

Workshop Chair: Wilhelm Hübner, Austria 12 September 2017 09:00 - 10:30

Start	End	Topic	Speakers
09:00	09:15	Artificial Urinary Sphincter, Tips and Tricks, Trouble Shooting	Emmanuel Chartier-Kastler
09:15	09:20	Discussion	All
09:20	09:30	Balloons: Technique, Tips and Tricks, Trouble Shooting	Andrea Gregori
09:30	09:35	Discussion	All
09:35	09:50	Fixed and Adjustable Slings: Tips and Tricks, Trouble Shooting	Flavio Trigo Rocha
09:50	09:55	Discussion	All
09:55	10:05	New Artificial Hydraulic Sphincters, Technique, New Possibilities, Limits	Wilhelm Hübner
10:05	10:10	Discussion	All
10:10	10:25	Differential Indications and Case Discussion	All
10:25	10:30	Take Home Messages and Closing Remarks	Wilhelm Hübner

Speaker Powerpoint Slides

Please note that where authorised by the speaker all PowerPoint slides presented at the workshop will be made available after the meeting via the ICS website www.ics.org/2017/programme Please do not film or photograph the slides during the workshop as this is distracting for the speakers.

Aims of Workshop

The aim of the workshop is to give a comprehensive overview of the current aspects of male urinary incontinence including an update of new developments in this field. However, the focus will not mainly be on these new options, but even more on limitations of all different methods in order to avoid failures and poor results. Highly experienced urologists will therefore discuss the current options for an optimal counseling and treatment of male urinary incontinence with a special focus on contraindications. Finally tips and tricks will be given for routine implantation as well as challenging situations.

Learning Objectives

Decision making for surgical therapy of male incontinence based knowledge of contraindications.

Update and realistic assessment of new developments.

Sharing experience and know how with distinguished experts.

Learning Outcomes

At the end of the session the participants will be familiar with all surgical treatment options available today, able to make correct decisions on which implant to use based upon possibilities but even more limitations of the different methods in order to avoid complications. Physiotherapist, physiatrists, nurse and continence advisors will learn all about surgical options to correctly judge perspectives for their patients and provide high quality consultation.

Target Audience

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

Advanced/Basic

Advanced

Conditions for Learning

This is not a hands on course, but intense discussion and case reports will make sure that we end with a solid clinical impact. limited to 60 delegates.

Suggested Learning before Workshop Attendance see

below

Suggested Reading

Treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy.

Adjustable continence therapy (ProACT): evolution of the surgical technique and comparison of the original 50 patients with the most recent 50 patients at a single centre. *Eur Urol.* 2007 Sep;52(3):680-6

Contemporary Management of Postprostatectomy Incontinence

European Urology, 2011 Jun, Vol.59(6), pp.985-996

Telephone - delivered quality of life after 365 male stress urinary incontinence (SUI) operations. *Int Braz J Urol.* 2016 Sep-Oct.

A prospective study evaluating the efficacy of the artificial sphincter AMS 800 for the treatment of postradical prostatectomy urinary incontinence and the correlation between preoperative urodynamic and surgical outcomes. *Urology*, 2008;71:85-9

A prospective study evaluating the efficacy and safety of Adjustable Continence Therapy (ProACT) for post radical prostatectomy urinary incontinence. *Urology*, 2006

ICS, AUA, EAU Guidelines on Incontinence

Fixed and Adjustable Slings: Tips and Tricks, Trouble Shooting

Flavio Trigo-Rocha

Associate Professor of Urology - São Paulo University - Brazil

Coordinator - Center for Treatment of Urinary Incontinence – Sirio Libanes Hospital – Sao Paulo, Brazil

The idea of compressing the urethra to treat post radical prostatectomy urinary incontinence (PRPUI) is not recent. Many authors tried to use the perineal musculature, cavernous corpora and prosthetic devices to treat post prostatectomy urinary incontinence. The silicon slings were also introduced with the possibility of post operative adjustments once the silicon is not incrustated by tissue scar. The way to insert and fix the sling can varies from supra pubic to transobturator approach.

Fixed Slings: Fixed sling are unusually made with polypropylene mesh usually placed beneath the bulbous urethra. The objective of system is not only to compress but also elevate the urethra improving its mucosal coaptation. This product is indicated for mild to moderate SUI resulting from prostatectomy or transurethral resection of the prostate (TURP). The success rate varies from 53, 6 to 87, 5% in different series. Success rates in more than 80 % of patients (49 of 61) was observed in patients losing an average of 200 grams of urine per day in a 26 months follow up (range 12-53). Surgical complications occur in an acceptable number of patients and include accidental sling misplacement, urinary retention, erosion, wound infection, urinary infection and persistent moderate perineal pain. In cases of misplacement the sling has to be replaced, in case of wound infection a conservative approach can be tried and in cases of erosion the system should be removed.

Adjustable slings:

The Argus system (Promedon, Argentina) consists in a silicon pad fixed to silicon columns to compress and elevate the urethra. The columns can be fixed and adjusted using washers in the supra pubic or transobturator (Argus T) locations. The placement is made through a perineal skin incision to expose and prepare bulbous urethra covered by bulbospongiosum muscle. In the supra pubic way cystoscopy is mandatory to detect eventual bladder perforation. Intraoperative Sling tension adjustment is performed pulling the columns until an RLPP of 30 to 40cmH₂O is achieved.

In a study involving 101 patients with mild, moderate and severe PRPUI, with a mean follow-up of 2.2 (2.1; 0.1–4.5) years.

authors reported 80/101 (79.2%) patients considered as dry, with a pad test of 0–1 g (70 patients, 0 g; 10 patients, 1 g).

Adjustments were necessary in 39 cases (38.6%). Complications also included erosion in 15% requiring system removal, infection and pain.

In a paper analyzing only the transobturator way (Argus T) in 30 patients the authors reported that at 30-month follow-up, 24/31 patients (77%) were dry, 3/31 (10%) improved and 4/31 (13%) were failures. In particular, in the mild-moderate group, 8/8 (100%) patients were dry. In the severe group, 20/28 patients (71%) were dry, 3/28 (11%) improved and 5/28 (18%) were failures. Complications included immediate postoperative infection in 2/36 patients (6%) and transient inguinal and/or perineal pain in 22/36 patients (61%). Argus T has a long-term high success rate (86% cure + improvement at the 30-month follow-up). Good outcomes were achieved even in severe incontinence cases and maintained for over 30 months.

Conclusions:

Slings represents a safe and effective alternative for mild to moderated Post prostatectomy urinary incontinence as demonstrated by the reduction in pads count and improvement in quality of life as demonstrated in many papers. The procedure is accompanied of a high index of satisfaction and acceptable complications rates. Studies with longer follow ups are desirable to confirm its efficacy over the time.

Established and new hydraulic systems, technique, new possibilities, limits W.

Huebner

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 their sphincter put in again 94,4%). Certain points of improvement have been raised repeatedly: a possibility to change the intra-device pressure postoperatively, a ready made implant to avoid connecting components during the operation, a pump less challenging to use for patients with impaired dexterity, and 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 addressing these points - the ZSI375 artificial urinary sphincter, the AROYO device and the Victo (formerFlowSecure) 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).

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

The AROYO sphincter:

The AROYO sphincter consists of a cuff, a control unit and 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 as well as 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 may be disturbing in the scrotum. The possibility of increasing the intra-device pressure during maneuvers with high intraabdominal pressure is an interesting feature.

The Victo device consists of a cuff, a pump and optionally an additional intraabdominal balloon for conditional pressure increase. The pressure within the system can be adjusted any time after implantation by puncture of the self sealing port. Implantation is performed through a perineal and inguinal incision.

Differences to AMS 800:

The Victo device is a one piece implant and provides adjustability, sudden pressure rises are covered by pressure transfer from the intraabdominal balloon to the cuff. This smart 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 maybe easier to use.

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

Artificial Urinary Sphincter, Tips and Tricks, Trouble Shooting

Emmanuel Chartier-Kastler

As Artificial urinary sphincter is known as the oldest and “gold standard” therapy for male urinary incontinence management, its indications and use have to be well known and learned.


Implanting AUS is today implanting the AMS 800[®] device (Boston Scientific, Boston, Ma, USA) which has the longest story and highest level of publications. Despite the fact that level of evidence is not 1 (no prospective studies never done), the recent report from the consensus group of ICS gave a high level summary of what has to be known.

Regarding men implantations, two places can be selected: around the prostate (usually neurogenic patients still having a prostate) or around bulbar urethra which is the historical placement. First described for patients suffering Stress Urinary incontinence (SUI) after prostatectomy, it is no more applied for post radical prostatectomy indications. Surgery has to follow step by step dissection that will be described during workshop. Post-op period as follow-up has to be strict and the patient has to be quickly confident with management and use of his prosthesis. Implanting such a prosthesis, there is a strong need to know the best indication and pre-op check-up of the bladder and urethra as to know how to manage troubleshooting. It will be quickly reviewed at workshop giving a big part for management of recurrent incontinence without mechanical failure and what should be the ideal prosthesis of the future.

Balloons: Technique, Tips and Tricks, Trouble Shooting

Andrea Gregori

During the workshop we'll discuss the surgical technique, tips and tricks, and trouble shooting of ProACT. The ProACT (male Adjustable Continence Therapy) system (Uromedica, Plymouth, MN, USA) is a postoperatively adjustable, permanently implantable device for the treatment of stress urinary incontinence (SUI) after prostate surgery. Initially, the system implantation was performed under twodimensional fluoroscopic guidance. More recently, the safety and feasibility of transrectal ultrasound (TRUS) guided ProACT system implantation has been described to achieve a more accurate placement by the use of multiplanar ultrasound imaging and to avoid radiation exposure. The ProACT system is composed of an expandable silicone balloon attached with a 2-lumen conduit to a reinjectable titanium port. The device is manufactured in two lengths: 12 cm and 14 cm. In general, the 12-cm device is employed for patients with residual prostate following benign surgery (ProACT balloons are placed more distally, on either side of the prostatic apex), and the 14-cm device is required for post-radical prostatectomy patients. Post-radical prostatectomy patients require two balloons, which are placed on either side of the vesicourethral anastomosis just above the pelvic diaphragm. A specially designed, sharptip, removable trocar contained in a U-shaped sheath is used to insert the balloons through a transperineal route. The two titanium ports are placed into a subcutaneous parascrotal position to allow easy percutaneous access for adjusting the balloons postoperatively using a noncoring needle. This allows the device to be adjusted by modifying the level of coaptation needed to achieve continence.

Wilhelm A. Hübner 

Affiliations to disclose[†]:

Speaker Boston Scientific (AMS)
 Speaker Promedon
 Speaker Astellas
 Shares Uromedica

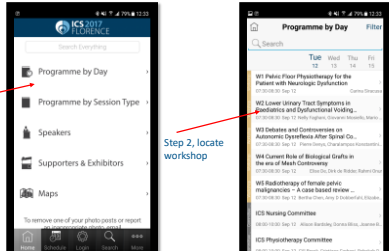
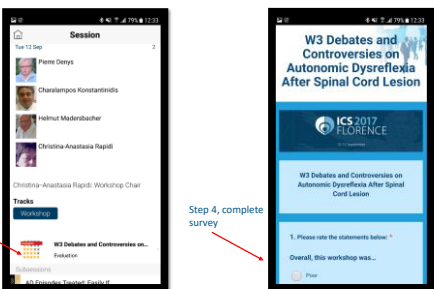
† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:


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

****NEW FOR 2017****

Please complete the in-app evaluation in the workshop before leaving.

- A shortened version of the handout has been provided on entrance to the hall
- A full handout for all workshops is available via the ICS website.
- Please silence all mobile phones
- Please refrain from taking video and pictures of the speakers and their slides. PDF versions of the slides (where approved) will be made available after the meeting via the ICS website.

Surgical therapy of male incontinence: techniques, decision making and trouble shooting 

09:00 - 09:15 **Artificial Urinary Sphincter, tips and tricks, trouble shooting**
 Emmanuel Chartier-Kastler

09:15 - 09:20 Discussion

09:20 - 09:30 **Balloons: technique, tips and tricks, trouble shooting**
 Andrea Gregori

09:30 - 09:35 Discussion

09:35 - 09:50 **Fixed and adjustable slings, tips and tricks, trouble shooting**
 Flavio Trigo Rocha



09:50 - 09:55 Discussion

09:55 - 10:05 **New artificial hydraulic sphincters, technique, new possibilities, limits**
 Wilhelm Hübner

10:05 - 10:10 Discussion

10:10 - 10:30 **differential indications and case discussion**
 Wilhelm Hübner/all

closing remarks
 Wilhelm Hübner





Artificial urinary sphincter in males Tips and tricks

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ICS 2017 : Workshop 6





Disclosure statement




- AMS/Boston Scientific:
 - Invited speaker, courses
- Coloplast
 - Consultant, investigator
- Medtronic
 - consultant, speaker, investigator
- Uromedica
 - Courses
- Astellas
 - Investigator, consultant, invited speaker
- Allergan
 - Investigator, consultant, invited speaker
- Ipsen Biotech
 - Investigator
- Pfizer/Pierre Fabre Médicaments
 - Consultant, speaker
- Promedon
 - Consultant, speaker
- Uromems
 - Consultant
- Axonics
 - Investigator

AUS : concept

- To reinforce sphincter function
 - Managing SUI to cure it
 - Without any impact on the voiding phase
 - Indication
- SUI related to sphincter deficiency
 - Children
 - Male
 - Female
 - Neurogenic and non neurogenic


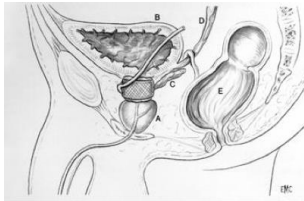



Scott FB, Bradley WE, Timm GW, 1973, Urology 1:252 Treatment of urinary incontinence by implantable prosthetic sphincter






AS 721 1974 AS 761 800

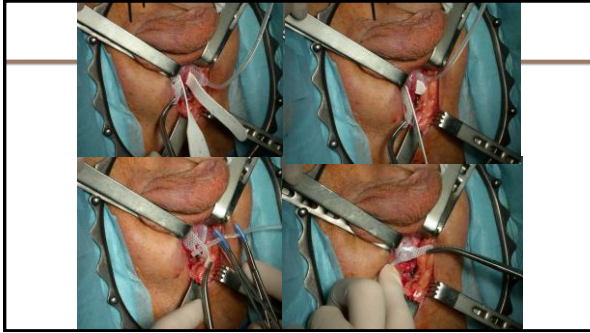
Placement of the cuff in men

Step by step



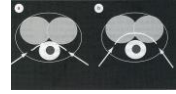
- Bulbar dissection
 - Cuff measurement
- Inguinal incision
 - Sub peritoneal space
- Preparation of device
 - Cuff (mean 4 cm), 61 to 70 cm of water balloon and pump
- Insertion of cuff
 - Channelization of the cuff tube from perineal incision to inguinal incision
- Pressurisation (optional in men)
- Placement of balloon (20 ml) and closure of abdominal wall
- Placement of pump
- Connection of tubes
- Closing and deactivation of the device



AUS: erosions and/or infections

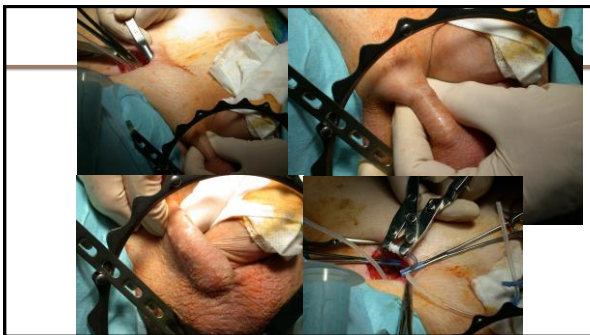
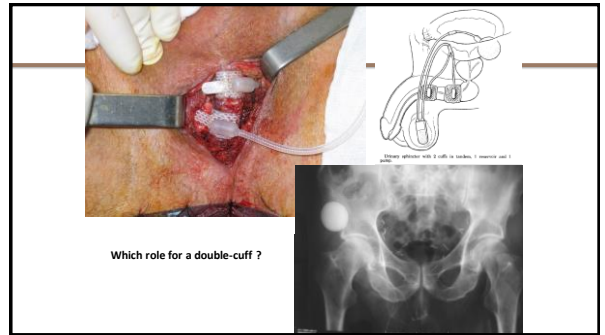
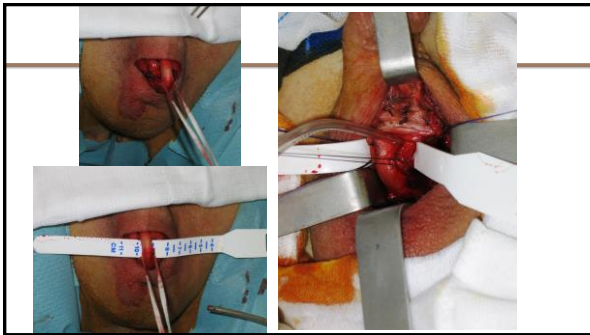
Modifications for high risk patients :

- urethral atrophy,
- small urethral circumference
- or previously eroded

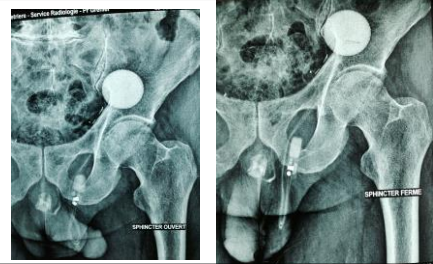


- Placing the cuff inside the corporal tunica albuginea,
- Combining an external urethral bulking.

