### Aims of Workshop

The aim of the workshop is to give an overview of the current aspects of surgical treatment of male urinary incontinence, including an update of new developments in this field. The focus will be on limitations of all different established and new methods in order to avoid poor results. Highly experienced urologists will discuss the current options for counseling and treatment of male urinary incontinence with a special focus on contraindications. Tips and tricks will be given for routine implantation as well as challenging situations.

A second focus will be on troubleshooting after failed AUS implantation. Tandem cuff, downsizing, temporary deactivation, component change, erosion and implantation of “stress cuff” will be covered.

### Learning Objectives

decision making for primary surgical therapy of male incontinence based knowledge of contraindications

### Target Audience

Urology

### Advanced/Basic

Intermediate

### Suggested Learning before Workshop Attendance

- A prospective study evaluating the efficacy of the artificial sphincter AMS 800 for the treatment of postradical prostatectomy urinary incontinence and the correlation between preoperative urodynamic and surgical outcomes. Urology, 2008;71:85-9
- A prospective study evaluating the efficacy and safety of Adjustable Continence Therapy (ProACT) for post radical prostatectomy urinary incontinence. Urology, 2006
- ICS, AUA, EAU - Guidelines on Incontinence

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<td>14:40</td>
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<td>Newer implants and future developments</td>
<td>Emmanuel Chartier-Kastler</td>
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<td>Discussion</td>
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<td>15:00</td>
<td>15:10</td>
<td>Decision making and differential indication</td>
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<td>15:15</td>
<td>15:30</td>
<td>Cases</td>
<td>Wilhelm Huebner, Emmanuel Chartier-Kastler, Ralf Anding</td>
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Current workup and surgical therapy of male incontinence

R. Anding

It was long-time postulated that post prostatectomy stress urinary incontinence (PPSI) is the result of direct damage to the external urinary sphincter during surgery. In fact the majority of PPSI is related to destabilization of the fibro-muscular components that keep the external urethral sphincter muscle in it's correct anatomical position and maintain continence function. The integrity of these structures as well as the nerval supply is essential for proper sphincter function.

Appropriate history taking is the basis for a successful treatment strategy. Several diagnostic tools are essential in the workup of PPSI, others are optional or still under debate.

Mandatory:

- History: previous surgery, co-factors, expectations
- Protocol: frequency, micturition volume, fluid intake
- Physical exam: DRE, dipstick, dexterity, able to interrupt stream
- Uroflowmetry: obstruction, bladder function
- Ultrasound: residual, bladder, upper tract, stones
- U'Cystoscopy: urethra, sphincter complex, repositioning test

Optional:

- Questionnaires: ICIQ-SF, ICSmaleIS, I-QoL, PGI-S, ...
- Pad Test: 24 h > 1 h [Klarskov, Hald] > 20 min [Hahn, Fall]
- TRUS: mobility of sphincter/anastomosis
- Urodynamics: neurological, contractility
- UPP: scientific interest
- CT / MRI: static and functional anatomy

Surgical therapy of post-prostatectomy incontinence

Therapy of PPSI is determined by incontinence severity, age, co-factors, mental status, dexterity, expectations, and residual sphincter function, e.g. the ability to interrupt the urinary stream. Male slings do not work tension-free like female TVT. Tension is used either for relocation of the urethral bulb (e.g. AdVance™, Boston Scientific) in fixed slings or for direct urethral compression (e.g. ATOMS™, A.M.I.) in adjustable slings. Today a variety of sling implants is available with regional market differences. For fixed slings good long-time data exist only for AdVance™ with 61.1% dry (80.5% improved) after 5 years. For adjustable slings good long-time data exist only for ATOMS™ with 64% dry and 90% improved after a median follow-up of 31 months and a median of 3 adjustments.

Another compressive device are the adjustable balloons ProACT™ (Uromedica) that are positioned at the bladder neck. A recent study with 4 years follow-up demonstrated a significant pad weight reduction (24h: 293 g to 73 g) as well as significant improvements in quality of life and pad use.

