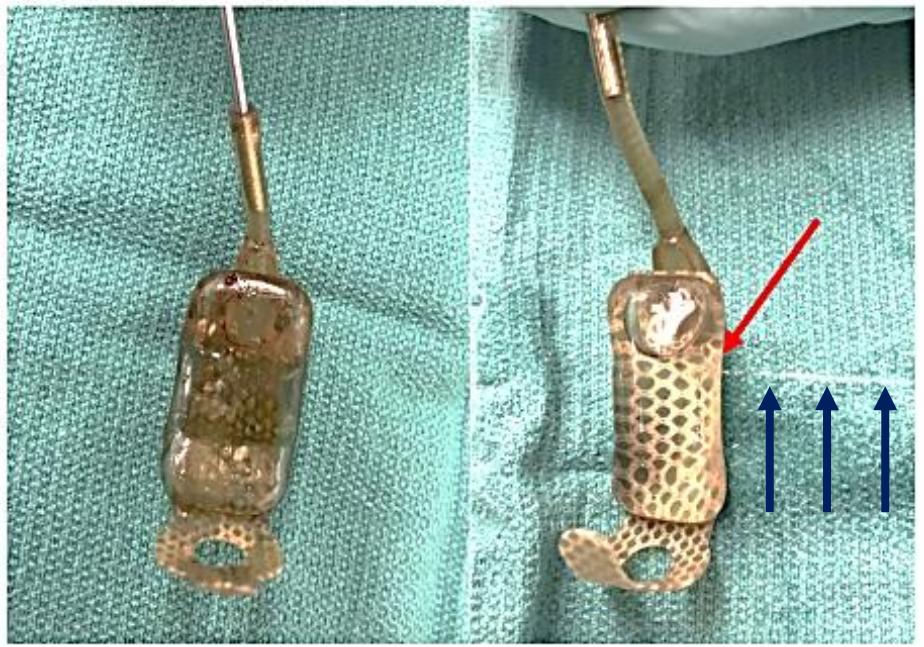
Figure 1 Comparison of erosion-free survival between TC cuffs and 3.5 cm cuffs. TC, transcorporal.

- Davenport Translational Androl and Urol, 2020

3.5 cm Cuff – Higher Failure Rate

- 12 years
- 486 patients
  - 31.5 months follow-up
- 48 mechanical failure
  - Cuff most common (56.3%), then PRB (12.5%), tubing (12.5%), control pump (10.4%), unsure (8.3%)
- 3.5 cm cuff had higher risk of failure (HR 7.313, < 0.001), compared to larger cuffs