Gurtnick M. Transcoperbal artificial urinary sphincter cuff placement in cases requiring revision for erosion and urethral atrophy. J Urol 2010; 183(7):2076-2079 May 2010.
 Rahman NQ et al. Combining external bulking and artificial urinary sphincter for urethral atrophy and stress urinary incontinence. BJU Int 2005; 95:824-826.



Pump misplacement

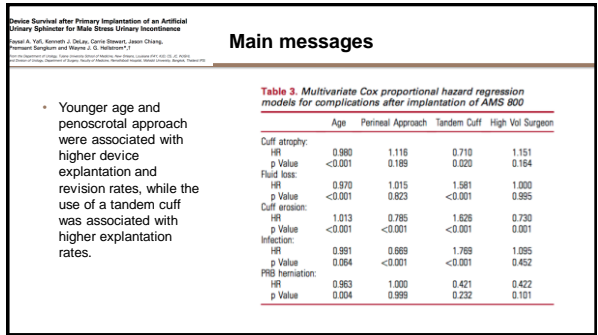
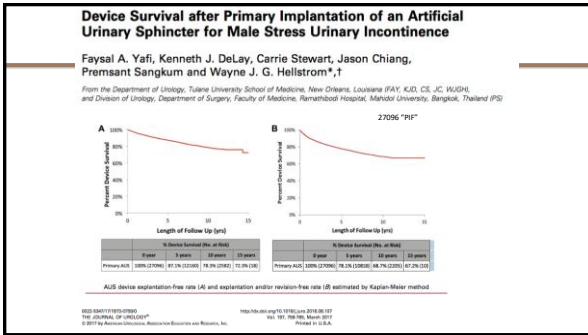
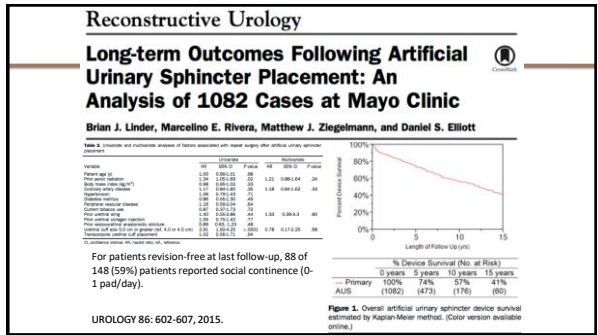


Comparison of results of single-cuff AUS placement in adult males with SUI.

Table 1 - Meta-analysis of reported studies

Author	Year	Study design	Evolution (year)	Multivariate meta-analysis of 85		Odds Ratio (95% CI)		95% CI	Overall Assessment
				OC	OC+penile prosthesis	OC	OC+penile prosthesis		
Smith et al (1992)	2006 (meta)	Retrospective	1992-2001	Median: 0.3	Median: 0.1-0.6	Statistically non-significant		NA	NA
Lau et al (1995)	2006 (meta)	Retrospective	1992-2001	Not published	NA			NA	NA*
Morgan et al (1991)	2006 (meta)	Retrospective	1991-2001	Not published	NA			NA	NA**
Rehman et al (1992)	2006 (meta)	Retrospective	1992-2001	Not published	NA			NA	NA**
Rehman et al (1993)	2006 (meta)	Retrospective	1993-2001	Not published	NA			NA	NA**
Rehman et al (1994)	2006 (meta)	Retrospective	1994-2001	Not published	NA			NA	NA**
Rehman et al (1995)	2006 (meta)	Retrospective	1995-2001	Not published	NA			NA	NA**
Rehman et al (1996)	2006 (meta)	Retrospective	1996-2001	Not published	NA			NA	NA**
Rehman et al (1997)	2006 (meta)	Retrospective	1997-2001	Not published	NA			NA	NA**
Rehman et al (1998)	2006 (meta)	Retrospective	1998-2001	Not published	NA			NA	NA**
Rehman et al (1999)	2006 (meta)	Retrospective	1999-2001	Not published	NA			NA	NA**
Rehman et al (2000)	2006 (meta)	Retrospective	2000-2001	Not published	NA			NA	NA**
Rehman et al (2001)	2006 (meta)	Retrospective	2001-2001	Not published	NA			NA	NA**
Rehman et al (2002)	2006 (meta)	Retrospective	2002-2001	Not published	NA			NA	NA**
Rehman et al (2003)	2006 (meta)	Retrospective	2003-2001	Not published	NA			NA	NA**
Rehman et al (2004)	2006 (meta)	Retrospective	2004-2001	Not published	NA			NA	NA**
Rehman et al (2005)	2006 (meta)	Retrospective	2005-2001	Not published	NA			NA	NA**
Rehman et al (2006)	2006 (meta)	Retrospective	2006-2001	Not published	NA			NA	NA**
Rehman et al (2007)	2006 (meta)	Retrospective	2007-2001	Not published	NA			NA	NA**
Rehman et al (2008)	2006 (meta)	Retrospective	2008-2001	Not published	NA			NA	NA**
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Rehman et al (2012)	2006 (meta)	Retrospective	2012-2001	Not published	NA			NA	NA**
Rehman et al (2013)	2006 (meta)	Retrospective	2013-2001	Not published	NA			NA	NA**
Rehman et al (2014)	2006 (meta)	Retrospective	2014-2001	Not published	NA			NA	NA**
Rehman et al (2015)	2006 (meta)	Retrospective	2015-2001	Not published	NA			NA	NA**

NA = Not Available, OC = On-Cuff, OC+penile prosthesis = On-Cuff with Penile Prosthesis, * = p < 0.05, ** = p < 0.01



Neurology and Uroynamics 35:55-67 (2016)

Artificial Urinary Sphincter: Executive Summary of the 2015 Consensus Conference

X. Blandeau, S. Aharony, the AUS Consensus Group*, L. Compeau, and J. Cozzoni**
Department of Urology, Jewish General Hospital, McGill University, Montreal, Quebec, Canada

- Here, we present the recommendations issued from the 2015 ICS AUS Consensus Group, regarding indications, management, and follow-up AMS800® implantation or revision.

AUS Consensus Group Conference Discussed topics

- AUS in males
 - Gold standard...worldwide
 - 40 years of experience
 - Specialized procedure
- Preoperative assessment
- Preoperative challenges
- Implantation technique
- Post-operative care
- Outcomes evaluation
- Trouble shooting
- Special populations
- Future of AUS

Ideal prosthesis

- Be easily manipulated and inactivated
- Modify cuff pressure after implantation
- Be able to adapt occlusive cuff pressure in a real-time manner
- Have a simple and robust design
- Be safely implanted via a minimally-invasive procedure
- Be as cost effective as possible

AMS 800®

- Positive aspects
 - High continence rate (> 85%)
 - Normal voiding pattern (no "resistance")
 - High level of satisfaction and QoL
 - No or few impact on sexual life
 - Good life expectancy of the device (>8 y. in men)
- Negative aspects
 - Infection may occur
 - Revision rate is significant

Yoklavic B, Rigaud J, Loyche F, et al. Female urinary incontinence and artificial urinary sphincter: study of efficacy and risk factors for failure and complications. Eur Urol 2011;59:1046-53.
 Chung E, Cornell RB. 25-year experience in the outcome of artificial urinary sphincter in the treatment of female urinary incontinence. BJU Int 2010;105:1664-7.
 Pavesio A, Vela D, Diabasy AC. Comparison of the long-term outcomes between incontinent men and women treated with artificial urinary sphincter. J Urol 2006;175:805-9.
 Rogstad M, Mørse V, Vesterlund C, et al. Laparoscopic approach for artificial urinary sphincter implantation in women with intrinsic sphincter deficiency incontinence: a single-center preliminary experience. Eur Urol 2010;57:499-506.

Key points not solved with AMS 800®

- No reinforcement of pressure when coughing
- Leakage may appear, standing up from the sitting position
- Patient has to pump, he has to be educated for, he has to obtain enough force...
- Atrophy of the urethra may appear with time
 - (if any...Bugeja S et al., BJU Int 2015 hypothesize for device failure?)
- 3 pieces to connect and not ready to use in OR (air)
- ICI 2016:
 - Listed most of these questions...

EAU guidelines 2015

Offer AUS to men with moderate to severe post-prostatectomy incontinence.	B
Implantation of AUS or ACT for men should only be offered in expert centres.	C
From men receiving AUS or ACT first, even in expert centres, there is a high risk of complications, mechanical failure or a need for explantation.	C
Do not offer non-circumferential compression device (ProACTs) to men who have had pelvic lymphadenectomy.	C

AUS = artificial urinary sphincter; ACT = artificial compression device.
 *the terms mild and moderate post-prostatectomy incontinence remain undefined.

Male urinary incontinence : Conclusion

- Within the last 10 years:
 - Some projects appeared
 - None come to a global marketbut
 - None suffered perfect evaluation
- However
 - AMS 800® as it has been designed is reliable despite no LoE 1 study
 - AMS 800® is a gold standard despite some non solved problems
- Will it be the comparator?

ICS 2017 FLORENCE **Workshop: Surgical Therapy of Male Incontinence**

BALOONS: TECHNIQUE, TIPS AND TRICKS, TROUBLE SHOOTING




Andrea Gregori
Dept. Urology – ASST Rhodense (Milan, Italy)



ORIGINAL FLUOROSCOPIC TECHNIQUE

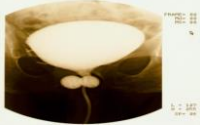
Treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy

Hubner and Schlarp
BJU Int 2005



PROSPECTIVE STUDY EVALUATING EFFICACY AND SAFETY OF ADJUSTABLE CONTINENCE THERAPY (PROACT) FOR POST RADICAL PROSTATECTOMY URINARY INCONTINENCE






Trigo-Rocha et al.
Urology 2006



TRUS/LOCAL ANAESTHESIA TECHNIQUE

Transrectal Ultrasound Guided Implantation of the PostCT Adjustable Continence Therapy System in Patients With Post-Radical Prostatectomy Stress Urinary Incontinence: A Pilot Study

Gregori et al. J Urol 2006

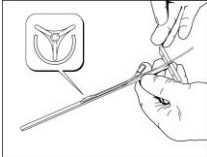
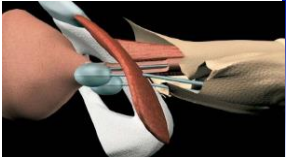
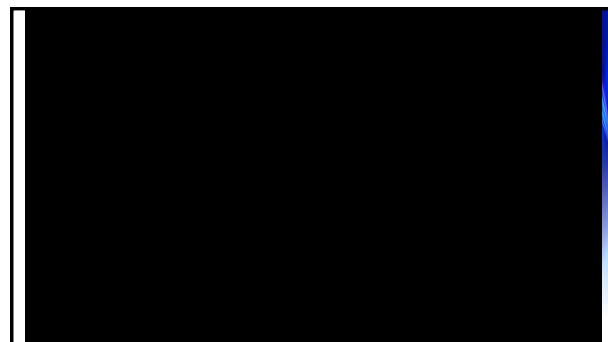
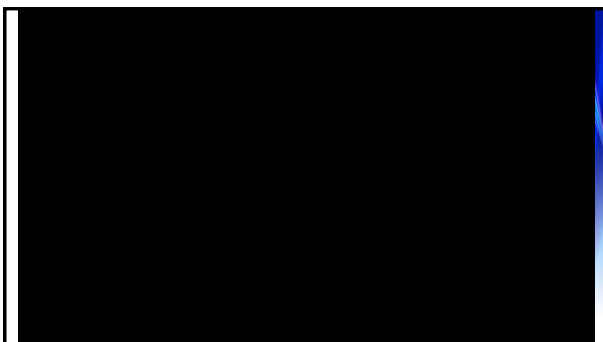






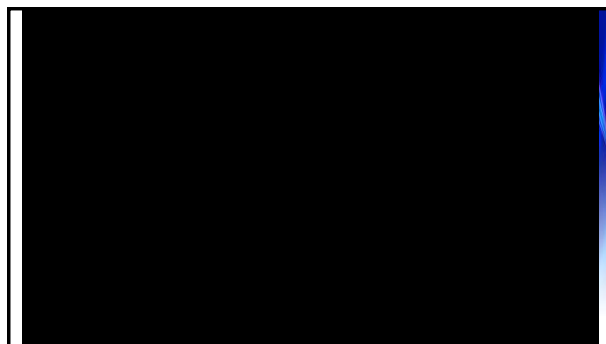
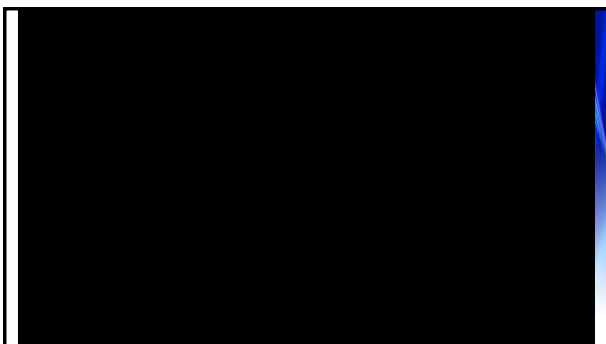
Implantation of an Adjustable Continence Therapy System Using Local Anesthesia in Patients With Post-Radical Prostatectomy Stress Urinary Incontinence: A Pilot Study

Gregori et al. J Urol 2008

THE PROACT SYSTEM

EVERY PATIENT REQUIRES 2 BALLOONS, WHICH ARE PLACED ON EITHER SIDE OF THE VESICO-URETHRAL ANASTOMOSIS JUST ABOVE THE PELVIC DIAPHRAGM



THE PROACT SYSTEM

THE BALLOONS ARE POSTOPERATIVELY FILLED WITH A 23 GAUGE NON CORING NEEDLE TO A MAXIMUM OF 8 ML.

