W24: What should you know about post - prostatectomy incontinence: From diagnosis to differential indication for specific treatment

Workshop Chair: Wilhelm Huebner, Austria
21 October 2014 09:00 - 12:00

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<td>Pathophysiology of male incontinence</td>
<td>• Flavio Trigo Rocha</td>
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<td>Pro act, current indications</td>
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<td>Artificial urinary sphincter, mainstay of male incontinence therapy?</td>
<td>• Ervin Kocjancic</td>
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<td>Case presentations/discussion</td>
<td>• Wilhelm Huebner</td>
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**Aims of course/workshop**

Urinary incontinence post radical prostatectomy has a negative impact on the Quality of Life and the treatment is a challenge. The aim of the workshop is to give a comprehensive overview of the current aspects of male urinary incontinence in a multidisciplinary fashion. Physical therapists and urologists will discuss the current possible options for optimal counselling and treatment of male urinary incontinence.

At the end of the session the participants will be able to perform specific diagnostic steps, familiarize with the most frequently performed physical therapy and other rehabilitation options, achieve the basic knowledge of different surgical options, management of difficult cases and complications.
Postprostatectomy incontinence: Pathophysiology and diagnostics

W. Huebner

Prostate surgery is the most common cause of incontinence in men. Stress incontinence is found in 5 to 48% of patients after radical prostatectomy and 2 to 77% develop overactive bladder (OAB) symptoms. Incontinence can be found in 2 to 4% of patients after SPP or TUR-P, although detrusor hyperactivity seems to be the leading factor here, which is usually already present before the procedure[1-6].

Background

Today the concept of Dorschner et al. [7], where a inner “bladdersphincter” and an exterior urethral sphincter (raptussphincter urethrae) is differentiated, is baseline for diagnostics and therapy of post-prostatectomy incontinence. The exterior sphincter, which is mainly responsible for continence, is once again split into a smooth and a striated muscle component. Following this idea the smooth muscle is responsible for baseline continence and as a smooth muscle is not affected by fatigue. Whereas stress continence is provided by the striated muscle component, which has a very high contractile force and can therefore ensure closing of the urethra in situations of high intraabdominal pressure, however, permanent contraction is not possible.

This approach has its practical equivalent in many patients suffering from post-prostatectomy incontinence. These patients, although suffering from severe incontinence, are able to stop the stream during micturition and often lack stress incontinence. In the second half of the day incontinence usually increases in such patients reflecting fatiguing of the striated muscle. With these facts in mind targeted and reasonable diagnostics is possible, which can lead to a successful therapy.

Baseline Diagnostics

Diagnostics in a patient after prostatectomy has many objectives: measuring the severity of the incontinence, baseline for any indication of therapy, baseline for any informed consent in case of surgery, to control the continuous process and success of the therapy, to determine and manage expectations of the patient. Targeted anamnesis must of course be mentioned first. Besides general urological anamnesis, one should specifically ask for coherence in time of the symptoms and the prostate surgery (or other/later procedures like TUR-P and radiation). Also asking about incontinence in the afternoon and stopping the stream while urinating can give a lot of information and build up some a mutual trust with the patient.

For basic examinations Uroflow, urine analysis, residual urine and micturition diary are obligatory. For years different methods of determining the severity have been discussed. The most widely accepted one is weighing the pads after 24
hours to determine the loss of urine. It is important to also document percental relations between the amount of fluid urinated and lost by leakage. This method may be extended by differentiating between losses of urine in the morning/afternoon and night [2, 6]. Number of pads and standardized pad-tests can give an outline of symptoms, yet lack evidence and should not be used for any academic consideration or comparison.

The psychological strain of the patient must also be determined since it may influence the therapy. To do so, the ICI-Q-SF, the UCLA/RAND-Prostate index urinary function score, the PGI-I (patient global impression and improvement) or the IIQ-7 (incontinence impact questionnaire – short form) are used [8-11]. Also a general assessment of the patients’ manual and cognitive capabilities is recommended. Here clock drawing test (patient is asked to draw a clock showing a certain time), or simply asking the patient to disassemble and reassemble a ball-pen have been successful [12].

**Extended Diagnostics**

If baseline diagnostics indicate surgical treatment, extending diagnostic measures is necessary. First of all it is important to differentiate between indications of different procedures, yet it also helps generating realistic expectations of the patient.

Flexible cystoscopy gives information about possible strictures, diverticula and variations within the anastomosis. If the patient is asked to contract during cystoscopy, the striated sphincter function can roughly be assessed. A positive “Reposition test” is a requirement for non-adjustable transobturator slings [13]. A contraction test (the patient is asked to contract the pelvic floor in order to hold the urine at a volume at 200ml minimum and leakage is recorded at 3,5 and 20 minutes), may give evidence for a functioning striated sphincter.

Urodynamics are not routinely necessary, but in any case of doubt the indication should widely be given. Cystometry is indicated if reduced bladder capacity, OAB, or detrusor hypocontractivity is suspected. In those cases cystometry is helpful to inform the patient about a possible high frequency after the procedure.

