New Tips and Tricks for Managing Incontinence after Prostate Surgery

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What is incontinence?

"The objective demonstration of involuntary loss of urine consequent to bladder and/or sphincter dysfunction."*

** International Continence Society*

Potential Pre – Therapy Risk Factors for Post-Prostatectomy Incontinence

- Bladder dysfunction
  - Pre-existing outflow obstruction
  - Inherent age-related changes
  - Nighttime incontinence

- ? Change in compliance after surgery
  - Denervation of bladder or bladder neck

Potential Pre – Therapy Risk Factors

- Various factors attributed
  - Age
  - BMI
  - Urethral Length
  - Operative factors (NVB resection, prostate volume, etc.)

- Better accepted
  - Prior radiation
  - Experience of surgeon

Post-Prostatectomy Incontinence Incidence

- Reported continence rates range from 51% to 97%
- Variability in continence due to
  - Differences in definition
  - Differences in source (patient versus physician)
  - Differences in recording methods

#Karakiewicz, et al, Erectile and Urinary Dysfunction after Radical Prostatectomy for Prostate Cancer in Quebec: A population-based study of 2415 men, Eur Urol 46:188, 2004

Kaul, et al, Functional outcomes and oncological efficacy of Vattikuti Institute prostatectomy with Veil of Aphrodite nerve-sparing: an analysis of 154 consecutive patients, BJUI 97:467, 2006

Krupski, et al, Variation in continence and potency by definition, J Urol 170:1291, 2003

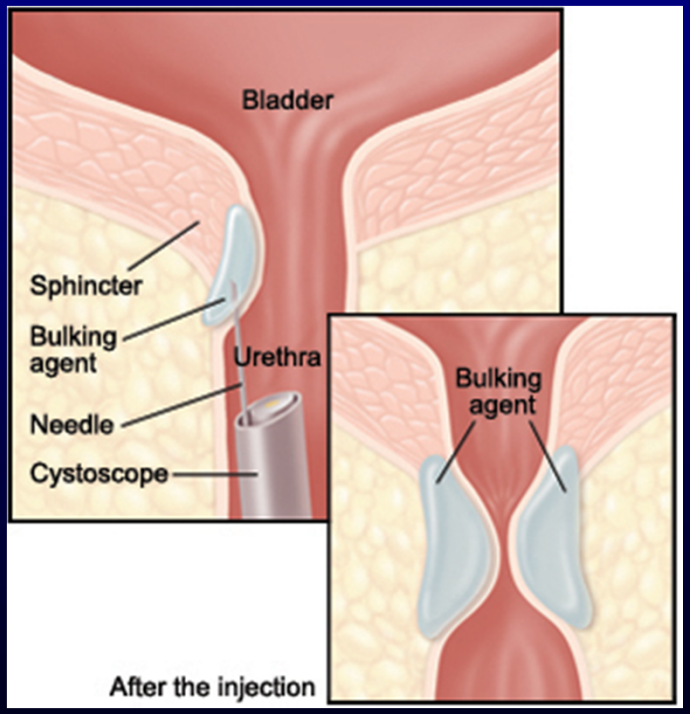
Litwin, et al, Differences in urologist and patient assessments of health related quality of life in men with prostate cancer: results of the CaPSURE database, J Urol 159: 1988, 1998

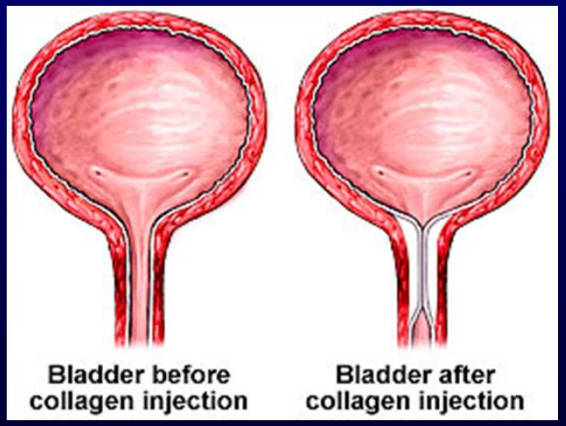
Management of Post Prostatectomy Incontinence

- Observation/Pelvic Floor Exercises
  - Best option early
- Medications
- External appliances
  - Clamps
  - Catheters
- Bulking agents
- Slings
- Artificial Urinary Sphincter

Periurethral Bulking

- Injection of filling agent into tissues to coapt the urethra





Periurethral Bulking

- Autologous Fat
- GAX Collagen
- Teflon Paste
- Contigen/Durasphere
  - Pyrolytic carbon-coated beads
- Bulkamid
  - Polyacrylamide Hydrogel
- Coaptite
  - Calcium hydroxylapatite
- Macroplastique/Urolastic
  - polydimethylsiloxane

When should Bulkamid not be used?

Bulkamid Urethral Bulking System must not be used in patients suffering from acute urinary tract infection.

Bulkamid should not be used in male patients.