Urethrosopic view
after adjustments
of the balloons

TRANSRECTAL ULTRASOUND: ADVANTAGES

✓ **SUPERIOR IMAGING OF SURGICAL ANATOMY IN CONTINUE, REAL TIME CORONAL AND SAGITTAL PLANES**

(Bladder wall thickness, Pelvic diaphragm and its thickness, Urethral bulb, Rectal wall)

✓ **NO RADIATION EXPOSURE**

(Patients, Surgeon and Operating Room Staff)

✓ **NO USE OF CONTRAST MEDIUM FOR INTRAOP AND POSTOP BALLOON FILLING**

(Simplified procedure, Simplified postoperative management, Cost reduction)

TRANSRECTAL ULTRASOUND: POSSIBLE DRAWBACKS

✓ **MANUAL DEXTERITY**

✓ **TRUS AVAILABILITY (LINEAR PROBE) IN THE O.R.**

✓ **PATIENTS WITH RECTAL AMPUTATION OR ANAL STRICTURES**

✓ **INADEQUATE RECTAL PREPARATION**

 **HOSPITAL SÍRIO-LIBANÊS**

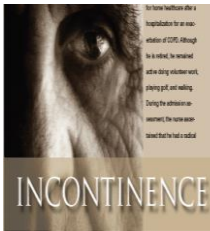
FIXED AND ADJUSTABLE SLINGS: TIPS AND TRICKS, TROUBLE SHOOTING

Flavio Trigo Rocha – flaviotrigor@uol.com.br
Associate Professor of Urology – University of São Paulo
Coordinator Center for Treatment of Urinary Incontinence
-Hospital Sírio Libanês SP – São Paulo – Brasil

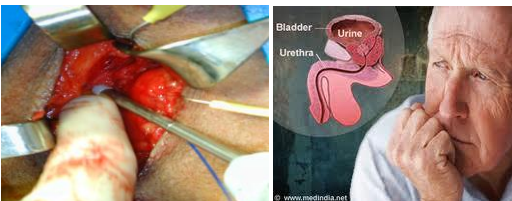


Male sling: History

- Berry, 1961: Acrylic device attached to the ischium and pubis by steel wire to angular urethra distally to the urogenital diaphragm.
- Kaufman, 1970: Kaufman type-I (penile crura over bulbar urethra) Success 30%. Kaufman II (affixed polytetrafluoroethylene fascia) - 50% success. Kaufman III (prosthesis filled with silicone gel). Success = 70%.
- Kishev, 1972: Abdomino-perineal approach; prosthesis compressed urethra and was attached to suprapubic Marlex plaques. Procedures abandoned due to failure, infection, pelvic pain and introduction of artificial sphincter




Male sling: Why have them failed?



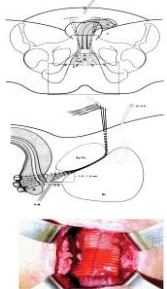
- Mainly compressive procedures
- Very complex surgeries
- No patient selection
- Male incontinence was not an important issue
- Artificial sphincter

SLINGS TYPES

- Aponeurotics: autologus heterologus
- Bone anchor slings
- Elevation slings (Mesh): Advance®, Dynamesh®
- Mixed: Elevation and compression: Virtue®
- Adjustable slings: Reemix®, Argus®, Argus T®



Modern Slings



- 64 patients suffering from PRPUI treated with bulbous-urethral polypropylene sling.
- 50% had severe incontinence (4.7 pads/day).
- Mean follow-up 18.1 mo. (6.5 to 53.8).
- 36 dry (56%), 5 (8%) significant improvement
- 17 required readjustments
- Final success rate 75% (67% cured, 8% improved).
- Revision in 27%, erosion in 6% and infection in 3%

Schaeffer AJ, J Urol 1998 Jul;160(1):136
J Urol. 2005 May;173(5):1654-6


Northwestern Memorial Hospital e Stanford University Hospital.

Bone anchor slings: Invince®

Obstructive technique

- 55% cured
- Improvement in 25%
- Fail in 20%
- 23% complications: pain, infection and erosion

Webster, state of the art lecture, AUA 2006
70 – 78% cured and improved
20% pain
2% infection
Raymond Rackley, Take Home Message



Bone anchor slings: Invance®

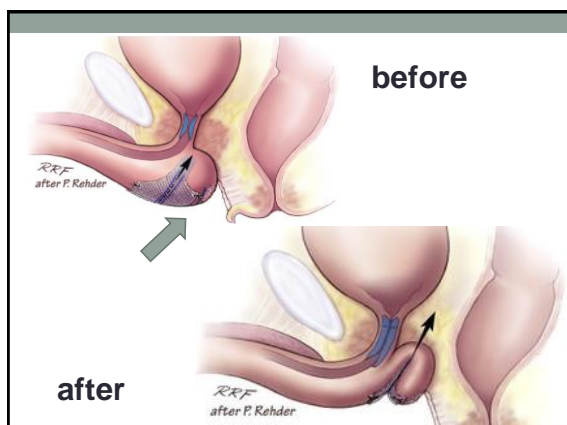
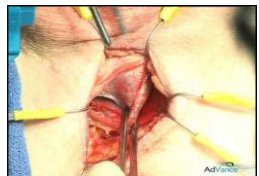
- 10 patients – 12 mo. Follow up
- 1 patient dry, 9 wearing more than 3 pads/day
- VLPP ↓
- 3 slings removal due to infection
- 1 patient with osteomyelitis

Lucon, M.; Trigo-Rocha, F; Srougi, M. et. Al., HCFMUSP 2006

Elevation Slings: Avance®; Dynamesh PRM®



- Sling placed in the bulbous urethra
- Elevates the bulbous 2,5 – 4 cm
- Improves urethral coaptation
- Restores continence



Male sling suspension - Advance®

- Prospective multicenter study
 - 46 patients - 36 with 12 months follow-up
 - efficacy: 24 hs test pad: ↓ 370 → 40 grs.
 - 0 to 1 absorbent / day: 14% → 72%
 - low success in patients using > 6 pads / day
 - adverse effects: transient retention - 20%, pain - 16%; without bladder injury or urethral erosion
 - few changes in urofluxometry

Webster, abstr 1644, AUA 2009
- Prospective study 64 patients with Advance:
 - 52% without pads or safety pads
 - 28% improvement - 1 to 2 absorbents per day
 - no major complications - erosion, infection, revision
 - 6.5% transient retention

Bauer, et. al, Germany, abstr 1645, AUA 2009

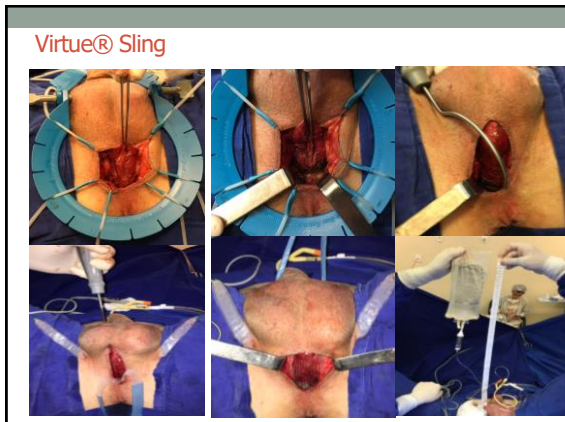
Advance®: Results

- 136 patients suffering from PRPUI
 - Cure= no pads, improvement= > 50% reduction in the number of pads/day
 - Follow-up 21 +/- 6 months, cure= 62% improvement = 16%
 - Best results if Pad test < 200 grs/24 hours
 - Worse results: Severe leakage (Pad test), urethral stenosis and Radiations Therapy
- Kornu, Haab, et al. BJU, 2010*

Virtue® sling: elevation and compression

- Polypropylene mesh
- 4 arms
- Single needle
- PRPUI mild to moderate
- Transobturator and pre pubic insertion
- Elevation and compression of the urethra





Sling Virtue®

Stage	RLPP (cm water)
Baseline	~35
TD	~45
PP	~55
Final	~75

- 80 patients 6 mo. f-u
- 79% with significant reduction in pad test weight
- 67% significant subjective improvement; 23% without improvement

Adverse effects: 1 bladder perforation, 1 wound infection, 1 hematoma, 1 urinary tract infection, 1 urinary retention, 11% hypoesthesia; 13% significant perineal pain

Comiter C., et al. the Journal of Urology, Volume 187, Issue 2, February, Pages 563-568. (2012)

Mesh slings: patient selection

- Post RP or TURP
- Mild to Moderate
- Residual sphincter function: Pad test, urethroscopy?, Urodynamics (VLPP?, UPP: rest and stress? – good correlation with cystoscopy)
- Prior radiation or strictures is ok (post 6+ months)
- Prior bulking agents ok

Mesh slings: patient selection

- Pad test 24 hours
- Pad weight during 24 hours
- Classification

- <200g: mild
- 200 - 400g: moderate
- > 400g > sever

Nitti VW e cols. Correlation of patient perception of pad use with objective degree of incontinence measured by pad test in men with post-prostatectomy incontinence: the SUFU Pad Test Study. J Urol 192(3):836-42; 2014

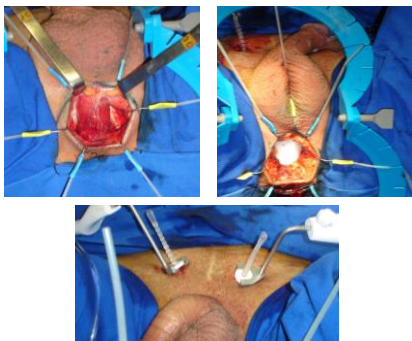
Sphincter residual function

Moser, D: Doctoral thesis, 2017

Adjustable Silicon Slings: Argus®

- Suprapubic
- Transobturator

Adjustable Suprapubic Slings: Argus®

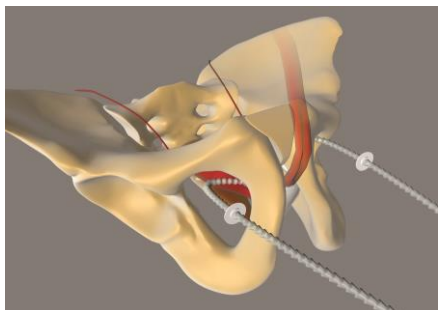


Adjustable slings: Argus®

- 48 patients, mean follow-up= 7,5 mo.
- 35 patients (73%) continents
- 5 improved (10%)
- 8 unchanged (17%)
- 4 patients (8%) required new adjustments
- 5 sling removed (erosion and/or infection)

Romano, S.V.; D'Ancona, CA; Vaz, FP; Hubner WA.: BJU Int., 2006

Transobturator adjustable Sling: Argus T®



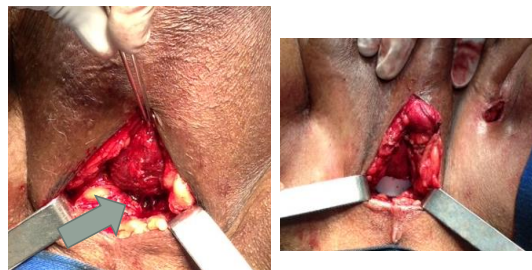
Transobutatory adjustable slings: Argus T®



Transobturator adjustable Slings: Argus T®



Transobturator adjustable Slings: Argus T®



Transobturator Adjustable Slings: Argus T®

- 37 patients, from November 2007 to August 2008
- Degree of Incontinence: severe (> 400 grs/day) in 29, moderate in 7 (100 – 400grs/day) and mild (< 100 grs/day) in 1 patient
- 27 patients (73%) continents
- 5 patients (13,5%) improved
- 5 patients (13,5%) unchanged
- 4 patients needed additional adjustments
- Complications: 2 had infection requiring sling removal, 1 patient with long lasting pain and 1 patient had long term retention

Romano, S.V.; Hubner, WA; Trigo-Rocha; Vaz, FP et. al.: *Int Braz J Urol*, 2014

Transobturator Adjustable Slings: Argus T®

- 20 patients suffering from severe PRPUI
- Mean age= 65 years
- Parameters: no. pads/day, QoL (visual scale), urodynamic.
- Follow-up: 17 to 29 mo. (mean= 22 months)
- Pad count reduction from 5,2 to 1,2 /day (mean)
- 70% dry or wearing 1 pad/day; 4 (20%) improved and 2 (10%) unchanged.
- Improvement in QoL: Bothersome reduction from 10,2 to 2 (p< 0,05).
- New adjustments in 4 patients (20%). One case of erosion

Trigo-Rocha; et. al. *ICS* 2010

What does the patient prefer?

- 133 males candidates to UI surgical treatment
 - Physician recommendation based on 24 hrs pad test:
- Severe UI (pad > 400 gm/24 hs) – artificial sphincter
- Moderate UI (100 to 400 gm/24 hs) - sling or artificial sphincter
- Mild (< 100 grs/24 hs) - sling
- Sphincter was recommended to 63 patients (47%) and sling to 46 (35%). In 24 (18%) both options were given.
 - All patients recommended to Slings and 75% indicated to artificial sphincter accepted the idea.
 - Among patients who have the choice 92% chose slings and 8% sphincters.



Kumar, Nitti; et. al *J Urol*, 2009

Male slings complications

- Early complications (up to 30 days) in patients submitted to Slings or AUS 800 (national multicenter database)
- Complications of medical records independent of surgeon 1205 surgeries for incontinence in men: 597 slices and 608 AUS.
- Slings had lower complication rates compared to AUS (2.8 vs. 5.1%, p = 0.046). Lower ITU index (0.3 vs. 2.0%, p = 0.020) and reoperations (1.0 vs. 3.0%, p <0.001).
- Risk factors for complications: Obesity. Age, race, Charlson comorbidity index did not change complication rates

Male slings complications

- Bladder or urethral perforation
- Pain
- Urinary retention
- Infection
- Erosion
- Voiding dysfunction
- Incontinence recurrence

Trouble shooting: Perforation



- Not a big problem is recognized during surgery
- Sling replacement and Foley catheter for 3 to 10 days

Trouble shooting: Urinary retention

- Reversible in the vast majority
- Clean intermittent catheterism
- Foley catheter
- Cistostomy in select cases



Trouble shooting: Infection

- Local and systemic antibiotics
- Local antiseptics
- Debridement
- Sling removal: partial or total



Trouble shooting: Extrusion/erosion

- Local and systemic antibiotics
- Local antiseptics
- Debridement
- Sling removal: partial or total

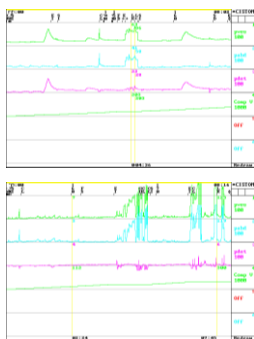


Sling+ Penile Prosthesis



Recurrence of Incontinence

- Bladder factors
- Lack of compression
- Sling break
- Muscle drilling by locking washers
- Urodynamics is Mandatory
- Check the sling position: RX, MRI

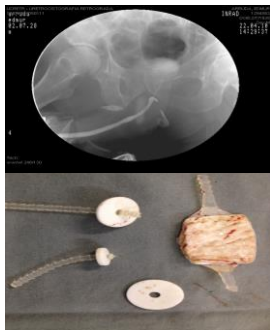


Argus T®: Position

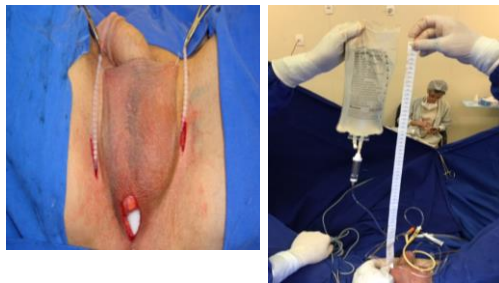


Recurrence of Incontinence

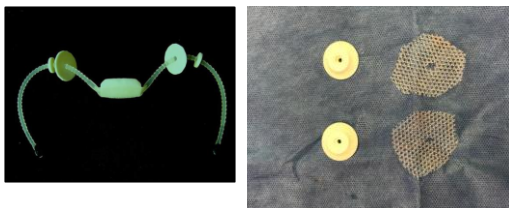
- Bladder factor: anticholinergics, botulin toxin
- Sling misplacement: Correct or make a new sling
- Rupture: Sling removal and immediate replacement
- Muscle erosion: muscle repair and repositioning washers over a mesh
- Lack of Compression: sling adjustment



Argus T® readjustment



Muscle erosion



Male sling complications: Conclusions

- Acceptable levels comparable to other techniques
- Conservative treatment in most cases
- More severe complications requires removal of the prosthesis
- Sling can be replaced in most cases
- Surgical treatment of male incontinence should be tailored for each patient

Conclusions

- Slings have similar efficacy of the sphincter in mild and inferior in moderate incontinence
- Silicon slings have good results in mild to moderate incontinence
- Slings and artificial sphincters have similar levels of adverse effects
- Slings have a lower cost and patients prefer to be treated by slings
- Slings may be considered the first line treatment in mild/moderate cases of PRPUI

Everybody gets old





- JEP, 70 years old. RP 2 years ago
- Pre-op: 4-5 pads/day
- Surgery: 30/01 AMS 800
- Training 13/05: 812m swimming, 32 Km bike, 7 km running
- Return to competitions: September 3 after losing 12 Kg

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*

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

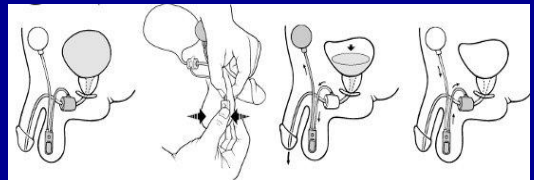
Current version: AMS 800 since 1982

Worldwide <100.000 Implantations

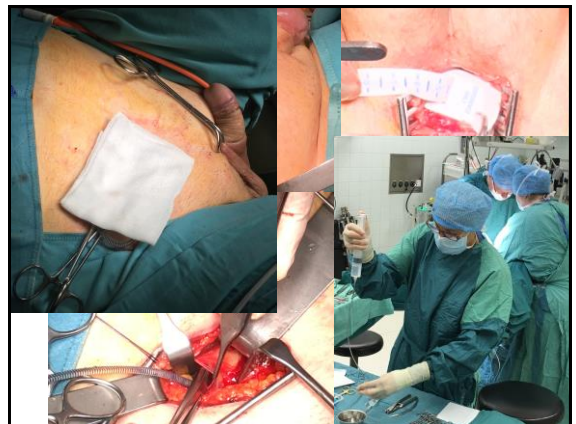
Open – close mechanism!