Measurement of the abdominal leak point pressure (ALPP) and the valsala leak point pressure (VLPP) has not proved practical and is also not very helpful for differential indication between procedures [14]. The retrograde leak point pressure (RLPP), however has been established to intraoperatively measure the “urethral resistance” of the relaxated patient, which allows us to adjust suburethral slings accordingly [15, 16]. This technique can also be helpful preoperatively to determine the function of a hydraulic sphincter before a revision. Urethral pressure profile plays a minor role in evaluation of PPI. Dynamic Imaging (UCG, VCUG) can give supportive information, video – urodynamics may be considered in complex cases with neurourological components involved, or in patients with unsuccessful therapy.
Tab.1

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<th>Baseline diagnostics</th>
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<tr>
<td>General Anamnesis</td>
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<td>Specific Anamnesis</td>
<td>Previous surgery</td>
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<td>Drugs</td>
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<td>Circadian loss of urine</td>
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<td>Pads</td>
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<td>Flow</td>
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<td>Residual urine</td>
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<td>24 hour pad test</td>
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<td>Q.o.l. Tests</td>
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<tr>
<td>Optional</td>
<td>Clock drawing</td>
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<td>„ball-pen“ test</td>
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Tab.2

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<th>Extended (preoperative) diagnostics</th>
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<tr>
<td>Flexible cystoscopy</td>
<td>Pinch test [??]</td>
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<td>Reposition test [??]</td>
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<td>optional</td>
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References:

Physical therapy and behavioral modifications: expert opinion and evidence based medicine

By: Heather Moky PT, DPT
University of Illinois Medical Center   Chicago, IL
hmoky@uic.edu

Lecture Objectives
1. Identify areas of practice in pelvic floor physical therapy
2. Formulate special questions to be included in pelvic floor PT exams
3. Understand general proceedings for a pelvic floor examinations
4. Identify treatment options for incontinence
5. Identify behavioral modification for Incontinence.
6. Identify commonly used treatments in physical therapy.
7. Formulate exercise programs
8. Identify pelvic floor resources

I. Incontinence Statistics
   A. General
      1. World wide 200 Million people
      2. 25 million Americans
      3. Women vs Men 2 to 1
      4. 17 % of men over the age of 60
   B. Post radical retropubic prostatectomy- 8% to 56% of men have UI at 1 year after (Yamanishi et al)
   C. Cost
      1. Financial Cost : Over 19.5 Billion dollars a year in the U.S.
      2. Emotional and Psychosocial costs as well.

II. Area’s of Practice of Pelvic Floor Physical Therapy
   A. Women
   B. Men
      1. Incontinence
      2. Pelvic Pain
      3. Erectile Dysfunction
      4. Over Active Bladder
      5. Benign Prostatic Hyperplasia- BPH
      6. Post Surgical
      7. Orthopedic Issues
      8. Other

III. Pelvic Floor Evaluation
   A. Patient History – Past medical and surgical history, present complaints
   B. Outcome tools
      1. International Prostate System Score
      2. PFDI-20 Pelvic Floor Distress Inventory – short form 20
      3. PISQ-12
      4. Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire
      5. PFIQ-7 Pelvic Floor Impact Questionnaire – short form 7
      6. UDI-6 Urogenital Distress Inventory – short form 6
      7. IIE Incontinence Impact Questionnaire
   C. Symptom Questionnaire
      1. Urination
         a. How often per day? Night?
b. Urinary Leakage?
   - How many times a day?
   - How much?
   - Protection worn and how many needed a day

c. Urinary Stream
   - Trouble initiating urine stream
   - Slow/ weak stream
   - Ability to stop the stream

d. Ability to delay urination
   - How long?
   - Pain associated with holding urine?

e. Night time toileting- frequency

f. Triggers
   - Key in the door
   - Hearing water run

2. Bowel
   a. How often do you have a bowel movement?
   b. Consistency of bowel movement
   c. Bowel Leakage
      - How often
      - How much
      - Protection worn and how many needed a day
   d. Constipation and management techniques
   e. Ability to delay bowel movement

3. Sexual Function/ Dysfunction
   a. Frequency
   b. Pain
   c. Urinary or Bowel Leakage
   d. Ability to Climax
   e. History of Abuse

D. Education for the patient
   1. Anatomy and Physiology
      a. Bony Pelvis/ Pelvic Girdle
         - Ilium, Ischium, Pubis. Sacrum, Coccyx
      b. Pelvic Floor Muscles
         - Pelvic floor muscles: muscular layer of the pelvic floor
         - Superficial- Urogenital Diaphragm/ Triangle
         - Bulbospongiosus, Ischiocavernousus, Superficial transverse perineal muscle
         - Deep- Levator Ani
         - **Pubococcygeus, Pubovaginalis, Puborectalis, Illiococcygeus**
      c. Sphincters
      d. Viscera
      e. Muscle attachments in and around the pelvis
   2. Basics of Micturition
   3. Basics of Defecation

E. Objective
   1. Posture
   2. Breathing
   3. Gait
   4. Lower Extremity Muscle Length and Strength
   5. Range of Motion: Spine and Lower Extremities
   6. Abdominal Strength, scars, and Diastasis Rectus Abdominis
   7. Visceral Assessment
8. Special Tests
9. Other

F. External Pelvic Assessment
1. Visual inspection
2. Skin Integrity
3. Scars
4. Perineal Body
5. Reflexes
6. Contraction
7. Valsalva
8. Palpation