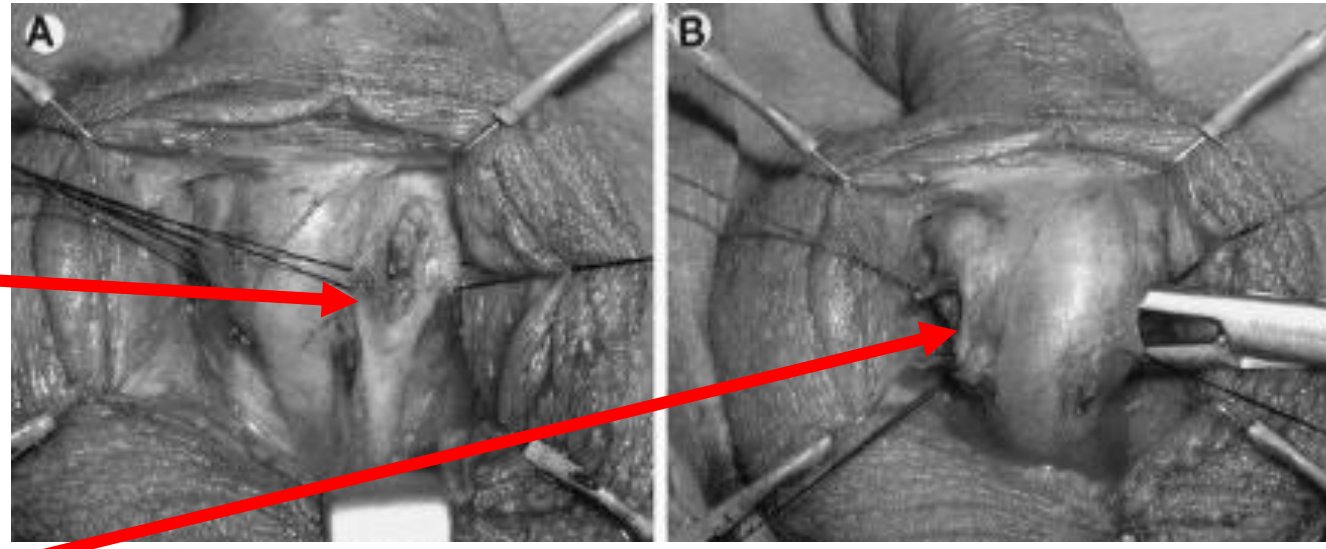


Trans-corporal AUS

Purpose:
leave corporal **tunica** albuginea on the dorsal surface of the urethra

larger circumference
better coaptation

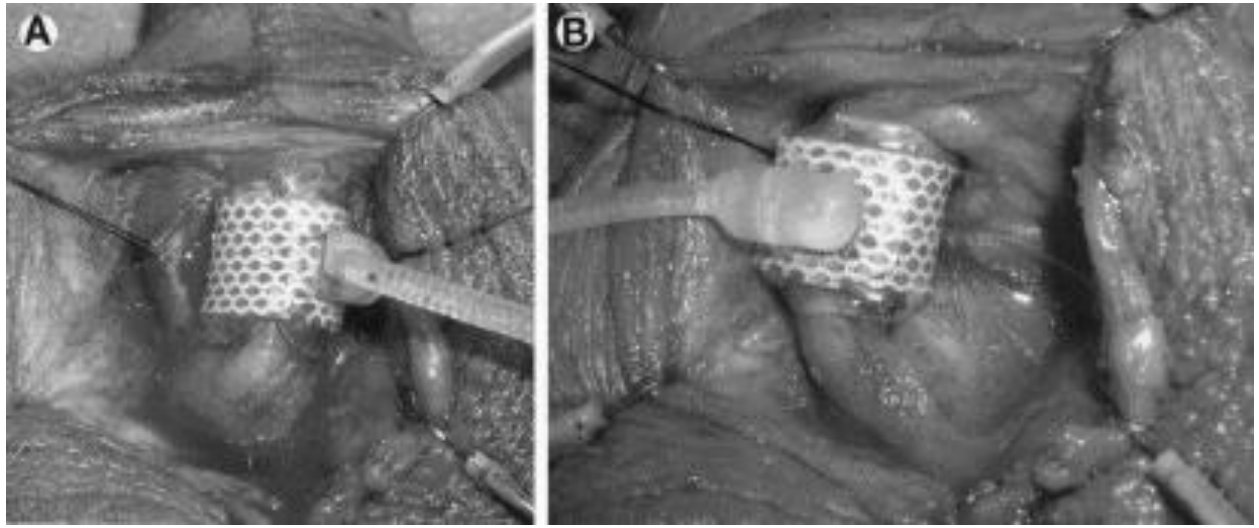
Guralnick ML, et al: J Urol, 2002



Also reduces risk of dorsal urethral injury during dissection

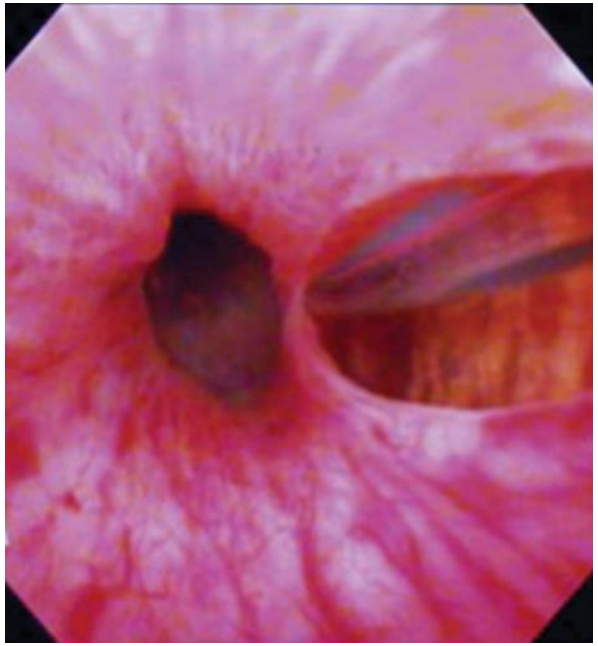
TC placement linked to higher continence rates and associated with decrease in revision rates among irradiated patient