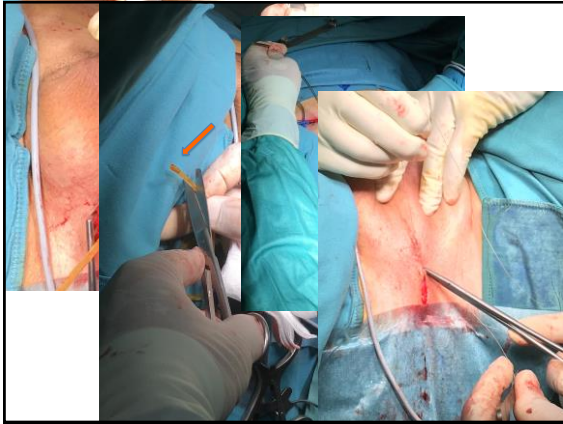


Hydraulic Sphincter-AMS 800®



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, Simmons CJ, Flynn B: J Urol 2008; 179:1475–1479.
Henry GD, Graham SM, Cornell RJ, Cleves MA, Simmons CJ, Vakilopoulos 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%%)

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) complication rate favours classic (no prosp. rd. trials)

AMS 800 - options for implantation

Single cuff / tandem cuff

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

Initially => favourable results (1993-1996)

Bruto 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

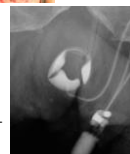
AMS 800 - options for implantation

Transcorporeal cuff placement – concerns/facts

Bleeding => insignificant

ED => majoritiy maintains!°

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



*Wiedemann L, Cornu JN, Haab E, et al. Transcorporeal 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

Transcorporeal 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 (8)
Reintervention (for any reason)	26.0 [14.8-44.8]	549 (10)
No. of patients social continence (≤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.

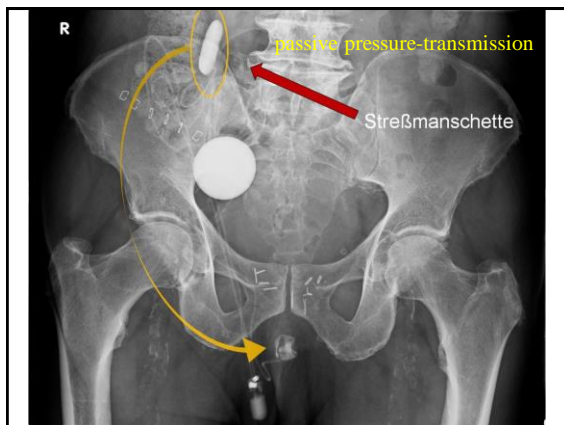
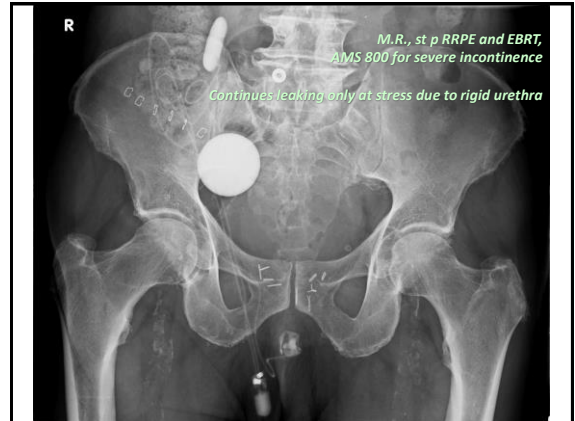
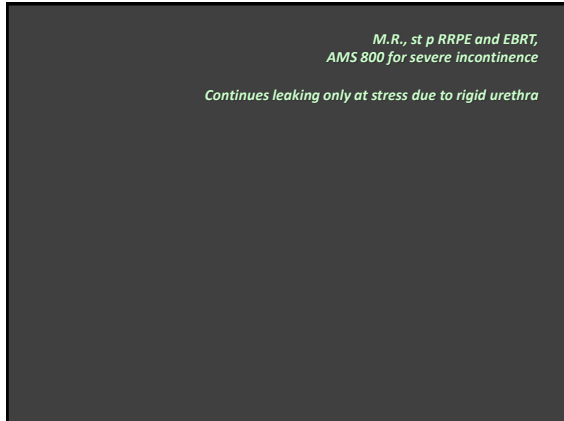
Long-term Outcomes Following Artificial Urinary Sphincter Placement: An Analysis of 1082 Cases at Mayo Clinic.

Linder BJ et al., *Urology*. 2015 Sep; 86(3):602-7

n=1082, median follow-up of 4.1 years
 Retrospective Study: chart analysis, FU visit, schriftl. Anfrage (Rücklauf 32%)
 338 of 1082 patients 31.2% underwent secondary surgery (1983-2012)
 (10% at 1 year, 26% at 5 years, 43% at 10 years, 59% at 15 years)
 Results @ last FU (4,1a): social cont. 59%, satisfaction rate: 94%

- 131 device malfunction
- 89 device erosion and/or infection
- 89 urethral atrophy
- 29 pump malposition or tubing complications

=> reduction of revision rate desirable!
RISK FACTORS: Irradiation, CHD, HT, DM, prev. Ops, cuff size,...



Zusammenfassung AUS (AMS 800)

soziale Kontinenz nach 5 Jahren zwischen 50 und 60%
 Ab 5a muss mit Revisionsraten über 35%
 Primäre u. sekundäre Implantationen haben gleiche Prognose
 (außer Salvage Ops nach Erosion/Infektion)

unabhängige Risikofaktoren:
 Frühexplantation: penoskrotaler Zugang
 mechanische Problem: Manschettengröße von 3,5cm
 Manschettenerosion:
 RTX, KHK, niedriger T Spiegel, Antikoagulantien

NEWS
next generation. flowsecure

ZSI 375

experimental

Magnetic and electronic sphincters

zephyre

ARTIFICIAL URINARY SPHINCTER ZSI 375

ARTIFICIAL URINARY SPHINCTER

For male severe incontinence

ZSI 375

ARTIFICIAL URINARY SPHINCTER ZSI 375

FUNCTIONING OF THE ZSI 375

The ZSI 375 is filled with normal saline solution. There are two compartments separated by the piston (3):

- The hydraulic circuit (1)
- the compensation pouch circuit (2)

The two circuits are separated by a piston (3).
The piston can move up and down in the tank.

The saline solution of the hydraulic circuit is never in contact with the saline solution of the compensation pouch.

ANIMATION FUNCTIONING ELEMENT ZSI 375

ARTIFICIAL URINARY SPHINCTER ZSI 375

FILLING OF THE COMPENSATION POUCH

Inject

4,5 ml

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?

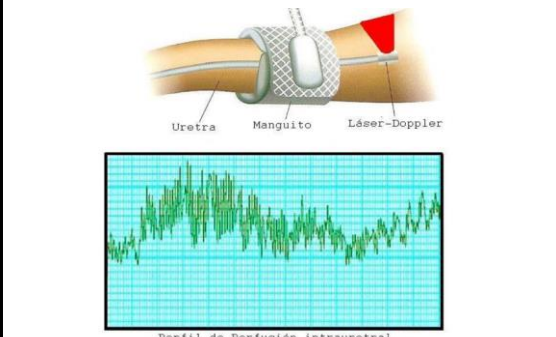
FS

Flowsecure



Knight SL, Susser J, Greenwell T, Mundy AR, Craggs MD
2006
first adjustable AUS

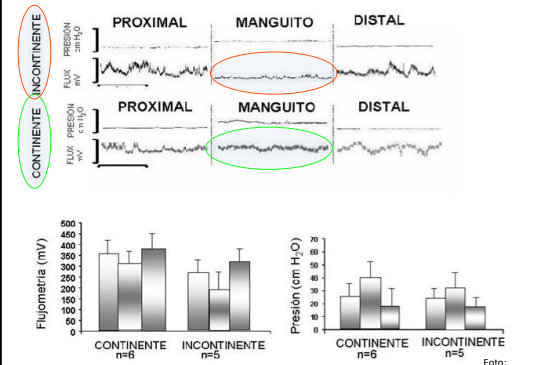
Garcia Montes F, Knight SL, Mundy AR & Craggs MD., ICS 1999 pathophysiology



Perfil de Perfusión intrauretral

Foto:
F Garcia Montes

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



Flujometria (mV) Presión (cm H₂O)

CONTINENTE n=6 INCONTINENTE n=5 CONTINENTE n=6 INCONTINENTE n=5

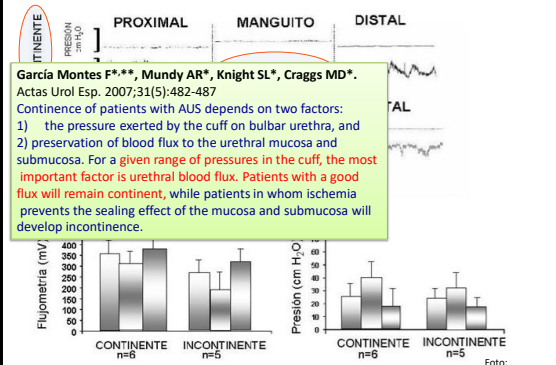
Foto:
F Garcia Montes

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

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:

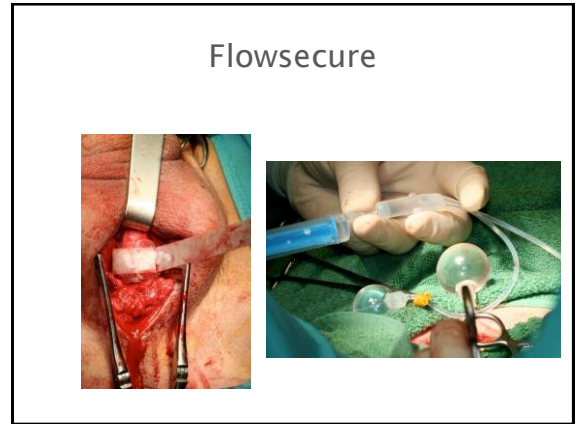
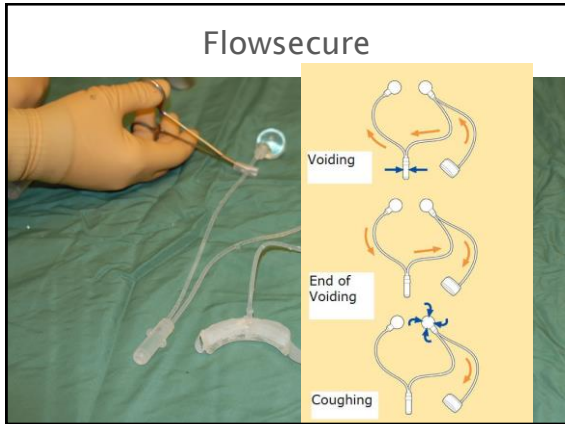
- 1) the pressure exerted by the cuff on bulbar urethra, and
- 2) preservation of blood flux to the urethral mucosa and submucosa. For a given range of pressures in the cuff, the most important factor is urethral blood flux. Patients with a good flux will remain continent, while patients in whom ischemia prevents the sealing effect of the mucosa and submucosa will develop incontinence.



Flujometria (mV) Presión (cm H₂O)

CONTINENTE n=6 INCONTINENTE n=5 CONTINENTE n=6 INCONTINENTE n=5

Foto:
F Garcia Montes



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%

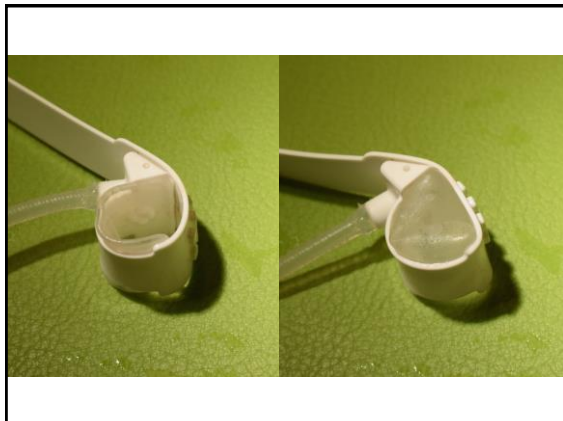
Removal in 28/100 patients (28%)
pump problems (accidental penetration, malfunction)



Similar to AMS 800
Long evolution period

Differences to AMS 800:
 Self acting smart pressure adjustment
 adjustability any time after implantation
 „one piece implant“
 Improvement concerning dexterity

aroyo



RESULTS

Zachoval R, et al.: Efficacy and safety of 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 Relief II results

n=48 patients

Differences to AMS 800:

Open/close control unit in the scrotum
adjustability

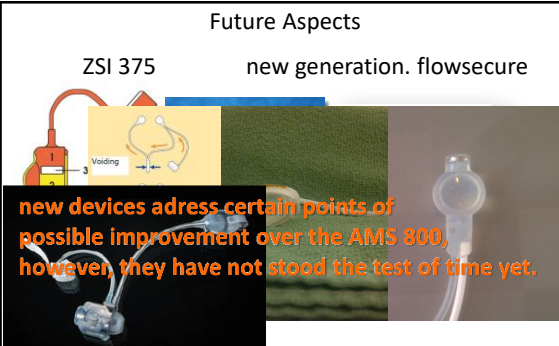
„one piece implant“

Pressure compensator for manual activation

Future Aspects

Future Aspects

ZSI 375 new generation. flowsecure




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

Aroyo

THE END

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



New Artificial Hydraulic Sphincters, Technique,
New Possibilities, Limits
W. Huebner

Aroyo
Zephyr
Flowsecure/Victo

Artificial hydraulic sphincter

First described 1974
Current version: AMS 800 since 1982
worldwide ca.100.000 Implantations
Open – close mechanism!



Telephone - delivered quality of life after 365 male stress urinary incontinence operations.
Bretterbauer KM, Hübner W.A. et al.
Int Braz J Urol. 2016.
AMS 800: 92% recommendation

however.....

Cystoscope

W.Hübner, Korneuburg

Long-term Outcomes Following Artificial Urinary Sphincter Placement: An Analysis of 1082 Cases at Mayo Clinic.

