W12: Decision Making for Treatment of Post Prostatectomy Incontinence

Workshop Chair: Wilhelm A. Huebner, Austria
13 September 2016 15:30 - 17:00

Start	End	Topic	Speakers
15:30	15:35	PPI incontinence, evolution and overview	Wilhelm A. Huebner
15:35	15:45	Pathophysiology of PPI	Flavio Trigo Rocha
15:45	15:55	Physical therapy: new approaches and limitations	Heather Lynn Moky
15:55	16:00	Discussion	All
16:00	16:15	Balloons, fixed and adjustable slings, possibilities and limitations	Ervin Kocjancic
16:15	16:20	Discussion	All
16:20	16:35	Established and new hydraulic systems, what they can and what they can not	Wilhelm A. Huebner
16:35	16:40	Discussion	All
16:40	16:55	case discussion	All
16:55	17:00	conclusion	Wilhelm A. Huebner

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 not only to give a comprehensive overview of the current aspects of male urinary incontinence, but also sets out to clarify the approach to treatment of PPI in order to reduce both duration of incontinence periods for patients and costs of therapy caused by wrong decision making in a multidisciplinary fashion. As certain diagnostic findings allow for different approaches the focus will not only be on new options, but even more on limitations of different methods in order to avoid of failures. Physical therapists and urologists will therefore discuss the current options for an optimal couns

Learning Objectives

After this workshop participants should be able to:

- Understand function of Implants for male incontinence
- Make decisions on necessary diagnostics
- Differential indications based upon knowledge of contraindications
- Update on latest developments

Target Audience

Urologist, physiotherapist, physiatrists, nurse, continence advisors interested in male urinary incontinence

Advanced/Basic

Advanced

Suggested Reading

- Stern JA, Clemens JQ, Tiplitsky SI, et al. Long – term results oft he bulbourethral sling procedure. J Urol 2005; 173: 1654-1656
- Hubner WA, Trigo-Rocha F, Gilling P, Sai M, Schlarp O: International multicenter study assessing the safety and efficacy of Pro-ACT for the treatment of post radical prostatectomy incontinence. J Urol 2003, 169:473.
- Comiter CV.: The male sling for stress urinary incontinence: a prospective study; J Urol Feb 167(2 Pt 1): 602, 2002.
- P. Rehder, F. Haab, J.N. Cornu, C. Gozzi, R.M. Bauer: Treatment of postprostatectomy male urinary incontinence with the transobturator retroluminal repositioning sling suspension: 3 year follow-up Eur Urol, 62 (2012), pp. 140–145
- Sousa-Escandon A, Rodriguez Gomez JI, Gonzalez CU, Marques-Queimadelos A. Externally Readjustable Sling for Treatment of Male Stress Urinary Incontinence: Points of Technique and Preliminary Results. J Endourol Jan18: 113-118, 2004
- J. Seweryn, W. Bauer, A. Ponholzer, P. Schramek: Initial experience and results with a new adjustable transobturator male system for the treatment of stress urinary incontinence J Urol, 187 (2012), pp. 956–961

- Hubner WA, Gallistl H, Rutkowski M, Huber ER. Adjustable bulbourethral male sling: experience after 101 cases of moderate-to- severe male stress urinary incontinence. BJU Int 2011;107:777–82.

- Hubner WA, S.Trigo Rocha, E.Plas, E.Tanagho: Urethral function after cystectomy: a canine in vivo experiment, Urol.Res. 21, 45-48, 1993

- Alonso Rodriguez D FAE, Fernandez Barranco L, Vicens, Vicens A GMF (2011) One hundred FlowSecure artificial urinary sphincters. Eur Urol Suppl 10:309

- Staerman F, C GL, Leon P, Leclerc Y (2013) ZSI 375 artificial urinary sphincter for male urinary incontinence: a preliminary study. BJU international 111 (4 Pt B):E202-206. doi:10.1111/j.1464-410X.2012.11468.x

Wilhelm A. Huebner

Urinary incontinence post radical prostatectomy has a negative impact on the Quality of Life. The treatment of urinary incontinence in men is a challenge. With the increase of diagnosis and surgical treatments of prostatic cancer, the number of patients with urinary incontinence will increase.

A comprehensive overview of the current diagnostic techniques will be presented, an experienced physical therapist will provide a basic non surgical management and also will give her expertise in identifying those patients, that most likely will not respond to physical therapy. The Physical Therapist will also present different techniques to preserve urinary continence after RRP, with rehabilitation exercises that acts on the entire circumferential rhabdosphincter musculature and the fascial tissues, and innervation of both the rhabdosphincter and the mucosal and smooth muscle.

Various surgical treatments have been introduced recently for the treatment of post-prostatectomy incontinence, such as, slings, ProACT, Bulking agent and artificial sphincter. The purpose of this workshop is to discuss in detail the evaluation and management of patients with urinary incontinence. Case discussions will give practical views of the problems.

The Physical Therapist will present different techniques to preserve urinary continence after RRP, with rehabilitation exercises that acts on the entire circumferential rhabdosphincter musculature and the fascial tissues, and innervation of both the rhabdosphincter and the mucosal and smooth muscle.

Beside the gold standard in the surgical management, the Artificial Urinary sphincter there are several other options for mild and moderate incontinence.

Male slings are supposed to reestablish the baseline continence provided by the smooth muscle system. It is the goal to support this function by a minimal increase of the urethral resistance. Adjustable male slings support the bulbar urethra thereby also using the bulbar venous tissue as a continence factor. The sling is placed under the bulbar urethra and passed through the retropubic space up to the suprapubic region, where it is fixed. The theory behind the transobturator male sling is that by repositioning and anchoring of the proximal urethra the sphincteric function could be restored. The surgery includes mobilisation of the bulbous urethra and transsection of the centrum tendineum. The bulb is fixed to the sling and the ends are guided through the obturator foramen in a typical outside - in fashion. The bulb is lifted up, however compression of the urethra should be avoided.

The Pro-Act involves two silicone balloons which are placed bilaterally above the pelvic floor using a perineal approach. Special instruments are used for placement, fluoroscopy or transrectal ultrasound is applied for exact positioning. Pro-Act can be considered an absolute minimally invasive procedure that has stood the test of time and will remain as a treatment option in the field of male incontinence.

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

However, other hydraulic systems like the Zephyre, Flowsecure and Arroyo sphincters seem to offer similar qualities adding the possibility of postoperative adjustment. Differences of these systems will be discussed. Post-operative failure to achieve urinary continence can be secondary to local complications, device problems and/or limitations of the method. The long-term durability and functional outcome of these procedures remain unclear.

Established and new hydraulic systems, what they can and what they can not

For more than 30 years the AMS 800 has been the gold standard of hydraulic sphincters. In spite revision rates of 10-41% (depending on FU) and social continence rates of 79% most patients would have had teheir sphincter put in again 94,4%). Still certain points of improvement have been raised repeatedly.

A possibility to change the intra-device pressure postoperatively without changing the whole balloon in a second operation, a ready made implant to avoid connecting all components of the AMS 800 during the operation, a pump less challenging to use for patients with impaired dexterity, and the possibility of increasing the intra-device pressure during maneuvers with high intraabdominal pressure.

Three alternative commercially available hydraulic implants are on the market today and will be discussed adressing these points - the ZSI375 artificial urinary sphincter, the AROYO device and the FlowSecure sphincter.

ZSI 375 artificial urinary sphincter:
The ZSI 375 consists of a cuff and a pump, which covers both the function of a pressure regulating reservoir as well as the opening activation. The regulation unit involves two hydraulic compartments, one to fill the cuff and a second one regulating the pressure in the system. Implantation can be performed through a trans scrotal approach or via two incisions (perineal and inguinal).

Differences to AMS 800:
The ZSI 375 provides adjustability by percutaneous filling any time after implantation. It is a „one piece implant“, thereby facilitating implantation. Improvement concerning challanges for dexterity over the AMS 800 are minimal. A possibility of increasing the intra-device pressure during maneuvers with high intraabdominal pressure is not given.

Data:
Early results (15mts) of a single center study are showing social continence in 78% at 3 months and 73% at 6 months after device activation. In this series 12,5% of the implants had to be removed. In a second multicenter study social continence rates were significantly lower and 61% of the devices had to be removed. For that reason the system has undergone a two-step modification in the meantime.

The AROYO sphincter:
The AROYO sphincter consists of a cuff, a control unit as well as a pressure compensator positioned in the lower abdomen to be activated manually whenever higher pressures to the bladder may be expected (cough, exercise etc). Implantation is performed through a trans scrotal approach or perineal incision.
Differences to AMS 800:

The AROYO provides adjustability by percutaneous filling at the time of implantation using a pressure monitoring electronic device. Adjustment is also possible postoperatively. It is a „one piece implant“, thereby facilitating implantation. Manipulating the control unit ist described as not challenging for dexterity, however, the scrotal unit ist heavy and my be disturbing in the scrotum. The possibility of increasing the intra-device pressure during maneuvers with high intraabdominal pressure is definitely a interesting feature.

Data:
Little data are available at this time for the AROYO sphincter. The first presentation at the ICS meeting 2015 showed a series of 9 patients, one lost for FU for internal reason. Two devices had to be explanted (one erosion, one malfunction). Of 7 pts followed for one year 71% had more tha 50% reduction in 24h pad weight.

The FlowSecure device consists of a cuff, a pump and an additional intraabdominal balloon for conditional occlusion. The pressure within the system can be adjusted any time after implantation. Implantation is performed through a perineal and inguinal incision.

Differences to AMS 800:
The FlowSecure device provides adjustability through the self sealing port in the pump, sudden pressure rises are covered by pressure transfer from the intraabdominal balloon to the cuff. This self acting system allows decreasing the resting pressure in the cuff to a minimum. The pump is similar to the AMS 800, however, softer and easier to use.the FlowSecure comes as a one piece implant.

Data:
The FlowSecure was described by Craggs et al. in 2006, in a study by Rodriguez et al 100 pts were implanted resulting in social continence for 89%. 28% had to be removed due to infection, pump perforation at adjustment or mechanical failure. The product has undergone several improvements since that time.

Concluding the new devices address certain points of possible improvement over the AMS 800, however, they have not stood the test of time yet.

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Staerman F, C GL, Leon P, Leclerc Y (2013) ZSI 375 artificial urinary sphincter for male urinary incontinence: a preliminary study. BJU international 111 (4 Pt B):E202-206. doi:10.1111/j.1464-410X.2012.11468.x

Kretschmer Alexander et al.: Efficacy and safety of the ZSI375 artificial urinary sphincter for male stress urinary incontinence: lessons learned. World J Urol. 2016 Feb 25.
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Knight SL, Susser J, Greenwell T, Mundy AR, Craggs MD: A new artificial urinary sphincter with conditional occlusion for stress urinary incontinence: preliminary clinical results. European urology 50 (3):574-580. doi:S0302-2838(06)00494-5 [pii]
10.1016/j.eururo.2006.03.065

Alonso Rodriguez D FAE, Fernandez Barranco L, Vicens, Vicens A GMF (2011) One hundred FlowSecure artificial urinary sphincters. Eur Urol Suppl 10:309

Flavio Trigo Rocha

Pathophysiology of Post Prostatectomy Urinary Incontinence (PPI)

PPI may result from bladder dysfunction, incompetence of the sphincter mechanism or both. More rarely it can be caused by an obstructive process leading to overflow incontinence.

Bladder disorders are frequent in patients before and after radical prostatectomy. Chronic obstructive processes from prostate or urethral obstruction are common in localized prostate cancer patients. The presence of chronic obstruction caused urethrovesical anastomotic stenosis may lead to change in collagen and elastic fibers leading to decreased bladder compliance (Kim, J.C. et al, 2000). Many patients undergoing radical prostatectomy are located in older age groups, where it is common the presence of degenerative bladder changes leading to detrusor overactivity (Weiss, B. D., 1983; Kleinhans, B. et al, 1999). Additionally, elderly patients present a greater number of associated pathologies (co morbidity), including neurological diseases such as Parkinson's, multiple sclerosis, stroke and diabetes, many of which may cause or aggravate urinary incontinence (Schurch, B. , 2000).

The existence of vesicourethral sphincter dysfunction preoperative such as incontinence or severe bladder dysfunction, confer worse prognosis for maintaining urinary continence after performing radical prostatectomy. However, few patients presenting for surgery with such disorders. Thus, most cases of PPI arises from surgical sphincter injury as well as its innervation or

supporting structures. After removal of the prostate continence depends of the remaining external urinary sphincter. The degree of its injury will determines the severity of incontinence. This can be reversible over time. In a small number of patients, bladder dysfunction resulting from surgical injury can cause IUPPR or aggravate incontinence resulting from sphincter injury.

Several studies have looked through pre and post operative urodynamic studies trying to predict urinary incontinence. Several changes were observed in the sphincter mechanism due to surgery, such as: a reduction of the functional sphincter length (Rudy, DC et al, 1984; Coakley et al, 2002; Philippe Paparel et al, 2009; Antonio Tienza et al, 2015), decrease in urethral closure pressure (Kleinhans, B. et al, 1999a) or both (Presti, JC Jr. et al, 1990). Less frequently, changes were described in bladder compliance as well as the emergence of detrusor overactivity (Tomschi, W. et al, 1998). More rarely, obstructive processes, usually located in urethrovesical anastomosis may lead to urinary retention and paradoxical incontinence (Desautel, MG et al, 1997) or lead to the emergence of secondary detrusor overactivity (Chao, R. Mayo and, ME, 1995). The coexistence of stenosis of the urethrovesical anastomosis and urinary incontinence by sphincter injury is a relatively common condition and with implications for assessment and treatment of patients.