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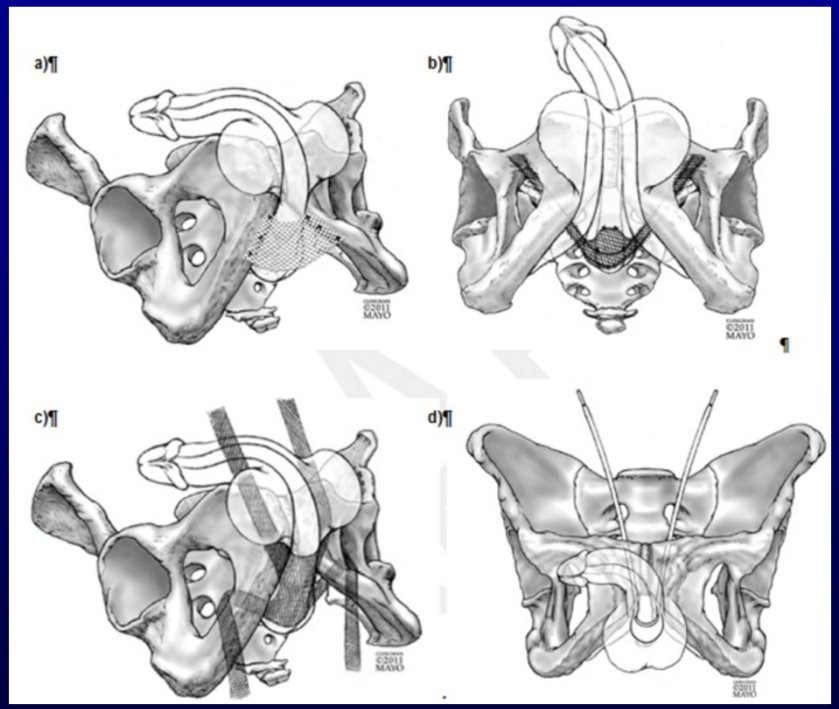
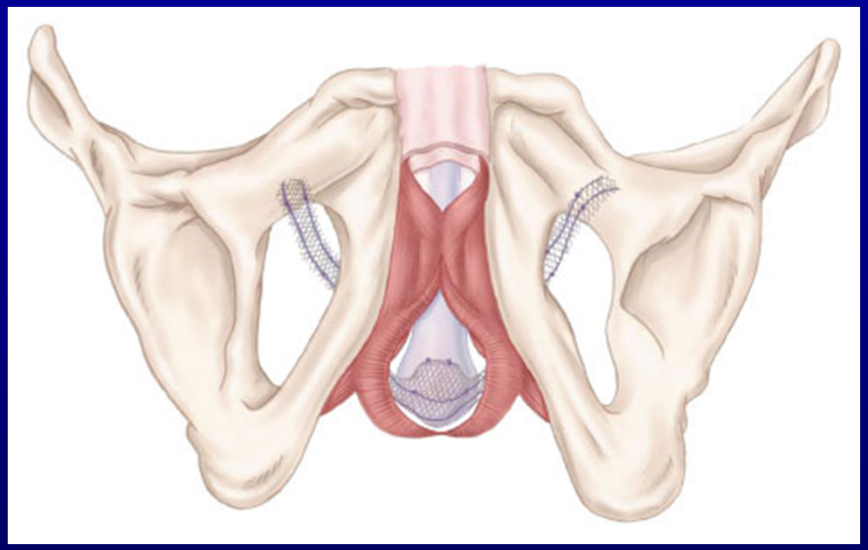
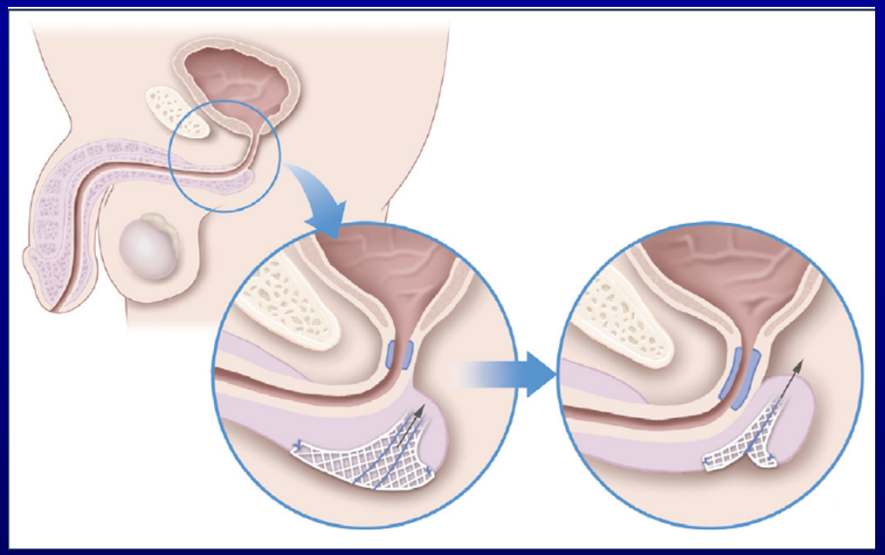
Male Sling

- Categories by anatomy
  - Bone anchor
  - Transobturator
  - Retropubic
  - Quadratic
- Categories by adjustability
  - Non-adjustable
  - Adjustable



AdVance™ and AdVance XP ™





- Repositioning of the bulbar urethra results in an increased functional urethral length and a backdrop of support to the distal membranous (sphincteric) urethra during stress events
  - Poor results in irradiated patients and sphincter deficiency
- AdVance XP: sling arm anchors updated needle shape, increased sling arm length

THE MALE SLING FOR STRESS URINARY INCONTINENCE: 24-MONTH FOLLOWUP WITH QUESTIONNAIRE BASED ASSESSMENT

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THE JOURNAL OF UROLOGY® Vol. 172, 207–209, July 2004

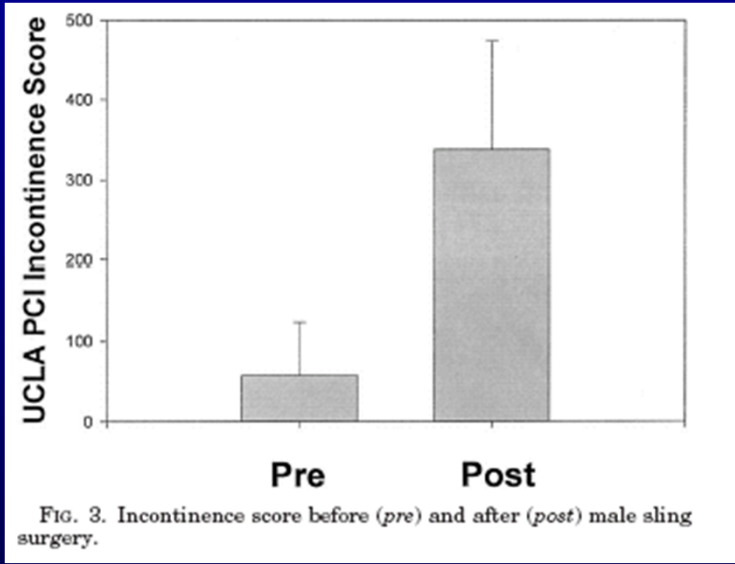

FIG. 3. Incontinence score before (*pre*) and after (*post*) male sling surgery.

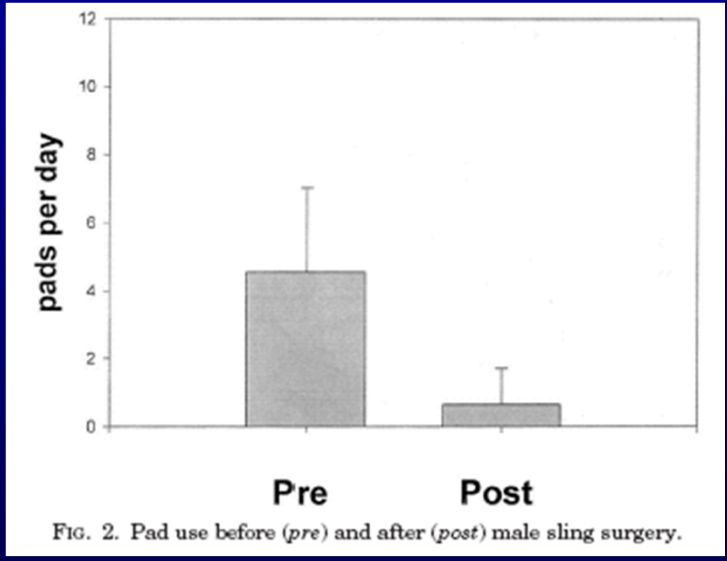

FIG. 2. Pad use before (*pre*) and after (*post*) male sling surgery.