Linder BJ et al., Urology. 2015 Sep; 86(3):602-7

n=1082, median follow-up of 4.1 years
Retrospective Study: chart analysis, FU visit, schriftl. Anfrage (Rücklauf 32%)

Results @ last FU (4,1a): social cont. 59%, satisfaction rate: 94%

338 of 1082 patients 31.2% underwent secondary surgery (1983-2012)
(10% at 1 year, 26% at 5 years, 43% at 10 years, 59% at 15 years)

- 131 device malfunction
- 89 device erosion and/or infection
- 89 urethral atrophy
- 29 pump malposition or tubing complications

=> reduction of revision rate desirable!

Possible improvements

- Avoid subcuff atrophy/erosion (adjustability)
- React on changing patient parameters (adjustability)
- Pressure compensation (sports..)
- Improve handling
- One piece implant

no clinical relevance

Ribbon
Tubing
Cylinder
Position
Gap 1
Metallic Part
Skin
Gap 2

New hydraulic sphincters

Aroyo

Zephyr ZSI 375



Flowsecure/Victo



aroyo

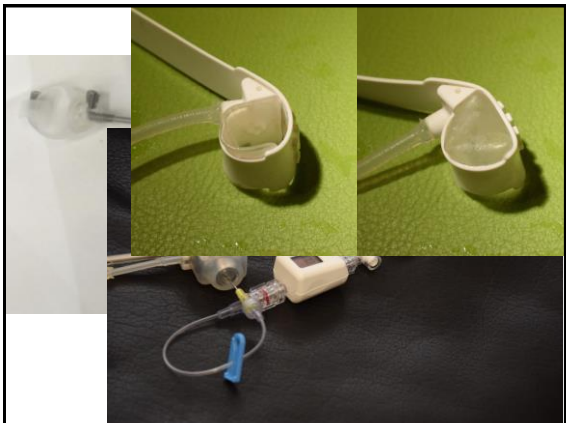
AROYO TM

UNISIZE CUFF

PRESSURE REGULATION

Zachoval R, Krhut J, Stejskal J, Mika D, Oelke M :
 Efficacy and safety of a new adjustable artificial
 urinary sphincter (AROYO TM) for the
 treatment of male stress urinary incontinence:
 relief I study with 12 months follow-up,
 ICS 2015, Abstr. No 205

OPEN/CLOSE

RESULTS

Zachoval R. et al. : intl. Multicenter study „Relief II“

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

=>av. 84% reduction in pad weight


Differences to AMS 800:
 adjustability
 „one piece implant“
 Pressure compensator for manual activation

zephyr

ARTIFICIAL URINARY SPHINCTER ZSI 375

ARTIFICIAL URINARY SPHINCTER

For male severe incontinence



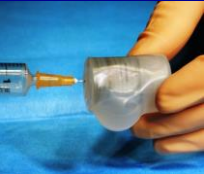
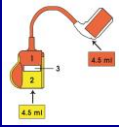
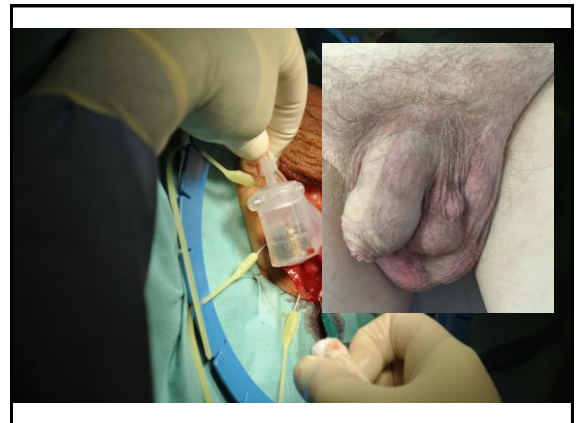
ZSI 375

ARTIFICIAL URINARY SPHINCTER ZSI 375

FILLING OF THE COMPENSATION POUCH

syringe + **HUBER** needle
Create a vacuum

Inject 4.5 ml of saline solution

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

Kretschmer A. et al.: Efficacy and safety of the ZSI375 artificial urinary sphincter for male stress urinary incontinence: lessons learned.
World J Urol. 2016 Feb 25.

n=13 patients FU: 13,5 mts
Social continence: 23%
Removal in 8/13 patients (61,5%!)
defect 1x, infection 3x, pain 1x, erosion 1x

Zephyr ZSI 375
next generation



Zephyr ZSI 375 (PF)



Preliminary outcomes of the European multicentre experience with the ZSI 375 artificial urinary sphincter for treatment of stress urinary incontinence in men.

Ireneusz Ostrowski¹, Tomasz Golabek², Janusz Ciechan¹, Emil Sledz¹, Mikołaj Przydacz², Mariusz Plewniewski³, Burkhard von Heudend, Tobias Pottke³, Frank Neumann⁴, Giuseppe Carrieri⁵, Oscar

Differences to AMS 800:
adjustability any time after implantation
„one piece implant“
prefilled

(infection: 1,8 – erosion: 17,9 - mechanical failure: 2,9)

Of the remaining 82 pts
83,6 (65)% dry, 8,2 (7)%improved, 8,2 (28)% failure

FS

EUROPEAN UROLOGY 50 (2006) 574-580

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

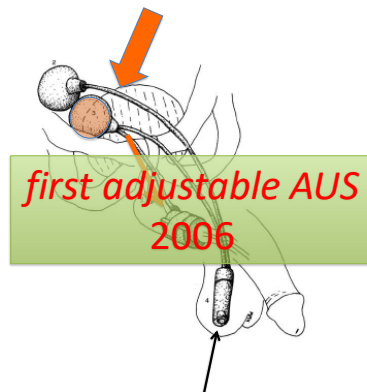


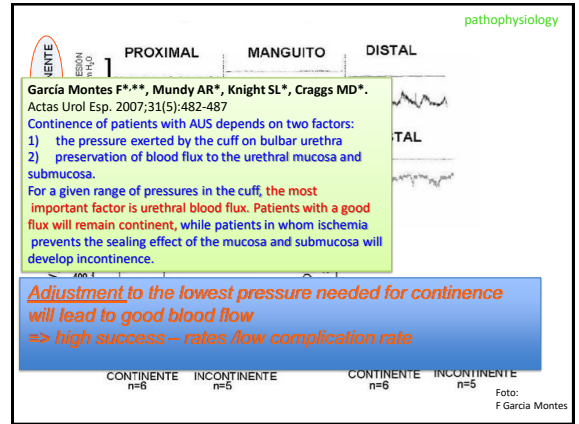
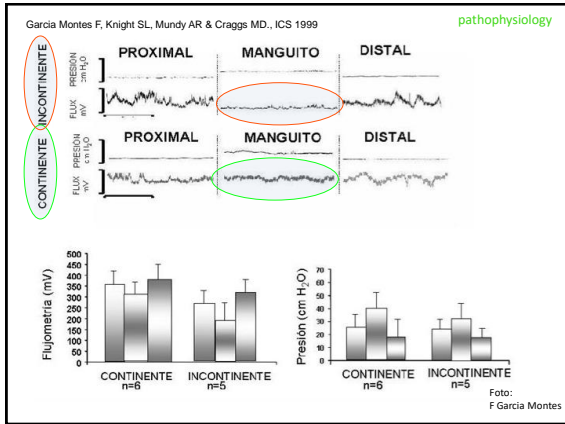
Incontinence

A New Artificial Urinary Sphincter with Conditional Occlusion for Stress Urinary Incontinence: Preliminary Clinical Results

Sarah L. Knight^{a,*}, Judith Susser^a, Tamsin Greenwell^b, Anthony R. Mundy^{a,b}, Michael D. Craggs^a

^aInstitute of Urology, Royal Free & University College Medical School, London, UK
^bInstitute of Urology, Royal Free & University College London Hospitals Foundation Trust, London, UK





RESULTS

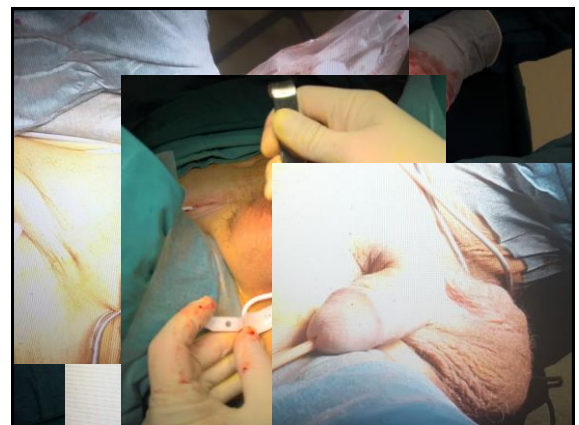
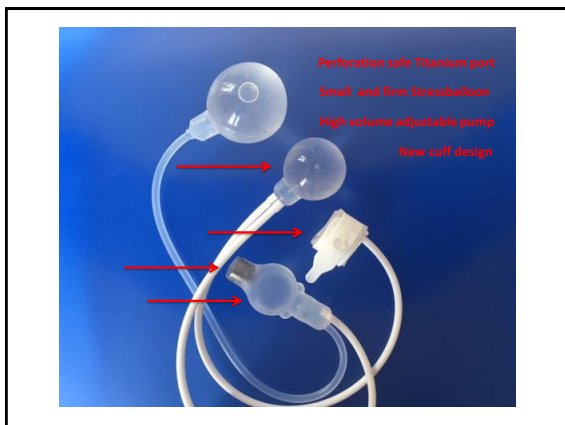
Alonso Rodriguez D F
Vicens A GMF (2011)
artificial urinary sphincter
n=100 patients

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

system

Flowsecure difficulties:

1. Pump problems (volume transfer, accidental perf.)
2. Balloon ruptures (production quality)
3. Cuff size and fitation



VICTO early experience

35 implantations at 5 Centers
(Austria, Netherland x 2, Italy, Germany)

FU: mean 103days (243 – 6); median 85 days
all patients activated dry or improved

one patient explanted due to intraop. difficulties

Similar to AMS 800
Long evolution period

Differences to AMS 800:
Self acting pressure adjustment
adjustability any time after implantation
„one piece implant“
Possible improvement concerning dexterity

New Artificial Hydraulic Sphincters, Technique,
New Possibilities, Limits
W. Huebner

Convincing concepts, improving quality,
so far advantages over AMS 800 not demonstrated

Not enough information available

Head to head studies desirable!

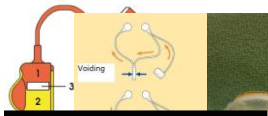

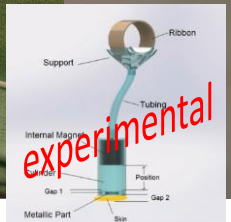
VICTO early Korneuburg experience

16 implantations
FU: mean 103days (243 – 6); median 85 days
all patients activated dry or improved
(some still under adjustment)

no explantation!

NEWS

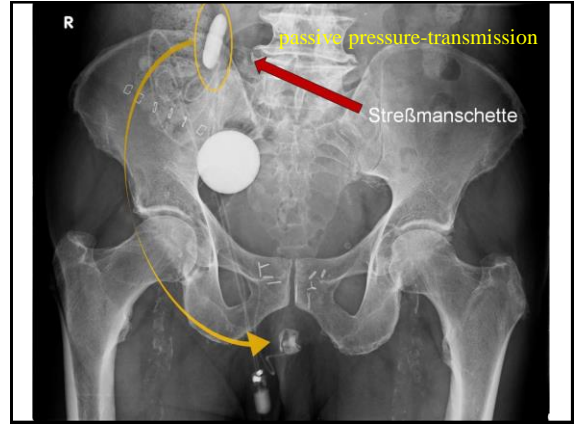
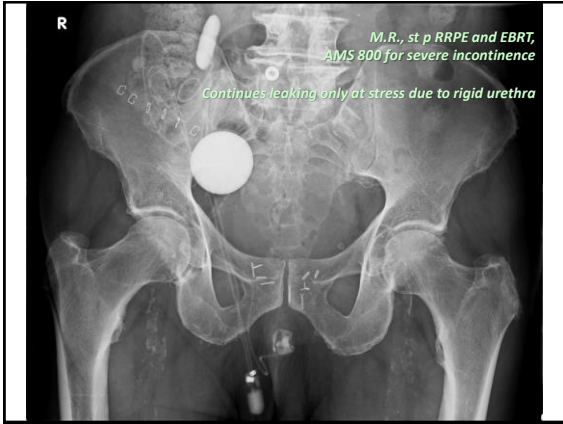
ZSI 375 next generation. flowsecure

Aroyo

Magnetic and electronic sphincters

experimental



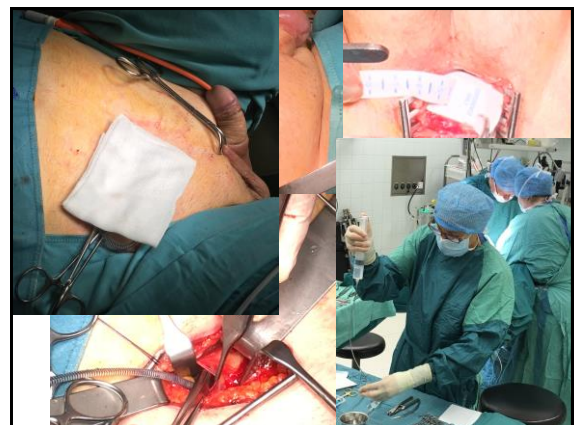
Hydraulic Sphincter-AMS 800®

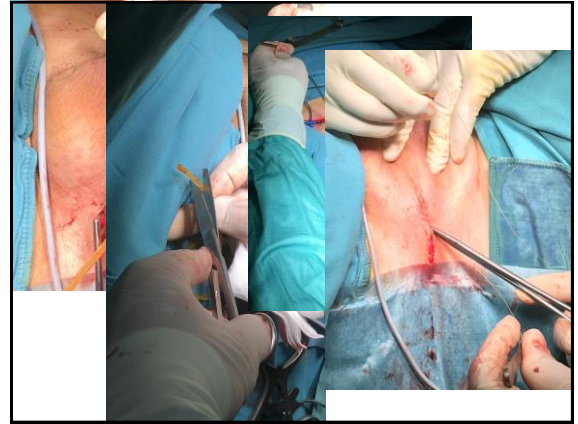
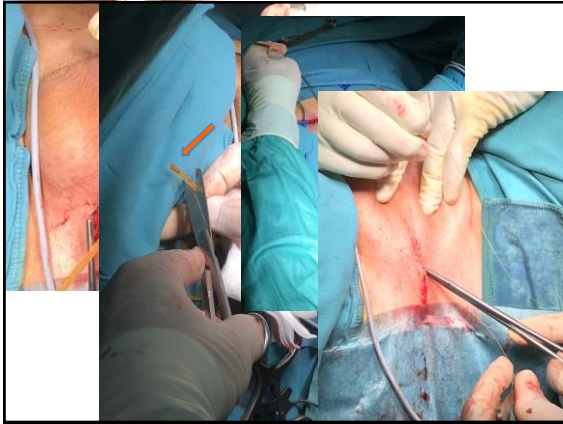
This slide contains two small photographs of the AMS 800 device components (reservoir and pump) and a series of four anatomical diagrams illustrating the device's placement and function around the urethra.

Hydraulic Sphincter-AMS 800®

This slide contains two small photographs of the AMS 800 device components, a series of four anatomical diagrams, and a large intraoperative photograph showing the surgical implantation of the device around the urethra.

AMS 800 – classic implantation





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, Simmons CJ, Flynn B: J Urol 2008; 179:1475-1479.
 Henry GD, Graham SM, Cornell RJ, Cleves MA, Simmons CJ, Vakilopoulos 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? or deeper extraperitoneal placement, n=294
 J Urol. 2015;194(1):202-206. Erosion rate identical 9% after 2 years

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

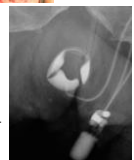
AMS 800 - options for implantation

Transcorporeal cuff placement – concerns/facts

Bleeding => insignificant

ED => majoritiy maintains!°

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



*Wiedemann L, Cornu JN, Haab E, et al. Transcorporeal 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

Transcorporeal 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 [14.8-44.5]	549 (10)
No. of patients social continence (≤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!
- Tandem cuff leads to higher complication rate without improvement of continence

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.