Although several studies have shown a high incidence of bladder dysfunction in patients undergoing radical prostatectomy, most of them are not accompanied by significant symptoms. Recent studies have shown that the sphincter deficiency is the determining factor of the IUPPR onset in most patients (Gudziak, MR et al, 1996b; Desautel, MG et al, 1997; Ficazzola, MA and Nitti,).

Risk factors for the emergence of IUPPR
Preoperative: several authors attempted to identify risk factors for the development of IUPPR. Among the factors determined preoperatively, the presence of severe voiding dysfunction and most advanced stage of the disease lead to a higher incidence of urinary incontinence (Van Kampen, M. et al, 1998; Bono, A. A. et al, 2001). Similarly, older patients have higher incidence of atrophy of the external sphincter (Burnett, AL and Mostwin, JL 1998) and neural degeneration with commitment of its innervation (Narayan, P. et al, 1995), which provides greater IUPPR incidence (Zincke, H. et al, 1994; Catalona, WJ et al, 1999b; Stanford JL et al, 2000).

Intraoperative: nerve preservation, the surgeon's experience and the number of radical prostatectomies of the institution appear to favorably influence the rates of urinary continence (Walsh, P.C., 1998a). Technical details of the surgery and the recognition of conformation and careful dissection of the prostatic apex (Myers, R. P., 1991b) leading to a preservation greater extension of the external sphincter, resulting in improved rates of continence (Walsh, P.C., 1998b). The joint ligature of pubo-prostatic ligament with dorsal vein complex results in better early continence rates. However, after one year, continence rates are similar to those obtained with the previous section thereof (Begg, C. B. et al, 2002; Jarow, J.P. 2000). The retropubic or the perineal access roads have long term urinary continence rates quite similar (Gray, M. et al, 1999; Ruiz-Deya, G. et al, 2001). Studies analyzing large series of radical prostatectomies using laparoscopic show similar continence rates to those observed with open access roads (Olsson, L. E. et al, 2001).

Predictors: Recent studies using magnetic resonance imaging (MRI) as urinary incontinence predictor after laparoscopic prostatectomy retropubic radical surgery showed lower rates of UI when it was possible to leave a larger membranous urethra (Coakley et al, 2002; Philippe Paparel et al, 2009; Antonio Tienza eT al, 2015). Other authors concluded that the volume of the prostate would be a predictor of recovery UI, and a volume above 50 cc would be associated with lower recovery rates of continence one year after surgery as a result of changes that a prostate above that volume would promote the bladder (Abrams P., et al, 2002; Kupelian V., et al, 2006; Br Konety, et al., 2007, Tienza Antonio et al, 2015). Tienza et al, 2015 using MRI in the preoperative evaluation of pelvic anatomy also found that the wall thickness of the urethra and the length of the membranous urethra and the thickness of internal obturator muscle would impact on the control of continence. Tienza et al concluded in their study that MRI may be useful as a predictor of UI alone or with other diagnostic tools.

Some authors have studied the possibility of identifying, through urodynamic preoperative evaluation, patients at higher risk for developing IUPPR. Although identified bladder changes as detrusor instability in a number of patients and several changes of urodynamic parameters from surgery, was not possible to establish predictors insurance IUPPR (Golomb, J. et al, 1999; Kleinhans, B. et al, 1999).

References:

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Wilhelm A. Hübner

Affiliations to disclose†:

Astellas speaker
Promedon speaker
AMS speaker

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

☐ Self-funded
☒ Institution (non-industry) funded
☒ Sponsored by: *Promedon*

PPI incontinence, evolution and overview
W. Hübner

Incidence of PPI: 3-63% (?)

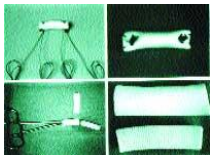
First line treatment:
PFT as routine care or treatment for persisting PPI

Placebo – controlled randomized studies:
Van Kampen et al. *Lancet* 355, 98 – 102, (2000):
88% vs 56% full continence at 3 mts pRPE

Filocamo et al. *Eur. Erol*. 48, 734-738, (2005):
74% vs 30% full continence at 3 mts pRPE

Earlier recovery, 3-8% with persisting PPI will receive surgical intervention

1970 Scott sphincter AMS 721, Kaufman – Prosthesis I-III
1982 AMS 800
1982 – 2000 AMS 800, Bulking agents
2002 InVance (BAMS), Schaeffer sling



Stern, Schaeffer et al J. Urol. 2005
Bulbourethral sling, n=71

*2 or less pads
Success rate (no XRT) *: **72%** (0 pads: 42%)
Success rate (XRT)*: **43%** (0 pads: 14%)

at 4 years followup
but 30% lost for followup!

Retightening procedures: 22%

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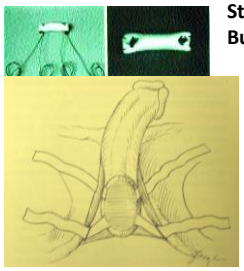
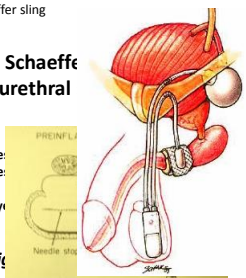


Stern, Schaeffe
Bulbourethral



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2002 *CE – mark ProAct (1st adj. System)*

Castle et. al. J. Urol. 2005
(Mayo Clinic)
Bone anchored male slings, n=38

Success rate after 6 -> 18mts: 67% -> 39%
ate after 6 -> 18mts : 47% -> 15%

after XRT: 12,5% success
Relevant factors:
incontinence grade, XRT

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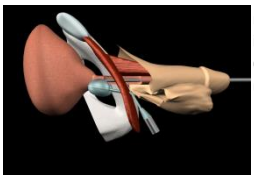

mean follow up 15mts (6mts - 4years)

incontinence degree	I	II	III
dry/improved (%)	89	78	85
unchanged (%)	11	22	15

Hübner WA, Schlarp OM.
BJU Int 2005, 96: 587-94.

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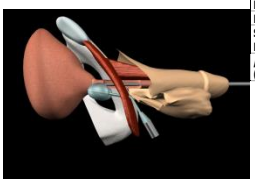

Table 4: Results of Quality of life questionnaire (I-QoL):

Parameter	Baseline	3 months	6 months	12 months	24 months
Number	117	101	90	63	47
Mean	34.7	60.3	64.8	64.9	66.3
Standard Deviation	22.6	23.2	23.9	25.9	27.3
p-value (Wilcoxon)	-	<0.001	<0.001	<0.001	<0.001

Limits:
Urethral changes/scars
RTX = contraindication

Hübner WA, Schlarp OM.
Eur Urol 2007, 52(3):680-6.

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OP Methods developed
2002 - 2016

Zephyr
Advance
Remeex
Argus
Atoms
Pro Act
Phorbas
Flowsecure
InVance
I Stop

OP Methods developed
2002 - 2016

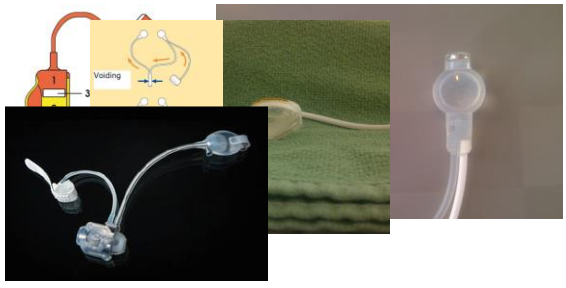
Adjustability, a key factor?

Zephyr
Advance
Remeex
Argus
Atoms
Pro Act
Phorbas
Flowsecure
InVance
I Stop

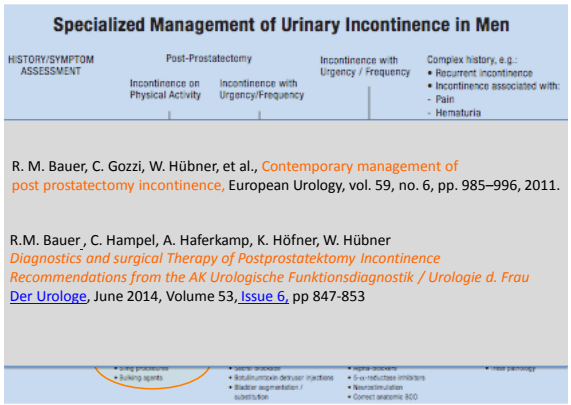
Future Aspects

ZSI 375

next generation. flowsecure



Aroyo



R. M. Bauer, C. Gozzi, W. Hübner, et al., Contemporary management of post prostatectomy incontinence, European Urology, vol. 59, no. 6, pp. 985–996, 2011.

R.M. Bauer, C. Hampel, A. Haferkamp, K. Höfner, W. Hübner
Diagnostics and surgical Therapy of Postprostatektomy Incontinence
Recommendations from the AK Urologische Funktionsdiagnostik / Urologie d. Frau
Der Urologe, June 2014, Volume 53, Issue 6, pp 847-853

Figure 5. Specialized management of urinary incontinence in men

Postprostatectomy Incontinence latest considerations and current approach

W. Hübner

Disclosures Wilhelm A. Hübner

Speaker for:
Promedon
AMS
Astellas

Shares:
Uromedica

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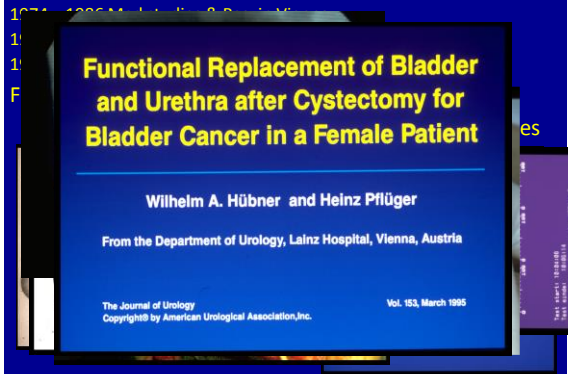
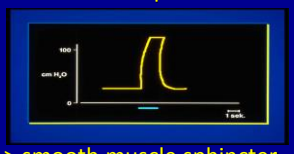
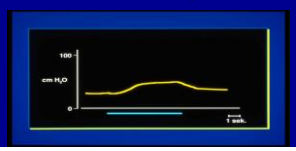


Functional differentiation of sphincteric components

Stress continence -> striated muscle sphincter (N. Pudendus)



Baseline continence -> smooth muscle sphincter (Pl. Hypogastricus)



Tanagho. Trigo-Rocha, Hübner et al UCSF 1991

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1998 Chairman Korneuburg Hospital

1999 first Pro Act Operation worldwide

Since 2001 focus on male incontinence, ProAct, Remeex, AMS 800, Flowsecure, InVance, Atoms, ARGUS and others
ca 100 cases/year

Pathophysiology of Male Incontinence

Flavio Trigo Rocha, MD
Associate Professor of Urology, São Paulo University
Coordinator of Continence Center – Hospital Sírio Libanês
São Paulo – Brazil – flaviotrigo@uol.com.br

HOSPITAL SÍRIO-LIBANÊS

Flavio Trigo Rocha

Affiliations to disclose†:

Promedon Brasil / consultant

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- [X] Self-funded
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São Paulo University Medical School

Hospital das Clínicas São Paulo

Hospital Sirio Libanes

Hospital Sirio Libanes

Prostate Cancer

- USA: The chance of a newborn to develop prostate cancer (PC) varies from 9% to 16,5%. In patients with diagnose the chance to die from this disease is about 3%.
- The USA National Cancer Institute estimated 241.740 new cases and 28.170 deaths due to prostate cancer in 2012.
  Altekruse, SF., et al, 2010; http://www.cancer.gov
- In Brazil, according to National Cancer Institute (INCA), PC is the most common male cancer . According to INCA there were 60.180 new cases in 2012. They estimates 62,54 cases/ 100.000 habitants
  Jemal, A., et al, 2010; http://www2.inca.gov.br).

PC and age

The Sting 1973

Oscar 2007

Radical Prostatectomy

Almost 100 years since the first cases

Initially accompanied by unacceptable morbidity

Better anatomic studies led to improvements in surgical technique reducing morbidity dramatically

- *Walsh, P.C. and Donker, P.J.: Impotence following radical prostatectomy: insight into etiology and prevention. J. Urol., **128**: 492, 1982.*
- *Walsh, P.C., Lepor, H., and Eggleston, J.C.: Radical prostatectomy with preservation of sexual function: anatomical and pathological considerations. Prostate, **4**: 473, 1983.*
- *Walsh, P.C. Radical retropubic prostatectomy with reduced morbidity: an anatomic approach. NCI. Monogr., 133, 1988.*
- *Walsh, P.C., Quinlan, D.M., Morton, R.A., and Steiner, M.S.: Radical retropubic prostatectomy. Improved anastomosis and urinary continence. Urol. Clin. North Am., **17**: 679, 1990.*
- *Walsh, P.C., Partin, A.W., and Epstein, J.I.: Cancer control and quality of life following anatomical radical retropubic prostatectomy: results at 10 years [see comments]. J. Urol., **152**: 1831, 1994.*
- *Walsh, P.C. Anatomic radical prostatectomy: evolution of the surgical technique. J. Urol., **160**: 2418, 1998.*

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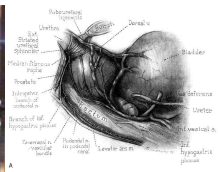
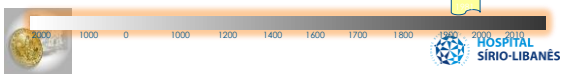
Modern Radical Prostatectomy



Walsh, P., 1979 – 843 citações

Walsh, P., 1981 – 541 citações

Brady Institute – Johns Hopkins



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Anatomic and neurological modifications after radical prostatectomy

- Lost of continuity of vesicourethral muscle
- Changes in bladder neck
- Rupture of fascias and ligaments
- Lesion of bladder basis and membranous urethral innervations
- Changes in blood supply
- Reduction of the functional length of membranous urethra
- Traumatic fibrosis

Radical Prostatectomy Urinary Incontinence (PRPUI): Urodynamics

	number	ISD (%)	bladder (%)	ISD + bladder (%)
Leach et al, 1996	210	40	20	40
Chao and Mayo, 1995	74	57	4	39
Desautel et al, 1997	39	59	5	36
Ficazzola and Nitti, 1998	60	67	3*	23

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Preoperative urodynamics vs continence

Urodynamics in 66 pts before and after radical prostatectomy

- No correlation between preoperative urodynamic evaluation and incontinence(1/44 pts!!)
  - Kleinhans B et al, Eur. Urol, 1999

Preoperative parameters vs continence

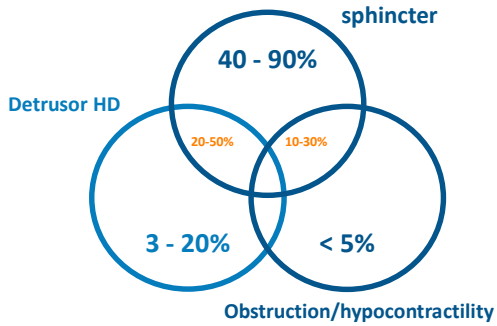
DO PELVIC FLOOR MUSCLES STRENGTH AND URODYNAMIC PARAMETERS PREDICT EARLY INCONTINENCE OUTCOMES AFTER RADICAL RETROPUBIC PROSTATECTOMY?