The gold standard of artificial sphincters is the AMS800™ (Boston Scientific) with a dry rate of 43.5% and 79.0% improved in a critical systematic review. The implantation technique of the perineal versus the transverse scrotal approach is a point of debate. Device failures usually occur only within the first 3 years after surgery. It is lacking the opportunity for later adjustment in case of recurrent incontinence. This is realized in newer devices like the Zephyr 375™ (ZSI) or the Victo™ sphincter (Promedon). These allow a later pressure adjustment only by transcutanous injection.

Outline of current options for surgical treatment of post-prostatectomy incontinence

Retrourethral sling:
AdVance, retrourethral – diaphragmal target location, sphincter repositioning, preoperative elevation test necessary, postoperative retention 10-20%, limited in patients with radiation, neobladder, and severe incontinence.

Adjustable slings:
Atoms, Argus, Remex - suburethral – diaphragmal target location, possible postoperative adjustment of the LPP, verification of stream interruption advised, limited in patients with neobladder.

Adjustable balloons:
Pro-ACT, bladder neck – supradiaphragmal target location, minimally invasive, lower dry rates, prolonged start-up phase until adjustment, contraindicated in patients after irradiation, limited in patients with previous surgery around the bladder neck.

Hydraulic sphincter:
AMS800, ZSI375, Victo, bulbar – infradiaphragmal target location, usable in patients with low detrusor contractility (open-close mechanism), limited through manual and/or cognitive impairments, expensive.
References:


Troubleshooting with artificial sphincter implantation

Wilhelm A. Huebner

Despite a high success rate, problems can arise after AUS:
Recurring incontinence because of morphological changes, technical failure, erosion/infection and individual factors (e.g. acquired loss of manual capabilities).

Diagnostics:

Targeted anamnesis
1. Transurethral procedures? sudden pain while urinating (indicating erosion of the cuff).
2. duration incontinence (since implantation, within 6 months, after?) - early onset: technical problems (wrong balloon/cuff-size), late onset: subcuff atrophy.
3. Differentiation permanent / stress-related incontinence

CT/MRT to determine filling status of system. However, exact localization of leak is hardly ever seen.
Cystoscopy and/or (V)CUG confirm cuff function, erosion, scar tissue, stenosis.
If there is distinct dynamic of the cuff without complete closing of urethra either the cuff implanted was too wide, or atrophy of urethral wall has occurred.
Retrograde Leak Point Pressure (RLPP) - around 40cmH2O if the cuff is fully closed.

Common complications

1. Subcuff Atrophy - Solutions (overlapping)
   1a. Smaller cuff
      If a cuff of 4 cm or larger was chosen primarily, cuff-size can be decreased. New cuff may be placed within the same pseudocapsule of the old one.

   1b. Tandem cuff
      If a primary cuff of 3,5 cm was chosen, double-cuff can be considered. Place second cuff parallel to the first one! Bending of the urethra must be avoided. Scrotal incision may be considered since the second cuff is usually implanted distal to the first one. 
      “Y”-connector is used, volume of system should be increased by about 4 ml.

   1c. Tissue transplant
      Pedicled flap (Dartos) may be used to increase urethral circumference. Flap is placed beneath the opened cuff, and fixated with 5/0 resorbable sutures - not placed under the cuff.

   1d. Change of the balloon
      Generally 61-70cmH2O balloons are used primarily, change to a 71-80cmH2O may be considered, but increase risk of erosion!

2. Isolated stress incontinence
   If Patient is completely continent but leaks at coughing etc., implantation of “Stress-relief-cuff” may be indicated. An open cuff is placed intraabdominally and connected between the urethral cuff and pump using a “Y”-piece. This leads to transmission of fluid and closing of the urethra at intraabdominal pressure rises.

3. Erosion of the urethra
   First symptom of erosion is sudden pain during urination. Cystoscopy and/or UCG verify this status. Any further decision depends upon assessment of infection. In the past explantation of entire system was standard procedure, today in absence of infection only cuff may be removed. Re-implantation of new cuff considered after 12 weeks. Transcavernosal implantation is advised.

4. Iatrogenic lesion
   4a. Lesion of the urethra
      Generally the approach is the same as described in 3., yet in some cases (very early revision) explantation of the cuff can be avoided. For that purpose cuff is opened, the urethra closed and protected using a Dartos-flap/fatty tissue. The cuff is left open 6 weeks, then closed in a short procedure. Advantage: cuff can remain at same (ideal) position.

