What's up in male urinary incontinence, resolving complications and fixing failures

Workshop 43
Tuesday 24 August 2010, 14:00 – 18:00

Time	Time	Topic	Speaker
14:00	14:05	Welcome	Carlos D'Ancona/ Ervin Kocjancic
		Part I	
14:05	14:15	How to evaluate the male incontinent patient	Carlos D'Ancona
14:15	14:30	Physiotherapy - expert opinion and evidence based medicine	Kathryn Burgio
14:30	14:45	AMS 800 is the gold standard?	Gommert Van Koeveringe
14:45		Why consider using other techniques ?	
14:45	15:05	Sling Adjustable sling	John J. Smith III Wilhelm Hubner
15:05	15:15	Urethral constrictor	Carlos D'Ancona
15:15	15:30	Pro-ACT	Wilhelm Hubner
15:30	16:00	Break	
16:00	18:00	Cases discussions – complications and manage failures	

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 achieve the knowledge on evaluation, different procedures, managing difficult cases, the complications of the most commonly performed procedures for male incontinence and fix failures through an active learning process. At the end of the session the participants will be able to recognize the most commonly performed procedures for male incontinence surgery, understand and recognize the possible complications and consider alternative options in unusual, complicated male incontinent patients.

Educational Objectives

This workshop will focus on the evaluation of incontinent patients, conservative treatment and surgery. After the course attendants are expected to know:

- how evaluate the incontinent patient

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- when to indicate conservative treatment
- select a surgical technique based on the expectations of the patient
- how to treat complications
- how to fix failures

How to evaluate the male incontinent patient

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Despite excellent oncologic results of radical prostatectomy, morbidity associated to the procedure as urinary incontinence and erectile dysfunction deeply affect patient's quality of life (QoL) (1). The reported incontinence rate after radical prostatectomy varies greatly from 2,9% to 87%, and depends on many factors. One of most important is the data collection method which defines the amount of incontinence (1). There have been various attempts to unify the measurements of continence after prostatectomy, but no consensus has been reach.

Urinary incontinence is a problem that affects the quality of life (QoL) (2), and the use of specific or generic questionnaires as evaluation tools of QoL has been intensified due to the growing interest of health research on clinical evaluation subjective methods that consider the patient opinion about his health condition (3).

Pad usage is one of the most used parameters to measure incontinence. Many articles used 0 to 1 pad a day as normal after surgery. However, there are different continence definitions based on pad status ranging from 0 pads or a security pad to 0 to 1 pad daily (4).

The evaluation of a urinary incontinent patient consists of: clinical and physical evaluation, urine exam and pad weight test, Quality of Life questionnaires, urethrocysitgraphy or cystoscopy and urodynamic evaluation. The patient should have sterile urine to complete the evaluation.

Pad weight test – The test is normally done for three days consecutive or not. This method is very important to measure the 24 hours of leakage per day. It is possible to classify the intensity of leakage: mild less than 10ml, moderate less than 200ml and severe more than 200ml.

Quality of Life - . After radical prostatectomy, urinary incontinence (UI) presents a negative impact on the quality of life (QoL) of the men who underwent this surgery (2). The QoL is based on the relationship between physical, psychological and socio-cultural domains, which are seen as different areas that constitute an important goal in clinical research. UI, a problem that affects several of these domains, the use of specific instruments that evaluate its impact on the QoL is recommended. There are quite a lot of studies on literature that involves the female population, but there are few articles which evaluate the impact of UI on the QoL in men. The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) is a simple, brief and auto-administrable questionnaire. The ICIQ-SF is composed of four questions that evaluate the frequency, the gravity and the UI impact, besides a set of eight auto diagnostic topics related to causes or situations of urinary leakage. The ICIQ-SF score ranges from 0 to 21, and the higher the value, the worst the QoL. The Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) is a generic multidimensional questionnaire composed of 36 questions, grouped in eight scales or components: Functional Capacity, Physical Aspects, Pain, General Health State, Vitality, Social Aspects, Emotional Aspects and Mental Health. It presents a final score that ranges from 0 to 100, where 0 is the worst general state of health and 100 the best state of health.

We have done a study of 25 incontinent male patients, of which 44% presented the maximum score in the ICIQ-SF. This means that they lost a great quantity of urine all the time (they had to use pads) and perceived that the urinary leakage had a great impact on their daily life. In fact, men who used one pad a day and complained of occasional dribbling, their QoL was not affected as those who required two or more pads (Sacco et al, 2006). Also, the urinary dribbling, mainly among the patients that used pads, had a more significant effect than the sexual function loss (Fowler et al., 1995).

Urethrocystography / cystoscopy - Contracture of the bladder neck at the level of the anastomosis between the bladder and membranous urethra is a well recognized complication after radical prostatectomy, reportedly occurring from 0.4 to 32% of

patients. Bladder neck contracture is usually the result of scar tissue encircling and narrowing the reconfigured bladder neck. This narrowing may result in significant BOO, resulting in symptoms of urinary frequency, urgency, poor stream and incomplete emptying of the bladder. Eventually acute urinary retention may develop. The diagnosis can be made by retrograde urethrocystography or cystoscopy.