G. Internal Pelvic Assessment: Digital Rectal Exam
1. Muscle Tone
2. Muscle Strength
   a. Manual Muscle Test: Laycocks PERFect method
      • Power: strength using mod Oxford
      • Endurance: How long can pt hold contraction
      • Repetitions: How many times can pt perform
      • Flicks: Quick flicks, contract and relax in 10 sec
      • Result 4 number representation of pelvic floor strength, endurance and coordination
      • Strength on a 0 to 5 scale
      • Example 3/10/10/10
3. Exam Contraindications/Precautions
   a. Contraindications
      • Lack of patient consent
      • Active pelvic infection (vagina or bladder)
      • Active infectious lesions (genital herpes)
      • Absence of previous pelvic exam (pediatric)
      • Inadequate training on part of examiner
   b. Precautions
      • Post Op vaginal/rectal surgery (6-8 weeks)
      • Surgeon clearance
      • Severe pelvic pain
      • History of sexual abuse

H. Biofeedback
1. Rectal/Vaginal Intracavity EMG
2. External Pelvic Muscle EMG
3. Real Time Ultra Sound
   a. Pelvic floor Muscles
   b. Sphincter
   c. Abdominal Muscles
   d. Multifidus

I. Bowel and Bladder Diary – Diary of food, drink, leakage, pain, urge, and bathroom trips

IV. Physical Therapy Treatment
A. Behavioral
1. Bowel and Bladder Diary
2. Dietary Education
   a. Proper hydration - 8 glasses of water a day
   b. Proper Fiber intake and what foods have fiber in them
   c. Bladder Irritants
      • Caffeine
      • Alcohol
      • Citrus
3. Delaying the Urge to Urinate
   a) Urge Protocol- Contract and Relax the Pelvic Floor Muscles 5-6 times quickly. Then distract yourself. (Count backwards by 100 by 3’s or sing a song)
   b) Deep breathing
   c) Retraining: Instead of “Mind over Matter” it is “Brain over Bladder”
   d) Gradual exposure to triggers
4. Timed Toileting
5. Toileting posture/Voiding mechanics
   a. Avoid Valsalva
   b. Pulsed Lip exhalation
   c. Better mechanics to assist relaxation of pelvic floor muscles
6. Body Awareness- Taking note of what certain muscles are doing during different parts of the day: jaw clenched, butt tight, etc. Relax and Release
7. Relaxation techniques

B. Postural Modifications
   1. Teach patient proper posture
   2. Important to stay in balance
   3. Activate Muscles

C. Body Mechanics
   1. Demonstrating proper body mechanics
      a. Lifting, in and out of bed, etc.
      b. Decreasing stress on other parts of your body to help avoid leakage
   2. Pelvic Floor Muscle Activation – “The Knack”
      a. Coughing
      b. Laughing
      c. Lifting
      d. Sneezing – “Squeeze before you sneeze”
      e. Transitions

D. Neuromuscular Re-education
   1. Purpose
      a. Re-educate muscles to perform correctly
      b. Coordination
      c. Contract/ Relax Properly
      d. Down – training
      e. Submaximal Contraction
   2. Muscles
      a. Pelvic Floor Muscles and Transverse Abdominis (Primarily)
      b. Multifidus
   3. Biofeedback
      a. Real Time Ultra Sound (RTUS)
      b. Surface EMG
      c. Internal EMG with Rectal sensor
      d. Other - Mirror

E. Manual work
   1. Trigger point release
   2. Myofascial release
   3. Connective Tissue Work – adductors, abdominal, gluteals
   4. Scar tissue mobilization
   5. Visceral Mobilization

F. Stretching
   1. Always treat what you find
   2. Make sure to access both hamstrings and psoas

G. Strengthening-
1. Pelvic floor Strengthening
   a. Visualize Pelvic Floor in mirror- anus tightening, penile movement
   b. Improper contraction: compensation with adductors, gluteals or abdominal muscles
   c. Progression: supine, side lying, sitting, standing, with movement, inverted
   d. Long holds: working up to 10 second holds and Quick flicks
      - Allows for activation of both Type I and Type II muscle fibers
   e. Coordination: steps or longs holds with quick flicks
   f. Muscle facilitation

2. Core strengthening

3. Address other weak areas in and around pt.’s pelvis
   a. Gluteal muscles, Adductor muscles, Abductor muscles, and others that are found to be weak
   b. Start basic and progress

H. Mobilization- spine, hips, or other restrictions that are found

I. Home Exercise Program
   1. Personal Responsibility
   2. 30 minutes of cardiovascular exercise on most days of the week
   3. Strengthening routine
      a. Pelvic Floor strengthening
      b. Core strengthening
      c. Add in what else patient needs
   4. Stretching
   5. Behavior Modifications
   6. Home muscle strengthening- Use of tactile feedback
      a. Insertion of fingertip into vagina or rectum
      b. Sitting on rolled hand towel, or ball
      c. Vaginal/ Rectal weights
   7. Basic Beginning Exercises
      a. Adductor squeezes
      b. Resisted Abduction with Theraband
      c. Abdominal Activation
      d. Sitting Piriformis Stretch
      e. Posture and Body Mechanics
      f. Pelvic Floor Muscle contractions if appropriate
      g. Progress as appropriate and as tolerated