Wesley Magnabosco[1], Carla Lourenzo[1], Fernanda Jabur[1], Monica Gameiro[2], Hamilto Yamamoto[2], Joao Luiz Amaro[2], Flavio Trigo Rocha[1]

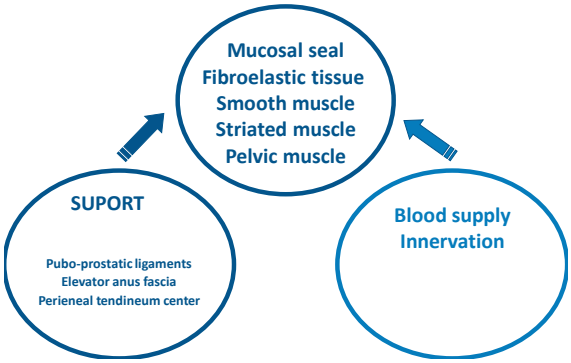
1- Barretos Câncer Hospital, 2 – Botucatu Medical School (UNESP), 3- São Paulo University

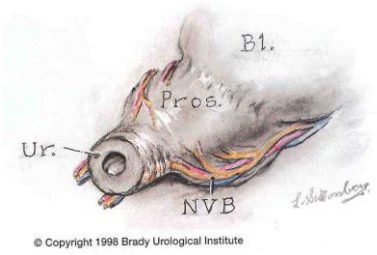
Older patient and pelvic floor muscles weakness were associated with UI 1 month after radical prostatectomy. There were no correlation between Urodynamic parameters and UI one month after surgery.

Radical Prostatectomy Urinary Incontinence (PRPUI): causes



Sphincter mechanism





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RP: Improvements in surgical technique

- Neurovascular bundles preservation
- Apex dissection
- Rabdosphincter preservation

Steiner, Morton e Walsh, J Urol, 1991

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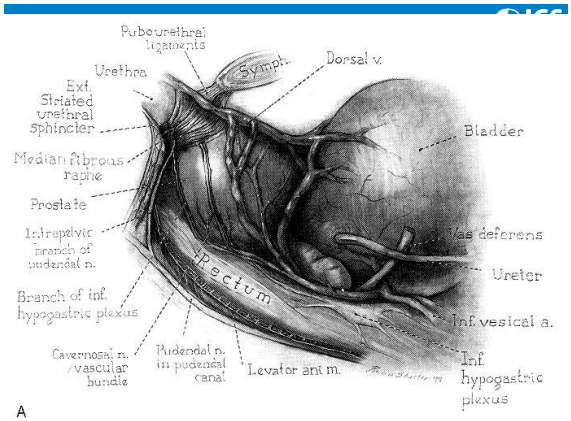
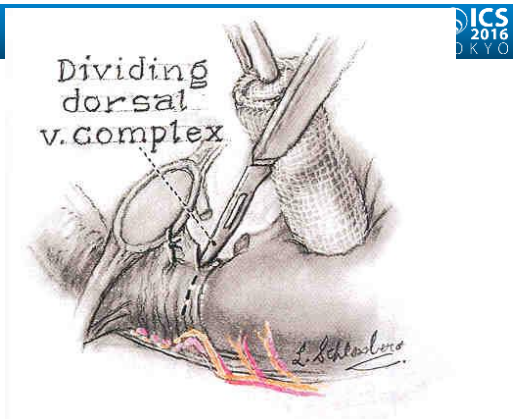




Patients with neurovascular bundle preservation have better continence results

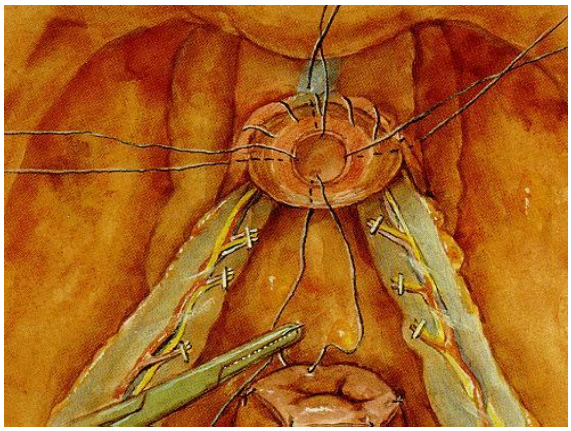
O'Donnell e Finan, J Urol, 1989
Steiner et al, J Urol, 1991

Preservation of NVB or less traumatic technique?

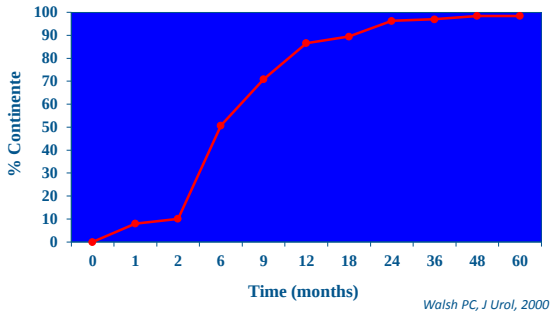
Urethral length and continence

	Pre-op	Pos-op (2 meses)	*Pos-op (6 meses)**
Urethral functional length	61 mm	25,9 mm	*29,5 mm (21,4)*
Maximum urethral pressure	89,6 cmH_2O	65,2 cmH_2O	*78 cmH_2O (54,6)*
Bladder capacity	396 ml	332 ml	*258 ml (239)*
Hyperactivity	17%	41%	*44% (55)*

Hammerer P e Huland H, J Urol, 1997



Time to recover conbtinencea after RRP

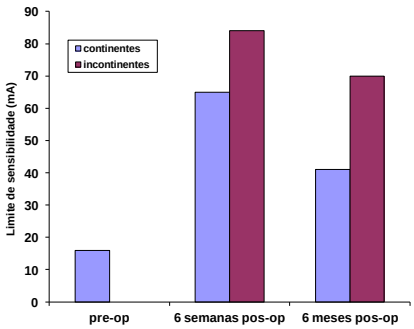


Walsh PC, J Urol, 2000

Temporal evolution of PRPUI

- Neurologic reflex adaptation
- Neuronal regeneration
- Sphincter adaptation
- Bladder adaptation

Regeneration of urethral aference



Urethral seal

Sphincter is 1 cm bellow anasthomosis but there is no contrastation in proximal segment => urethral coaptation

O'Donnell et al, Urology, 1990

Caine e Edwards, Br J Urol, 1958

Reduction in urethral compliance

Surgical trauma/schemia

↓

Urethral fibrosis

↓

Reduced urethral coaptation

↓

Incontinence

Reduction in urethral compliance after prostatectomy

83 pts with PRPUI (sphincter: 88%)

- Free Q max and Qmax with 7 Fr catheter
- Reduced urethral compliance:

Reduction in Q max > 10 ml/sec

- Groutz, Blaivas, Chaikin et al, J Urol, 2000

Reduction in urethral compliance

In a normal urethra a 7 Fr cateter does not affect Qmax

Reynard et al, J Urol, 1996

Q max reduction by catheter

- obstruction
- Sphincter not relaxing

Reduction in urethral compliance

Obstruction by the 7Fr catheter

↓

Reduced urethral compliance

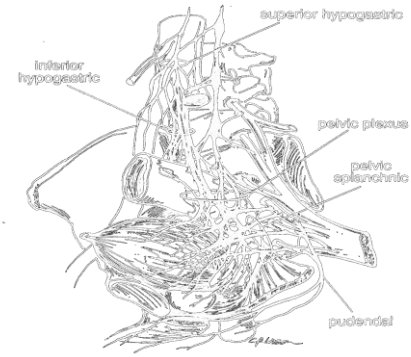
↓

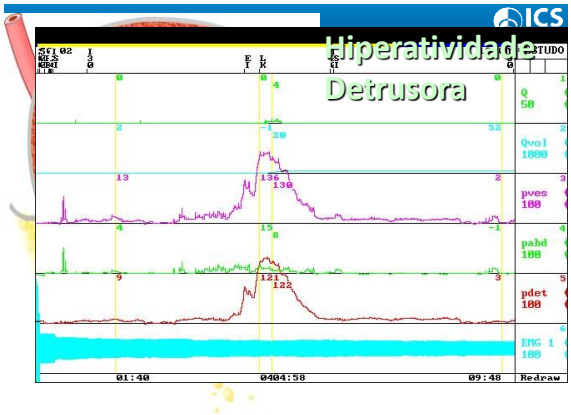
Stenosis/fibrosis

Reduction in urethral complianceuretral/stenosis

	Urethral fibrosis
Chao e Mayo, 1995	26%
Desautel et al, 1997	67%
Ficcazola e Nitti, 1998	27%
Groutz et al, 2000	30%*

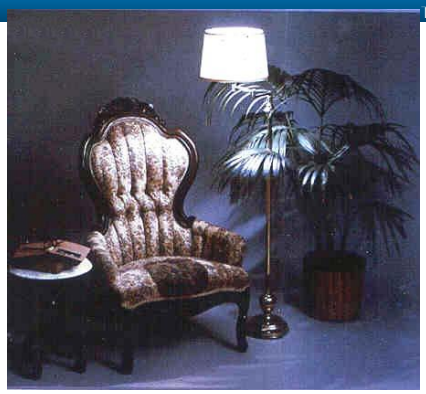
BLADDER HYPERACTIVITY





Postprostatectomy incontinence: Conclusions

- Sphincter deficiency is the main cause
- Sphincter muscle preservation as well as preservation of its irrigation, inervation and support minimizes the problem
- Detrusor dysfunction and obstruction may contribute for incontinence in some cases



Physical Therapy in Male Incontinence- approaches and limitations

ICS 2016 Tokyo
46th Annual Meeting
By : Heather L . Moky Cordova PT, DPT
University of Illinois Hospital

Heather L. Moky Cordova PT, DPT

Affiliations to disclose:

University of Illinois Hospital and Health Science Systems

International Continence Society- guest speaker

Funding for speaker to attend conference:

[x] Sponsored by: Self

Pelvic Floor Physical Therapist

Common Treatment approaches for Incontinence

- Pelvic floor Muscle training
- Biofeedback
- Education
- Scar Care/ Scar mobilization when appropriate
- Bladder Retraining
- Pelvic floor muscle training with functional integration
- Posture, Body mechanics and lifting
- Lifestyle modifications
- Core Stabilization
- Electrical stimulation
- Many Other techniques

What if physical therapy is not working ?

You have to figure out the Why ?
Compliance Issue ?
Not interested?
Not understanding?
Is there a motor learning problem?

Case 1- Richard

64 year old male- Works as a janitor – lifting 10 to 20 lbs.

SX: Prostatectomy April 7, 2016

Evaled on June 16, 2016
Reports being able to achieve an erection 100% of the time
Withholds water to decrease urinary leakage- uses about 6 pads a day-soaked
Strength 4-/5
Very motivated.

Attended 4 physical therapy TX session at 1 time a week with little to no change

Compliant – almost over complaint

Case 1 – Richard

Re-evaled on 7/22

6 shields a day
Still withholding water

Objective Findings
Hamstrings : R 48 degrees L 46 degrees
Pelvic floor Strength: 3-/5
Bearing down, Holding breath
DRA: 2 fingers above umbilicus
Cant isolate or activate his Transverse Abdominal

Case 1 – Richard

Discussion
Tell me what you are doing at home

Show me what you are doing at home
(Everything – really have them show you)

Are they holding their breath ?

Look for Compensations

Case 1 - Richard

Pt reported little to no benefit after 4 weekly visits

We should be asking ourselves why ?

After reassessing - What are the underlying problems ?