It is particularly important that urethral anastomosis contracture should be resolved before continence technique has been done, because instrumentation after the procedure can be difficult or risk return incontinence. Before surgical treatment of urinary incontinence is recommend to perform retrograde urethrocystography or cystoscopy.

Urodynamic evaluation - Although there is extensive literature on urinary incontinence after radical retropubic prostatectomy, few data are available on detrusor function after the operation. Thus, it is not clear if the anatomic dissection due to the surgical technique may involve both the filling phase and the emptying phase of the micturition reflex. Possible limitations in analyzing the results from the literature may be due to the evolution of surgical techniques over the years and to the lack of standardized methodology used in urodynamic tests. Continence nerves contained in the neurovascular bundles can be damaged by blunt dissection of posterior periurethral tissues beneath the urethra at the prostatic apex, and sutures placed for vesicourethral reanastomosis. Moreover, seminal vesicle dissection can injure the pelvic plexus, which is located on the lateral surface of the rectum with its midpoint at the tip of the seminal vesicles and provides autonomic innervation to all pelvic organs.

Considering the urodynamic examination reported in the literature, it appears that most studies were performed without a standardized method, thereby making it difficult to draw clear conclusions from the results. The significant reduction in bladder compliance, as observed in most studies, may be related to reduce bladder perfusion induced by long-term elevated intravesical pressure, inflammation and fibrosis, or surgery-linked altered bladder wall geometry. It may also be due to partial surgical decentralization of the bladder, because wide anatomic dissection around the prostate may disrupt trigone, neobladder neck, and posterior urethral afferent and efferent

innervation, causing outlet incompetence and partial detrusor muscle denervation. With regard to detrusor overactivity, the question of whether or not it is a consequence of the operation has not been resolved, because few studies compared preoperative versus postoperative urodynamic conditions. In cases in which detrusor overactivity presents only after the operation, it is probably due to surgical decentralization of the bladder or, if associated with sphincter incompetence and urinary incontinence, it may be caused by the activation of a vesicourethral reflex. Most studies underscored the role of urodynamics in the assessment and management of postprostatectomy incontinence. Indeed, preoperative and postoperative symptoms seem unreliable in defining the cause of urinary incontinence. Although urodynamic diagnosis of intrinsic sphincter deficiency has a positive predictive value of 95% and a negative predictive value of 100% versus genuine stress incontinence on a clinical level, diagnosis of detrusor overactivity shows a positive predictive value of 44% and a negative predictive value of 81% versus urge incontinence. It was observed that urodynamics is useful in predicting the risk of incontinence, particularly in asymptomatic patients before surgery. With a normal preoperative detrusor function, postoperative urinary incontinence was 3%; in the presence of any abnormality, the incidence ranged from 17% to 71% ($p < 0.001$) [7].

The abdominal leak point pressure (ALPP) did not correlate significantly with the 24-hr pad test in patients with post-prostatectomy stress incontinence. This suggests that in this patient subset, the ALPP is a relatively poor predictor of incontinence severity and, therefore, has limited clinical value in the urodynamic evaluation of post-prostatectomy incontinence. The urodynamic assessment of these patients should focus on the presence or absence of stress incontinence and on the presence of associated bladder dysfunction (8).

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ICS Workshop

What's Up in Male Urinary Incontinence: Resolving Complications and Fixing Failures

"Physiotherapy and Behavioral Interventions"

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Objectives

- Describe methods of pelvic floor muscle training (PFMT) and exercise in men
- Describe other behavioral interventions for urinary incontinence and overactive bladder (OAB) in men
- Review evidence for behavioral treatments in men
- Review evidence for behavioral prevention of post-prostatectomy urinary incontinence using PFMT and other behavioral interventions

Pelvic Floor Muscle Training and Exercise in Men

- Widely accepted conservative treatment for post-prostatectomy incontinence
- Appropriate for other etiologies (post-stroke, Parkinson's disease, unknown etiology)
- Appropriate for symptoms of OAB: frequency, urgency, nocturia
- Teaching methods
    - Digital anal sphincter palpation with verbal feedback
    - Biofeedback
    - Electrical Stimulation

Urge Suppression Techniques

- Teaching methods are the same as for women
- Includes education about why rushing to the toilet is counterproductive
- Focuses on active use of pelvic floor muscles
- Teaches a more adaptive response to urgency
- Can be used to reduce nocturia

Delayed Voiding

- Builds on urge suppression skills
- Instead of going to bathroom when the urge subsides, voiding is delayed
- Delay interval is increased incrementally
- Using a bladder diary helps to increase awareness and guide treatment