Le Long, Int Braz J Urol, 2016



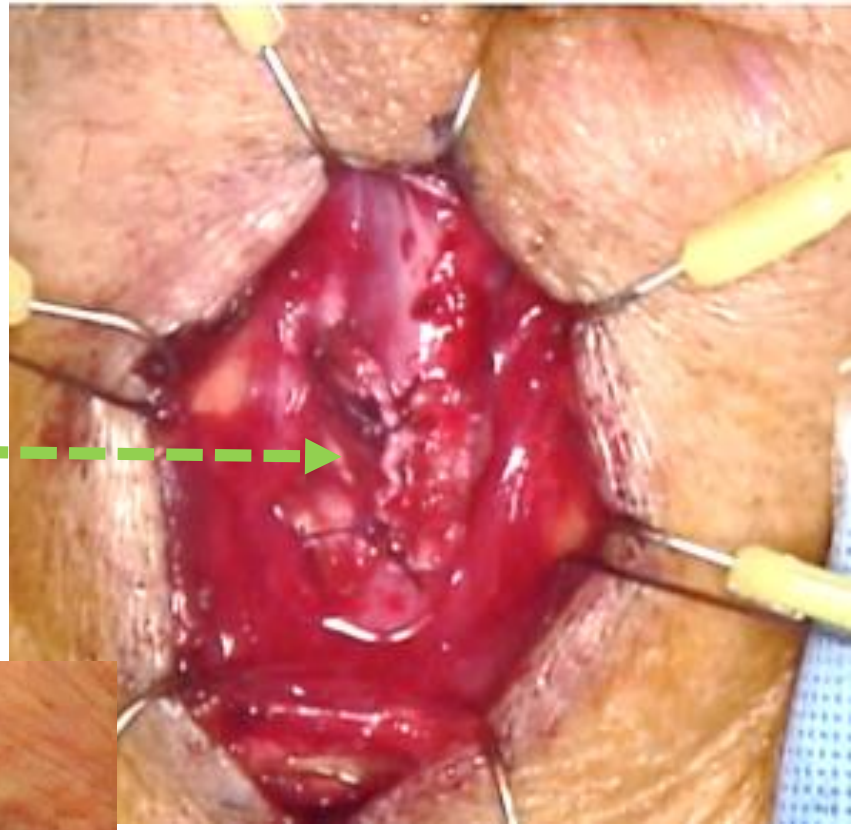
What's Wrong with the Transcorporal AUS?