J. Electrical Stimulation
   1. Home Unit
   2. Rectal sensor
      a. Urge: 12.5 HZ
      b. Stress: 50 HZ

K. Others
   1. Supports
      a. Sacroiliac joint braces
      b. Abdominal Binders
      c. Pressure garments
      d. Others
   2. Tens
   3. Ultrasound
   4. Dilators
   5. Taping
   6. Penile Clamps
      a. Talk with MD
      b. Examples: J Clamp, C3 incontinence clamp, Cunningham Clamp, Gyrex Squeezer Klip, Greenwald

L. Resources
   1. ICS www.icsoffice.org/
2. Australian Government Department of Health and Aging
   http://www.bladderbowel.gov.au
   Has incontinence handouts in many different languages
3. International Organization of Physical Therapists in Women's Health
   www.iopthw.org
4. Section on Women’s Health of American Physical Therapy Association
   www.womenshealthapta.org
5. Many other

Questions
● Email: Hmoky @uic.edu

References:
Male slings

Ricarda M. Bauer, Department of Urology, Ludwig-Maximilians-University, Munich, Germany

Since 2000 male slings have gained increasing interest for the treatment of male stress incontinence. In recent years several adjustable and fixed sling systems were introduced. Today male sling systems are widely used as a result of success rates of up to 70% and easy handling for the patient. In general, surgical treatment for post-prostatectomy incontinence should be offered if the incontinence status is stable despite intensive conservative treatment. However, no recommendations in terms of specific diagnostic tools and differentiated treatment options for everyday life are available. Our aim is to provide some clinical relevant recommendations for the selection of the different male sling systems for the treatment of post-prostatectomy incontinence to support clinical decision in everyday life.

Adjustable sling systems

The most commonly used adjustable sling systems are the Argus sling system (Promedon Argentina), the ATOMS system (AMI, Austria) and the Remeex System (Neomedic, Spain). The newest development is the Phorbas system, a further development of the Argus sling. The aim of adjustable sling systems is to support the postoperatively reduced baseline continence provided by the smooth muscle system by a minimal increase of the urethral resistance (10–15 cmH₂O). These slings are positioned suburethrally on top of the bulbospongious muscle. In general, outcome of the different adjustable sling systems is comparable as well as the outcome in irradiated and non-irradiated patients. However, there is a difference regarding complications. Main complication is all adjustable sling systems seems to be postoperative pain with persistent pain in up to 5% of the patients.

The Argus sling (Promedon, Argentina) consists of a radiopaque cushioned system with a silicone foam pad for soft compression of the bulbar urethra. Two silicone columns formed by multiple conical elements are attached to the silicone foam and allow system readjustment while two radiopaque silicone “washers” allow regulation of the desired tension (recommended increase of intraoperative retrograde leak point pressure + 10-15 cmH₂O, recommended maximum final RLPP 40 cmH₂O). The Argus sling can be implanted via a retropubic (Argus classic) or transobturator (ArgusT) approach. The sling is fixed with “washers” in the suprapubic (Argus classic) or inguinal (ArgusT) region on the fascia. In patients with mild to moderate SUI after a mean follow-up of 45 months dry rates of 66% were achieved. In patients with moderate to severe SUI and a mean follow-up of 2.1 years a dry rate of 79.2% (pad test of 0–1 g) was reported. Another study with patients with severe SUI showed success rates of up to 67%. Re-adjustments are required in approximately one third of the patients. In irradiated patients equal success rates compared to non-irradiated patients can be achieved. Reported complications of the Argus sling include acute urinary retention, sling removal (up to 12%, due to urethral/bladder/abdominal wall erosion), infections, system dislocation, urinary retention and persistent pain.

After failed Argus sling, AUS implantation is still possible and shows good results.
The further development of the Argus system is the Phorbas system, launched in April 2014. It consists of an adjustable silicone cushion with silicone sling arms fixed around the Ramus inferior of the Os pubis and a scrotal port for easy percutaneous adjustments without additional surgeries. The implantation is performed via a single incision and a transobturator approach. The implantation needle is extendable for easy connection of the arms. The system is fully siliconized therefore complete and easy explantation without damage of the surrounding tissue is possible if necessary.

In a prospective pre-marketing study, 21 patients with moderate to severe SUI were treated with the Phorbas system. After a mean follow-up of 4.7 months (1-16 months), patients showed a significant reduction of urine loss in the pad-test from 639g preoperatively to 31 g. Cure rate was 71.4% with 12 patients using no pads and 3 using one security pad/day. Mean number of adjustments was 1.7 (0-4). Quality of life improved significantly (p>0.001). Only grade I and II complications according to the Clavien-Dindo classification occurred. No intraoperative complications and no postoperative urinary retention or residual urine occurred. No sling was explanted. Besides 2 local wound infections no postoperative complications occurred. The majority of the patients experienced only mild postoperative pain and no persistent pain occurred. At max. follow-up VAS was 2 and PGI score was 1.3.

The ATOMS system (AMI, Austria) consists of an adjustable silicone cushion with two Polypropylene sling arms. The slings are drawn around the Ramus inferior of the Os pubis through the Foramen obturatorium and attached to the cushion like a backpack. The cushion can be adjusted by a port system (in the left symphysis region or in the scrotum). Due to the port system easy percutaneous re-adjustments without additional surgeries are possible.