Stress Strategies

- Counterbracing, the Knack

Behavioral Treatment of OAB in Men

- Burgio et al, 2010 (USA): 143 men with OAB without significant obstruction
- 2-site randomized equivalence trial
- Randomized to 4 visits of:
    - Behavioral therapy with PFMT + urge suppression + delayed voiding
    - Control group: Drug therapy (oxybutynin)
- Results
    - Decreases in voids/24 hours significant in both groups ($p<0.001$)
    - Not differ by group (2.2 in behavioral and 1.9 in drug)
    - Nocturia reduced by .72 in behavioral and .32 in drug ($p=0.04$)
    - Patient satisfaction: 56% vs. 43% completely satisfied
    - Patient perception of improvement: 39% vs. 29% "much better"
- Conclusion: Behavioral treatment as effective for reducing frequency of voiding in men with OAB (without obstruction)

Pelvic Floor Muscle Training and Other Behavioral Interventions to Reduce Post-Prostatectomy Incontinence:

- Prostate cancer is the most common internal malignancy in men (in the U.S)
- For early prostate cancer, radical prostatectomy is often the treatment of choice
- Urinary incontinence is a common sequela of radical prostatectomy (established risk factor)
- Prostate Cancer Outcomes Study - mailed survey after radical prostatectomy
    - 1,288 Men: 77% incontinent at 6 months, 65% at 12 months, 65% at 24-months

- Treatment for Persistent UI: Pelvic floor muscle exercises and bladder control strategies +/- biofeedback and electrical stimulation widely accepted conservative treatment

- Goode and colleagues (USA): 208 men with persistent post prostatectomy UI
    - Randomized to:
        - pelvic floor muscle training + behavioral strategies + estim
        - pelvic floor muscle training + behavioral strategies
        - Control group: no treatment (wait list)
        - Outcome: reduction in UI episodes on bladder diary

- Prevention with Perioperative Training:
    - Studies have yielded mixed results
    - 5 adequately powered RCTs

- Filocamo et al. 2005 (Italy): 300 men undergoing radical prostatectomy
    - Randomized to:
        - 3 sessions: pelvic floor muscle training via physical exam during hospital stay + home exercise and diaries + 2 post-op reinforcement visits.
        - Control group: no formal exercise training
        - Outcome: pad use – one "precautionary" pad or no pads

- Van Kampen et al. 2000 (Belgium): 102 men still incontinent 15 days after catheter removal
    - Randomized to up to 1 year of:
        - Weekly individualized treatment in physiotherapy clinic with pelvic floor muscle training with biofeedback, and pelvic floor estim with anal probe if muscles weak
        - Control group: weekly false transdermal electrical stimulation of abdominal and thigh adductor muscles
        - Outcome: 2- and 24-hour pad tests < 2 grams, no report of leakage for 3 days

- Manassero et al. 2007 (Italy): 152 men undergoing radical prostatectomy
    - Randomized to
        - Pelvic floor muscle exercises taught on physical exam 7 days after catheter removal and progressive home exercises (continued for up to 1 year)
        - Control group: usual care
        - Outcome: < 2 grams on 24-hour pad test

- Burgio et al. 2006 (USA): 125 men undergoing radical prostatectomy
    - Randomized to:
        - Single session of pre-operative, biofeedback-assisted pelvic floor muscle exercise training and instructions for home exercises
        - Control group: usual care
        - Outcome: No incontinent episodes on bladder diary

- Perioperative behavioral training can hasten recovery of bladder control and reduce the severity of incontinence following radical prostatectomy
- No studies of post-prostatectomy FI prevention
- No studies of risk factors for UI or FI after brachytherapy

Summary of Research on Behavioral Interventions for Incontinence in Men

- Male urinary incontinence remains under-studied compared to female incontinence.
- PFMT with digital feedback or biofeedback shows benefit in first year after surgery.
- Behavioral treatment with PFMT + urge suppression + stress strategies improves incontinence persisting for over a year post-prostatectomy.
- Behavioral therapy with PFMT + urge suppression + delayed voiding beneficial for male OAB.
- Insufficient data to evaluate effects of electrical stimulation as a stand-alone therapy. Does not appear to enhance digital or biofeedback training.
- Prevention: Some evidence that men who undergo behavioral therapy including PFMT achieve continence sooner after prostatectomy.

Future Research Needs:

- More research is needed in all areas related to behavioral prevention and treatment for men with incontinence or OAB.
- Who should be targeted for PFMT?
- What is the optimal time to begin a PFMT program?
- How can we sustain the person's efforts over time?
- Models of prevention for FI and UI in older men
- Models to integrate behavioral interventions into health care systems
- Public education on lifestyle decisions such as diet, weight, smoking, bowel and bladder habits

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Van Kampen M, De Weerdt W, Van Poppel H, et al. Effect of pelvic floor re-education on duration and degree of incontinence after radical prostatectomy: A randomized controlled trial. *The Lancet* 2000; 355: 98.