- At a median 25 month follow-up,
  - 67% pad free
  - 92% improved

J Urol 2004:172(1): 204-6

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AdVance™ and AdVance XP ™

Study	Device	Patients included	Study design	Major findings
Bauer et al (2017) [52]	AdVanceXP	115	Prospective, multicenter	3 mo: dry rate 64.9%, 31.6% improved; mean urine loss decreased significantly ($p < 0.001$ compared with preoperatively)/24 mo: dry rate 68.8%, 22.5% improved/36 mo: dry rate 66.0%, 23.4% improved, significant improvement of HRQOL ($p < 0.001$)/no significant postoperative changes in IIEF-5 and IPSS/no intraoperative and long-term complications, erosions, and explantations
Bauer et al (2016) [51]	AdVanceXP	94	Prospective, multicenter	12 mo: dry rate 66.3%, 25.3% improved/24 mo: dry rate 73.1%, 19.6% improved; significant decrease in daily urine loss ($p < 0.001$)/safety: no intraoperative complications, five Clavien IIIb complications in total, no explantation
Kretschmer et al (2016) [53]	AdVanceXP	41	Prospective, single-center	Mean follow-up: 33.1 mo/mean pad use: 0.6 pads ($p < 0.001$ vs baseline); cure rate: 46.3%, 29.3% improved/no significant changes in mean daily pad use (0.8 at 12 mo; $p = 1.000$), ICIQ score (5.0 at 3 yr vs 5.2 at 12 mo; $p = 0.500$), and IQOL score (89.2 at 3 yr vs 86.8 at 12 mo; $p = 0.500$) over time/univariate analysis: no significant differences in efficacy in patients with previous radiotherapy

Eur Urol Focus 2017:3; 364-76

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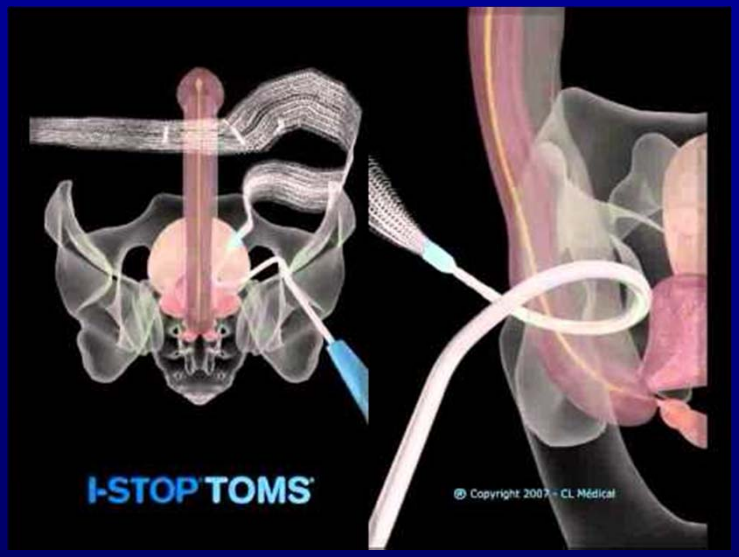
I-Stop TOMS



- 100 patients with mild-moderate SUI evaluated with a median follow-up of 58mo
- 1 and 5 year dry-rate: 40% and 15%
  - Socially continent (0-1ppd): 77% and 22%

Prog Urol 2017;27(17): 1084-90

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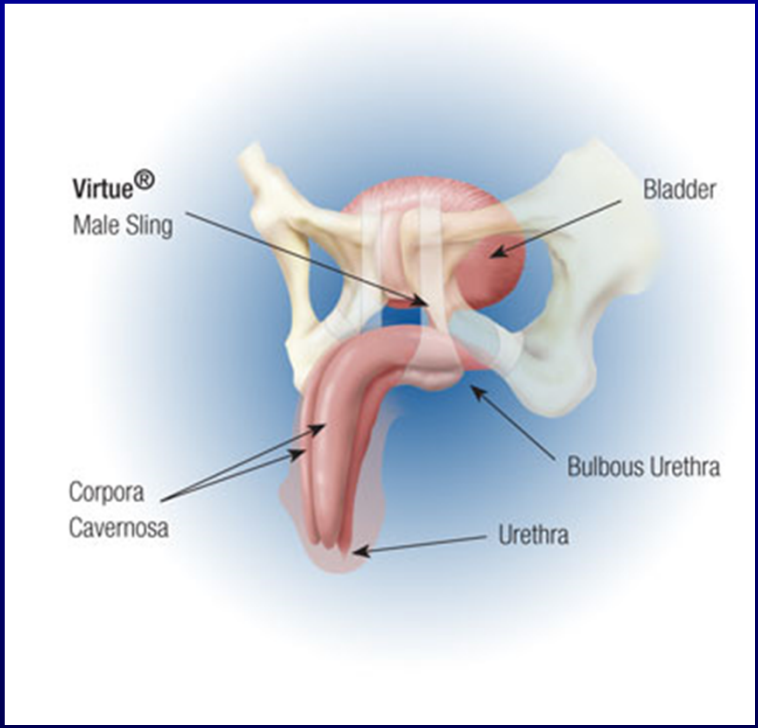
Virtue Male Sling



- Two possible mechanisms: direct urethral compression vs ventral elevation from transobturator arms and distal urethral compression from prepubic arms

Virtue Male Sling

Ferro et al (2017) [59]	Virtue	23	Prospective, single-center	Efficacy: 12 mo FU: significant decrease of daily urine loss (128.6 vs 2.5 g, $p < 0.001$) and ICIQ-SF score (14.3 vs 0.9, $p < 0.001$)/outcomes remained stable after 36 mo of FU/safety: total complication rate: 59.8%, Clavien I exclusively
McCall et al (2016) [58]	Virtue	32	Retrospective, single-center	Median FU: 55 mo/efficacy: median postoperative pad usage: 2 (IQR 1–2.5)/68% classified as procedure failures/safety: chronic pain in 7%, explantation rate 22% (pain, continence failure)/univariate analysis: failure more likely in patients with previous irradiation (19%, $p = 0.02$), no significant correlation with age ($p = 0.65$)
Sourial et al (2017) [60]	Virtue	48	Retrospective, two-center	Comparison of two groups: sling tensioning by cystoscopy ($n = 18$) versus perioperative RLPP ($n = 30$)/median FU: 22 mo (15–41)/significantly increased cured and improved rate if RLPP measurement was performed (70% vs 39%, $p = 0.03$)/safety: transient pain in 48%