The first published study with 38 patients from Austria showed after a mean follow-up of 16.9 months a continence rate of 60.5% (0-1 pad/d and <15 ml urine loss in 24h-Padtest). 23.7% were improved and 15.8% failed. Mean re-adjustment rate was 3.97 (0-9 x). In a European multicenter study with 99 patients and a mean follow-up of 17.8 months continence rate was 63% (0 pads/d and < 10ml urine loss in 24h-Padtest). 29% of the patients were improved. Mean re-adjustment rate was 3.8 (0-6 x). In both studies no intraoperative complications occurred. Postoperative urinary retention rate was up to 2%. Explantation due to wound infection occurred in 4% respectively 10.5%. One patient had an urethral erosion (2.6%). Main postoperative complication was postoperative pain (perineal, scrotal, penis) in 52.6% respectively 68.7% with an explantation rate due to persistent pain of 2.6%.

The Remeex system (Neomedic, Spain) consists of a mesh connected via two monofilament traction threads to a suprapubic mechanical regulator (so called “varitensor”). The varitensor is permanently implanted subcutaneously over the abdominal rectum fascia 2 cm above the pubis. Adjustment is conducted via an external manipulator. The manipulator is left in place at end of implantation. On day 1 the sling will be adjusted using the manipulator until the patient is dry during coughing. The manipulator is removed and the wound is closed.

In an average follow-up of 32 months, success rates (no or one small pad per day) of up to 65 % can be achieved in patients with mild to moderate SUI. To achieve these success rates the majority of the patients need at least one readjustment. The main complications are intraoperative bladder injuries (up to 11%) and removal of the device (up to 12%) due to infections or urethral erosion. In addition, most patients report perineal discomfort or even pain after implantation.

No data exist concerning second line treatment after failed Remeex sling implantation.
Fixed slings

The AdVance sling (American Medical Systems, USA) is a polypropylene monofilament mesh that is placed retro-urethrally under the proximal part of the urethral bulb, passing bilaterally through the obturator fossae. The mode of actions seems to be multi-factorial: stabilisation of a postoperative urethral hypermobility, elongation of the function urethra and a venous sealing effect. After 3 years of follow up, a success rate of 77% can be achieved (53% no pad or 1 security pad). In irradiated patients, the AdVance sling showed reduced treatment success with dry rates between 25-53%. After implantation physical activities should be reduced to a minimum for 8-12 weeks to reduce the risk of postoperative sling dislocation. Severe complications including explantations are rare. The main postoperative complication is a transient acute postoperative urinary retention (up to 21%) requiring temporary re-catheterization.

The ideal population for the AdVance sling is still under discussion. Several studies showed that with the “repositioning test” a preoperative patient selection is possible. The “repositioning test” is performed in lithotomy position with a cystoscope positioned distal to the membranous urethra. Gentle midperineal pressure is applied parallel to the anal canal and below the bulbar urethra for repositioning the membranous urethra. The test is positive if 1) the sphincter closes autonomously, reflex, concentrically and complete during repositioning of the membranous urethra and 2) if the functional urethra length = coaptive zone during additional active sphincter contraction (circumferential coaptation of the membranous urethra) is ≥1cm. In addition, patients loosing urine during the night seem to be poor candidates.

In 2010, the second generation, the AdVanceXP sling was introduced. The AdVanceXP Male Sling System was marketed in 2010 and shares many characteristics with the AdVance sling; both are functional retro-urethral slings with the same indication for use, mesh materials, implant technique and implant locations. However, the AdVanceXP sling includes updated mesh weave with integrated tensioning fibres in place of biodegradable sutures to stabilize sling configuration upon implantation, and the addition of chevron anchors on the sling arms which are intended to provide enhanced acute tissue fixation of the sling arms. In addition, the AdVanceXP sling arm length has also been increased to better accommodate a variety of patients, Tyvek® liners have been added to prevent the chevrons from tearing the plastic sheath, and the helical needles have been redesigned to allow for easier tunnelling. Outcome of the AdVanceXP is comparable to the AdVance. However, with the AdVanceXP, overtensioning of the sling especially during removal of the Tyvek liners resulting in persistent urinary retention is possible.

New fixed sling systems

In last years, several new sling systems were introduced: e.g. Virtue quadratic sling (Coloplast, Denmark) and I-stop TOMS (CL Medical, USA). However, in comparison to the AdVance sling these sling systems are not widely used and mostly only limited data on small numbers of patients with short follow-up are available.
### Outcome of adjustable and fixed sling systems