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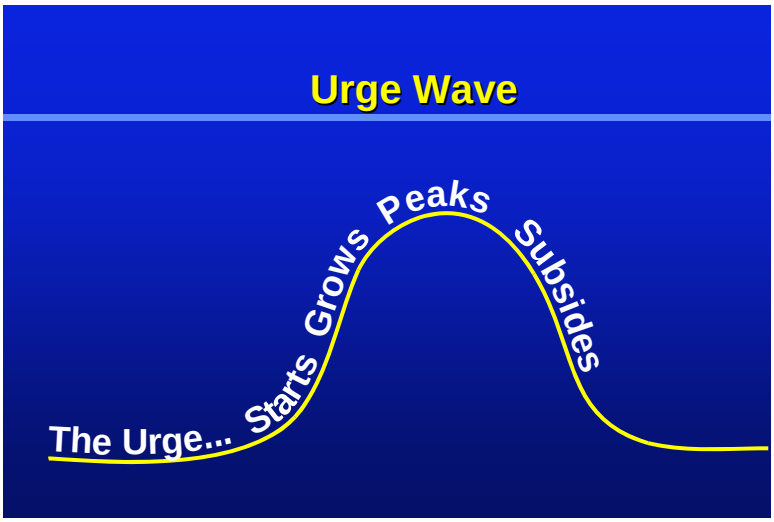
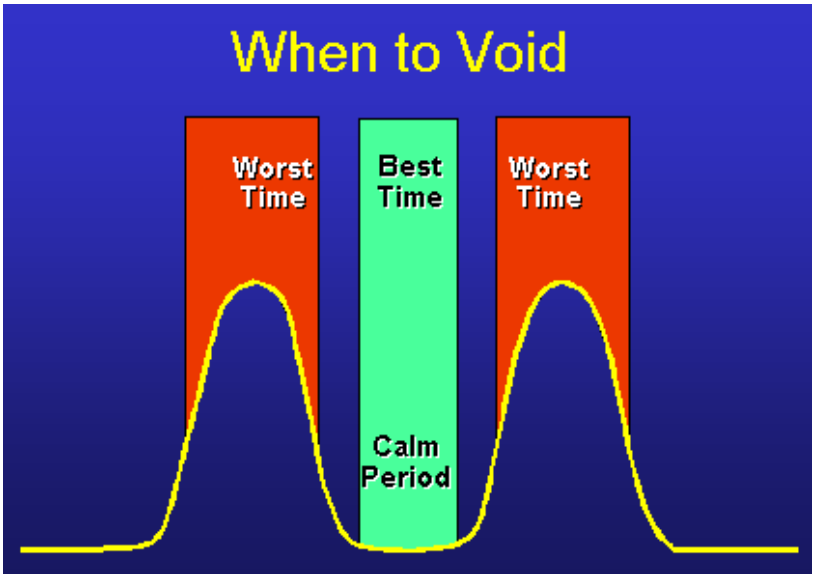
URGE SUPPRESSION STRATEGY



When the Urge Strikes…

- Stop and stay still. Sit down if you can.
- Squeeze your pelvic floor muscles quickly 3 to 5 times and repeat as needed.
- Relax the rest of your body. Take a deep breath.
- Concentrate on suppressing the urge.
- Wait until the urge calms down.
- Walk to the bathroom at a normal pace.
- If the urge returns on the way to the bathroom, stop and repeat.



Alternative approaches to the surgical treatment of male urinary incontinence using the artificial urinary sphincter

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This handout, provides an overview of recently described new surgical techniques for the implantation of the AMS 800 artificial urinary sphincter.
These surgical techniques include the scrotal and transcorporal sphincter cuff insertion and alternative balloon placement during both perineal and scrotal cuff placement.

In the last decade the artificial urinary sphincter has become definitive management for urinary incontinence in men, particularly after radical prostatectomy. In the majority of cases the rather high patient expectations can be realized [1].
Placement of an artificial urinary sphincter via a scrotal approach is a natural extension of the penoscrotal technique for implantation of an inflatable penile prosthesis[3].

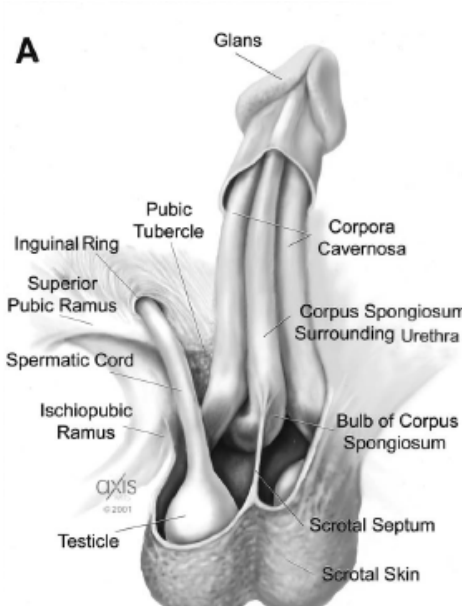

FIGURE 1. exposure of proximal corpora and division of septum reveal proximal bulbar urethra

Using an upper transverse scrotal incision, rapid access to the proximal bulbar urethra can be achieved by exposing the proximal corpora as for penile prosthesis surgery (Figure 1). The location of the occlusive cuff around the urethra as it emerges from the diverging corpora is the same location as that achieved by the traditional perineal approach. The pressure regulating balloon is placed in the retropubic space in a manner similar to the way the reservoir for the 3-piece penile implant is placed via the inguinal canal between fascia transversalis and abdominal muscles. The same approach can also be used during perineal cuff placement. A subdartos pouch within the scrotum is then created to house the control pump [2].