- Improper pelvic floor contraction
  - Instead of a lift and compress it was a lift and push
  - Push ultimately bearing down
- subconsciously holding breath
- Valsalva with lifting techniques
- Lack of integrating the abdominals
- overall muscle fatigue

Case 1- Richard

Treatment:
Diaphragmatic Breathing

Avoiding Bracing and Valsalva – changing that pattern

Pelvic floor muscle isolation
with constant verbal cues to breath
different position
25 % effort

Simulate work and retraining of breathing to avoid Valsalva

Abdominal Activation and isolation

Hamstring stretching

Case 1 - Richard

5 weeks later- pt. reports being 65 to 70 % improved

6 pads a day to
2 pads a day when not working
3-4 a day when working

Less leakage on the pad
Drinking fluid normally

Pelvic floor muscle training

- Able to contract ?
- Able to relax?
- Bearing down to compensate ?
- Quality of contraction
  - Strength and Endurance
  - Timing of contraction
- Breathing - are they holding their breath ?
- Effort ?
  - Use 50 % effort
  - Use 25 % effort
- Hypertonic muscles or hypotonic muscles
- Posture
- Co-activation of other muscles and muscle compensations

Effects of Prostatectomy

Physical

- Surgical Approach
- Removal of prostate
- Loss of smooth muscle- loss of tonic support for continence
- Potential Damage striated urethral sphincter
- Possible loss of the sphincter muscle
- Damage or irritation to nerve supply

Mental and Emotional

- Other referrals
- Support Group
- Emotional
  - I had cancer
  - Loss of manhood

Different Cues for activating pelvic floor

Tighten the around the anus – commonly used in research- not effective

Use different cues- Stafford et al., 2016

Try to pretend to stop the flow of urine

Try to prevent from passing gas

Pretend you are a turtle, and pull your head into the shell

Shorten the penis

Others

Different muscle activation patterns

Stafford et al, 2013 found

2 different dominant muscle activation patterns found in men with pelvic floor muscle activation

- Striated urethral sphincter dominant -compresses
- Puborectalis dominant –pull up towards the pubic bone

Develop different strategies

Striated Urethral sphincter patterns responded best to the cue "shorten the penis" (Stafford et al., 2015)

Give patients different cues ?

Palpate and feel which cue gets more muscle recruitment.

What do you feel ?

What does the patient feel?

Questions to ask ourselves

- Are the correct muscle being activated?
- How do we know?
- Is the pt. overcompensating?
- When you are told to do something as hard as you can what happens to your breathing pattern?
  - People tend to hold their breath. Wrong approach.

Muscle assessement

- Palpation
- Surface/ anal EMG
- Ultrasound imaging
- Biofeedback

Real Time Ultrasound

- RTUS is a non-invasive option that is valid and reliable to assess the pelvic floor muscle function
- Sherburn et al, 2005

Real time Ultra Sound- RTUS

Novel Insight into the Dynamics of Male Pelvic Floor Contractions Through Transperineal Ultrasound Imaging
- Stafford et al, 2012

Should we train other muscle besides the pelvic floor muscles ?

There are over 45 different muscles that attached in and around the pelvis.

Muscle stability

Pelvic floor muscles work in conjunction with the diaphragm. Transverse abdominal muscle works in conjunction with multifidus muscles of the spine

(Sapsford et al., 2001)

Diaphragm (roof) and the Pelvic floor muscles (foundation) work together

PFM will get co-contractions with Tra and Multifidus

What if its not working ?

Patience and realistic expectations

Importance of compliance

PFM contraction: Biofeedback or Estim

Use different cues

Work with different muscles to assist.

More Involved- Other PT techniques or incontinence tools

Talk with Md or send pt. back to MD

Take Home Messages

1. With incontinence, there are many valid treatment options, but pelvic floor muscle training is recommended as a first line treatment, but make sure the pt. is doing it correctly.
2. You need to Individualize a program for your patient and use different cues to get better pelvic floor muscle activation.
3. We say to treat the whole person, but treat their whole body not just the pelvic floor.
4. Resolution of muscle dysfunction is essential to improving quality of life in men with incontinence .

Slings and Balloons for Male Stress Urinary Incontinence

ERVIN KOCJANCIC
Director of Pelvic Health and Reconstructive Urology
University of Illinois at Chicago

University of Illinois Medical Center

POST PROSTATECTOMY STRESS URINARY INCONTINENCE (SUI)

The current EAU guidelines define post prostatectomy continence as the use of 0 or 1 pad (“safety pad”) per day

EPIDEMIOLOGY

- 90,000 RP perfomed in US annually
- 4%-31% SUI for laparoscopic radical prostatectomy robotic assisted
- 7%-40% SUI for open radical prostatectomy
- 5%-34% SUI for laparoscopic radical prostatectomy

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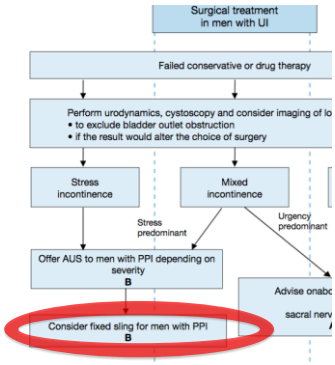

Guidelines on **Urinary Incontinence**

M.G. Lucas (Chair), D. Bedretdinova (Guidelines Associate), L.C. Berghmans, J.L.H.R. Bosch, F.C. Burkhard, F. Cruz, A.K. Nambiar, C.G. Nilsson, A. Tubaro, R.S. Pickard

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Historical Perspective

• 1927 Player & Callander	gracilis muscle flap
• 1947 Cooney & Horton	abd-perineal fascial strip
• 1972 Kaufman JJ	penile crura
• 1973 Kaufman JJ	silicone gel prosthesis
• 1974 Servadio C	fascial sling
• 1976 Pettersson & Bratt	fascial sling
• 1979 Kaufman & Raz	silicone gel prosthesis
• 1995 Janknegt et al	gracilis urethromyoplasty
• 1998 Schaeffer et al	Gore-Tex bulbar sling

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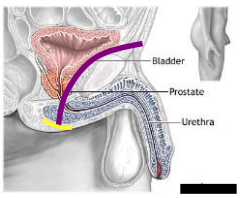
male slings :

permanentely increase the urethral resistance
use bulbar venous tissue



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W.Hübner, Korneuburg

CLASSIFICATION

- Non-Adjustable
  - Bulbo urethral slings
  - BAMS (Invance®)
  - Trans obturator slings (Advance®)
  - Quadratic sling (Virtue®)
- Adjustable
  - -MR Remeex®
  - -Argus®
  - -Atoms®

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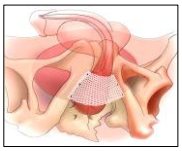
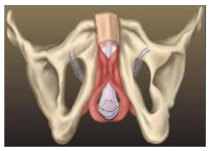
Non adjustable Slings





InVance Bone Anchor

AdVance Transobturator

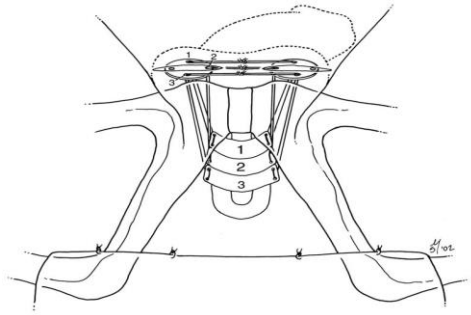
VIRTUE Quadratic Sling

1.Bulbo-Urethral Sling

Technique

- Perineal incision
- 3 tetrafluoroethylene bolsters placed under bulbar urethra
- Stamey needle is used to transfer sutures
- Suture ends are tied over rectus fascia
- Intra-op resting urethral pressure & ALPP measured for sling tension

Bulbo-Urethral Sling (BUS)



Bulbo-Urethral Sling

Results:

- Total # patients 71
- Mean follow up 48 m
- 0 pads 36%
- ≤ 2 pads 68%
- Patient satisfaction 69%

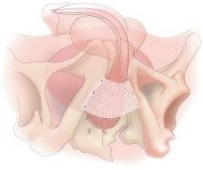
Stern, JA et al. J Urol 2005;173(5):1654

Bulbo-Urethral Sling

Complications:

- Sling removal 10%
- Sling revision 21%
- Bolster removal 10%
- Chronic pain 18%

2. Bone Anchored Male Sling (BAMS)



Bone Anchored Male Sling (Invance®)

Shaft and Shaft Sleeve Cover

- 8cm metal shaft
- Plastic sleeve cover
  - Prevents tissue or anything else from getting wrapped up or around the shaft

University of Illinois Medical Center

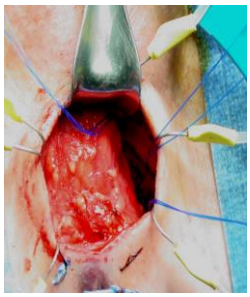
Bone Anchored Male Sling

Bone Screws

- 5mm titanium bone screw with pre-attached #1 Prolene suture
- Self-tapping design allows for faster bite, quicker insertion and firmer fixation into the bone without chipping

University of Illinois Medical Center

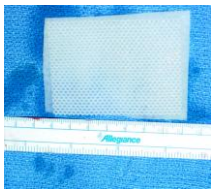
Insertion of Bone Screws



University of Illinois Medical Center

Sling Material

Allograft Demis
Silicone Mesh
Allograft Fascia
SIS
Composite



University of Illinois Medical Center

2. Bone Anchored Male Sling (BAMS)

10 studies between 2005 and 2011, at least 30 pts, minimum mean follow up of 12 months

- Success rate 13%-66%
- Improved 8%-39%

University of Illinois Medical Center

2. Bone Anchored Male Sling (BAMS)

- Erosion rate 0%-2%
- Urinary retention 0%
- Malfunction/displacement 0%-10%
- Pain 0%-10%
- Infection 0%-15%
- De novo detrusor overactivity 1%-14%

University of Illinois Medical Center

2. Bone Anchored Male Sling (BAMS)

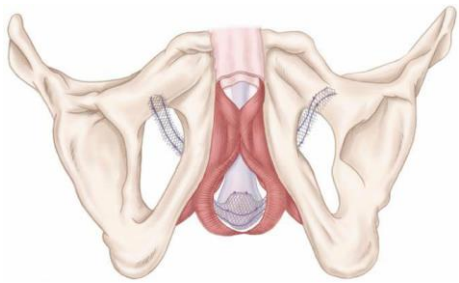
- Bothersome scrotal pain or numbness affects 16%-72% of patients postoperative, but disappear in nearly all patients by 3 months
- 76% of men with postoperative mesh infections required surgical explantation of sling
- Bone screw dislodgment can happen as a late complication that cause recurrent incontinence and require a second operation

2. Bone Anchored Male Sling (BAMS)

InVance® device has now been removed from the market in some countries

due to the morbidity related to bone screws (infections, pubic bone osteitis, perineal pain, lack of efficacy)

Trans obturator slings



Trans-Obturator Sling (Advance®)

- Polypropylene mesh tape is placed sub-urethrally
- Tape is placed by passing helical needles through obturator foramen
- Tape is then pulled to reposition and relocate urethra

3. Trans obturator slings

5 studies between 2010 and 2012, at least 30 pts, minimum mean follow up of 12 months

- Success rate 9%-73%
- Improved 16%-45%

3. Trans obturator slings

- Erosion rate 0%
- Urinary retention 0%-15.1%
- Malfunction/displacement 0%-0,8%
- Pain 0%-17%
- Infection 0%-2,7%

3. Trans obturator slings

- Permanent retention is rare, the need for catheterization can persist for up to 12 weeks, with rare instances of retention lasting longer than 3 months.
- Less commonly experienced is wound infection, with only rare sling infection or erosion requiring explantation

Quadratic (4- Point) Sling (Virtue®)

Reconstructive Urology

The Virtue Sling—A New Quadratic Sling for Postprostatectomy Incontinence—Results of a Multinational Clinical Trial

Craig V. Comiter, Eugene Y. Rhee, Le-Mai Tu, Sender Herschorn, and Victor W. Nitti

Quadratic (4- Point) Sling (Virtue®)

- 12 months objective success rate 41.9%
- 12 months cure rate 15%

NB. Authors considered as objective success rate >50% improvement in pad weight, and as cure rate a pad weight <1.3 g

Quadratic (4- Point) Sling (Virtue®)

Complications:

- 12.2% short term paresthesias
- 14.3% temporary perineal pain
- 1 case of scrotal hematoma
- 1 case of UTI
- No sling infection or erosion reported after 12 months
- No changes in mean PVR

Prostatic Diseases and Male Voiding Dysfunction

Long-term Follow-up of the Virtue Quadratic Male Sling

Andrew N. McCall, Marcelino E. Rivera, and Daniel S. Elliott

OBJECTIVE To report our long-term outcomes of Virtue Quadratic (VQ) sling since male slings have been introduced as a potential alternative treatment option to the artificial urinary sphincter (AUS), with limited long-term data available for proof of efficacy. Herein, we report our data.

METHODS A retrospective review was performed on all Virtue slings performed at our institution over a 2-year period. Patient-reported outcomes regarding procedure success, complications, as well as subsequent procedures were identified. Procedure failure was defined as the inability to reduce patient's preoperative pad use, sling explant for complications, and need for AUS due to continued incontinence.

RESULTS We identified 32 consecutive male patients who were implanted with the VQ sling over the study period. One patient was excluded due to no follow-up. Median follow-up was 55 months. Median preoperative and postoperative pads per day were 3 (interquartile range: 1-3) and 2 (1-2.5). There were 21 (68%) patients who were considered procedure failures. Two (7%) patients reported chronic pain following placement and 7 (22%) underwent subsequent sling explant due to pain or for failure (1 vs 6). Six (20%) patients underwent subsequent AUS placement. Failure was more likely in patients with external beam radiation therapy (6, 19%) ($P = .02$). There was no association between procedure failure with age ($P = .65$) or severity of incontinence ($P = .17$).

CONCLUSION This study demonstrated a significant procedure failure and complication rate with the VQ sling. Thus, we do not recommend the use of the VQ sling and have abandoned all further implantation of the device. UROLOGY ■■: ■■–■■, 2016. © 2016 Elsevier Inc.

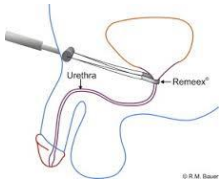
Table 1. Patient demographics with success and failure

Characteristic	Success (n = 10)	Failure (n = 21)	*P* Value
Median age (years) (IQR)	70.5 (63-77)	73 (66-77)	.75
Median BMI (IQR)	30 (28-32)	28 (27-30)	.35
Preoperative radiation (%)	0	29	**.02**
Diabetes (%)	6	5	.37
Hypertension (%)	70	48	.28
Hyperlipidemia (%)	70	62	.59
Cardiac disease (%)	10	29	.11

CONCLUSION

This study demonstrates a significant procedure failure and complication rate with the VQ sling. As a result, we do not recommend the use of the VQ sling and have abandoned all further implantation of the device.