   4b. Lesion of the tubing
      Lesions of the tubing, usually caused by open surgery (hernia repair). If leak is identified, the part is clamped using armed mosquito clamps. Then system is flushed until the fluid is clear, and closed using a tube connector.
      If the leak cannot be identified, one of the connectors is clamped up and removed. Then each part of the system is examined seperately using AMS-blunt cannula for filling. Once leak is found, procedure is continued as above.

5. System Leak
   Symptoms: loss of function, soft pump, empty balloon (ultrasonography/CT). Exact location of leak usually cannot be seen in imaging. Finding leak location see 4b. It can be difficult to identify a lesion of the cuff, since the capsule can mimic intact cuff, thus the cuff has to be exposed to verify the situation.

Newer implants and future developments
Emmanuel Chartier-Kastler, Urologist, F

Surgical therapy remains the best option (and probably the only one) to obtain cure of male stress urinary incontinence. The armamentarium changed a lot within the last 20 years with the new passive therapies named “male slings” or “adjustable balloons”. Artificial urinary sphincter AMS800® developed since 40 years by the companies American Medical System and now Boston Scientific is known as the “gold standard” even if level of evidence is not 1!
Looking for the future we have to focus on many aspects for the next surgical therapies:
-Evaluation and how to obtain the best level of evidence?
Which level of “cure” and how to define “continence rate”?  
Which of the novel therapies will be the most interesting for patients?  
Do each novel therapy preserve voiding function?  

At this moment just looking for clinical aspect of new implantable devices, it has to be as minimally invasive as possible, adjustable upon activity and continence status and able to obtain a long term longevity. Just listing new artificial urinary sphincters which are under development, most of them will be adjustable (pressure control) and electronically or mechanically driven. Adjustable slings are also emerging, even if with time none appears to obtain quick international validation.

At the end pricing and reimbursement by health system has no to be forgotten. It could be the last judge of any device, which is understandable but most of the time reducing the speed of prospective clinical evaluation.

**Differential indication for surgical treatment of male post-prostatectomy incontinence**

W.Huebner

Today a variety of surgical treatment options for male incontinence are available. Although they differ in therapeutic potential, complexity, price, limits and long-term experience, some methods can be used as alternative for each other, in case of treatment failure [1-8]. Hence, today many patients can be offered several treatment options. The choice of the most appropriate procedure should still be done with extraordinary diligence, which requires understanding of the pathophysiology of post-prostatectomy incontinence as well as an open mind concerning the entirety of the patient in regard to cognitive, manual and physical attributes.

**Post-prostatectomy incontinence**

The notion of Dorschner et. Al. [9] distinguishing between the interior bladder neck sphincter and an external urethral sphincter (raptussphincter urethrae) can be seen as foundation for diagnostics and treatment of post-prostatectomy incontinence. The external sphincter, which is mostly responsible for continence is also divided into a smooth (musculus sphincter urethrae glaber) and a striated (musculus sphincter urethrae transversostriatus) muscle component. Following this approach the smooth muscle component is responsible for baseline continence, and does not suffer from fatigue. Yet during surgery the innervating structures can be damaged, leading to impaired baseline continence [10].

The striated muscle component, together with the (also striated) pelvic floor muscles, has a much stronger contraction and can provide sufficient closing of the urethra during short periods of elevated abdominal pressure, ensuring stress continence. The innervation of the striated muscle component through the pudendal nerve is usually not compromised by the radical prostatectomy, thus allowing even severely incontinent patients to interrupt their urinary stream, also visible as a short closing of the urethra in cystoscopy after the patient is prompted to clench [11,12]. The clinical presentation of most post-prostatectomy incontinent patients also supports this claim, where the urinary stream can be interrupted and coughing does not prompt any loss, while suffering from a substantial baseline incontinence, especially during the second half of the day, caused by fatigue of the striated sphincter. With understanding of these mechanisms, targeted and reasonable diagnostics can be done, leading to a successful and individually adjusted therapy.