With time some patients experience a recurrence of less severe incontinence, which is usually attributable to urethral atrophy beneath the cuff. If the patient already has the smallest 4 cm. cuff, this problem cannot be remedied by simple cuff down sizing and a new cuff site must be sought or a second tandem cuff must be implanted.[1, 2] At the more distal urethral site of such secondary or tandem cuff implantation urethral circumference is often too small for a good fit with a 4 cm. cuff. In addition, dissection of the urethra from the corporal bodies at a more distal location often leaves the roof of the urethra precariously thin.
For this situation the technique of transcorporal cuff implantation is developed.

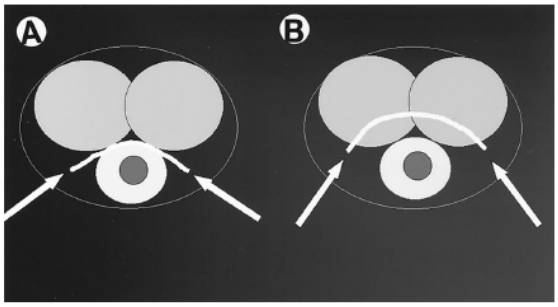

FIGURE 2. Difference in dissection depth. *A*, for standard artificial urinary sphincter cuff placement dissection plane (arrows and curved line) is between urethra and corpora cavernosa superficial to tunica albuginea of corporal bodies. *B*, for transcorporal cuff placement dissection plane is deep to tunica albuginea of corporal bodies.

This technique not only adds bulk to the urethra, allowing for larger cuff use, but also leaves the urethra protected on its roof (Figure 2), which is a common location of urethral thinning and erosion. This technique has also enabled safe and successful reimplantation in patients with multiple previous urethral erosions.

A long term outcome study shows over a 10 year period, an overall complication rate of 37%. Most events occur in the first 4 years[4].

Implantation is possible through one incision, though some report worse dry- and higher erosion rates.

The AMS 800 sphincter prosthesis is still mainstay of treatment for moderate to severe stress incontinence in men.

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Male slings in the treatment of post prostatectomy urinary incontinence

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Male stress urinary incontinence (SUI) is a potential complication of prostate surgery and although more frequent after radical prostatectomy it can also occur after endoscopic or open surgery for BPH. It is reasonable to accept that ≈10% of the affected men will consider their UI after prostatectomy bothersome enough to seek medical attention. The artificial urinary sphincter (AUS) has been considered the 'gold standard' treatment for all cases of SUI that do not improve after 6–12 months of conservative management. However, the AUS requires that the patient possess manual dexterity and a normal cognitive status that will enable him to activate/deactivate the urethral cuff. Although it is unclear how many patients are omitted from AUS surgery due to these prerequisites, it is likely that a sizeable number is eventually excluded. In addition, residual UI after AUS implantation, once supposed to be minimal, is increasing as series with longer follow-up become available. At 5 years after AUS implantation more than half of the patients may consider their residual UI as moderate to severe. In addition, revisions may be necessary in a quarter of patients, either due to mechanical failure or to urethral atrophy caused by the circumferential compression exerted by the cuff. These inconveniences may be exacerbated in elderly people. In a recent study, almost half of the sphincters implanted in patients in the seventh decade of life were removed, inactivated or revised. Bulking procedures have been suggested to constitute an alternative to the AUS. Unfortunately, although injections of agents such as DurasphereTM, ContingenTM or MacroplasticTM are simple surgical procedures, the results are frustrating, with a 20% UI cure rate at 1 year. Another concept for treating male SUI is the bulbo-urethral sling. The device was first deployed in 1961 by Berry and Kaufman and was thereafter revived by Schaeffer who suspended the sling by strings passed into the abdominal wall. However, the decrease in UI cure rates seems to indicate that those slings failed to maintain a constant tension over time. In addition, tension was exerted in a small extension of the urethra leading to high rates of urinary retention and urethral erosion. Altogether, these inconveniences prevented a larger acceptance of this technique by the urological community. Raz initially performed the perineal male sling procedure in 1998 (personal communication), and Jacoby presented the first series at the International Continence Society in 1999.

The bone-anchored male perineal sling was introduced by Comiter, who reported a UI cure rate of 65% and an UI improvement rate of 15%. Subsequently, other studies provided success rates of 55–76%.