- McCall, et al: sling failure rate of 68% with 22% explantation due to chronic pain or incontinence
- Ferro, et al: stable 36mo efficacy but 60% Clavien 1 complication rate

Eur Urol Focus 2017:3; 364-76

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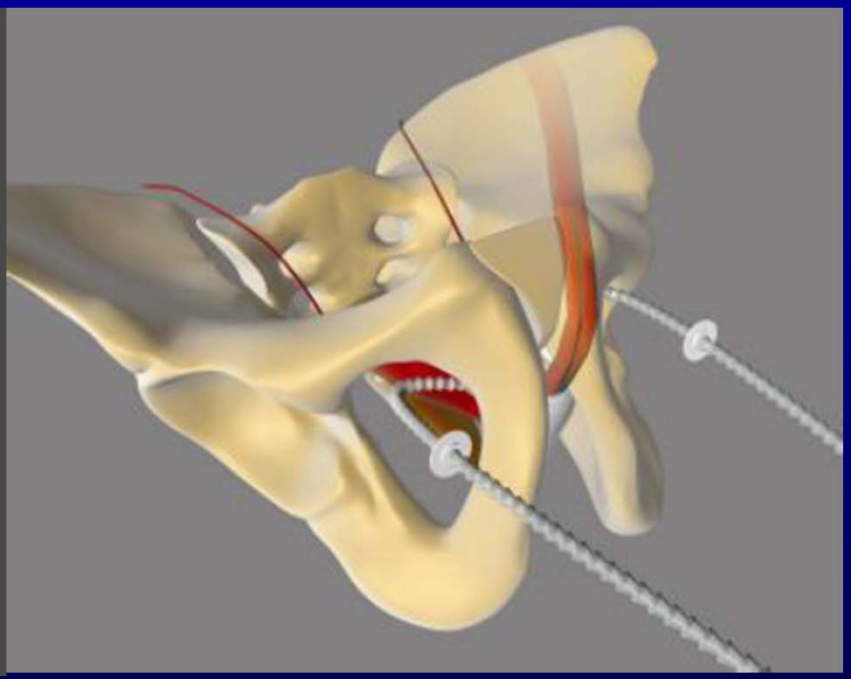
Male Sling

Overview of Fixed Mesh Slings for Post-prostatectomy Incontinence

Study	No. of Patients	History of Pelvic Radiation (%)	Success Rate (%) at 12 mo	Cure Rate (%) at 12 mo	Overall Success Rate (%)	Overall Cure Rate (%)	Complications	Mean Follow-up (mo)
AdVance Sling (Boston Scientific, Marlborough, MA)								
Rehder 2012[23]	159	14.1	76.9	53.8	76.8	53.0	Mild perineal pain (50%) 1 sling explant (symphsitis)	40.1
Zuckerman 2014[24]	102	23	74.0	58.0	62.0	40.0	Urinary retention (11.8%) 1 sling explant (infection)	36.2
Li 2012[25]	66	6.1	—	—	62.5	39.3	Urinary retention (9.1%) Chronic pain (4.5%)	23.8*
AdVance XP Sling (Boston Scientific, Marlborough, MA)								
Bauer 2017[26]	115	0	92.8	61.0	89.4	66.0	Sling incision for de novo urgency and retention (3.4%)	36
Virtue Quadratic Male Sling (Coloplast, Humlebaek, Denmark)								
Comiter 2014[28]	98	0	41.9	15	41.9	15	Temporary perineal pain (14.3%) Short-term paresthesia (12.2%)	12
McCall 2016[30]	32	21.9	—	—	32	—	Urinary retention (44%) 7 sling explants (pain or failure) Chronic pain (7%)	55*
I-Stop TOMS Sling (CL Medical, France)								
Grise 2012[15]	122	0	87.0	59.4	87.0	59.4	Corporal cavernosal injury (4%)	12
Malval 2017[31]	100	0	77	38	22	15	Chronic pain (1%)	58*

Argus Classic/ArgusT



- Silicon foam pad for compression with tension regulated by silicon washers and columns
- Original Argus Classic retropubic approach vs. ArgusT with transobturator approach

Argus Classic/ArgusT

Lima et al (2016) [62]	ArgusT, AdVance	11 (ArgusT), 11 (AdVance)	Randomized, prospective, two-center	Maximum 18 mo	Decrease in daily pad usage after 18 mo (4.2 vs 1.5, $p = 0.066$) after ArgusT implantation/significant improvement of daily urine loss based on pad testing (674 vs 97 g, $p = 0.038$)/continence rate: 77.8%
Chung et al (2016) [63]	Argus classic, AdVance	25 (Argus classic), 19 (AdVance)	Prospective, single-center	Median 36.2 mo	Social continence rate: 92% (Argus) versus 84% (AdVance; $p = 0.45$)/no significant differences regarding patient satisfaction and PGI-I score ($p = 0.36$)
Kretschmer et al (2017) [64]	ArgusT, Argus classic, AMS 800	95 (Argus classic), 32 (ArgusT), 155 (AMS 800)	Retrospective, multicenter	Mean 1.5 mo	Significantly increased intraoperative complication rates after Argus classic implantation compared with AUS (15.9% vs 4.2%, $p = 0.003$)/significantly increased explantation rates after AUS implantation (9.7% vs 21.5%, $p = 0.030$)/multivariate analysis: postoperative infection as an independent predictor of decreased device survival (OR 6.556, $p = 0.001$)

- Argus vs. AdVance: no difference in social continence rates: 92% vs. 84% (p=0.45)
- ArgusT vs. AdVance: improvement in 24hr pad testing in ArgusT but not in AdVance (4.2 vs 1.5ppd, p=0.066) but higher complication rate
- Argus and ArgusT vs. AMS800: 15.9% vs. 4.2% (p=0.003) complication rate for Argus vs AMS800 but highest short-term explantation rate with AMS800 (21.5% vs, 9.7%, p=0.03)