Adjustable slings: MR Reemex®



Adjustable slings: MRS II Reemex®

24-48h after the intervention the system is adjusted to give the exact urethral support level needed.
If at any moment, during patient's lifetime, he is incontinent again, surgeon can adjust the sling urethral support easily. This re-adjustment can be performed whenever needed, every time it is necessary.

Dynamic pressure transmission system

When coughing, the patient advances the rectus muscle, advancing the varitensor, and increasing the sling urethral support while it's needed.

Adjustable slings: MR Reemex®

EUROPEAN UROLOGY 52 (2007) 1473–1480

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Incontinence

Adjustable Suburethral Sling (Male Remeex System®) in the Treatment of Male Stress Urinary Incontinence: A Multicentric European Study

Alejandro Sousa-Escandón [a,], Javier Cabrera [b], Franco Mantovani [c], Marco Moretti [d], Evangelos Ioanidis [e], Nikolaos Kondelidis [e], Joerg Neymeyer [f], Rui Noguera [g]*

There was one urethral erosion of the mesh, which was removed; the patient remains incontinent. There were two infections of the varitensor,

EUROPEAN UROLOGY 52 (2007) 1473–1480

three mild perineal haematomas (5.9%) that needed no aggressive treatment; most patients felt transient pain or perineal discomfort, which was treated with oral medications.

micturition, and requ
used; surgical revisior
occur in 12–53% of
erosion and infection
Various surgical tec

Reconstructive Urology

Male Readjustable Sling (MRS) System for Postprostatectomy Incontinence: Experiences of 2 Centers

Sang Woon Kim, Rhonda Walsh, Yitzhak Berger, and Jang Hwan Kim

OBJECTIVE To evaluate the outcomes of Male Readjustable Sling (MRS) in patients with postprostatectomy incontinence at 2 unrelated centers and to determine preoperative factors relevant to the outcome.

MATERIALS AND METHODS From January 2007 to January 2014, a total of 64 men with urinary incontinence following radical prostatectomy were treated with MRS at 2 centers. Patients were evaluated based on medical history, daily pad usage, urodynamics, and cystoscopy. The clinical outcome was evaluated according to daily pad usage and questionnaires. Success was defined according to reductions in the number of pads used per day after surgery, and factors related to surgical outcome were investigated.

RESULTS The median age of the patients was 70 years (range: 53-84), and the mean follow-up duration was 46.0 ± 19.47 months (range: 12-89). During follow-up, readjustment of the sling was required 1.9 times on average. Daily pad usage decreased significantly from 3.42 ± 2.00 to 0.84 ± 1.20 ($P < .001$), and the International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form score improved (18.65 ± 2.61 to 10.55 ± 6.21, $P < .001$) without deterioration of voiding symptoms at the last follow-up. MRS was successful in 46 of 64 patients (71.9%). Of the 18 patients who experienced surgical failure, 12 patients required secondary artificial urethral sphincter implantation. The number of daily used pads (odds ratio 1.414) and a history of pelvic irradiation (odds ratio 8.400) were potential risk factors for surgical failure.

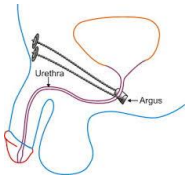
CONCLUSION According to our midterm follow-up data, MRS is an effective and a safe treatment option for radiation-naïve patients with a mild degree of postprostatectomy incontinence. UROLOGY ■■: ■■–■■, 2015. © 2015 Elsevier Inc.

CONCLUSION

At the midterm follow-up, the MRS using the REMEEX system was effective in treating PPI, with a success rate of 72% and an acceptably low complication rate. Success rates were similar between the 2 unrelated centers included in this study. The MRS could be an attractive surgical option for treating radiation-naïve patients with a mild degree of PPI.

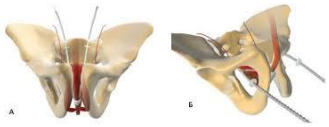
Adjustable slings: Argus®

The Argus sling is an implant consisting of two polydimethylsiloxane elastomer fixation arms and a central radiopaque pad made of foam of the same elastomer.



Adjustable slings: Argus®

- **The Argus Adjustable Male Sling system** is specially designed for the retropubic approach and is indicated for treating moderate to severe SUI cases. Five years of experience backs up the standardized, reproducible Argus retropubic technique.
- **The Argus T Adjustable Male Sling system** is specifically designed for the transobturator approach. It is indicated for patients with mild to moderate SUI. It involves a less invasive surgical technique, minimizing the risk of bladder perforation



Actas Urológicas Españolas
Volume 33, Issue 3, 2009, Pages 309–314

Resultados a largo plazo del estudio multicéntrico fase III del tratamiento de la incontinencia de orina post prostatectomía con un sling masculino ajustable: seguimiento mínimo 3 años

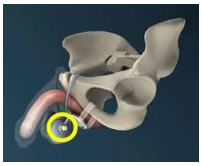
Long term results of a phase III multicentre trial of the adjustable male sling for treating urinary incontinence after prostatectomy: minimum 3 years

V. Salomon Romano, E. Sergio Metrebian, Vaz Fernando, Muller Valter, A. Carlos Levi D'Ancona, A. Eugenio Costa de Souza, Fabio Nakamura

Adjustable slings: Argus®

- Cure rate 66%-79.2%
- Improved 12.8%
- Erosion rate 12.7%
- Urinary retention 8.5%-38.6%
- Malfunction/displacement 0%
- Infection 4%-6.4%

Adjustable slings: Atoms®



- Long-term, adjustable implant
- Hydraulic system with no mechanical parts
- Anatomical 4-point fixation
- Scrotal Port

Adjustable slings: Atoms®

Original article

Adjustable transobturator male system – ATOMS – for the treatment of post-prostatectomy urinary incontinence: The surgical technique

WILHELM BAUER, CLEMENS BRÖSSNER
Krankenhaus Göttlicher Heiland, Department of Urology, Vienna, Austria

Adjustable slings: Atoms®

- Series of 120 patients
- Non intraoperative and perioperative complications reported
- Temporary perineal/scrotal dysaesthesia or pain in 62% of patients (controlled with non-opiate painkiller)
- 4 port infection

Original article

Adjustable transobturator male system – ATOMS – for the treatment of post-prostatectomy urinary incontinence: The surgical technique

WILHELM BAUER, CLEMENS BRÖSSNER

Authors suggest to avoid infection:

change of the port only, or to a complete explantation (port and silicone components). Successful reimplantation of the ATOMS system in all patients followed after a healing phase of three months. Having observed no further infections since, we can draw the following considerations: a) the implant should not be removed from the packaging until we have finished preparing the site, b) the perineal implantation should be completed before we move to the port area, c) the port should be positioned subcutaneously as deep as possible, and d) the port should not end up lying directly under the skin incision (the edge of the port should be at least 1 cm away from the skin incision). On average, our patients are discharged on the third post-operative day (range 2-7), which is standard practice in the Austrian healthcare system. An earlier discharge is certainly possible from a medical point of view, however is not advisable before removal of the permanent catheter.

Conclusion

- The complications of newer male slings are uncommon.
- The bulbourethral sling had the highest incidence of complications
- Perineal pain is the most frequent complications with all types of male sling

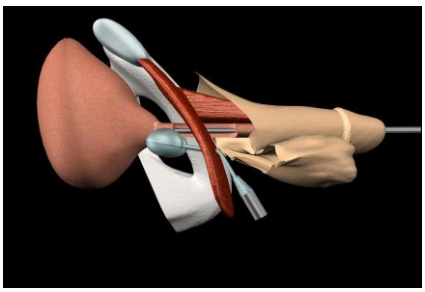
Conclusion

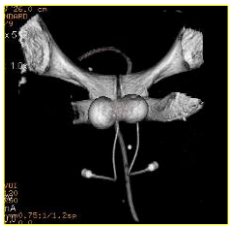
Guidelines on
Urinary Incontinence

M.G. Lucas (Chair), D. Bedretdinova (Guidelines Associate), L.C. Berghmans, J.L.H.R. Bosch, F.C. Burkhard, F. Cruz, A.K. Nambiar, C.G. Nilsson, A. Tubaro, R.S. Pickard

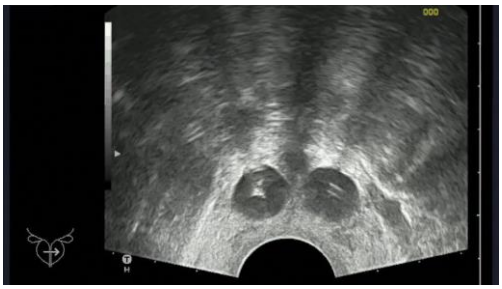
Evidence summary	LE
There is limited short-term evidence that fixed male slings cure or improve post-prostatectomy incontinence in patients with mild-to-moderate incontinence.	3
Men with severe incontinence, previous radiotherapy or urethral stricture surgery may have less benefit from fixed male slings.	3
There is no evidence that one type of male sling is better than another.	3

ProACT™





Stepper guided US



Courtesy of S. Crivellaro

Overview of All Published ProACT™ Series

Author	# pts	% post RP	Avg f/u months	Avg # adjust	% pats impr.	0-1 pds /day %	Pre-op pds/d	Last f/u pds/p	Explan-ted %	% com-plctns
Hübner/ Schlarp	117	88	13	3	90	67	6	1	27	46
Gilling	33	81	24	3.3			2.8	0.7	9	
Trigo-Rocha	23	100	22.4	4.6		65	4.6	1.8	17	
Hübner/ Schlarp	50	100	20	4	82	60	5	1.8	24	
Crivellaro	44	100	19		84	68	5.1	2.5	14	
Lebret	56	98	6		89	71	4.6	1.8	33.9	
Kocjancic	64	100	12	3	80	68	5.2	1.5	17	
Martens	29	100	41	3.7	56	31	4.8	3.1	44.8	
Luyckx	60	93	8.9	2.7	85	64	2.5	1.2	20	40
Hidalgo	69	87	22	2-3	84	70			9	
Gregori	62	100	25	3.6	92		3.7		4	12

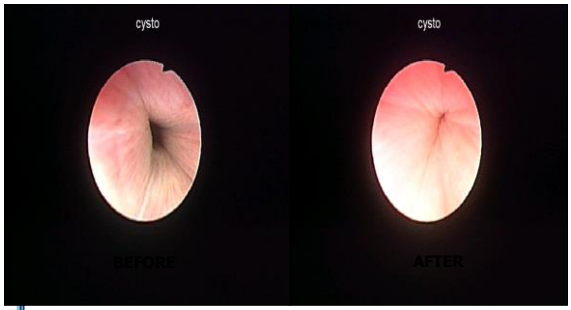
Conclusions

Are male slings for post-prostatectomy incontinence a valid option?

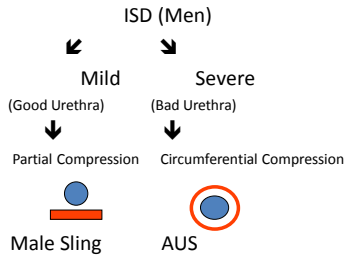
Male slings are a valid option for treating male stress incontinence, and do offer several advantages over the artificial urinary sphincter. However, long-term data and multicenter series are needed in order to compare directly with the artificial urinary sphincter.

Curr Opin Urol. 2010 Nov;20(6):465-70, Herschorn S.

Urethral coaptation



Which Procedure To DO?



Wilhelm A. Hübner

Affiliations to disclose†:

Astellas speaker
Promedon speaker
AMS speaker

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- [ ] Self-funded
- [X] Institution (non-industry) funded
- [x] Sponsored by: *Promedon*

Established and new hydraulic systems, what they can and what they can not
W. Huebner

AMS 800 results, Qs and As
Zephyr
Flowsecure
Aroyo

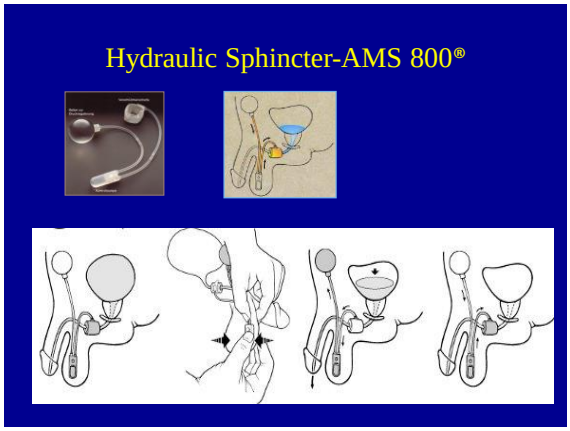
Artificial hydraulic sphincter

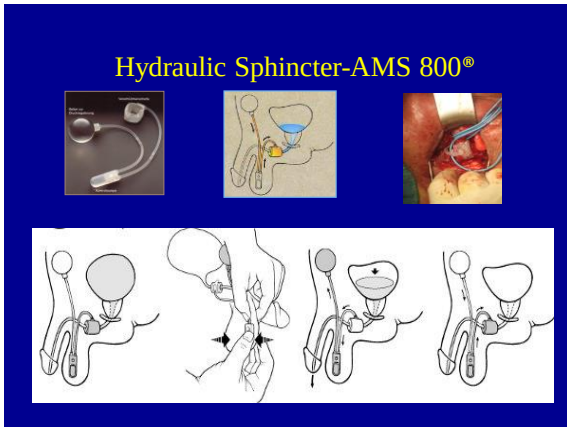
First described 1974

Current version: AMS 800 since 1982

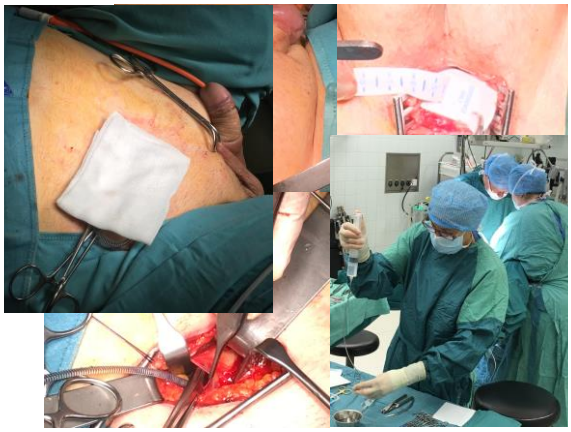
Worldwide <100.000 Implantations

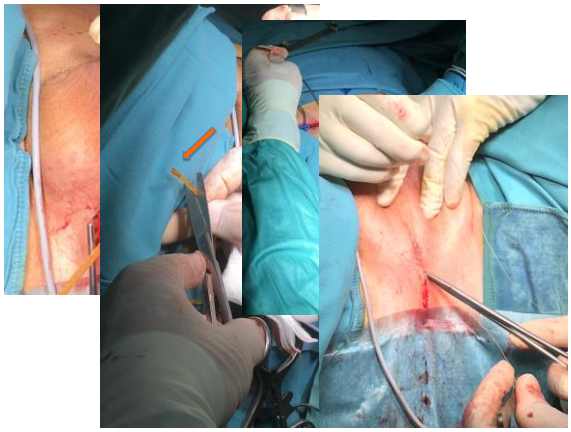
Open – close mechanism!