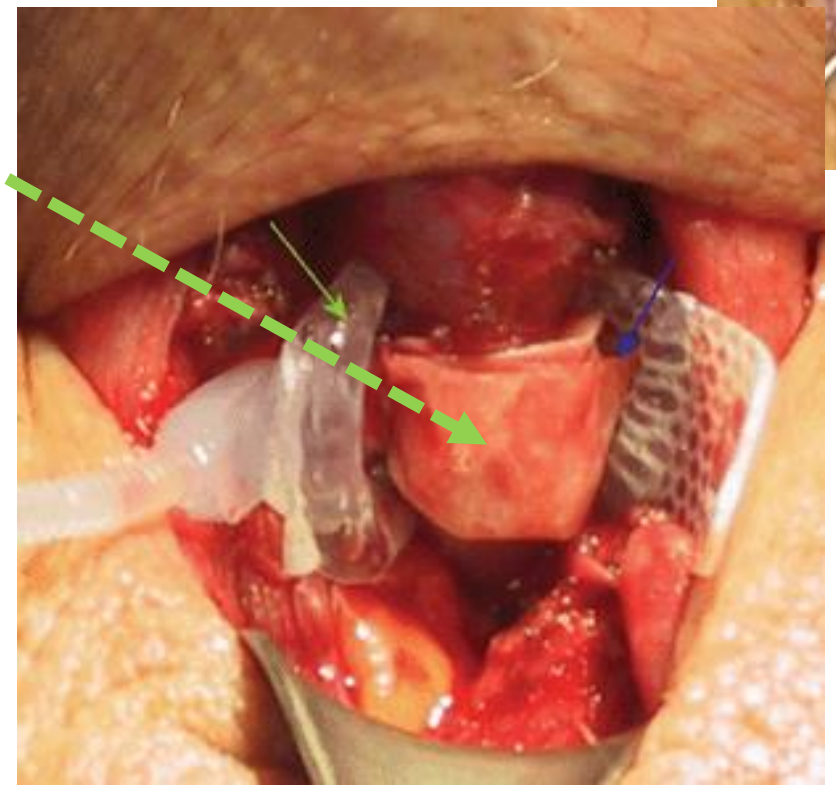
- Nothing is wrong with it
  - But it may not reduce **erosion**
- Assumption that dorsal urethra is at highest risk for AUS erosion
  - Blind passage, difficult plane, etc.
- In fact, ventral and lateral are the most common sites of cuff erosion
    - Ortiz, J Urol 2020
- Following early success, overall device survival may not be increased in patients undergoing transcorporal cuff placement
- Nor is the site of erosion different compared to bulbar urethral AUS (dorsal remains least common)
    - Ortiz, J Urol, 2020



Urethral Wrap

- Alternative approach: Can wrap urethra with
  - Autologous Rectus Fascia
  - Xenograft
    - Gani J, et al: Int Urol Nephrol, 2020
    - Trost L, et al: Urology, 2012
    - Rahman NU, et al: BJU Int 2005