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	29.2 [21.1-45.1]	562 (10)
Urethral atrophy	7.9 [1.9-28.6]	456 (6)
Reintervention (for any reason)	60.1 [48.8-71.4]	549 (10)
No. of patients social continence (<1 pad/24 h)	79.0 [60.9-100]	262 (7)
No. of patients completely dry (0 pads/24 h)	43.3 [4.3-85.7]	338 (7)

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

Telephone - delivered quality of life after 365

Limitations: dexterity, mental status

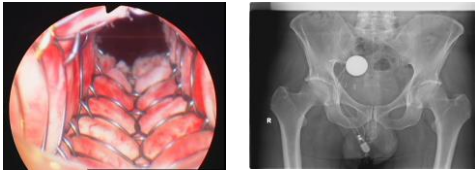
Durasphere
Cystoscope

W.Hübner, Kornelburg

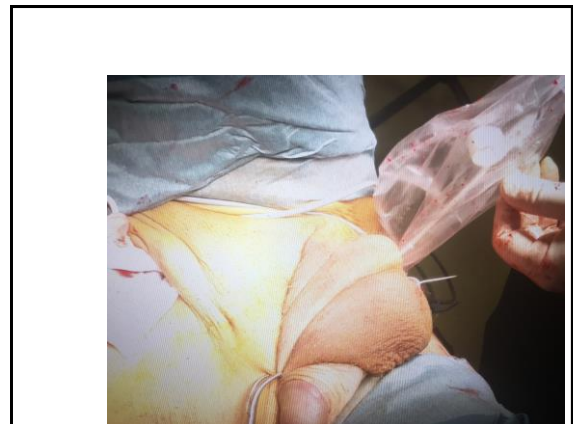
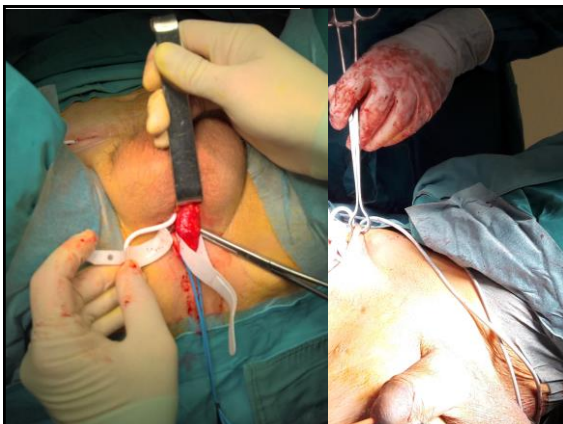
S.K., 12.05.1947

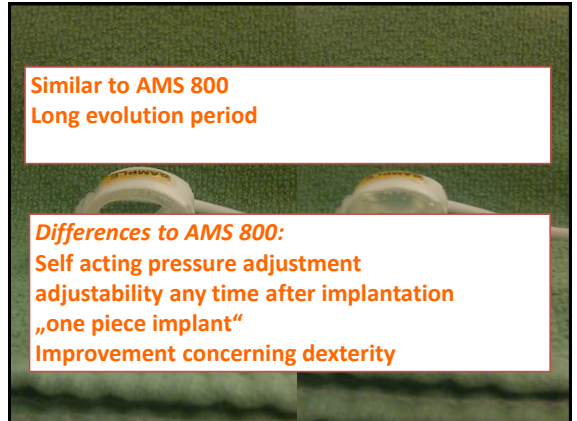
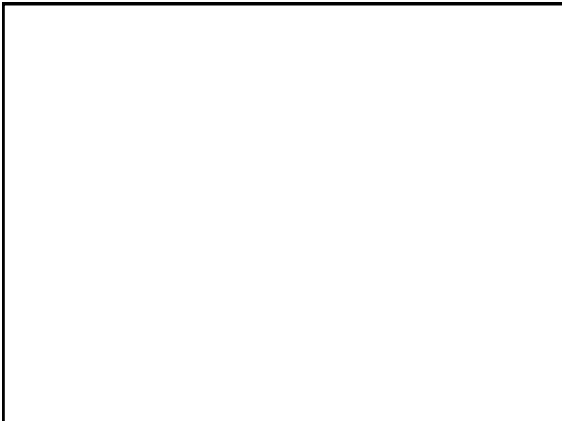
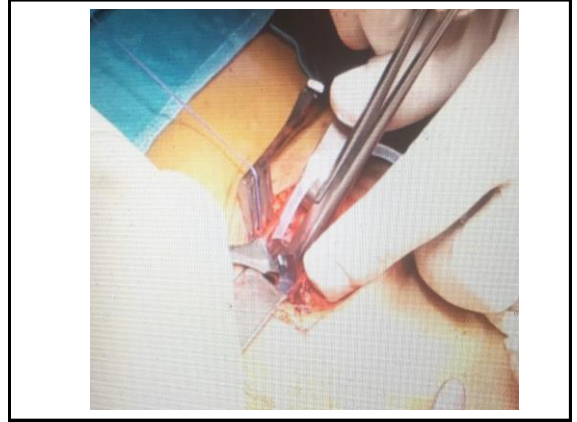
X/2006rad Cystoprostatektomy, (PT4, GS9, R+)
Ileum Neobladder => PSA = 0,3ng
=> rez. Anastomotic stricture

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



M.R., st p RRPE and EBRT,
AMS 800 for severe incontinence
Continues leaking only at stress due to rigid urethra





Similar to AMS 800
Long evolution period

Differences to AMS 800:
Self acting pressure adjustment
adjustability any time after implantation
„one piece implant“
Improvement concerning dexterity

VICTO early experience

32 implantations at 5 Centers
(Austria, Netherland x 2, Italy, Germany)
FU: mean 103days (243 – 6); median 85 days
all patients activated dry or improved

so far no explantations reported!

RESULTS

Alonso Rodríguez 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)

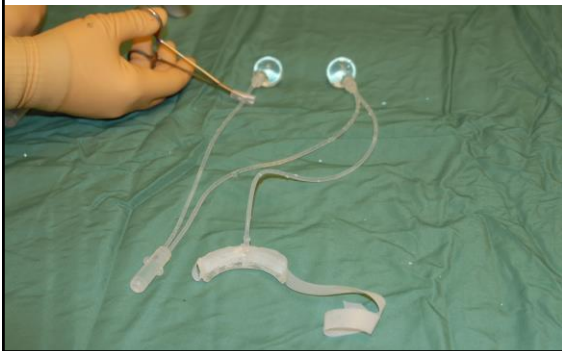
Flowsecure



Flowsecure

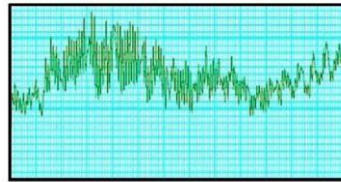
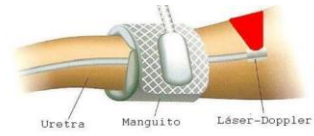


Flowsecure



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

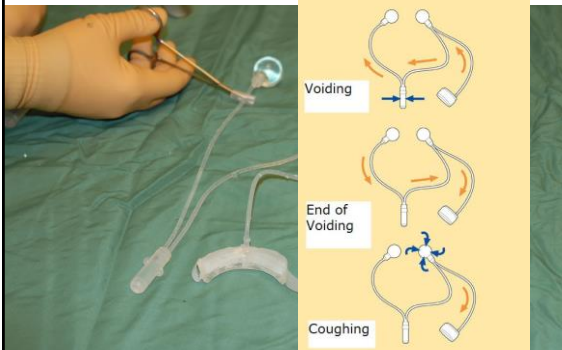
pathophysiology



Perfil de Perfusión intrauretral

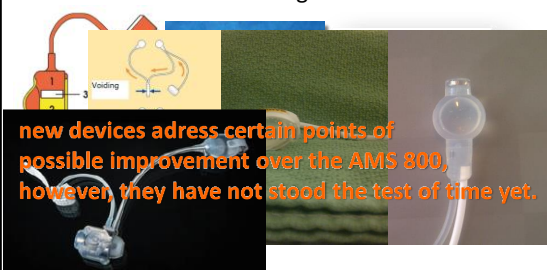
Foto: F Garcia Montes

Flowsecure



Future Aspects

ZSI 375 next generation. flowsecure

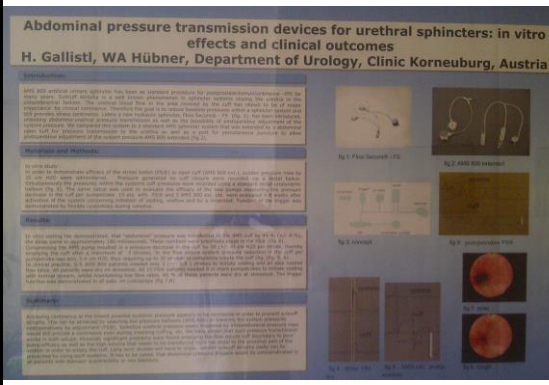


new devices address certain points of possible improvement over the AMS 800, however, they have not stood the test of time yet.

Aroyo

Abdominal pressure transmission devices for urethral sphincters: in vitro effects and clinical outcomes

H. Gallisti, WA Hübner, Department of Urology, Clinic Korneuburg, Austria



Flowsecure®: Einleitung

- 12 Pat (7/06 - 10/07) 15 Mo
- Ø 68,5a (56 -79)
- 2 TURP, 7 RRPE, 2 PRPE, 1 Irradiatio bei N. recti
- alle vorbehandelt (Brachytherapie, Irradiatio, andere Inkontinenz OP`s)!

Flowsecure®: Ergebnisse

Ø follow up: 9 Mo

41,7% kontinent - 1 SVL

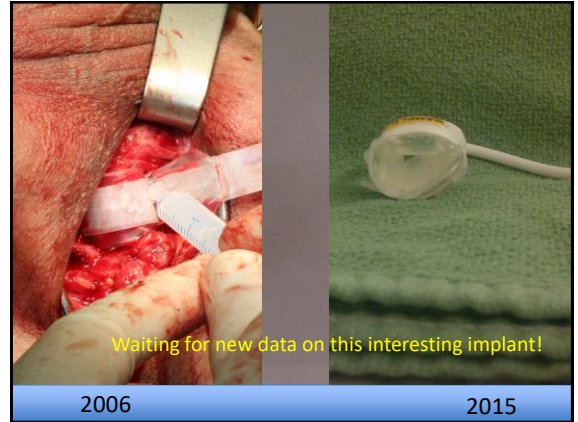
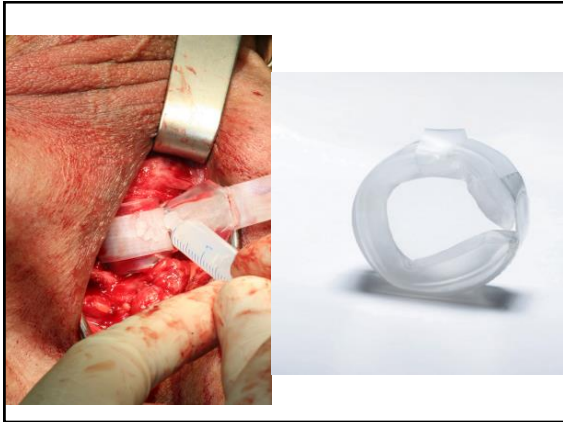
25% deutlich verbessert

33,3% Explantationen

=> technische Probleme....

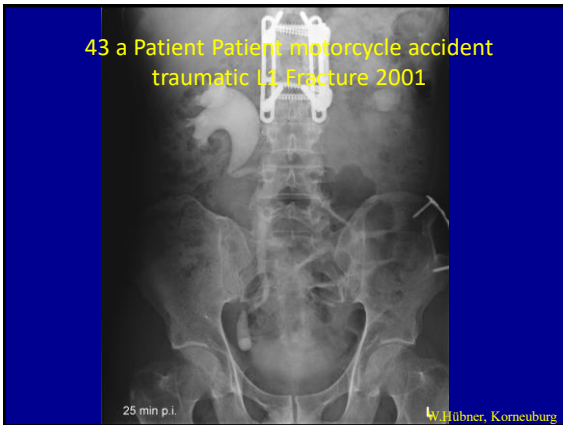
=> Bedienungsprobleme





2006

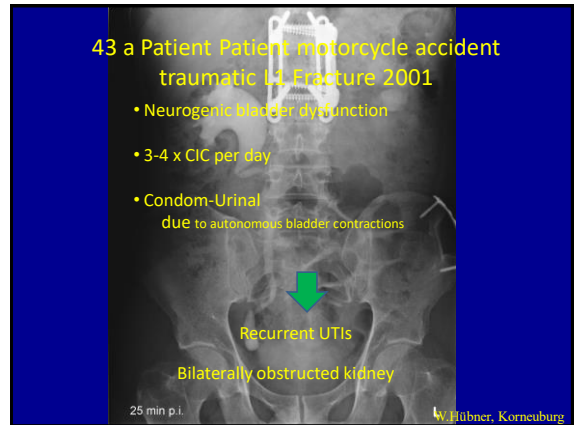
2015



43 a Patient Patient motorcycle accident
traumatic L1 Fracture 2001

25 min p.i.

Hübner, Korneuburg



43 a Patient Patient motorcycle accident
traumatic L1 Fracture 2001

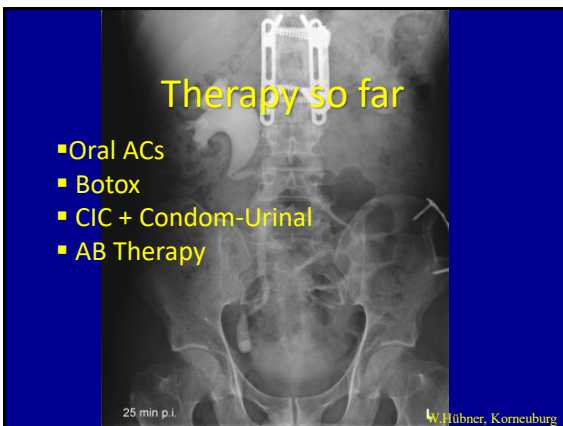
- Neurogenic bladder dysfunction
- 3-4 x CIC per day
- Condom-Urinal
due to autonomous bladder contractions

Recurrent UTIs

Bilaterally obstructed kidney

25 min p.i.

Hübner, Korneuburg

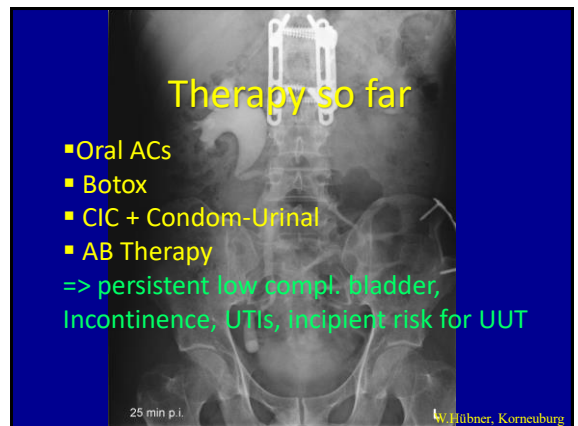


Therapy so far

- Oral ACs
- Botox
- CIC + Condom-Urinal
- AB Therapy

25 min p.i.

Hübner, Korneuburg



Therapy so far

- Oral ACs
 - Botox
 - CIC + Condom-Urinal
 - AB Therapy
- => persistent low compl. bladder,
Incontinence, UTIs, incipient risk for UUT

25 min p.i.

Hübner, Korneuburg

- Bladderaugmentation with Ileum (low pressure system)

W.Hübner, Korneuburg

- Bladderaugmentation with Ileum (low pressure system)
- Sphincterotomy => iatrog. incontinence

W.Hübner, Korneuburg

- Bladderaugmentation with Ileum (low pressure system)
- Sphincterotomy => iatrog. incontinence

- 6 weeks suprapubic

W.Hübner, Korneuburg

- Bladderaugmentation with Ileum (low pressure system)
- Sphincterotomy => iatrog. incontinence

- 6 weeks suprapubic

- => AMS 800 (continence, vol. mict.)