AMS 800 – classic implantation





AMS 800 - options for implantation

- scrotal approach

shorter OP time
single incision
Less invasive
⇒*Smaller cuffs?*
⇒*PRB position?*

Wilson S, Delk J 2nd, Henry GD et al (2003) New surgical technique for sphincter urinary control system using upper transverse scrotal incision. J Urol 169:261–264

AMS 800 - options for implantation

Classical two incisions/scrotal approach

Henry GD et al, multicenter study n=158
Higher dry rates (44 vs 27%)
Less sec. tandems (5 vs 11%)
outcome favours classic (no prosp. rd. trials)

Henry GD, Graham SM, Cleves MA, Sim- mons CJ, Flynn B:
J Urol 2008; 179:1475–1479.
Henry GD, Graham SM, Cornell RJ, Cleves MA, Simmons CJ, Vakalopoulos I, et al
J Urol 2009;182:2404–2409.

AMS 800 - options for implantation

Classical two incisions/scrotal approach

Kretschmer et al. (European DOMINIO study) n=467

Higher early explantation rate with scrotal approach (19,2 vs 8,6%%)
complication rate favours classic (no prosp. rd. trials)

Urol Int. 2016 Jun 17. [Epub ahead of print]. Complications and Short-Term Explantation Rate Following Artificial Urinary Sphincter Implantation: Results from a Large Middle European Multi-Institutional Case Series. Kretschmer A.

AMS 800 - options for implantation

More vulnerable (distal) part of the urethra
(Henry et al: smaller cuffs in the transsc. cohort)

Recommendation for transscrotal approach cannot be given

Inadequate angles of tubes =>
erosion/device dislocation
(Kretschmer et al: erosion, dislocation)

AMS 800 - options for implantation

Single cuff / tandem cuff

Theoretic advantages: increasing urethral resistance with equal pressure => higher LPP

Initially => favourable results (1993-1996)

Brito CG, Mulcahy JJ, Mitchell ME, Adams MC.. J Urol. 1993;149(2):283–285.
Kabalin JN. r. J Urol. 1996;156(4):1302–1304.
Kowalczyk JJ, Spicer DL, Mulcahy JJ. J Urol. 1996;156(4):1300–1301.

AMS 800 - options for implantation

Single cuff / tandem cuff

Higher complication rates with tandem cuffs

Tandem cuff only recommended for Trouble shooting (failed single cuff, subcuff – atrophy)

Van der Aa et al, *Eur Urol 2013*; O' Connor et al, *Urology, 2008*
O'Connor RC, Lyon MB, Guralnick ML, Bales GT.. *Urology. 2008*;71(1):90–93.
Kretschmer A et al., : Results from a Large Middle European Multi-Institutional Case Series, *Urol Int. 2016* Jun 17.

AMS 800 - options for implantation

Capsule around the PRB may change (increase) system pressures =>

Little information

Recommendation
Whenever possible intraperitoneal PRB

Does pressure regulating balloon location make a difference in functional outcomes of artificial urinary sphincter?
J Urol. 2015;194(1):202–206.

or deeper *extraperitoneal* placement, n=294

Erosion rate identical 9% after 2 years

Own series (n=218, FU 5,1years): => 4,8% erosions*!*
98% intraperitoneal placement

AMS 800 - options for implantation

Transcorporal cuff placement – concerns/facts

Bleeding => insignificant

ED => majoritiy maintains!°

Special appearence at X-Ray
(compr. at 12h position)

°Wiedemann L, Cornu JN, Haab E, et al. Transcorporal artificial urinary sphincter implantation as a salvage surgical procedure for challenging cases of male stress urinary incontinence: surgical technique and functional outcomes in a contemporary series. BJU Int. 2013;112(8):1163–1168.

AMS 800 - options for implantation

Transcorporal cuff placement - indications

for re-do

when distal placement needed

difficult preparation of urethra

additional bulk with small urethras

Artificial Urinary Sphincter

- **Perineal** and **scrotal** approach

Van der Aa et al, Eur Urol 2013; O' Connor et al, Urology, 2008

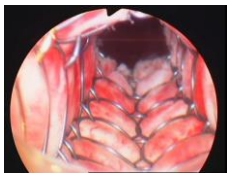
Outcomes	Results, % [range]	No. of included participants (no. of studies)
Infection/erosion	8.5 [3.3–27.8]	562 (10)
Mechanical failure	6.2 [2.0–13.8]	562 (10)
Urethral atrophy	7.9 [1.9–28.6]	456 (6)
Reintervention (for any reason)	26.0 [14.8–44.8]	549 (10)
No. of patients social continent (≤1 pad/24 h)	79.0 [60.9–100]	262 (7)
No. of patients completely dry (0 pads/24 h)	43.5 [4.3–85.7]	336 (7)

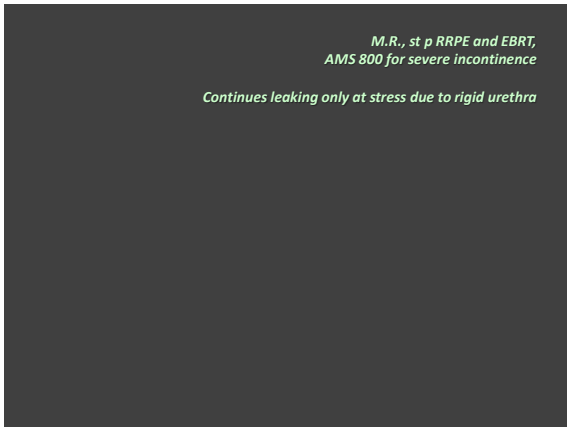
- high Revision rates (20-30%)
- *satisfaction rate* correlates with continence, *not dependent of revision rate!*

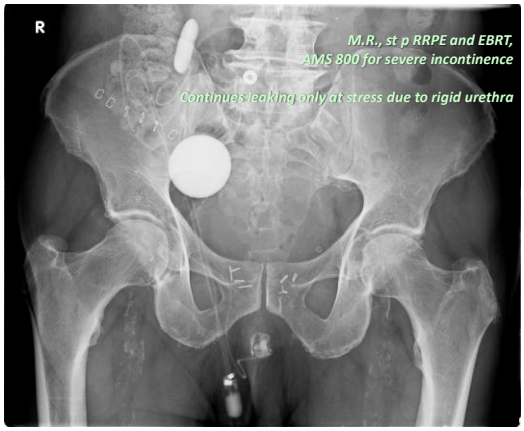
PD49-01 LONG-TERM OUTCOMES FOLLOWING ARTIFICIAL URINARY SPHINCTER PLACEMENT: AN ANALYSIS OF 1082 CASES AT MAYO CLINIC (n=1082)
Brian Linder, Marcelino Rivera, Matthew Ziegelmann, Daniel Elliott
Secondary surgery-free survival:
90% at 1 year, 74% at 5 years, 57% at 10 years, and 41% at 15 years.

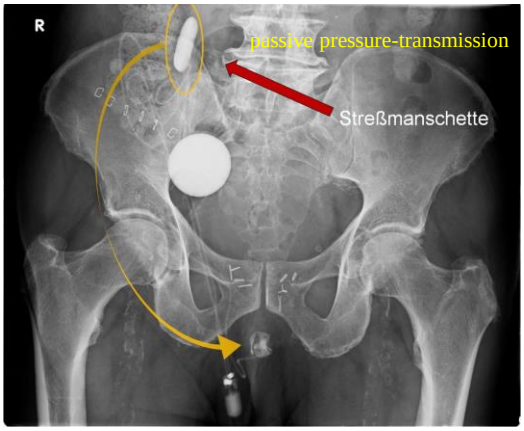
S.K., 12.05.1947
X/2006rad Cystoprostatektomy, (PT4, GS9, R+)
Ileum Neobladder => PSA = 0,3ng
=> rez. Anastomotic stricture

III/2009 Memotherm Stent + AMS 800
voiding volume 700ml, RU = 0, nycturia: 0





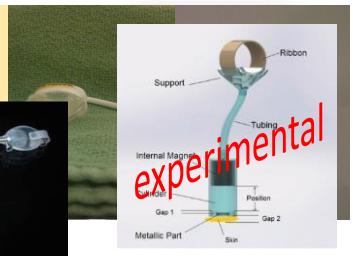




NEWS

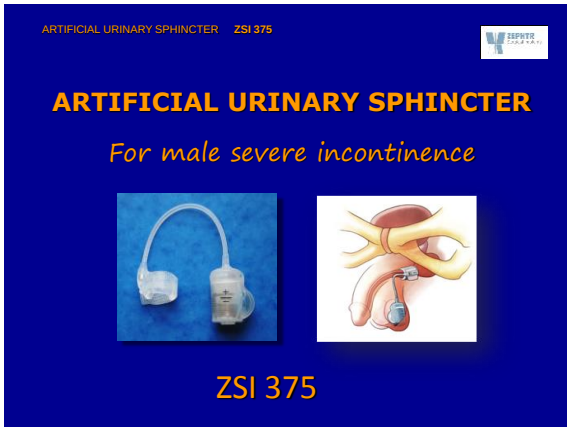
ZSI 375 next generation. flowsecure

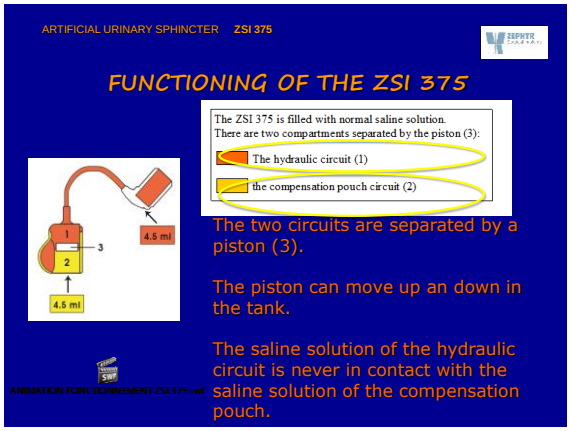
Aroyo

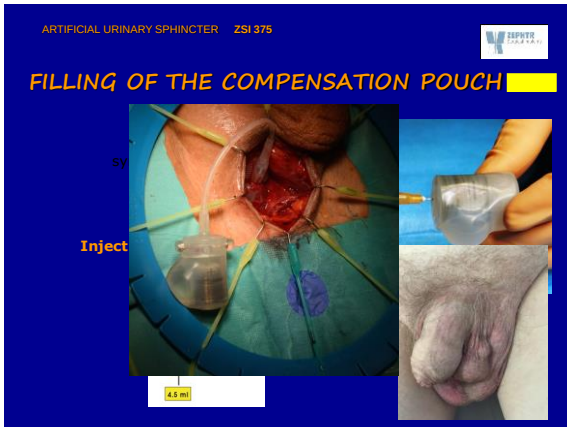


Magnetic and electronic sphincters

zephyre







RESULTS

Staerman F. et al.: ZSI 375 artificial urinary sphincter for male urinary incontinence: a preliminary study.
BJU international 111 (4 Pt B):E202-206. (2013)

n=36 patients FU: 15.4 (6-28) months
Social continence *at 6 mts:* 73%
Removal in 4/36 patients (12,5%)
infection 3x, erosion 1x

RESULTS

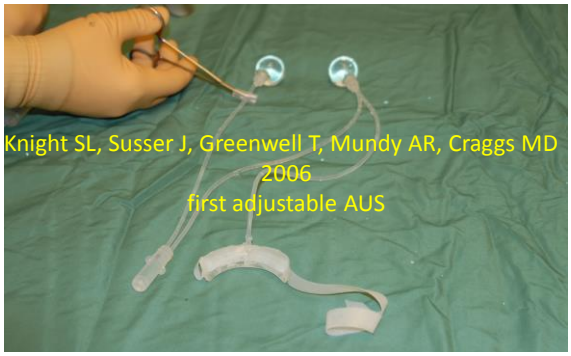
Changes have been made, now prefilled implant, new data needed

World J Urol. 2016 Feb 25

Differences to AMS 800:
adjustability any time after implantation
„one piece implant“
Improvement concerning dexterity?