Eur Urol Focus 2017:3; 364-76

Remeex Sling

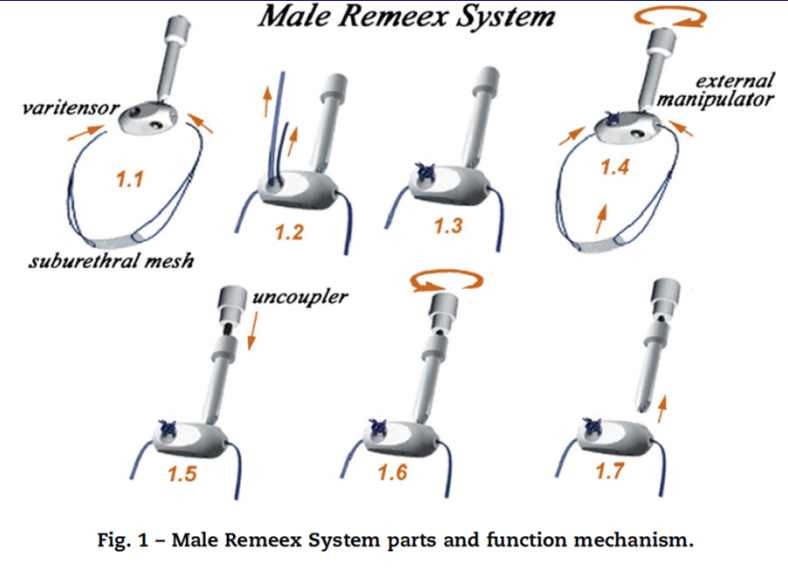


Fig. 1 – Male Remeex System parts and function mechanism.

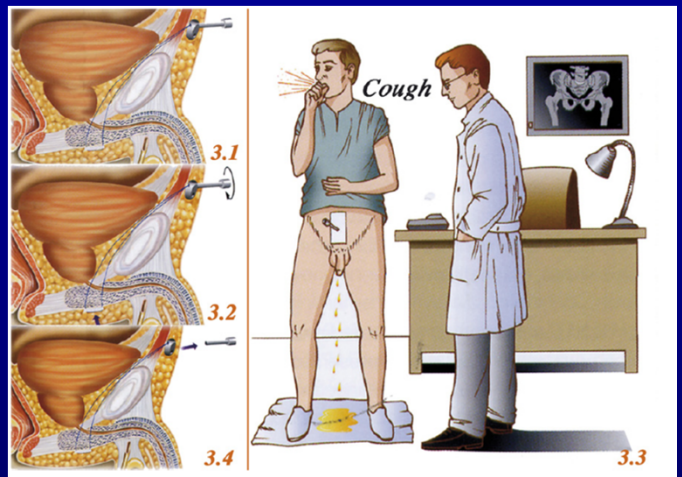


Fig. 3 – Suburethral pressure regulation.

- Adjustable bulbar sling tensioned via suprapubic mechanical regulator

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

- 51 patients treated from Oct 2002 to Aug 2005
- 44 patients required adjustment 1-4mo after surgery
- 33 (65%) considered cured
  - 0ppd: 25
  - 1ppd for safety: 8
- 8 (16%) no change
- Complications
  - 5 (10%) intraoperative bladder perforations
  - 1 urethral and 2 varitensor erosions
  - 3 (6%) perineal hematomas

Eur Urol 2007; 52(5): 1473-9

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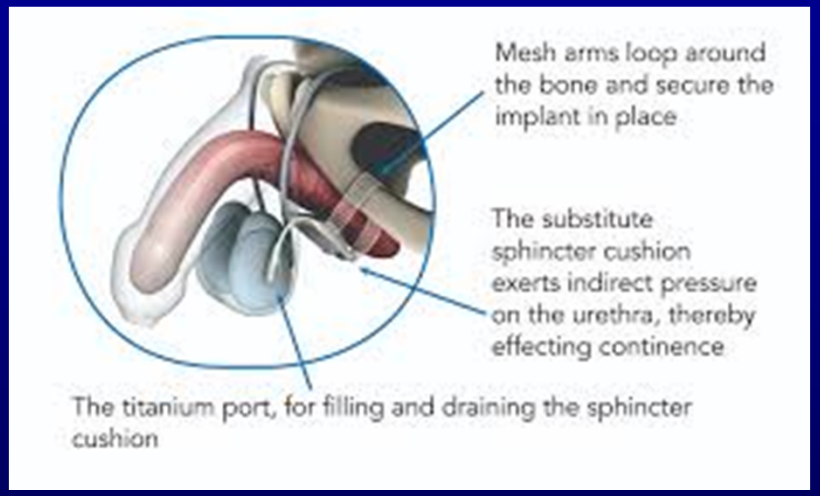
Adjustable Transobturator Male Sling (ATOMS)



- Adjustable male sling that functions similarly to AUS but does not create circular compression and is designed for postoperative adjustment
- Adjustment performed by altering pressure through filling of cushion via titanium port
- Multiple generations of device with different port systems and antibiotic coating

Long-term outcome of the adjustable transobturator male system (ATOMS): results of a European multicentre study

	Baseline, median (IQR)	Follow-up, median (IQR)		P*
		<12 months	Full	
Pads use, pads/day	4 (3–5)	1 (0–2)	1 (0–2)	<0.001
Pad test, mL/day	400 (300–700)	10 (0–100)	18 (0–105)	<0.001
ICIQ-SF	17 (15–18)	5 (0–7)	5 (0–7)	<0.001
PGI-I	4 (4–4)	2 (1–2)	1 (1–2)	<0.001
Q_{max}, mL/s	17 (15–19)	14 (13–15)	15 (13–16)	<0.001
Voiding volume, mL	155 (110–200)	190 (156–215)	192 (155–254)	<0.001
PVR, mL	0 (0–0)	0 (0–14)	0 (0–10)	<0.001
VAS	0 (0–0)	1 (0–2)	0 (0–1)	<0.001
LANSS	0 (0–0)	0 (0–3)	0 (0–0)	<0.001

- Overall success rate: 90% over medium term: 31mo
- Median pad usage: 4 to 1ppd
- 20% devices removed: Ti port intolerance (41%), malfunction (30%)