<table>
<thead>
<tr>
<th></th>
<th>Argus</th>
<th>Atoms</th>
<th>Remeeex</th>
<th>Advance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Max. FU</strong></td>
<td>Up to 50.4 mo</td>
<td>Up to 30 mo</td>
<td>Average 77 mo</td>
<td>Up to 3 years</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>· Cured 54-79.2%</td>
<td></td>
<td>Cured 63%</td>
<td>Cured 72%</td>
<td>Cured up to 65.9%</td>
</tr>
<tr>
<td>· No difference with and without radiotherapy</td>
<td>· No difference with and without radiotherapy</td>
<td>· Improved 20.6%</td>
<td>· After radiotherapy lower success rates</td>
<td></td>
</tr>
<tr>
<td><strong>Complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>· Adjustment rate 38.6%</td>
<td></td>
<td>Mean number of adjustment 3.8</td>
<td>100% 1x readjustment</td>
<td>Up to 18% temporary residual urine/retention</td>
</tr>
<tr>
<td>· ≤15.8% explantation due to infection/erosion</td>
<td>· 4% explantation due to infection</td>
<td>· 1.5% erosion</td>
<td>· &lt;1% persistent pain</td>
<td></td>
</tr>
<tr>
<td>· Explantation due to pain 1%</td>
<td>· 68.7% postop. perineal/scrotal numbness/pain</td>
<td>· 4.4% Varitensor seromas</td>
<td>· Expantation rate &lt;2%</td>
<td></td>
</tr>
<tr>
<td>· Persistent pain ≤5%</td>
<td></td>
<td></td>
<td></td>
<td>Caveat: AdvanceXP overtensioning -&gt; persistent residual urine</td>
</tr>
</tbody>
</table>

### Preconditions for success of male sling systems

<table>
<thead>
<tr>
<th></th>
<th><strong>Advance</strong></th>
<th><strong>Adjustable slings</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>· Functional sphincter length ≥ 1cm (=coaptive zone)</td>
<td>· Residual sphincter function</td>
<td></td>
</tr>
<tr>
<td>· Mobile posterior urethra</td>
<td>· No complete incontinence</td>
<td></td>
</tr>
<tr>
<td>· No radiotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>· Risk factors:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>· Weak sphincter function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>· Incomplete sphincter closure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>· Sphincter defect</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Individual patient treatment for post-prostatectomy incontinence**

<table>
<thead>
<tr>
<th>AdVance</th>
<th>Adjustable slings</th>
<th>AUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• SUI I-II°</td>
<td>• SUI II-III°</td>
<td>• SUI III°</td>
</tr>
<tr>
<td>• Mobile posterior urethra</td>
<td>• AUS impossible or not accepted</td>
<td>• Severe/complete sphincter defect</td>
</tr>
<tr>
<td>• Coaptive zone ≥1cm</td>
<td>• No decreased outcome</td>
<td>• Complete incontinence</td>
</tr>
<tr>
<td>• No SUI III°</td>
<td>– Radiotherapy</td>
<td>• High psychological strain</td>
</tr>
<tr>
<td>• No sphincter defect</td>
<td>– Sphincter defect</td>
<td>• Tumor progress</td>
</tr>
<tr>
<td>• Caveat: Radiotherapy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion**

The selection of the treatment should be based on contraindications. However, there is a wide overlap of the different surgical options.
Artificial urinary sphincter, mainstay of male incontinence therapy?

Ervin Kocjancic, United States
Director of Division of Pelvic Health and Reconstructive Urology, Assistant Professor of Urology at University of Illinois at Chicago, USA.

Introduction

The AMS 800 artificial urinary sphincter prosthesis has been used for more than 30 years. Physicians worldwide have implanted the device in about 100,000 men as a treatment for stress urinary incontinence due to prostatectomy, TUR P, trauma or neurogenic reasons. The success rates of the AUS are still the highest compared to all other treatment options for male SUI.

The AMS 800 artificial sphincter - function

The AMS 800 is a hydraulic system which consists of three components: the cuff around the urethra, the pump positioned in the scrotum, and the pressure regulating reservoir balloon. The implant is made up from solid silicone elastomer, the system is filled with isotonic fluid. The system mimics normal sphincter function by opening and closing the cuff around the urethra voluntarily by the patient by pressing the pump. Thereby the fluid is transferred from the cuff to the reservoir and the cuff opens, allowing urine to pass. Within a few minutes after urinating, the fluid automatically will flow from the balloon back to the cuff, closing the urethra and providing continence.

Patient selection

The few contraindications for implanting an AMS 800 include patients with inadequate dexterity and/or mental acuity to use the pump, poor motivation to use the device, skin diseases in the implantation field and UTI.

Careful consideration of pros and cons will be needed in the following situations:
- Recurrent need for transurethral manipulations
- Recurrent strictures
- Urethral diverticulum
- Detrusor insufficiency
- Low capacity bladder (augmentation)
- Obstruction (BN incision/sphincterotomy/stents)
- Detrusor overactivity (Botox)

Implantation technique

Implantation of the AMS 800 usually takes 45 to 90 minutes. Following is a brief summary of the surgical procedure.

There are a number of possible surgical approaches for implanting the AMS 800. In the
following steps we outline both the transverse scrotal approach and the perineal approach.

**Classic Perineal Approach**

Incision and Dissection
Place a Foley catheter into urethra to help identify it during dissection. Make a midline perineal incision and bluntly dissect bulbocavernous muscle from around the bulbous urethra. Some surgeons prefer to leave the bulbocavernous muscle on the urethra, particularly when it is atrophic. Completely dissect the urethra off the cavernous bodies for about 2 cm. Injury to the cavernous body can be tolerated, urethral injury leads to abortion of the operation. Place cuff sizer around urethra where the cuff is to be implanted. It should fit snugly without constricting urethra. Note: If catheter or sound is in urethra, remove it before measuring the urethra. Do not stretch cuff sizer before use. Surgeon should use his or her judgment in choosing an appropriate cuff size, the measuring tape only provides approximate measurement of bulbous urethra circumference. The inside circumference of cuff is somewhat smaller than the outside circumference of cuff.