FS

Flowsecure



Garcia Montes F, Knight SL, Mundy AR & Craggs MD., ICS 1999

pathophysiology

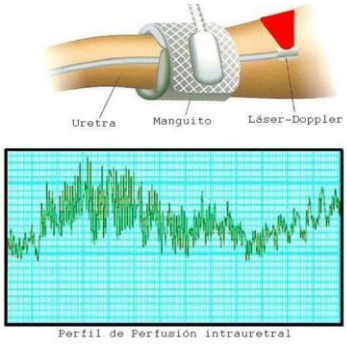


Foto:
F Garcia Montes

Garcia Montes F, Knight SL, Mundy AR & Craggs MD., ICS 1999

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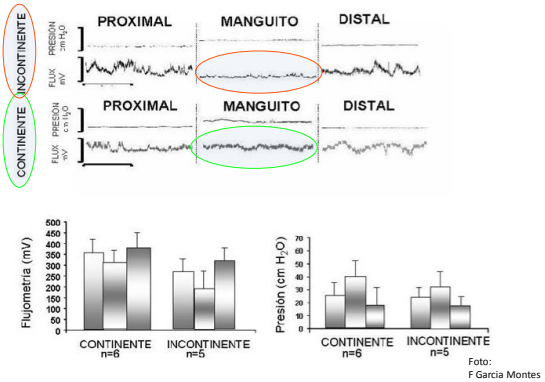

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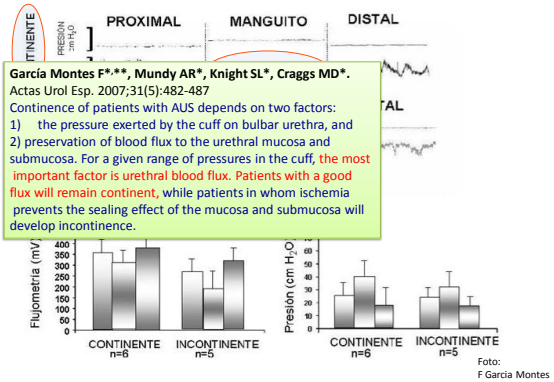
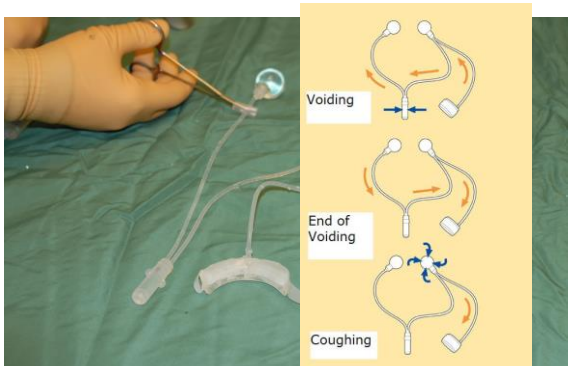


García Montes F*,, Mundy AR*, Knight SL*, Craggs MD*.**
Actas Urol Esp. 2007;31(5):482-487
Continence of patients with AUS depends on two factors:
1) the pressure exerted by the cuff on bulbar urethra, and
2) preservation of blood flux to the urethral mucosa and submucosa. For a given range of pressures in the cuff, the most important factor is urethral blood flux. Patients with a good flux will remain continent, while patients in whom ischemia prevents the sealing effect of the mucosa and submucosa will develop incontinence.

Foto:
F Garcia Montes

Flowsecure



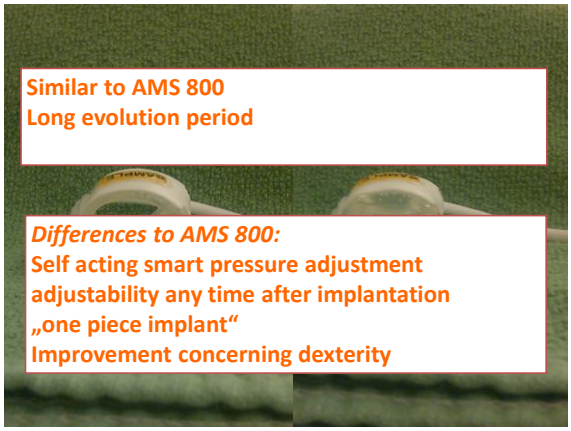
Flowsecure

RESULTS

Alonso Rodriguez D FAE, Fernandez Barranco L, Vicens A GMF (2011) One hundred FlowSecure artificial urinary sphincters. Eur Urol Suppl 10:309

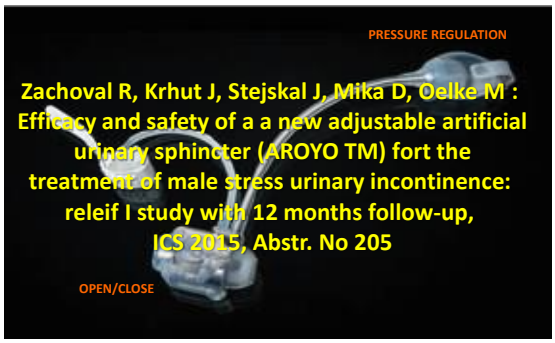
n=100 patients FU: 15.4 (6-28) months

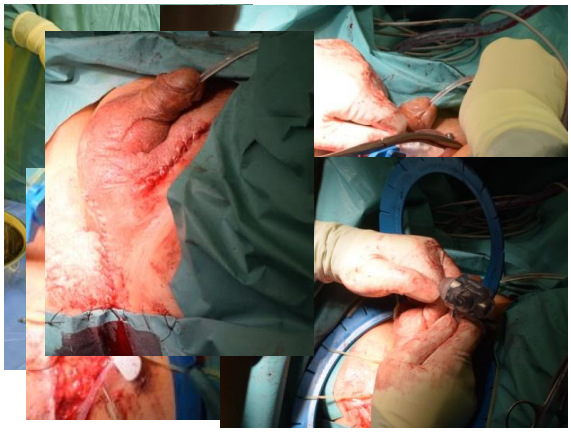
Social continence : 89%
Removal in 28/100 patients (28%)
pump problems (accidental penetration, malfunction)



aroyo

AROYO TM





RESULTS

Zachoval R, et al.: Efficacy and safety of a a new adjustable artificial urinary sphincter (AROYO TM) ICS 2015, Abstr. No 205

n=9 patients FU: 12 months

7/9 pts: „more than 50% reduction in pad weight
2/9 pts removal (erosion, malfunction)

RESULTS

Interesting concept
„young“ product, results not yet conclusive
wait for final Releif II results

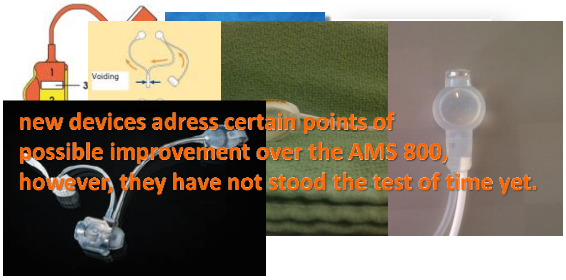
n=48 patients

Differences to AMS 800:
Open/close control unit in the scrotum
adjustability
„one piece implant“
Pressure compensator for manual activation

Future Aspects

Future Aspects

ZSI 375 new generation. flowsecure



Aroyo

THE END

Case Presentations

Case presentation

- 64 y.o. 2 m. post ERPE, pT2b, N0,R-,
- Post op PSA o.o1 ng/ml
- 24h Pad test = 150 g
- Pad count 3

Case presentation

- 64 y.o. 2 m. post ERPE, pT2b, N0,R-,
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- Pad count 3
- Evaluation?

Case presentation

- 64 y.o. 2 m. post ERPE, pT2b, N0,R-,
- Post op PSA o.o1 ng/ml
- 24h Pad test = 150 g
- Pad count 3
- Evaluation?
- Pad count had been 4-5 initially

Case presentation

- 64 y.o. 2 m. post ERPE, pT2b, N0,R-,
- Post op PSA o.o1 ng/ml
- 24h Pad test = 150 g
- Pad count 3
- Evaluation?
- 1st option?

Case presentation

- 64 y.o. 2 m. post ERPE, pT2b, N0,R-,
- Post op PSA o.o1 ng/ml
- 24h Pad test = 150 g
- Pad count 3
- Evaluation?
- 1st option? => physical therapy

Case presentation

- 66 y.o. 3a. after RRPE, pT3a, N0,R-, used 2 pads/day
- underwent EBRT, now 3-4 pads per day

- Evaluation?

Case presentation

- 66 y.o. 3a. after RRPE, pT3a, N0,R-, used 2 pads/day
- underwent EBRT, now 3-4 pads per day
- *380ml/day, mainly in the afternoon, can interrupt his stream, contracts well at cysto, no RU*
- *UD: no OAB*
- *Options?*

PFT?
ProAct?
Fixed sling?
Adjustable sling?
AUS?

Case presentation

- 66 y.o. 3a. after RRPE, pT3a, N0,R-, used 2 pads/day
- underwent EBRT, now 3-4 pads per day
- *380ml/day, mainly in the afternoon, can interrupt his stream, contracts well at cysto, no RU, UD: no OAB*
- *UD: no OAB*
- *options* *Argus "T" RLPP 22 => 31cm H2O*

=> dry

case

IV/2005 63 a WM, Dg PC, PSA: 12,4 ng/ml

RPE aborted for N+ ⇨ LHRH Therapy

IX/2005 „IC", conservative Th., Botox, total incontinence,
The patient was told that there are no other options for him!

presents with SP tube , still pain and incontinence => pre suicidal!

case

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X/2006 rad. Cystoprostatectomy, Histology: PT4, GS9, R+

Ileal neobladder

case

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X/2006 rad. Cystoprostatectomy, Histology: PT4, GS9, R+

Ileal neobladder ⇨ rec. anastomotic stricture!

Cystoscopy

case

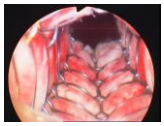
Ileal neobladder, rec. anastomotic stricture, wet intervals!

Deobstruction

case

Ileal neobladder, rec. anastomotic stricture, wet intervals!

Memotherm Stent
Deobstruction



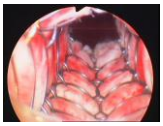
Continence surgery

Adj. Sling?
Retrourthr. Sling?
Pro Act?
AUS?

case

Memotherm Stent + AUS 800

Capacity 700ml, nykt. 0, no RU



VIII/2012:
intermitt. AB, PSA 0,8 – 3,66

CASE

72 y.o. WM after RPE, initially 380ml/day, refused AUS, received Pro Act balloons 7mts postop.

After 4 adjustments still leaking 60mls/day, 2 pads filling status R:8ml, L: 11ml, no improvement after last adjustment

Evaluation?

Options?

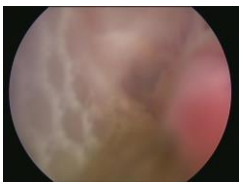
combine with sling or 3rd balloon

Case presentation

- 62 y.o. WM, AUS after RPE, presents with burning pain at micturition, underwent cysto the day before
- Evaluation?

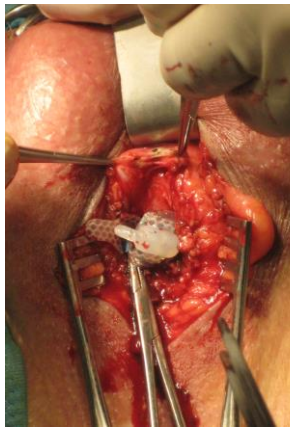
Case presentation

- 62 y.o. WM, AUS after RPE, presents with burning pain at micturition, underwent cysto the day before
- Evaluation? Urine appears sterile



AMS 800

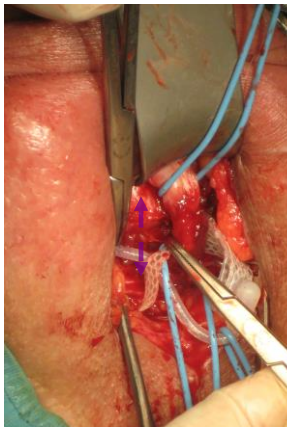
iatrogenic lesion (cysto)



AMS 800

iatrogenic lesion (cysto)

mobilisation using cuff

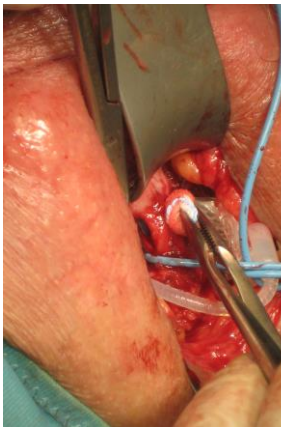


AMS 800

iatrogenic lesion (cysto)

mobilisation using cuff

ID of lesion



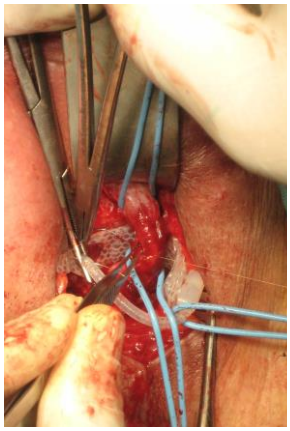
AMS 800

iatrogenic lesion (cysto)

mobilisation using cuff

ID of lesion

closure



AMS 800

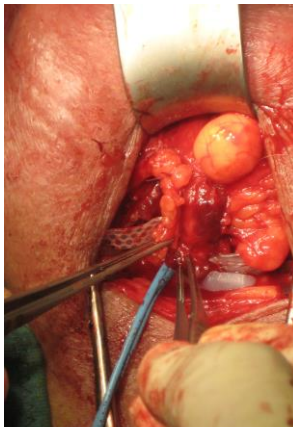
iatrogenic lesion (cysto)

mobilisation using cuff

ID of lesion

closure

protection flap



AMS 800

iatrogenic lesion (cysto)

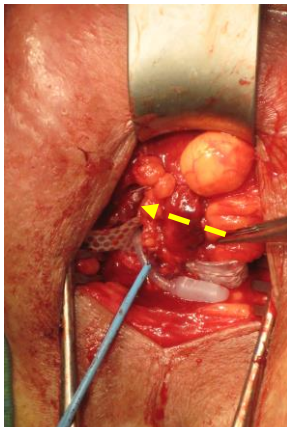
mobilisation using cuff

ID of lesion

closure

protection flap

cuff left open!