BJUI 2017;119:785-92

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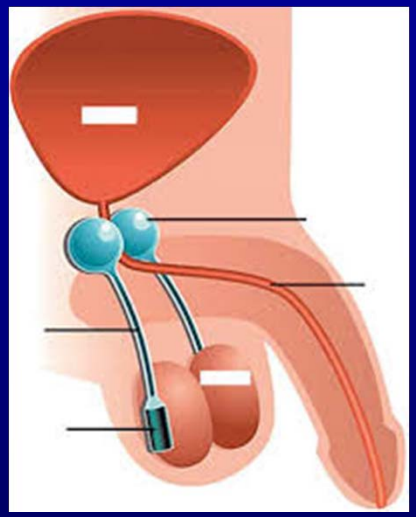
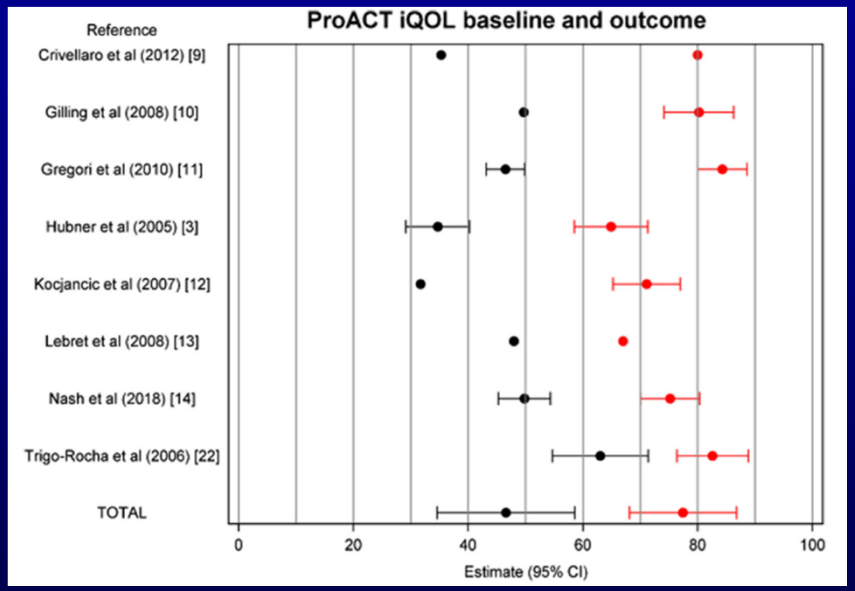
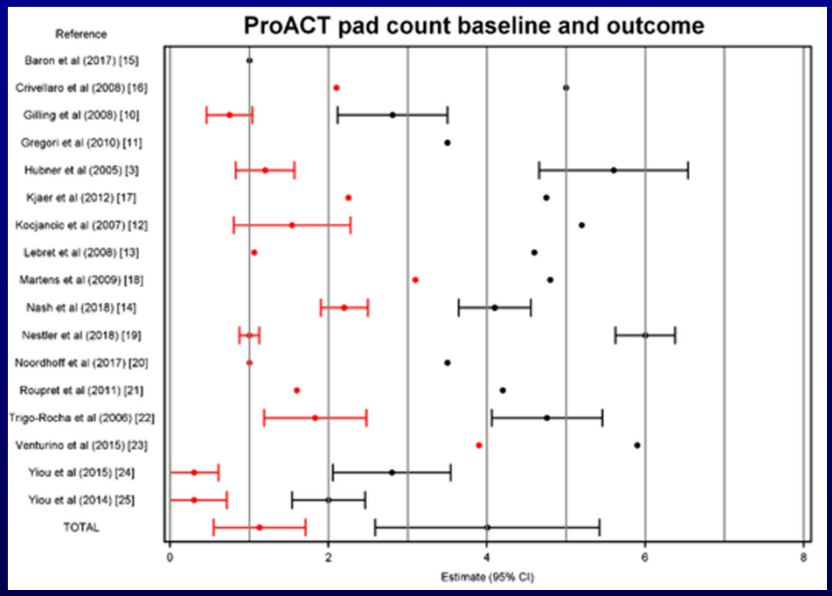
ProAct



- Adjustable device using 2 silicon balloons with a titanium port placed transperineally
- Low morbidity, low cost, lack of circumferential urethral dissection
- Initial series with higher complication rates but more recent studies show safety and efficacy in patients with moderate SUI

Adjustable continence therapy (ProACT) for the treatment of male stress urinary incontinence: A systematic review and meta-analysis





- 19 study meta-analysis
  - 30.8 point (66%) improvement in I-QOL
  - Average: 4ppd to 1.1ppd with 60.2% dry rate
  - Complication: 5% intraop perforation, 2.2% infection, 1.5% retention
  - Revision rate: 22.2% over 3.6 years

Neurourol Urodyn 2019;38:2051-9

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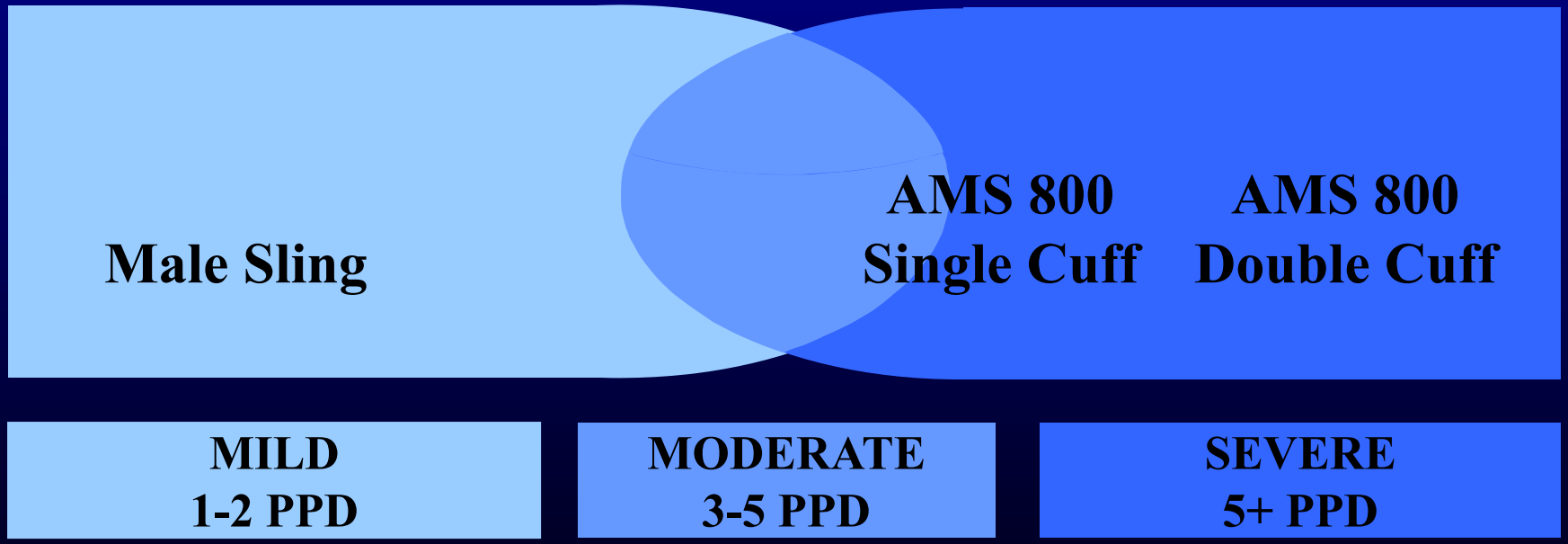
Artificial Urinary Sphincter

The AMS 800 is the gold standard, time-tested surgical solution for control of moderate to severe stress urinary incontinence.