The use of bone anchors obviates the need for the blind transfer of suture suprapubically to achieve bulbar urethral compression and eliminates any abdominal incision. Pudendal nerve branches are not compressed. Therefore, no instance of chronic postoperative pain occurred. Additionally, the pubis is a fixed structure unlike the penile crura, that is the Kaufman procedure, which can stretch with time. Unlike the artificial urinary sphincter that compresses the urethra circumferentially thereby interfering with venous blood flow, and predisposing to urethral atrophy and even erosion, the male sling compresses only the ventral aspect of the bulbar urethra, leaving the dorsal and lateral blood flow intact.

Another advantage of the sling procedure over the AUS is represented by the conserved

voiding pattern. As soon as the catheter is removed,
normal voiding may occur. Additionally, the risk of “mechanical” malfunction is minimized without any fluid filled chambers and potentially tenuous tubal connections.
The importance of urethra compression for obtaining continence, as suggested by the increase of the LLP, also helps to explain the poor efficacy of bone anchored male slings in patients that had received adjuvant radiotherapy or had had previous failed surgery for SUI. In particular, an increased periurethral fibrosis, urethral atrophy and diminished urethral compliance might impede a correct coaptation between the urethra walls with the tension exerted by the sling.
When counseling our patients on the expected and possible outcomes after the BAMS procedure, questions regarding further treatment options, such as an AUS, are often asked. Encouraging results have been reported with the use of the male sling in the treatment of SUI. Short-term success rates for the perineal male sling range between 76% and 90%.
Experience with new slings delivered trough the obturator route such as Advance tm or Argus T has been reported and the results are very promising.

Early outcomes of the male sling to correct post-prostatectomy incontinence have been promising in select patients. Long-term data are lacking to determine whether the male sling is as effective as the artificial urinary sphincter, which is the current gold standard. In a recently published article in J. Urol: Artificial urinary sphincter versus male sling for post-prostatectomy incontinence-what do patients choose? Khumar et.al conclude that when men with post-prostatectomy incontinence are offered the choice of an artificial urinary sphincter vs a male sling, the opportunity to avoid using a mechanical device is preferable to undergoing a well established procedure. Men who strongly wish to avoid a mechanical device are willing to go against the surgeon recommendation for an artificial urinary sphincter.

Recommended reading

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ADJUSTABLE MALE SLINGS / PRO-ACT

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Surgical therapy of male incontinence follows different strategies compared to female incontinence. The vast majorityof cases will need therapy for incontinence that was caused by surgical procedures, mainly radical prostatectomies. Due to that etiology clinical findings are also different than in the female. Most patients will be able to interrupt their stream even if they leak heavely. Additionally you will find the leakage to increase in the afternoon in the most cases. This is the clinical impact of an impaired striated muscle function (innervated by the pudendal nerve). However, the striated muscle is not capable of a long term contraction, which finally results in the clinical sign of incontinence due to fatigue.

It is well understood, that during radical prostatectomy the structures compromised usually include the autonomous innervation of the smooth muscle of the sphincter system. Therefore our goal must be to support this smooth muscle function.

Adjustable male slings

Adjustable male slings are supposed to reestablish the baseline continence provided by the smooth musce system. It is the goal to support this function by a minimal increase of the urethral resistance (10-15cmH20). Adjustable male slings (Argus, Reemex) support the bulbar urethra thereby also using the bulbar venous tissue as a continence factor. Both systems (Argus, Reemex) are placed under the bulbar urethra and passed through the retropubic space up to the suprapubic region, where it is fixed. The argus-sling may as well be fixed using a transobturator approach. Anytime after placement of the sling the tension under the urethra maybe adjusted.

Surgical technique
A 10 cm longitudinale perineal incision is carried out after placement of a foley catheter. The subcutaneous tissue ist divided and the bulbo-spongiosus muscle is prepared. With the intact muscle covering the bulbar urethra the crura are freed on both sides of the bulbo-cavernosus muscle to show a triangular space between crus and muscle. Now a horizontal incision is made just above the symphysis and the rectus fascia is freed bilaterally approximately 3 cm off the midline. The implantation needle is placed in the triangle between crus and bulbo-spongiosus muscle, protecting the urethra with the tip of an index finger. The needle ist passed through the pelvic floor and in direct and gentle contact with the pubic bone and finally brought up to the suprapubic incision. The sling is then attached to the needle and finally pulled up to the suprapubic region. This procedures ist done bilaterally.

For the Argus „T“ a helical needle is used, which is introduced in an outside-in fashion in the typical transobturator manner. The washers used fort he transobturator route are smaller, the excess ends of the columns are brought up to the suprabubic region subcutaneously.