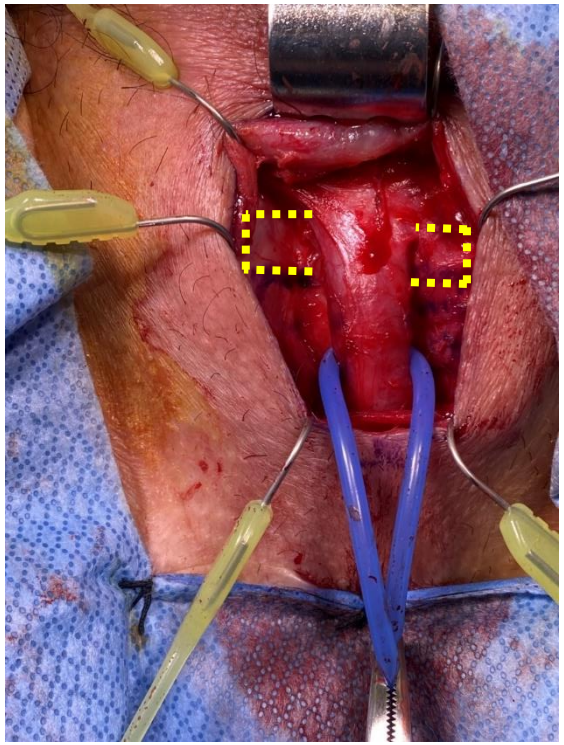


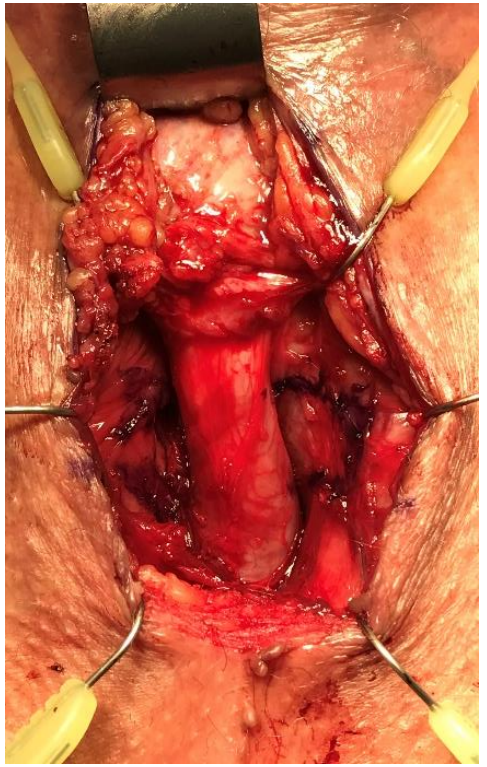


Next Gen Transcorporal AUS Cuff Placement: Tunica Albuginea Circumferential Wrap

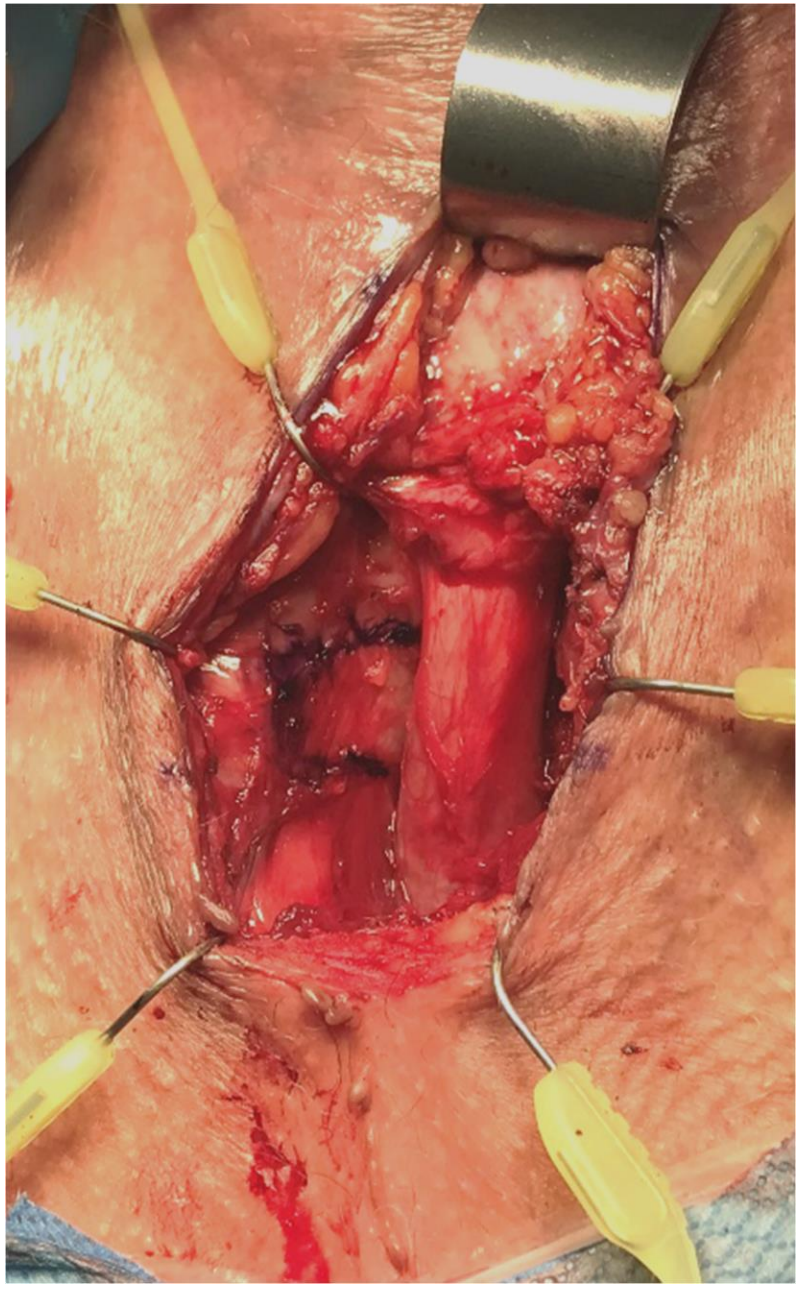
- Novel technique using tunica albuginea that protects not only dorsal aspect, but wraps around entire urethral circumference