Place the Cuff
Select cuff size that corresponds to measured length. Prepare cuff for implantation. Position cuff around the urethra with the "pillow" side toward urethra. If preparation of the cuff (unpacking, removal of air, rinsing) will take a few minutes, placement of the pressure regulating balloon may be commenced meanwhile.

Place the Pressure Regulating Balloon
Select appropriate size pressure regulating balloon. Make a suprapubic incision, divide rectus fascia transversely, and use a spreading motion to separate the linea alba to reach prevesical space. Use blunt dissection to create a space for balloon. Position the balloon in prevesical space. Many surgeons prefer an intraperitoneal position for the balloon in order to ensure reliable constant pressure which may be influenced by extraperitoneal formation of pseudocapsules.

Place the Pump
Use blunt dissection to create a dependent subdartos pouch in the scrotum. Note: Control pump should be placed on same side as the pressure-regulating balloon. Place pump into scrotal pouch with deactivation button facing outward so that it is palpable. Route the tubing to abdominal incision. Note: The pump tubing should be above rectus muscle and fascia in abdominal incision.

Make Connections
AMS Suture-Tie Connectors or AMS Quick Connect Sutureless Window Connectors may be used to connect the tubing, today the latter are preferred in most institutions. Normally we use the straight connectors. Right angle connectors should always be used.
when the tubing makes a sharp curve at the point of connection.

Deactivate and Close
To deactivate the device, squeeze and release the pump several times to empty the fluid from the cuff. When the pump is refilled so there is a slight dimple in it, push the button to lock the cuff open during the healing process. It is important to leave a slight indentation in the pump bulb to ensure that there is enough fluid in the pump to activate the device later. Close the incision.

Transverse Scrotal Approach

Incision
Make an upper transverse scrotal incision through the subcutaneous tissue. Move the incision up the penis and stabilize with a surgical retractor and blunt stay hooks at 1, 3, 5, 7, 9 and 11 o’clock.

Expose the Tunica Albuginea
Sharply expose the tunica albuginea of both corpora cavernosa. Pass the Metzenbaum scissors proximally along the ventral surface of the tunica to the proximal corpora. When deep exposure of the proximal corpora is secured, place an intact Deaver retractor on the side of the urethra for caudal traction. Repeat on the contralateral side, exposing the scrotal septum.

Dissection
Sharply dissect the scrotal septum off the bulbar urethra. To mobilize the urethra, sharply dissect the webs of Buck’s fascia binding the diverging corpora cavernosum to the corpora spongiosum.

Dissect and Measure Urethra - Place the Cuff
Because the patient is in the supine position, the urethra is mobile. Use a right angle clamp to conduct the posterior dissection of the urethra almost under direct vision. Spread the right angle clamp to create sufficient space for the placement of the occlusive cuff. Measure the urethra. Then place the proper size cuff around the circumference of the urethra.

Place the Pressure-Regulating Balloon
There are two ways to place the pressure-regulating balloon (PRB):

- With the bladder empty and the surgical retractor and stays removed, retract the tissue to the side of the penis. Place the PRB in the retropubic space by locating the inguinal ring and sharply piercing the transversalis fascia. After the PRB implantation, narrow the opening with an absorbable suture.
- Alternatively, displace the scrotal incision over the inguinal area and inguinal ring location. Finger dissection is used to develop a pouch beneath the rectus but anterior to the transversalis fascia (cephalad to the inguinal ring). This avoids the necessity of piercing the fascia in patients with scarred retroperitoneum after the PRB is implanted. Narrow the opening with an absorbable suture. Balloon tubing is rooted superficially to the control pump.

Place the Pump
Elevate the inferior aspect of the scrotal incision. Develop a space underneath the scrotal skin and dartos muscle to serve as a pouch for the pump. Begin the development of the tunnel about 2 cm from the skin edge in order to facilitate eventual tubing and connector concealment. Loosely tie purse string suture around the opening of the tunnel to secure the pump position.

Finally Trim Tubing and Make Connections and deactivate the system as described above, then close the incision.
Troubleshooting with artificial sphincter implantation

Wilhelm A. Huebner

Despite a high success rate, problems can arise after artificial sphincter implantation (AMS 800), most notably:
Recurring incontinence because of morphological changes, technical difficulties within the system, erosion, infection and individual factors that are subject to change (e.g. manual capabilities of the patient to use the pump).
The following chapter is concerned with the most common problems:

Diagnostics:

Targeted anamnesis can be seen as basis for any further diagnostics. Transurethral procedures must be noted (Cystoscopy, Catheter). Sudden pain while urinating is indicating towards erosion of the cuff. Concerning persisting incontinence knowledge of the duration is imperative (since the implantation, within 6 month, after?). Early onset usually points towards technical problems (wrong balloon/cuff-size). Also differentiating between permanent and stress-related (coughing) incontinence is of utmost importance.
Within the imaging diagnostics standard radiography is helpful to determine functioning of the system. If a contrast medium was used within the system, radiography can also be used to determine the level of filling; otherwise ultrasonography, CT or MRI is needed. Exact localization of a leak is hardly ever seen in imaging (CT), but usually only possible during revision. A (V)CUG may confirm cuff erosion.