Intraoperative adjustment
For the **argus male sling** we recommend intraoperative adjustment using a retrograde LPP. Therefore a rigid cystoscope with obturator is placed in the mid urethra. An infusion bottle is

connected to the cystoscope. The assistant is asked to slowly move the infusion bottle downward from a level of 50cm until the infusion-flow stops. The upper fluid-level in the infusion bottle is measured against the level of the symphysis with a meterstick, it represents the retrograde leak point pressure (RLPP). This RLPP is taken before placement of the sling (usually 15 – 25 cmH2O) and after placement of the sling. The sling should be adjusted to a RLPP of 25-35cmH20 depending on the preoperative degree of incontinence, thus obtaining an increase of about 10cm which represents the support of the smooth muscle sphincter (baseline continenc). The sling is then fixed with the provided washer.

The **reemex system** works in a slightely different way. The suture, that has been brought up to the suprapubic incision will be connected to a so called „varitensor". The varitensor consists of a mechanic system involving a cable winch, that can be adjusted using a little screw driver. This screw driver is left in place at the time of surgery sticking out of the wound. On day 1 after the operation the patient will be asked to void and cough. The sling ist adjusted using the screw driver until the patient bcomes dry, but still is able to void. Then the screw driver is removed and the wound is definitively closed.

Assessment
Sousa et al reported of 51 Remeex patients with the follow up of 32 month. 48 % were found to be dry, 26 % improved, 16 % not improved. Explantation had to be carried out in 6 % of cases.

Victor Romano and co-workers published 48 patients using the Argus system with a follow up of up to 18 months and found 73 % to be dry, 10 % improved, 17% showed no improvement. In 10 % the sling had to be removed. The first serious of argus T was presented at the EAU meeting in Stockholm 2009 with similar results, however so far only with short follow up.

In our own series including 101 *patients with moderate to severe incontinence* between prostatectomy and Argus® sling placement, 74,3% had undergone a variety of procedures for SUI or bladder neck pathologies thereby representing a negative selection. 22 patients had undergone secondary irradiation therapy following surgery . All patients were evaluated pre and postoperatively with a 20 min pad tests, I-QoL questionnaires, cystoscopy and uroflowmetry.The mean follow up was 2, 1 years (0, 1-4, 5).

Adjustment was done in 39 cases (38.6 at an average of 104.3 days (14-910 days) after the initial implantation. The sling had to be removed in 16/101 patients (15.8%) at an average of 371.1 days (range 20-1260) after surgery due to urethral erosion or infection. However 6 out of those 16 patients were within the first 22 patients representing the learning curve. 13 of these patients received later successful treatment (7 with an AUS, 5 with re-implantation of the sling). After a median follow up of 2.2 years, 80/101 (79.2%) patients were considered as dry (pad test 0-1g, 70/101: 0g, 10/101:1g). The I-QoL improved from an average of 28.8 (range 14.5 – 61.8) to a mean of 63.2 (range 16.4-115) postoperatively. Both the 20 minute pad weight tests and I-QoL responses improved significantly compared to presentation at baseline ($p<0.001$).

EBRT subgroup:
Patients in this subgroup where incontinent after RPE (n=20) or TURP (n=2) and only 2 of them had implanted another device before implantation of the Argus® sling (1 Pro ACT®, 1 Invance®). Median FU in this group was 1,5 years (mean: 1,8 years). Of these 22 patients who had received their irradiation therapy prior to implantation of the sling, only 2 erosions

and 1 infection emerged. In two cases the sling had to be explanted and this occurred 22 or 430 days after implantation of the Argus sling. The remaining 20 irradiated patients all were dry at their last follow-up contact (dry rate 13%).

Index (standard) patients
As our cohort included a high number of pre-operated and / or irradiated patients which were implanted different other devices to treat the SUI prior to Argus® placement, we evaluated a subgroup of "index patients" (n=32), defined as I. >1y year FU, II. no EBRT, III. no previous surgery for SUI except UTI and IV. SUI only after RPE (n=25) or TURP (n=7).The median FU in this subgroup was 2.3 years (mean 2.3). The 20 min pad test decreased from preoperative mean 31.5g (range: 5-117) to postoperative mean 0.9g (range: 0-10). 87,5% in this subgroup were considered as "dry" at the time of the last follow up. Within this group only 2 urethral erosions and 3 infections occurred. In 4 of these cases (12.5%) the sling had to be explanted. The I-QoL within this subgroup could be raised to a mean of 58.3 from a preoperative mean of 29.7 points.
In our series success the dry rates showed no correlation between preoperative pad rate or irradiation therapy, the dry rates were similar after short and intermediate follow up.

In conclusion it can be stated, that with ajustable slings the dry-rate remains stable over a longer follow up, about 10 - 15% of implants will have to be removed. The number of intermediate results is small.
The postoperative adjustability allows reaction on dynamic changes in the postoperative course, both on possibly changing livestyle of the patient or changing urodynamic parameters.

Pro – Act

The first Pro - Act device was implanted in 1999 in the Korneuburg Hospital in Austria.
The system involves two silicone balloons which are placed bilaterally above the pelvic floor using a perineal approach. Special instruments (trocar, tissue expansion device) are used for placement, fluoroscopy or transrectal ultrasound is applied for exact positioning. At the end of the procedure the balloons basically are in the position where the prostate used to be. The whole surgery usually takes 15 to 20 minutes.