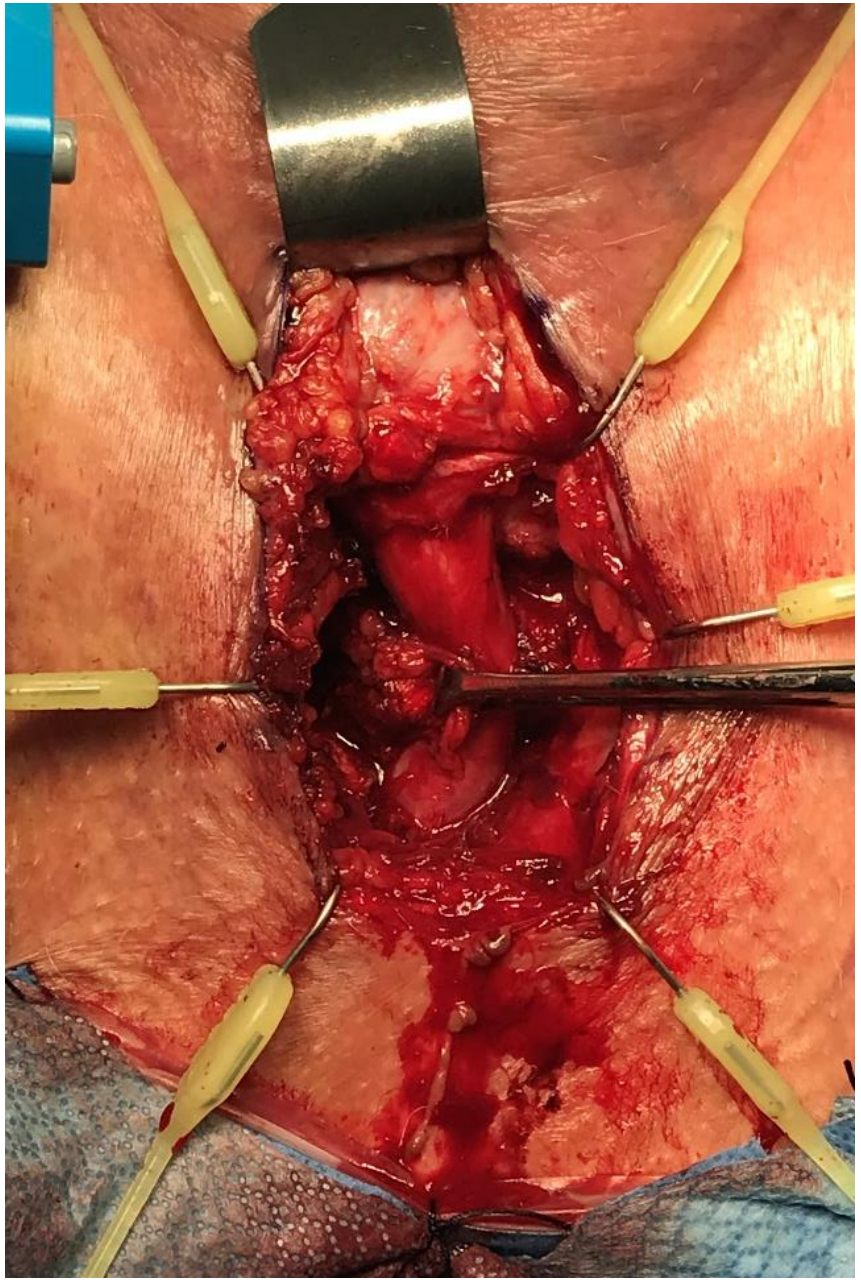
- Demonstrated to me by Ofer Shenfeld
- Director at Center for Reconstructive and Functional Urology
  - Shaare Zedek Medical Center (Gates of Justice)