Cystoscopy gives evidence of cuff-function, scar tissue, stenosis and possible erosion. If there is a distinct dynamic of the cuff without complete closing of the urethra either the cuff implanted was too wide, or atrophy of the urethral wall has occurred.

If OAB Syndrome is suspected, urodynamics can confirm the diagnosis. For better documentation and monitoring of function of the AMS 800-System we also use the retrograde Leak Point Pressure (RLPP), which should be around 30cmH2O if the cuff is fully closed and at least a 10-15 cmH2O difference to the open cuff.
To measure the RLPP a foley catheter is blocked in the fossa navicularis in the anesthesized patient with empty bladder. An infusion is connected to the foley and the bottle lowered from about 60cm above symphysis level until the dripping stops. The level of the infusion in the bottle represents the RLPP. To get a rough idea of the cuff function the RLPP may be used without anesthesia, comparing the RLPP with the cuff open and closed.
Common complications

1. **Atrophy of the urethra beneath the cuff**
   Four different solutions are possible to treat persisting incontinence, all of which have overlapping indications.

   1a. **Smaller cuff**
   If a cuff of 4 cm or larger was chosen primarily, cuff-size can be decreased down to 3,5 cm. The new cuff can be placed within the same pseudocapsule of the old one. Inguinal or perineal connection to the system can be used depending on the anatomical situation.

   1b. **Second cuff**
   If a primary cuff of 3,5 cm was chosen a double-cuff can be considered. It is important to place the second cuff parallel to the first one. Bending of the urethra must be avoided which is usually easiest if the cuffs are implanted in close proximity to each other. A scrotal incision may also be considered for this intervention since the second cuff is usually implanted distal to the first one. Most of the time the “Y”-connection piece will be positioned perineally, yet if there is not enough space inguinal placement is possible. Depending on the size of the second cuff and the length of the tube, filling of the system should be increased by about 2-4 ml.

   1c. **Tissue transplant**
   Alternative to the double-cuff a pedicle flap (Dartos) may be used to increase the urethral circumference. The flap is placed beneath the opened cuff, and fixated with 5/0 resorbable sutures, not placed directly under the cuff.
   The system needs to stay deactivated for about 3 weeks until the partly opened capsule has reformed.

   1d. **Change of the balloon**
   Generally 61-70cmH2O balloons will be used but other balloons are available for selected cases. However changing to a stronger balloon as treatment for persisting incontinence after atrophy of the urethra has a very high risk of erosion and should thus be considered with care.

2. **Isolated stress incontinence**
   If a Patient completely continent with the exception of coughing and/or getting up implantation of a “Stress-relief-cuff” may be considered together with the options mentioned in 1a-1d. The “Stress-relief-cuff” is a open cuff placed intraabdominally and connected to the system using a “Y”-piece between the primary cuff and the pump. This leads to a short transmission of fluid and closing of the urethra if there is a rise in intraabdominal pressure,
yet a permanently increased pressure in the system, which leads to increased risk of erosion, is avoided.

3. Erosion of the urethra
The first symptom of erosion is usually sudden pain during urination. Assurance of the diagnosis can be achieved with cystoscopy and/or UCG. Any further decision depends greatly upon an assessment of infection. While in the past explantation of the entire system was the standard procedure, today if there are no signs of infection only the cuff may be removed. After the removal, the tubes are closed up and the urethra is taken care of. Re-implantation of a new cuff can be considered after 12 weeks, yet a new position for the cuff must be chosen. In many cases a transcavernosal implantation will be advised. Dacron SIS may also be used to protect the urethra. Since erosion is mostly caused by a disproportion of pressure in the system and size of the cuff/urethra these factors should be changed (if possible) to minimize the risk of another revision.

4. Iatrogenic lesion
4a. Lesion of the urethra
Once or twice a year we see iatrogenic lesions of an artificial sphincter, which consist mostly of injuries of the urethra after transurethral procedures. 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 the cuff is opened, the urethra closed and protected using a Dartos-flap/fatty tissue. The cuff then is left open for 6 weeks when it can be closed again in a very short procedure. The advantage of this is that the cuff can remain at the same (ideal) location.

4b. Lesion of the tubing
Lesions of the tubing, usually caused by open surgery (hernia repair), are rare and get noticed very early. If the leak is easily identified the part is clamped using armed mosquito clamps. Then the 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 separately using the AMS-blunt cannula for filling. Once the leak is found the procedure is continued as above.

5. Leak
System leakage becomes apparent through loss of function, a soft palpable pump and an empty balloon in ultrasonography/CT. However the exact location of the leak cannot be seen in imaging. Finding the correct location is done using the method described in 4b. It can be difficult to identify a lesion of the cuff, since the capsule can imitate impermeability thus the cuff has to be exposed to verify the situation. With systems older than 8 years we have a wide range of indications for replacement of the entire system.
6. **Manual capability**

Even in very high age most patients keep the ability to use the pump, if the implantation happened a few years back at full mental capacity. If a patient still loses the ability to use the pump and help by an auxiliary person is not possible, deactivating the system while the cuff is filled to about one quarter may be an acceptable solution. In the future change to an abdominal pump could be a possibility, however this is not routinely possible yet.