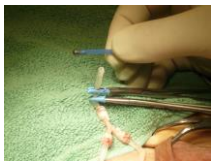
- 14 fr foley 5d
- SP tube 14d
- Cuff closure after 4-6 weeks

- 14 fr foley 5d
- SP tube 14d
- Cuff closure after 4-6 weeks

- What to do if the urine was infected??

end

- What to do if the urine was infected?



Remove AUS and wait 3 mts

or

remove only cuff, irrigate wound, use mushroom-plug, oral AB for one month, reimplant cuff

TAKE HOME MESSAGES

- MSUI works differently than female SUI
- establishment of Patient groups should be encouraged
- Physical therapy remains 1st line treatment
- Medical therapy mainly for OAB, little evidence for duloxetin
- With correct indications high success rates can be accheived
  - even in complex cases –
- Most newly developed implants are adjustable
- The last pad may be the most difficult to get rid of

Weinviertel Klinikum Korneuburg - Austria
= referral center for male incontinence

between 2001 and 2008: 558 operations for male incontinence
42,4 % re - operations.

telephone survey conducted in I -III/2009 :
satifaction rate 85,76% (all severel different methods)
No difference between primary surgeries and reoperations =>

Reoperations should be looked upon positively whenever considered.

Case

- 58 years old patient RRP & EBRT.
- H/O recurrent PPI using 3-4 pads a day.
- AUS 1 Y after RRP
- infected AUS.

Case

- 58 years old patient RRP & EBRT.
- H/O recurrent PPI using 3-4 pads a day.
- AUS 1 Y after RRP
- infected AUS.
- Patient refuses another AUS. ➔ BAMS
  - Develop infection
  - Male sling removed and underwent AUS through transverse scrotal incision.

Infection

If no erosions, can salvage

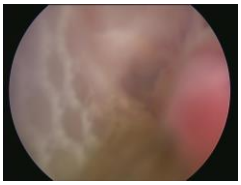
- Salvage Protocol*
  - Remove AMS 800 and foreign material
  - Irrigate wound w/ 7 antiseptic solutions
  - Change gowns, gloves, surgical drapes and instruments
  - Insert new AMS 800
  - Close wounds w/ no drains or catheters
  - Treat w/ oral antibiotics for 1 month
- If erosion – remove <u>all</u>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

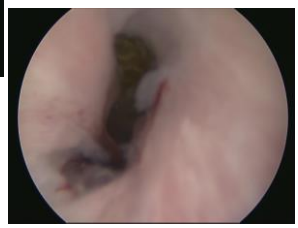
*Mulcahy JJ. *J Urol*. 2000;163;481-482.

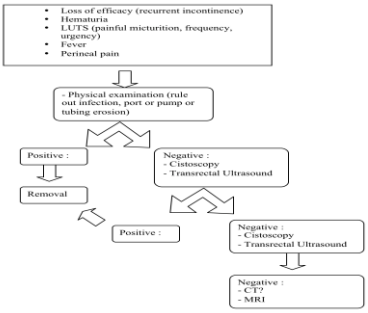
Antiseptic Irrigating Solution for Infected AMS 800

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. Vacomycin and 80 mg. gentamicin in 5 l. 0.9% normal saline
5. ½ strength povidine-iodine
6. ½ strength hydrogen peroxide
7. Antibiotic irrigation (bacitracin and gentamicin in 0.9% normal saline)

Mulcahy JJ. *J Urol*. 2000;163;481-482.







Remedying failed AUS

- Options
  - Down size cuff
  - Tandem Cuff
  - Transcorporeal cuff
  - Other opstions: Sling; proACT; Constrictor; Urinary Diversion

AMS 800 - Reasons for Revisions

Of 554 men undergoing AUS implantation – 21% had revision

- Mechanical (23%)
  - Cuff leak – 16 cases
  - Other leak – 8 cases
  - Pump malfunction – 3 cases
- Non-mechanical (77%)
  - Atrophy – 63 cases
  - Cuff size – 4 cases
  - Erosion – 21 cases

- Every procedure which involves antiincontinence devices can have complications : BE PREPARED !
- The most common complications are INFECTION, EROSION, FAILURE
- The main risk factor is RADIATION THERAPY : good counseling for those patients is crucial
- Complication is detected by Symptoms : LISTEN TO THE PATIENT!

Ensure your patients and yourself tha you are not alone

Case presentation

- 64 y.o. 14 m. post RRP, pT2, N0,R-,
- Post op PSA o.o1 ng/ml
- 24h Pad test = 150 g
- Pad count 3

Holiday in Greece 2011

intermitt. AB
-V/2010:
-PSA 3,88 ng /ml

CASE

65 years old

ProACT

3 months post op.

3 adjustments; After each adjustment total continence

for less than 1 week

3 days after the last adjustment T 38 C.

Case presentation

- 64 y.o. 14 m. post RRP, pT2, N0,R-,
- Post op PSA o.o1 ng/ml
- 24h Pad test = 150 g
- Pad count 3

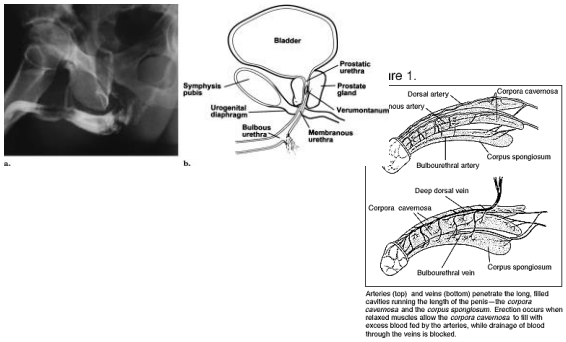
- **Cystoscopy?**
- **Urodynamics?**
- **Physical therapy?**

CASE

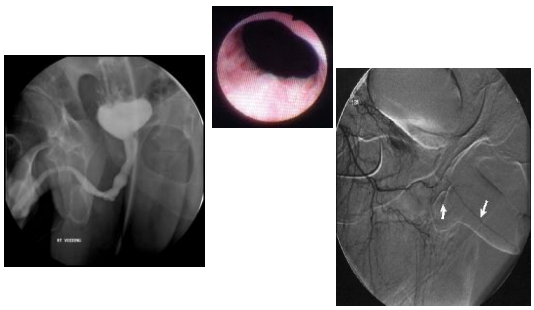
- 20 yo WM
- MVA R femur fracture R superior/inferior pubic rami fracture
- Urethral posterior injury
- Urethroplasty ….open BN
- continued incontinence

Initial RUG

ANATOMY

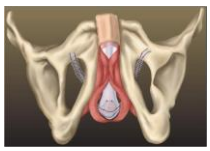


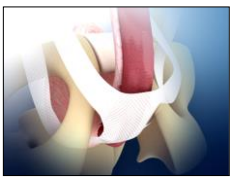
Arteries (top) and veins (bottom) penetrate the long, tilled cavities running the length of the penis—the *corpora cavernosa* and the *corpus spongiosum*. Erection occurs when relaxed muscles allow the *corpora cavernosa* to fill with excess blood fed by the arteries, while drainage of blood through the veins is blocked.



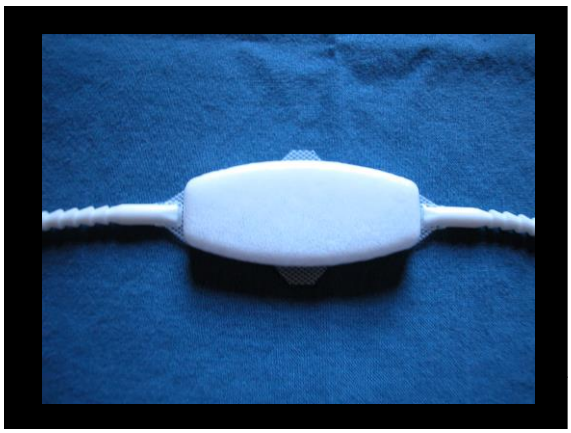
Treatment Options
AUS or Sling

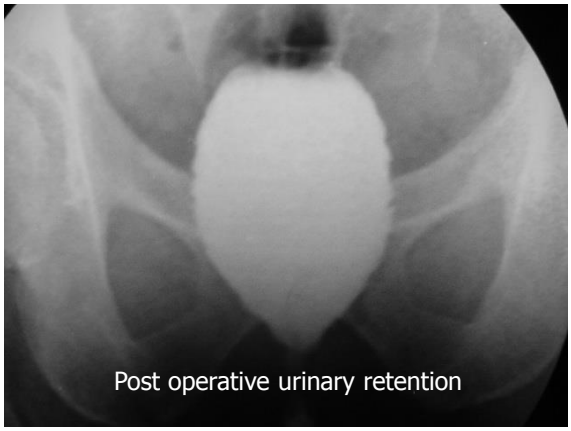
- Sling no cylindrical compression of urethra
  limited dissection
  compression ? Elevation





- 62 years old
- Radical retropubic prostatectomy 2 years ago
- Pad weight test 280 g/day
- Unsatisfied
- Underwent sling procedure





One week afterwards, urethral catheter

No improvement

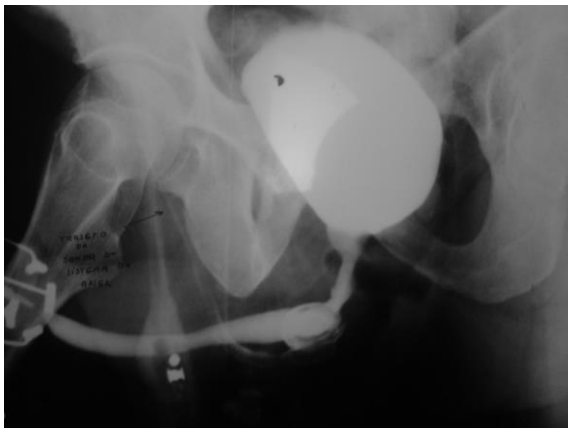
What's next?

67 y.o G.C. status post RRP and SUI

Underwent artificial urinary sphincter

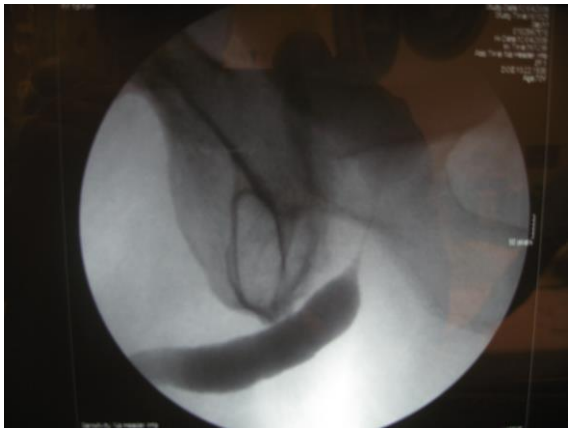
Procedure uneventfull

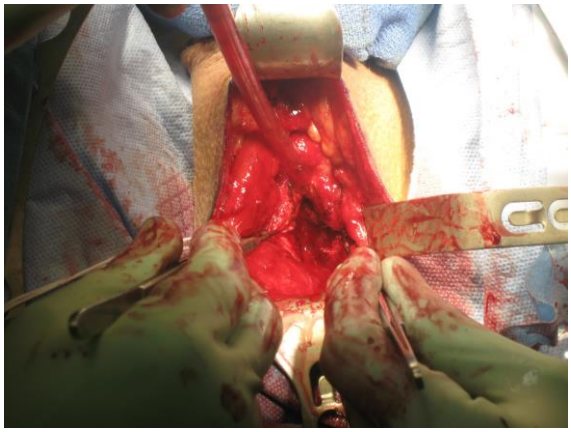
Post op day 1 – incision urinary leakage

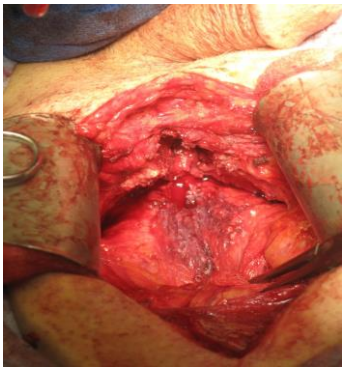


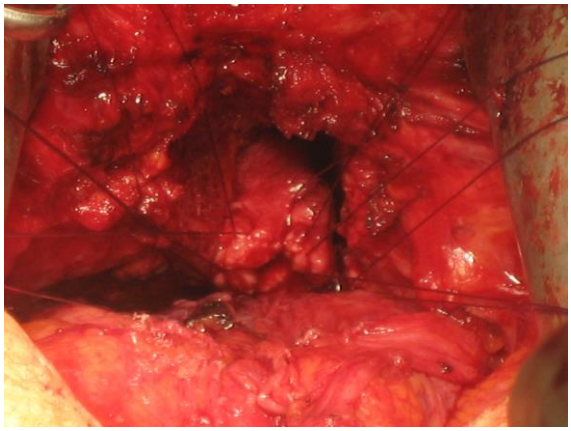
- **Foley catheter**
- **cystoscopy**
- **urethrocystography**
- **AUS explantation**
- **suture the lesion**

65 year old male s/p rrp and adjuvant XRT with multiple dilations of obliterative BN









Controversies

- Mild?
- Moderate?
- Severe?
  - What treatment?
  - When to start?
  - How to manage failures?