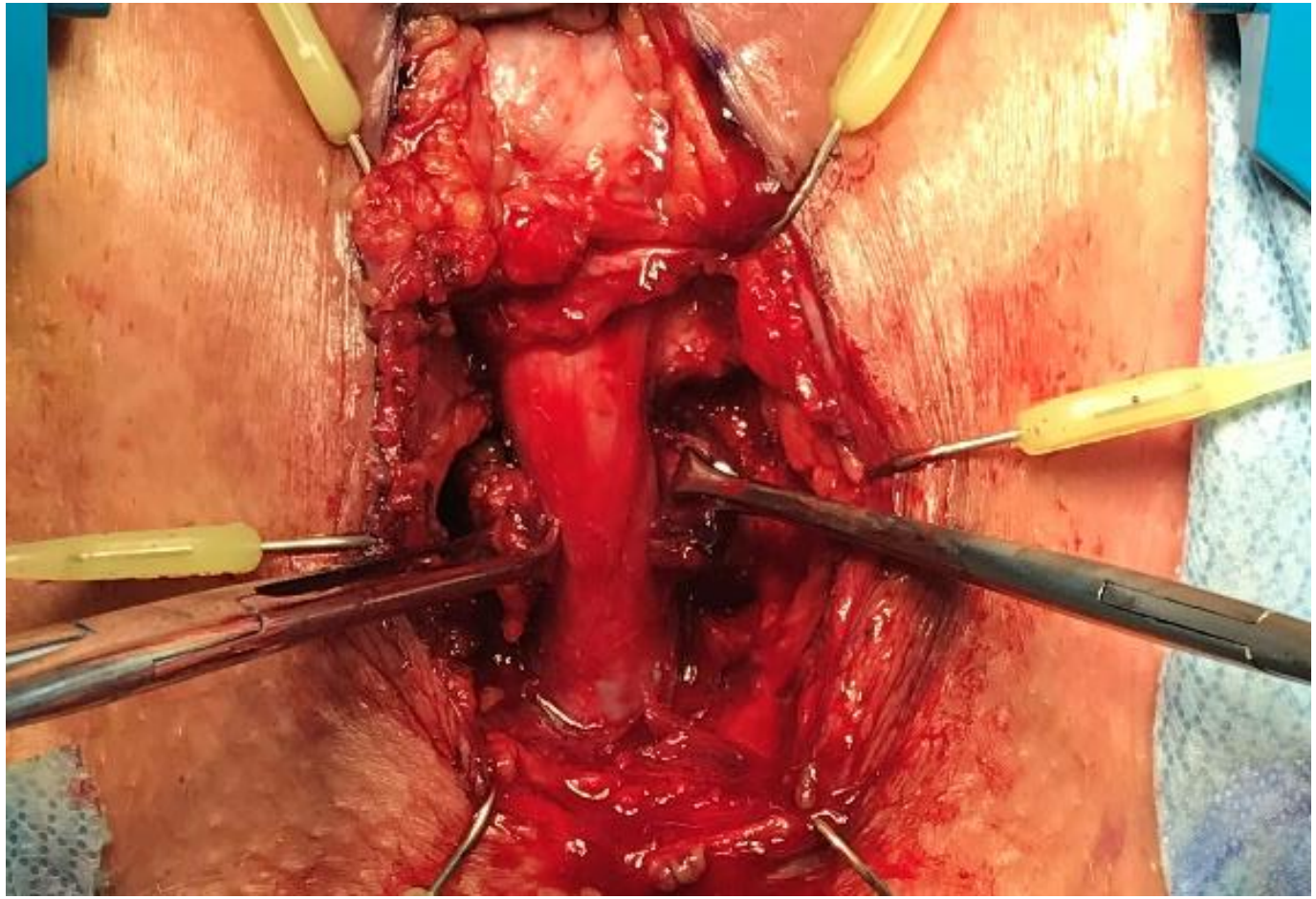


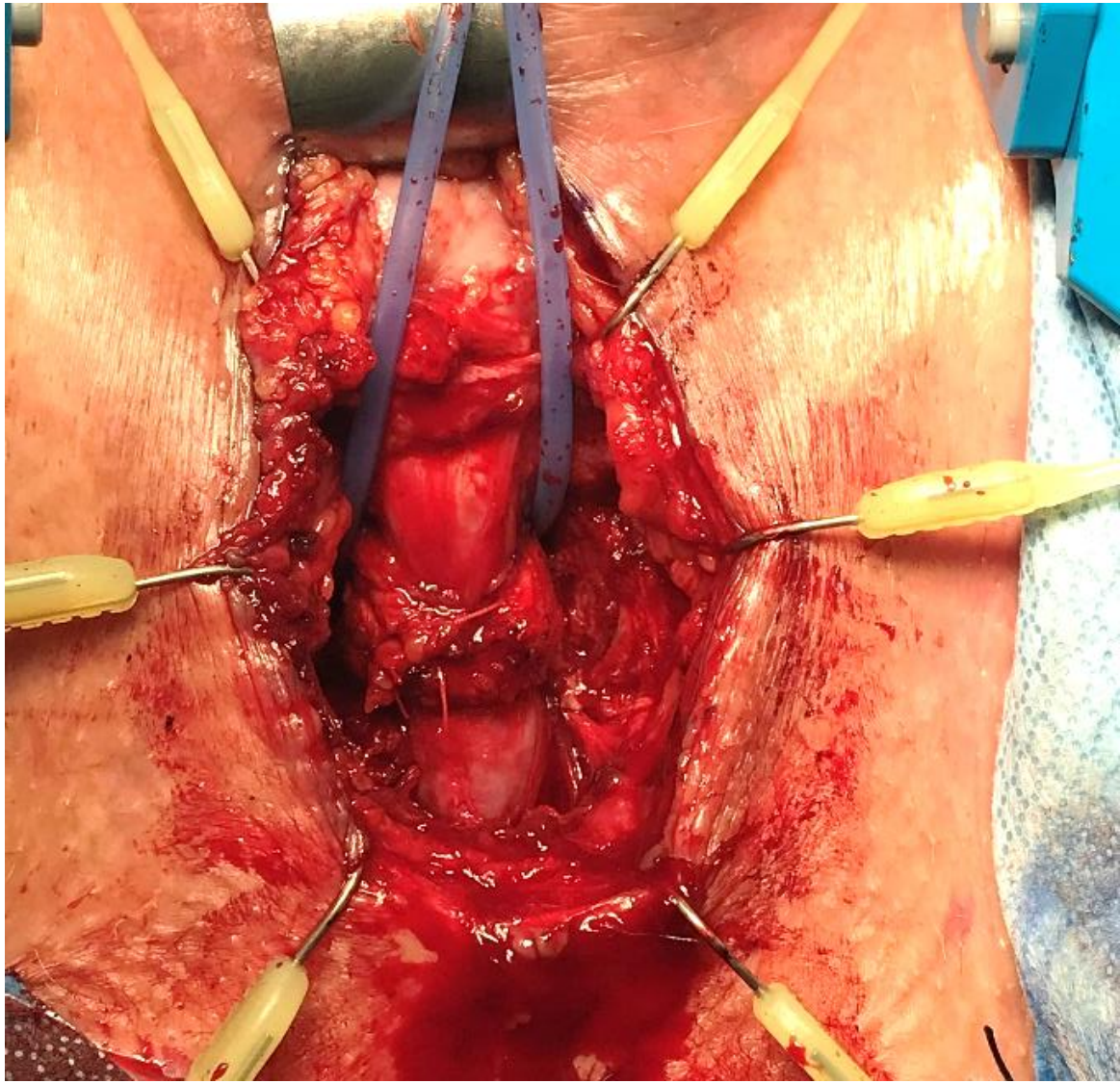
One wing pulled





Wings together





6 patients, minimum 2 prior erosions, 2 years follow-up, 1 erosion

This pilot study makes me optimistic….

Summary

- Make the diagnosis of recurrent ISD
- Discover the pathophysiology
- Locate the problem
- Fix or replace the device
- Minimize risk of:
  - Iatrogenic urethral injury
  - Insufficient coaptation
  - Urethral atrophy
  - Urethral erosion

- Thank You