W.Hübner, Korneuburg

After activation of the AMS 800

- *continent Patient
- *low pressure system
- *UUT unobstructed
- *voluntary micturition
- *no RU
- * 480 ml bladder capacity
- *=> Sexual live!



W.Hübner, Korneuburg

Artefizieller Sphinkter

- Erstbeschreibung 1974
- Erste Version AMS 721 seit 1972
- Aktuell: AMS 800 seit 1982

Weltweit ca. 100.000 Implantationen

Hohe Zufriedenheitsraten

auf – zu Mechanismus





ARTIFICIAL URINARY SPHINCTER ZSI 375

FILLING OF THE COMPENSATION POUCH

syringe + HUBER needle
Create a vacuum

Inject 4.5 ml of saline solution

RESULTS

Kretschmer A. et al.: Efficacy and safety of the ZSI375 artificial urinary sphincter for male stress urinary incontinence: lessons learned.
World J Urol. 2016 Feb 25.

n=13 patients FU: 13,5 mts
Social continence: 23%
Removal in 8/13 patients (61,5%!)
defect 1x, infection 3x, pain 1x, erosion 1x

RESULTS

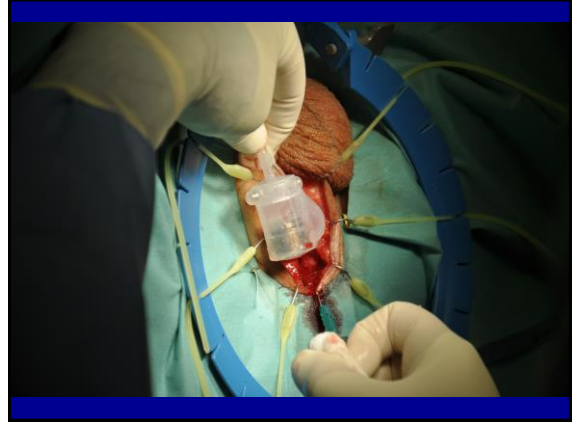
Changes have been made, now prefilled implant, new data needed

World J Urol. 2016 Feb 25.

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



Zephyr ZSI 375



CLINICAL TRIAL

Preliminary outcomes of the European multicentre experience with the ZSI 375 artificial urinary sphincter for treatment of stress urinary incontinence in men.

Ireneusz Ostrowski¹, Tomasz Golabek², Janusz Ciechan¹, Emil Sledz¹, Mikolaj Przydacz², Mariusz Blewniewski³, Burkhard von Heyden⁴, Tobias Pottek⁵, Frank Neugart⁶, Giuseppe Carrieri⁷, Oscar Selvaggio⁷, Francesco Iori⁸, Wojciech Dys³, Waldemar Rozanski³, Piotr L. Chlosta²

¹Department of Urology, Regional Specialistic Hospital, Pulawy, Poland.

²Department of Urology, Collegium Medicum of the Jagiellonian University, Krakow, Poland

³Department of Urology, District Specialistic Hospital, Lodz, Poland

⁴Urology Practice, Gaildorf, Germany

⁵Department of Urology, Asklepios Westklinikum Hamburg, Germany

⁶Department of Urology, Baden-Baden, Germany

⁷Department of Urology, Foggia, Italy

⁸Department of Urology, Umberto I Hospital, Rome, Italy

Results

- 106 patients with the mean age of 71.56 years (8.9; 26-85).
- The mean (range) period of incontinence: 48.6 (11-132) months,
- 91% were incontinent > 1 year before implantation.

Among the total patient population:

- The mean number of urinary pads used daily was 4.22,
- 96 patients (90.6%) were considered to have had a severe incontinence, with a daily pad usage ≥ 4 at baseline.

Results

Postoperative complications occurred in 24 patients (22.6%):

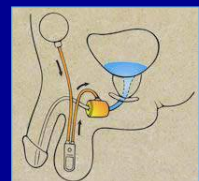
Infection: 2 cases (1.8%), one at the site of mesh implantation and the other in the perineal area leading the explantation of the device. All infections occurred early in the series.

Postoperative erosion of the urethra: 19 cases (17.9%) and it occurred at the mean time of 13.5 months.

Mechanical failure (saline leakage) with resultant device re-implantation 3 patients (2.8%), due to intraoperative injury of a silicone tube that connects a urethral cuff with a pump.

The device had to be explanted in 24 patients (22.6%).

Hydraulischer Sphinkter-AMS®:



Future Aspects

ZSI 375 next generation. flowsecure

The image shows two types of artificial urinary sphincters. On the left is the ZSI 375, with a diagram illustrating the voiding process. On the right is the Aroyo sphincter, with a detailed cross-sectional diagram showing its components: Support, Ribbon, Tubing, Internal Magnet, Cylinder, Piston, Gap 1, Gap 2, Metallic Part, and Skin.

Magnetic and electronic sphincters

Summary

- No conclusive guidelines
- Understanding of pathophysiology not consolidated
- New diagnostic tests not yet established
(elevation - test, RLPP, evaluation of residual sphincter)
- animal experiments not feasible
- Differential – indikation => per Exclusion
- Preference of patient / expertise of surgeon

However, decision needs to be made upon the patient's needs, and not on the surgeon's preference!!

AMS 800

Implantation technique:
 classic/scrotal
 Tandem cuff
 Transcaverous placement
 Results/Reoperations
 Trouble shooting

°ZSI 375 artificial urinary sphincter for male urinary incontinence: a preliminary study.

36 patients - follow-up 15.4 (6-28) months

Recent german DOMINO study:
61% explantation rate

Changes have been made, now prefilled implant, apparently works better now

*Staerman FG-Llorens C, Leon P, Leclerc Y. BJU Int. 2013 Apr;111(4 Pt B):E202-6. doi: 10.1111/j.1464-410X.2012.11468.x. Epub 2012 Sep 3.

**Kretschmer A et al., : Results from a Large Middle European Multi-Institutional Case Series, Urol Int. 2016 Jun 17.

°ZSI 375 artificial urinary sphincter for male urinary incontinence: a preliminary study.

36 patients -follow-up 15.4 (6-28) months
 Social continence (0 or 1 pad/day)
 6 mts 26/36 (73%)
 Removal in four patients (one case of erosion, three cases of infection).

*Staerman FG-Llorens C, Leon P, Leclerc Y. BJU Int. 2013 Apr;111(4 Pt B):E202-6. doi: 10.1111/j.1464-410X.2012.11468.x. Epub 2012 Sep 3.

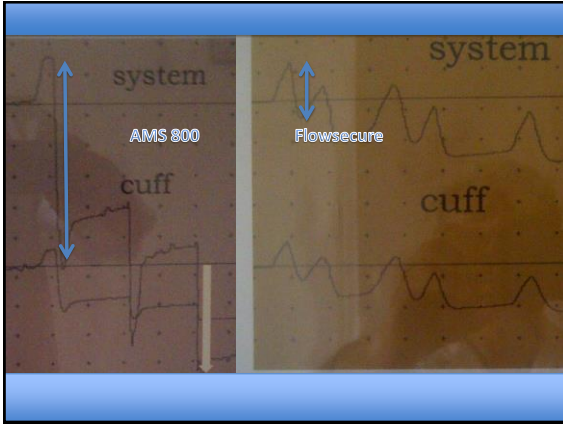
ARTIFICIAL URINARY SPHINCTER ZSI 375

FILLING OF THE COMPENSATION POUCH

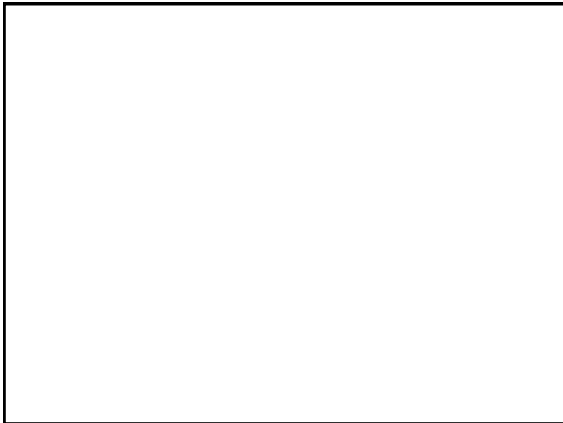
syringe + HUBER needle
 Create a vacuum

Inject 4.5 ml of saline solution

The diagram shows a syringe connected to a Huber needle, which is inserted into a compensation pouch. The pouch is being filled with 4.5 ml of saline solution. A photo shows the physical compensation pouch being filled.



This block contains a collage of images. At the top left is a blue mesh-like component. Next to it is a hand holding a white tube. To the right is a 3D anatomical model of the bladder and urethra. Below these are two smaller images: one of a hand holding a device and another of a device with a tube. A green banner across the middle contains the text: **Limitations: dexterity, mental status**. Below the banner is a diagram of the bladder and urethra with labels 'Durasphere' and 'Cystoscope'. At the bottom right, the text 'W. Hübner, Kornelburg' is visible.



ARTIFICIAL URINARY SPHINCTER ZSI 375

FUNCTIONING OF THE ZSI 375

The ZSI 375 is filled with normal saline solution. There are two compartments separated by the piston (3):

- The hydraulic circuit (1)
- the compensation pouch circuit (2)

The two circuits are separated by a piston (3). The piston can move up and down in the tank.

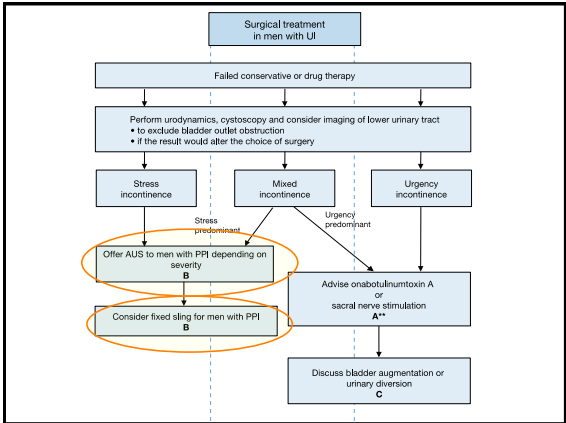
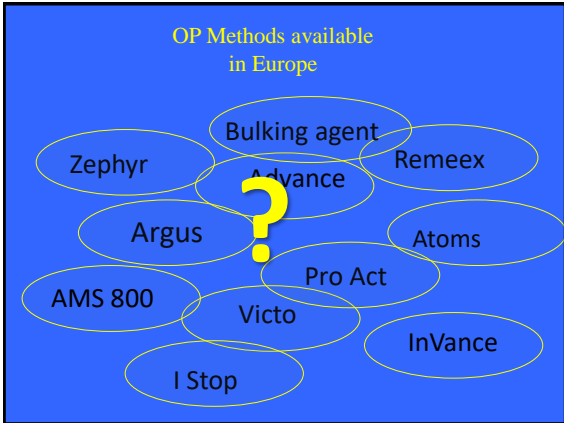
The saline solution of the hydraulic circuit is never in contact with the saline solution of the compensation pouch.

The diagram shows a cross-section of the device with two chambers, labeled 1 and 2, separated by a piston labeled 3. Chamber 1 is at the top and chamber 2 is at the bottom. Both chambers contain 4.5 ml of fluid. A tube is connected to chamber 1.

ANIMATION FORTENNELEMENT ZSI 375.ppt

Differential indications

Bulking agent
AMS 800



- Surgical therapy of male incontinence:**
- adjustable balloons:
Pro ACT®
 - fixed retrourethral slings:
Advance®, I-Stop®, (Invance®)
 - Adjustable slings:
Argus®, Remeex®, Atoms ®
 - hydraulic Sphincters:
AMS 800®, Victo®, Zephyr®

- Surgical therapy of male incontinence:**
- adjustable balloons:
Pro ACT®
- above the pelvic floor (irrad!)
increases urethral resistance
Elevation of the bladder neck
minimally invasive
sometimes delayed result!
irradiation = contraindication
lower success rate

Surgical therapy of male incontinence:

- fixed retourethral slings:**
Advance®, I-Stop®, (Invince®)

at the pelvic floor (irrad.!)
supports genuine sphincter
positive elevation test required
not suitable for severe incontinence
lower success rate when irradiated

Surgical therapy of male incontinence:

- Adjustable slings:**
Argus classic™“T”®, Atoms®, Remeex®

below the pelvic floor
prompt result (?)
Adjustment of RLPP possible
treatment of severe incontinence possible
Pain issue (TO)
normal Detrusor required

Surgical therapy of male incontinence:

- hydraulic Sphincters:**
AMS 800®, Victo®, Zephyr®

highly reliable results (AMS 800)
treatment of severe incontinence and severely altered urethras possible
open/close mechanism
highest satisfaction rate! (AMS 800)
mental and manual capabilities required
costs

Basis for decision making in male incontinence

- Grade of inkontinence history, 24h test
- interruption of stream history
- Previous operations history, cysto
- irradiation history
- Sphincteric function history, elevation test, RLPP
- Mental status history, clock test
- Manual capability ballpen test
- Neobladder/Detr. Insuff. history, UD
- Invasivity
- Pat. Attitude history
- Psyche history

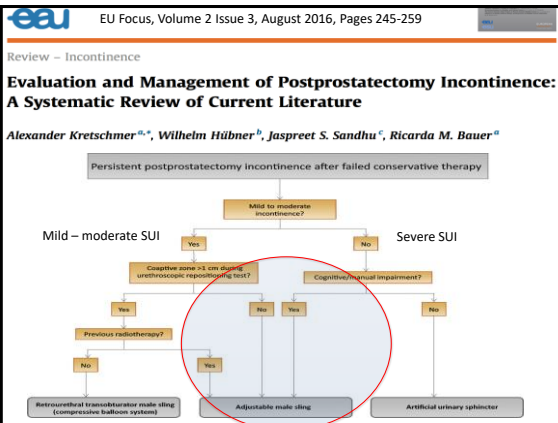
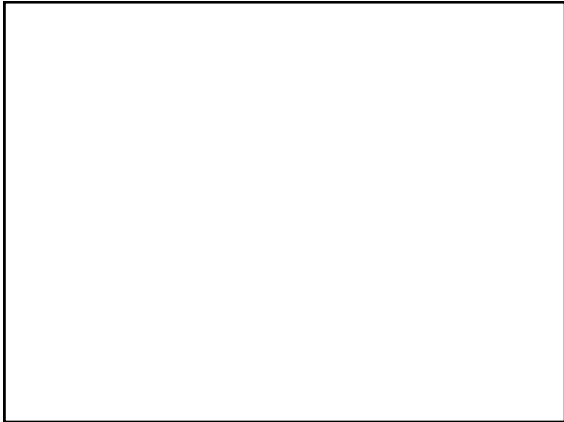


Table 2 - Contraindications, optional indications, and ideal indications for different surgical treatment options of male stress urinary incontinence based on current expert opinions

Device system	Ideal indication	Optional indication	Contraindication
AUS	Complete intrinsic sphincter insufficiency in the urethrosopic repositioning test	Mild to moderate SUI with high level of suffering	Patients mentally or manually unable to use the AUS properly
Adjustable male sling	Complete incontinence High level of suffering Patient able to interrupt urine stream and capability to store urine	Patients not able or not willing to undergo AUS implantation	Retropubic systems not suitable for patients with SUI after orthotopic neobladder
Retourethral transobturator male sling	Previous radiotherapy Mild to moderate SUI	SUI after TURP or open enucleation with positive repositioning test and coaptive zone >1 cm	Nocturnal incontinence
Compressive balloon system	Coaptive zone >1 cm during repositioning test No previous radiotherapy Mild to moderate SUI	Previous radiotherapy and positive repositioning test with coaptive zone >1 cm Urine loss >500 ml in 24-h pad test History of previous urethral manipulation	Negative repositioning test with coaptive zone <1 cm Previous radiotherapy
Bulking agents	None	Elderly patients; just fit for surgery	History of bulking agents None

Decision making by exclusion (contraindications!)
Kretschmer A. et al., Eur Urol Focus. 2016 Aug;2(3):245-59



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

Conclusion Postprostatectomy-Incontinence

Guidelines of limited help in daily practice, low GR
 New diagnostic procedures need to be validated
 adjustable hydraulic sphincters may offer new indications
 Comparative studies/animal experiments not available
 Differential indication based upon contraindications
 Specific needs of a patient must dominate the decision over Drs preference!
 Recommended literature

Review – Incontinence

**Evaluation and Management of Postprostatectomy Incontinence:
 A Systematic Review of Current Literature**

Alexander Kretschmer^{a,*}, Wilhelm Hübner^b, Jaspreet S. Sandhu^c, Ricarda M. Bauer^d

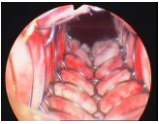


case

R.S., 63a, Salvage CPX + Ileal neobladder after LHRH, PT4, GS9, R+ rec. anastomotic stricture, wet intervals!

case

R.S., 63a, Salvage CPX + Ileal neobladder after LHRH, PT4, GS9, R+ rec. anastomotic stricture, wet intervals!
Deobstruction


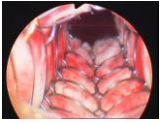


Continenence surgery

Adj. Sling?
Retrouthr. Sling?
Pro Act?
AUS?

case


Memotherm Stent + AMS 800
Capacity 700ml, nykt. 0, no RU

Survived 48mts continent
With good QoL

Conclusion Postprostatectomy-Incontinence

Guidelines of limited help in daily practice, low GR
New diagnostic procedures need to be validated
adjustable hydraulic sphincters my offer new indications
Comparative studies/animal experiments not available
Differentialindication based upon contraindications
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Review – Incontinence

Evaluation and Management of Postprostatectomy Incontinence: A Systematic Review of Current Literature

Alexander Kretschmer^{a,c}, Wilhelm Hübner^b, Jaspreet S. Sandhu^c, Ricarda M. Bauer^a

EAU Guidelines

Differentialindication?