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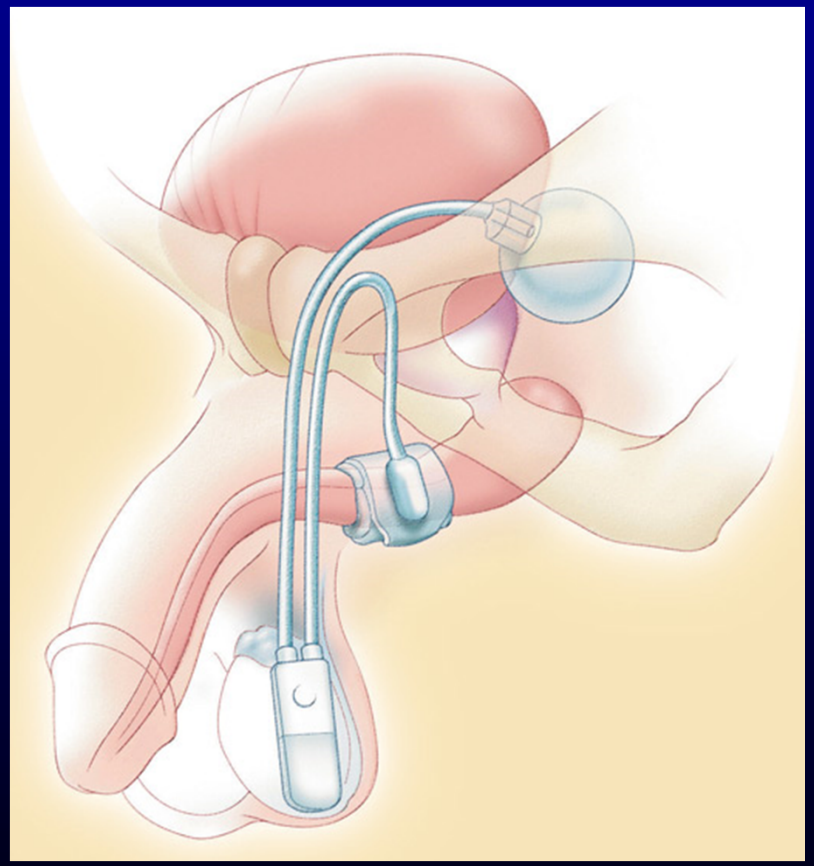
PPD figures according to Singla, New Perineal Bone-Anchored Male Sling: Lessons Learned, Urology, 64:58-61 July, 2004.

Artificial Urinary Sphincter

- Hydraulic device used to coapt urethra



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13 Years of Experience With Artificial Urinary Sphincter Implantation at Baylor College of Medicine

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THE JOURNAL OF UROLOGY® Vol. 177, 1021-1025, March 2007

TABLE 1. *Patient demographics*

No. pts	218
Mean ± SE age (range)	67.3 ± 0.7 (18.9–85.3)
No. men/women	215/3
No. bulbar urethral/bladder neck cuff	216/2
No. cm cuff size (%):	
4.0	48 (22)
4.5	145 (71)
5.0	11 (5)
6.0	1 (bladder neck cuff)
7.0	1 (bladder neck cuff)
No. pressure regulating balloon (cm H_2O):	
61–70	215
51–60	3 (radiotherapy in 2)
Preop pad use (No. pads/day):	
Mean ± SE	5.3 ± 0.2
No. 1 (%)	6 (3)
No. 2–3 (%)	40 (18)
No. 4–5 (%)	37 (17)
No. greater than 5 (%)	135 (62)
Postop pad use (No. pads/day):	
Mean ± SE	1.1 ± 0.1
No. 0 (%)	77 (35)
No. 1 (%)	74 (34)
No. 2–3 (%)	20 (9)
No. greater than 3 (%)	47 (22)

TABLE 4. *Complications and management outcomes*

Complications + Management	No. Pts
Cellulitis/wound abscess:	4
Successful antibiotics + local drainage	3
Underlying device infection, AUS removed	1
AUS infection without erosion:	8
Immediate removal of all components	4
Failed salvage (removed remaining components)	3
Successful cuff and pump salvage	1
Total infection (%)	12 (5.5)
Leakage at pump neck	4
Leakage at pressure regulating balloon	2
Leakage at tubing/connector	2
Pump failure	2
Leakage at cuff	1
Total mechanical failure (%)	13 (6.0)
Downsizing existing cuff:	7
Recurrent atrophy at 75 mos	1
Leakage at reservoir tubing	1
Success	5
Placing tandem cuffs:	9
Cuff erosion at 1 + 27 mos	2
Leakage at tubing, infection, removed at 4 mos	1
Success	6
Downsizing and placing tandems	3
Total urethral atrophy (%)	19 (9.6)
Removal of all or part of components	8
Intractable urge incontinence (greater than 3 pads/day)	7
Intractable bladder neck contracture	5
Loss of hand dexterity (stroke)	1
Refused surgical revision	1
Total nonfunctioning AUS (%)	22 (10)

J Urol 2007;177(3):1021-5

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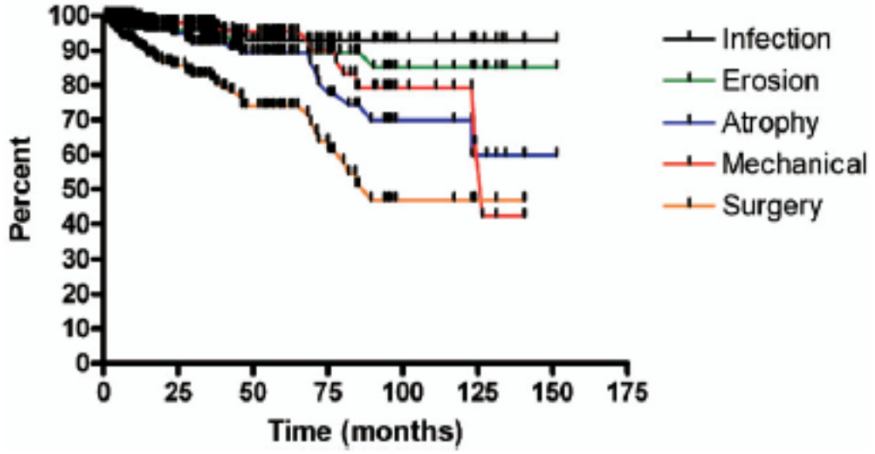
TABLE 2. *AUS complications*