Operative technique:
Under general anesthesia the patient is placed in a lithotomy position and prepared and draped in sterile fashion. A rigid cystoscope is inserted under direct vision, and 50 cc of contrast medium is instilled to visualize the bladder neck. Leaving the cystoscope sheath in place with the obturator, a 1. 5 cm horizontal skin incision is made at the perineum, using a Kelly-clamp the urethra and the descending pubic ramus are palpated and bluntly dissected under fluoroscopic control. The pelvic floor was then perforated next to the urethra in cephaled and lateral direction. Using a specially designed insertion instrument combining a trocar and a 'u-shaped' cannula to create a suitable tract under fluoroscopic guidance, the two balloons are then positioned peri-urethrally above the pelvic floor with the cystoscope sheath functioning as a parallel guide for correct placement. The balloons are filled with 1-5 cc contrast and sterile water mixed to an isotonic medium and an urethrogram is performed to confirm the correct position of the device. Finally the two ports are brought into a subcutaneous scrotal position to allow for future percutaneous needle puncture and postoperative volume adjustment .

A major advantage of the Pro Act System is the easy adjustment at any time after the operation. In fact, the Pro Act system was the first widely used continence prosthesis, that offered postoperative adjustabilit. Continence is provided by a minimal increase of the urethral resistance, thus supporting the smooth muscle function of the spincter mechanism.

The first larger series of 117patients was published in the European Journal of Urology 2005 by Hübner et al. The average age of this group was 68 a, follow-up was 13 months (3-53mts). The population included patients with mild, moderate and severe incontinence, with the latter group being the largest. Postoperatively 52% of patients were dry, 22 improved, the average pad use was reduced from 5 to 1 pad. The re-operation rate was 18% including the learning- and development rate. It should be noted, that the dry /improved rate what's similar in all groups showing now correlations to the preparative degree in continence. However, the results are less favourably in patients after endoscopic manipulation of the urethra such as urethrotomy or bladder neck incisions, which may lead to the development of scar tissue. Pro-Act should not be used in irradiated patients due to a high erosion rate in this particular patient group.

Pro-Act can be considered an absolute minimally in invasive procedure that has stood the test of time and will remain as a treatment option in the field of male incontinence. However, above, correct indication as well as expertise in the implantation technique are necessary to acheive good results.

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Periurethral Constrictor

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Radical prostatectomy has a high rate of cancer cure, but not without the risk of post-operative complications. Urinary Incontinence (UI) is one of the most troublesome complications and it is usually secondary to sphincter insufficiency.

Urethral Constrictor is made of silicon, consisting of two elements, a cuff and an inflating port (Fig. 1). The urethral constrictor can be implanted by perineal incision or penoscotal access. The pre-operative evaluation consists of: urinalysis, urodynamic evaluation, ultrasound and retrograde urethrocystography. Exclusion criteria are bladder overactivity resistant to medical therapy, presence of urethral or vesical urethral anastomosis stricture and previous pelvic radiation therapy.

A 5 cm perineal incision is perform, the bulboespongeosus muscles are separated, the bulbar urethra dissected and 1 cm of urethra is circumferentially freed. The urethral diameter is measured and a cuff size is selected (3 sizes are available). Before implanting the device, air is removed and the system is filled with saline solution. The cuff is placed around the urethra and closed. Then, the cuff is connected to the port and positioned in the scrotum in an easy position to access the port (Fig.2). Antibiotic prophylaxis is started one hour prior to surgery. A 16 Fr. Foley catheter is inserted during surgery to facilitate identification and dissection of the urethra and removed 24 hours after the procedure.A penoscrotal access done at the base of penis, it was abandoned due to variable results (1).

Activation of the urethral constrictor is performed six weeks after the surgery. Patients with a full bladder are placed in a standing position. The port is accessed, the skin is prepped and saline solution is injected until the patient becomes continent. After one week continence is assessed and, if necessary, more fluid is inserted.

Thirty male patients with urinary incontinence after radical prostatectomy who failed in clinical treatment underwent urethral constrictor implantation. The mean follow up was 42 months (range from 13 to 72). Overall success rate was 73.3% (22 cases), among them, 20 patients voided spontaneously, whereas two performed intermittent catheterization. Revisions to exchange leaking valves were necessary in four cases. Complications occurred in seven (23.3%) patients, four had erosion and three had infections that required complete removal of the device (2). In other study 43 patients underwent surgical implantation of urethral constrictor and the overall success rate was 87% (3)

This device offers a new option to treat male urinary incontinence with the advantages of low cost and easiness of use, without the need for pump manipulation. A larger number of patients and a longer follow-up are paramount to confirm these results.

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Figure 1 – Urethral constrictor, the cuff and port.

Figure 2 - The positioning the port in the scrotum.