Recommendations for surgery in men with stress urinary incontinence	GR
Only offer bulking agents to men with mild post-prostatectomy incontinence who desire temporary relief of incontinence symptoms.	C
Do not offer bulking agents to men with severe post-prostatectomy incontinence.	C
Offer fixed slings to men with mild-to-moderate " post-prostatectomy incontinence.	B
Warn men that severe incontinence, prior pelvic radiotherapy or urethral stricture surgery, may worsen the outcome of fixed male sling surgery.	C
Offer AUS to men with moderate-to-severe post-prostatectomy incontinence.	B
Implantation of AUS or ACT for men should only be offered in expert centres.	C
Warn men receiving AUS or ACT that, even in expert centres, there is a high risk of complications, mechanical failure or a need for explantation.	C
Do not offer non-circumferential compression device (ProACT®) to men who have had pelvic radiotherapy.	C

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-,
- Post op PSA o.o1 ng/ml
- 24h Pad test = 150 g
- Pad count 3
- Evaluation?

Case presentation

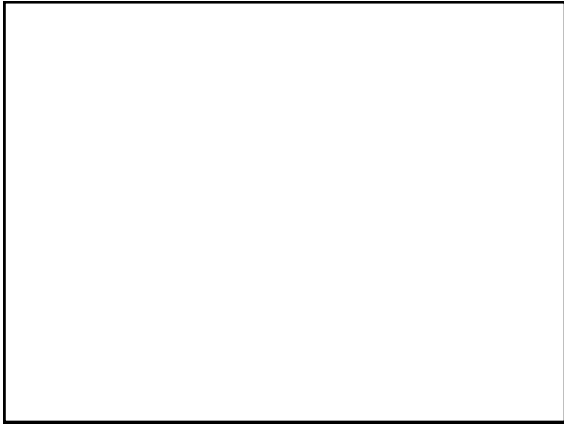
- 64 y.o. 2 m. post ERPE, pT2b, N0,R-,
- Post op PSA o.o1 ng/ml
- 24h Pad test = 150 g
- Pad count 3
- Evaluation?
- Pad count had been 4-5 initially

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

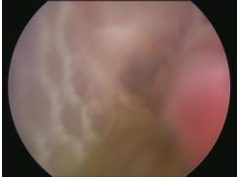


Case presentation

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

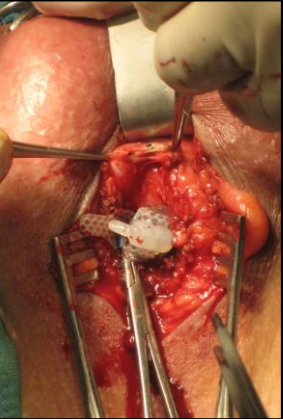
Case presentation

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



AMS 800

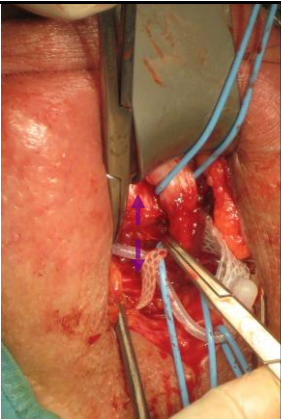
iatrogenic lesion (cysto)



AMS 800

iatrogenic lesion (cysto)

mobilisation using cuff



AMS 800

iatrogenic lesion (cysto)

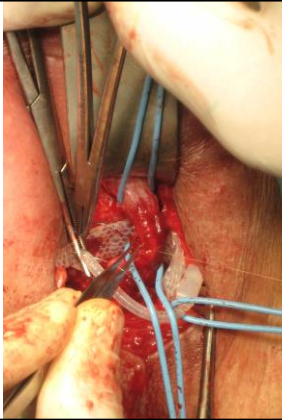
mobilisation using cuff

ID of lesion



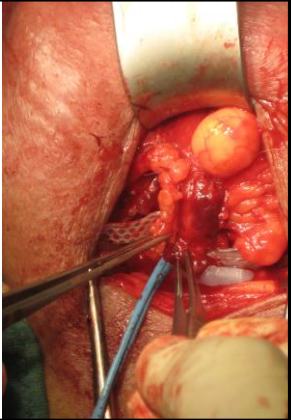
AMS 800
iatrogenic lesion (cysto)

mobilisation using cuff
 ID of lesion
 closure



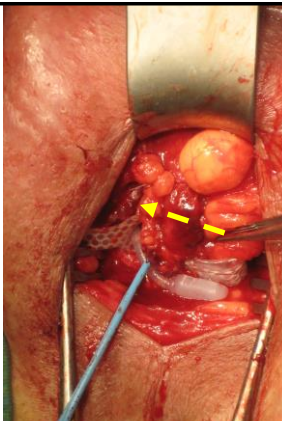
AMS 800
iatrogenic lesion (cysto)

mobilisation using cuff
 ID of lesion
 closure
 protection flap



AMS 800
iatrogenic lesion (cysto)

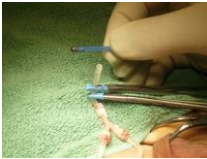
mobilisation using cuff
 ID of lesion
 closure
 protection flap
 cuff left open!



- 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??

- 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

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

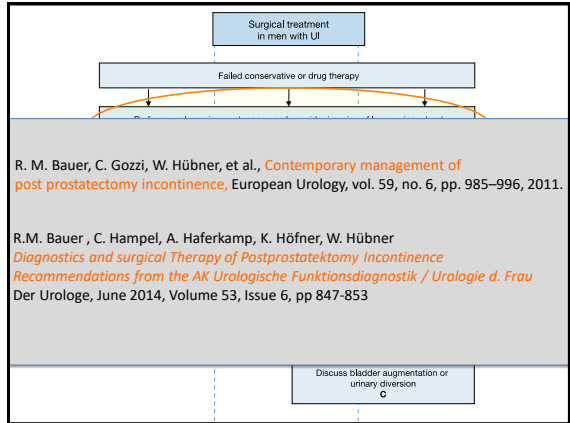
Evaluation?

Options?

combine with sling or 3rd balloon



EAU Guidelines	
Adjustable slings	
Evidence summary	LE
There is limited evidence that adjustable male slings can cure or improve SUI in men.	3
There is limited evidence that early explantation rates are high.	3
There are conflicting data on whether previous pelvic radiotherapy affects the outcome of AUS implantation.	3
AUS	
Evidence summary	LE
There is limited evidence that primary AUS implantation is effective for cure of SUI in men.	2b
Long-term failure rate for AUS is high although device replacement can be performed.	3
There are conflicting data on whether previous pelvic radiotherapy affects the outcome of AUS implantation.	3
Men who develop cognitive impairment or lose manual dexterity will have difficulty operating an AUS.	3
The usefulness of tandem-cuff placement is uncertain.	3
There is insufficient evidence to state whether one surgical approach for cuff placement is superior to another.	3
Very limited short-term evidence suggests that the non-circumferential compression device (ProACT [®]) is effective for treatment of post-prostatectomy SUI.	3
The non-circumferential compression device (ProACT [®]) is associated with a high failure and complication rate leading to frequent explantation.	3
The rate of explantation of the AUS because of infection or erosion remains high (up to 24% in some series).	3
Mechanical failure is common with the AUS.	3
Revision and reimplantation of AUS is possible after previous explantation or for mechanical failure.	3



Diagnostics

New relevant terms:

Residual sphincter

Baseline continence/Stress continence

urethral mobility

Leak Point Pressure (RLPP)

Urethral resistance

AUA

incontinence pattern

Table 1
Evaluation of the incontinent male[16]

- History
- Physical examination
- Urinalysis
- Urine cultures
- Post void residual (by ultrasound)
- Voiding diary (2-7 days)
- Pad test
- Cystourethroscopy
- Multichannel urodynamics

EAU Guidelines

Bulking agents

Evidence summary	LE
There is no evidence that bulking agents cure post-prostatectomy incontinence.	2a
There is weak evidence that bulking agents can offer temporary, short-term, improvement in QoL in men with post-prostatectomy incontinence.	3
There is no evidence that one bulking agent is superior to another.	3

Fixed slings

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

Diagnostik

Neue relevante Begriffe:

Restsphinkter

Basiskontinenz/Stresskontinenz

Harnröhrenmobilität

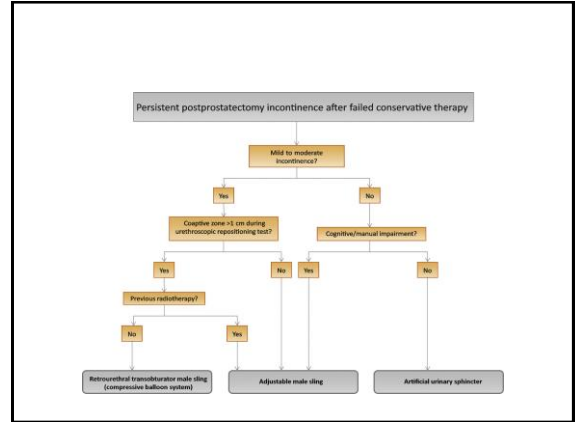
Leak Point Pressure (RLPP)

Urethraler Widerstand

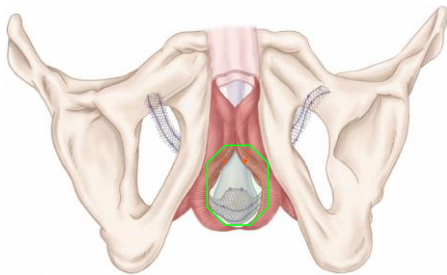
Elevationstest usw.

AUA

Table 1
Evaluation of the incontinent male ^[16]
History
Physical examination
Urine analysis
Urine culture
Post void residual (by ultrasound)
Voiding diary (2-7 days)
Pad test
Cystourethroscopy
Multichannel urodynamics



Retrourethral sling "Advance"



repositioning of perineal body

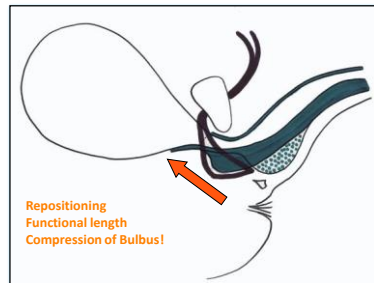
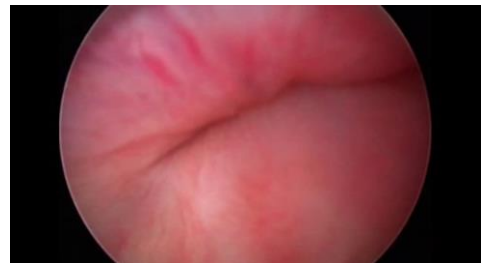
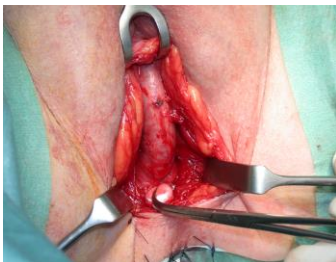
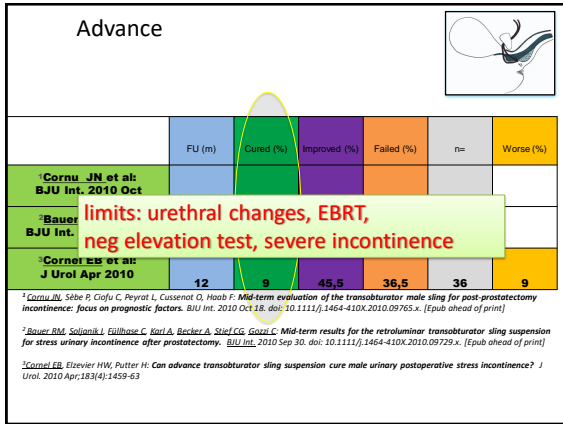


Bild: Peter Rehder

repositioning of perineal body



Rehder, P., Gozzi, C.: Transobturator Slingsuspension for Male Urinary Incontinence including Post-Radical Prostatectomy. *Europ. Urol.*, Sept. 2007, S. 860-867



Summary

- No conclusive guidelines
- Understanding of pathophysiology not consolidated
- New diagnostic tests not yet established (elevation - test, RLPP, evaluation of residual sphincter)
- animal experiments not feasible
- Differential – indikation => per Exclusion
- Preference of patient / expertise of surgeon

However, decision needs to be made upon the patient's needs, and not on the surgeon's preference!!

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!

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Ileal neobladder

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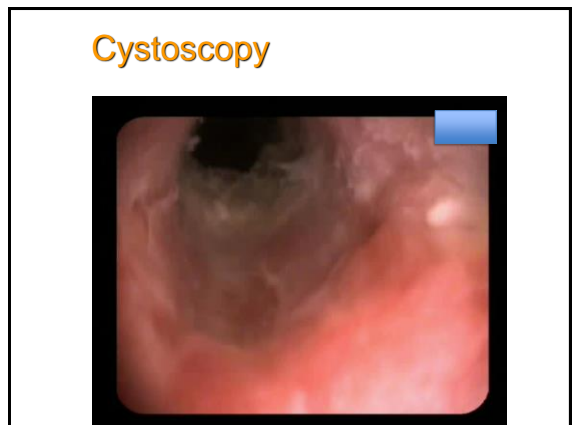
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X/2006 rad. Cystoprostatectomy, Histology: PT4, GS9, R+

Ileal neobladder → rec. anastomotic stricture!



Tabelle

Differentialindikationsstellung bei männlicher Inkontinenz

	AMS 800	Advance	Adj. slings	Pro Act
Hoher Ink grad	+	Vorsicht	+	o
Vorops	+	o	+	Vorsicht

**Differenzialindikation per Exclusionem
Präferenz von Patient und Arzt kann einfließen**

Invasivität	o	o	o	+
Pat. Einstellung	o	+	+	+
Psych. Faktoren	+	o	o	Vorsicht

Operative Behandlung der Inkontinenz nach Prostateoperationen. Wilhelm Hübner und Markus Hohenfellner. 1. Auflage - Bremen: UNI-MED, 2014 (UNI-MED SCIENCE)