**Outline of the current options for surgical treatment of post-prostatectomy incontinence**

**Hydraulic sphincter:**
AMS-800 bulbar – infradiaphragmal target location, long-term experience, very reliable outcome, usable in patients with low detrusor contractility (open-close mechanism), limited through manual and/or cognitive impairments, expensive.

**Retrourethral sling:**
Advance, retrourethral – diaphragmal target location, sphincter repositioning, preoperative elevation test necessary, postoperative retention 10-20%, limited in patients with radiation, neobladder and severe incontinence.

**Adjustable slings:**
Argus, Remeex, Atoms - suburethral – diaphragmal target location, possible intra/postoperative adjustment of the LPP, verification of stream-interruption advised, limited in patients with neobladder.

**Adjustable balloons:**
Pro-ACT, bladder neck – supradiaphragmal target location, over 10 years of experience, minimally invasive, lower dry rates, prolonged start-up phase till adjustment, contraindicated in patients with radiation, limited in patients with previous surgery around the bladder neck.

**Bulking agents:**
Numerous products, target location mostly right at the anastomosis, very restricted effect in male incontinence.
Differential indication

Basically all methods mentioned above can potentially provide very positive outcome. Therefore differential indication is mostly done through contraindications and limits of the possible treatments (differential indication through exclusion!). Secondly the decision is influenced by such factors surgical expertise and personal preference of the patient. Table 1 shows which method should be indicated positive, neutral or only with great caution in patients with certain medical findings.

Given all these factors the indication for a certain procedure must be made upon the patients needs and not on the surgeons preference or repertoire.

Although the choice of surgery should not be solely based on the extent of incontinence, suburethral devices (adjustable slings, AMS-800) with comparable success rates seem to achieve higher dry rates than retrourethral slings. Pro-ACT shows similar success in patients with different grades of incontinence, yet overall those are a little lower than those of suburethral procedures [1-3, 13-21]. Bladder voiding dysfunction (detrusor insufficiency/neobladder) presents a contraindication for slings (of any kind). Here, only treatment with an AUS or the easily adjustable pro-ACT implants should be used. If this is not possible due to radiation or manual restriction the necessity of self-catheterization should be expected.

Cerebral and manual limits should be considered contraindications of the AMS-800, yet new adjustable sphincters (Victo, Zephyre) can be adjusted to a pressure that allows micturition even without using the pump (similar to adj. slings/ProAct). If the proximal urethra was damaged (through incision or radiation) or otherwise compromised, the conditions for implantation of Pro-ACT or retrourethral slings are unfavorable. In these cases more distal (suburethral) devices are recommended (AUS, suburethral slings).

The psychological situation must also be considered, as (e.g.) the idea of using a pump can be a personal obstacle for many patients. If a patient s circumstances have already brought him to the edge of his coping capacity (e.g. insufficient/untreatable erectile dysfunction), we prefer an AUS, since it has the lowest rate of treatment failure.

The time between surgeries does not factor in to the indication. Even years after prostatectomy, a surgery can lead to complete success. However, the possibility of a high micturition frequency due to decrease in bladder capacity should be discussed.

Table 1

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<tr>
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<th>Advance</th>
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<td>High level incontinence</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Prev. surgery</td>
<td>+</td>
<td>o</td>
<td>+</td>
<td>+/-</td>
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<tr>
<td>Radiation</td>
<td>+/-</td>
<td>o</td>
<td>+</td>
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<td>Residual sphincter</td>
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<td>Mental capability</td>
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<tr>
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<td>+</td>
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<td>Pat. Attitude</td>
<td>o</td>
<td>+</td>
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<td>Psych. factors</td>
<td>+</td>
<td>o</td>
<td>o</td>
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References:


Anlage einer Neoblase und Einlage der funktionellen retrourethralen Schlinge
Der Urologe A, Volume 48, Number 6, 645-648
Affiliations to disclose:

†:

Funding for speaker to attend:
- Self-funded
- Institution (non-industry) funded
- Sponsored by:

Complications

Re-op rate
50% of these reoperations within 8 mts

I Technical failure
2-14%

II Rec. incontin./ Subcuff-atrophy
2-29%

III Infection/arrosion
3-28%

...Incontinence due to sec. OAB, bladder capacity, cerebral impairment etc.