	Overall	Prostatectomy		Neurogenic Bladder*	Secondary Implantation†
		No Radiation	Pelvic Radiation		
No. pts	218	116‡	60‡	11	31
Mean age	67.3	68.7	70.0	46.3§	65.2
Mean followup (mos)	36.5	38.6	40.5	28.5	23.9
Mean pads/day:					
Preop	5.3	5.2	5.6	5.7	6.0
Postop	1.1	1.0	1.4	0.13	1.2
% Infection	5.5	6.9	3.3	9.1	3.2
% Cuff erosion	6.0	5.2	5.0	9.1	9.7
% Urethral atrophy	9.6	12.1	3.3	9.1	12.9
% Mechanical failure	6.0	8.6	1.7	0	6.5
% Surgical revision or removal	27.1	30.2	20.0	36.4	25.8
% No function at last followup	10.1	8.6	15.0	9.1	6.5

* Including spinal cord injury, spina bifida, tethered cord and pelvic fracture.
† Patients presented to Baylor College of Medicine with AUS complications, including 16 with prior infection or erosion with AUS already removed, 3 with tubing leakage, 6 with mechanical failure, including pump failure in 3, and 6 with urethral atrophy.
‡ Total of 176 patients includes 160 with radical retropubic prostatectomy and 16 with transurethral prostate resection.
§ $p < 0.0001$.



Kaplan-Meier complication curves

J Urol 2007;177(3):1021-5

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Reasons for Revisions

Of 554 men undergoing AUS implantation – 21% had revision. Of those:

- Mechanical – 25%
  - Cuff leak – 16 cases
  - Other leak – 8 cases
  - Pump malfunction – 3 cases
- Non-mechanical – 75%
  - Atrophy – 63 cases
  - Cuff size – 4 cases
  - Erosion – 21 cases

Webster G. et al. *J Urol*. 173; 1242.

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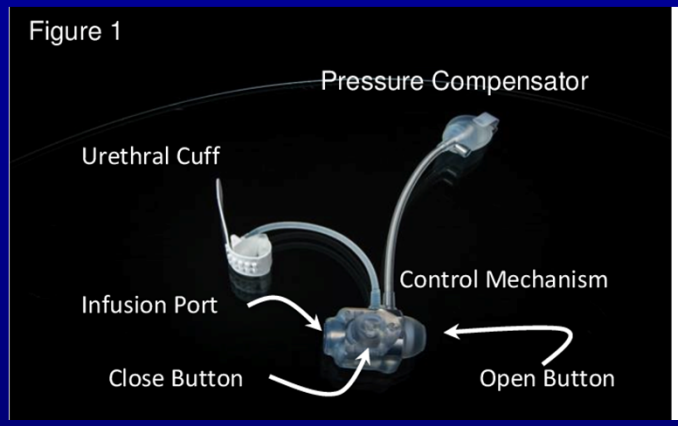
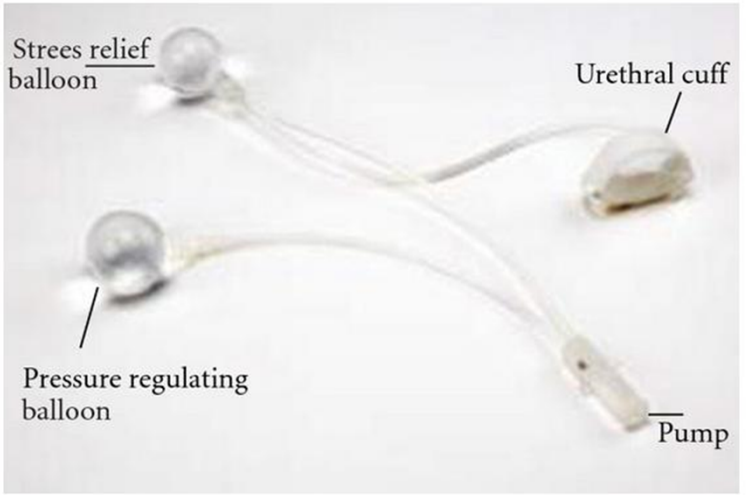
Other alternatives: AUS



- Aroyo
  - Pre-connected, one-touch system with on-demand occlusive pressure increases
  - RELIEF II trial with 48 of 82 men recruited
  - 7 to 2.8ppd reduction
  - SAE rate: 15%

Other alternatives: AUS

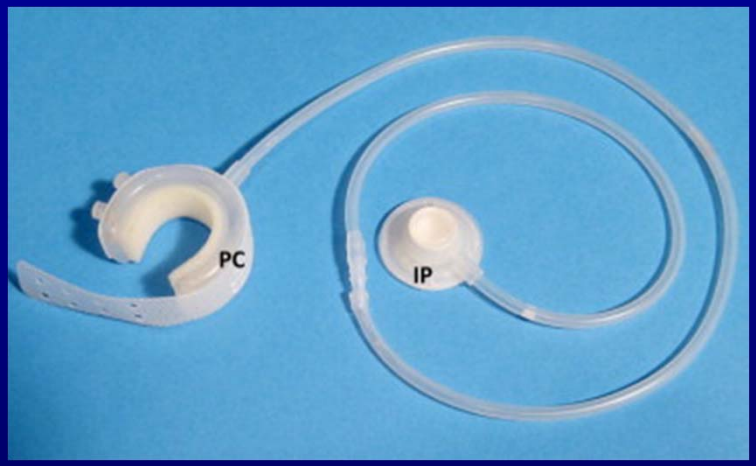


- Zephyr Surgical Implants (ZSI) 375
  - Less complex AUS
  - 50 patients treated from 2013-17
  - 30% achieved improvement (50% fewer ppd)
  - 12% failure rate

- FlowSecure
  - Less complex AUS
  - Mean ppd decreased from 3.3 to 1.6

Cent European J Urol 2018;71(3):320-25
Arch Esp Urol 2009;62(1): 845-50
Sage Open Med Case 2019:23: 7

Other alternatives: AUS



- Silimed Lima Periurethral Constrictor
  - Less complex and expensive AUS
  - 78% complication rate in 30 men, including 23 urethral erosion and 1 rectourethral fistula
  - Risk of erosion elevated in irradiated patients

- VICTRO from AUA 2019
  - 52 patients treated from 12/16-10/18
  - Continence rate: 53.3% (max 1ppd)
  - Ppd improved from 6.4 to 1.6
  - Overall satisfaction: 83.8%

Urol Int 2016;97:26-31
AUA 2019

Treatment of Post-prostatectomy Incontince

- Many options to treat post-prostatectomy incontinence
  - Traditional delineation between slings vs. AUS by severity of incontinence has been blurred by presence of adjustable slings
- New artificial urinary sphincters simpler (fewer parts) and potentially less expensive but less experience than AMS800
- Don’t forget about need for manual dexterity
  - All systems fare worse with irradiated patients!

Thank You

Weill Cornell