Wide range dependent on expertise

Diagnostics I

Targeted anamnesis

=> (salvage) RTX?

=> Transurethral procedures?

=> sudden pain while urinating (indicating cuff-erosion)

=> duration incontinence (since implantation, within 6 months, after?)

early onset => technical problems (wrong balloon/cuff-size)

late onset => subcuff atrophy.

=> Differentiation permanent / stress-related incontinence

Assessment of risk factors (for erosion/atrophy)

=> EBRT?

=> Internal status: DM, CHD, Anticoag., Charleston Comorbidity Index

=> prim./sec./mult. Implantation

=> Hypogonadism

Diagnostics II

Imaging

=> VCUG - easy backflow, contrast around the cuff, strictures...

=> CT/US - PRB status (position of ev. System leak

will never be seen on imaging!)

Functional tests

=> 24h PWT

=> cysto VU (visual assessment of cuff function, stenosis/fibrosis, pelvic floor function...)

=> UD

=> RLPP with cuff closed (> 45cm H2O) and open (< 25cmH2O)

Technical failure

I System Leak

1. pump malfunction/position

Dg: suspicion

=> "soft pump"

=> Imaging
I. Technical failure

I.1. System Leak

I.2. pump malfunction/position

Dg: suspicion => „soft pump“ => Imaging

Special case – iatrogenic lesion at hernia repair

2. persisting/recurrent incontinence

Rule out system leak
Cysto => open cuff at with backflow to bladder
VCUG, RLPP <40cmH2O

=> Evidence of insufficient closure

2. persisting/recurrent incontinence

„high pressure“ stress incontinence (coughing etc.)

=> implantation of „stress-cuff“

m3, secondary impl. of stresscuff,
=> direct pressure transmission to urethra
Technique:
Y connector between pump and cuff
preperitoneal placement, add 3ml,

Brian Linder et al, Mayo Clinic
Artificial urinary sphincter revision for urethral atrophy: comparing single cuff downsizing and tandem cuff placement

Amri G, Wahi P, Rutkove M, Hubner WA.
ICS 2018, CEM 2018

OPBLD-stressmanschette
3. Urethral erosion

Clinically typical burning pain, usually rec. Incontinence, Possible TUR manipulation risk factors DM, CHD, Anticoag., Hypogonadism., Charleston Comorbidity Index

=> Cystoscopy, VCUG

System preservation after urethral erosion using deactivation plug

n=17 revisions with plug (13 pts.)

Mean follow-up 35.8 mts (Range 0.9-122.5) Preservation of system 13/13 (100%)

5 re- erosions in pts with no Transcorporeal placement (all RTX and multiple surgeries)

no re – erosions in pts with transcoporeal placement

Recommendation in patients with sterile urine and erosion a single component change can be done safely, re – cuffs in such high risk patients should be placed transcoporeally.

4. Infected AUS

If no erosions (rare!), => can salvage

• Salvage Protocol*
  • Remove AMS 800 and foreign material
  • Irrigate wound w/ 7 antiseptic solutions
  • Change gowns, gloves, surgical drapes and instruments
  • Insert new AMS 800
  • Close wounds w/ no drains or catheters
  • Treat w/ oral antibiotics for 1 month
• If erosion – remove all components and return in 3-6 months ?


4. Infected AUS

If more than one component infected => complete explantation

1. Antibiotic irrigation (bacitracin and gentamicin in 0.9% normal saline)
2. ½ strength hydrogen peroxide
3. ½ strength povidine-iodine
4. Pressure irrigation w/ 1 gm. Vancomycin and 80 mg. gentamicin in 1.0.9% normal saline
5. ½ strength positive saline
6. ½ strength hydrogen peroxide
7. Antibiotic irrigation (bacitracin and gentamicin in 0.9% normal saline)

4. **Infected AUS**

- Subclinically infected AUS
- No obs. Inflamm., elderly, no reimplantation considered, intact urethra

Excision of affected parts

- Intense irrigation
- 4 weeks AB

**Recovery to clinically satisfactory result possible!**
Reoperations after AUS are common (depending on FU)
Primary and secondary implantations have equal outcome (exc. Inf. Erosion)
with systematic approach excellent outcome can be achieved
Satisfaction > 90%

Take Home message: