Controversies in the Management of Post-Prostatectomy Incontinence
Workshop 17
Monday 23 August 2010, 14:00 – 17:00

Time	Time	Topic	Speaker
14.00	14.00	Introduction	Ajay Singla
14.00	14.30	Pathophysiology & office evaluation of Post-prostatectomy incontinence:	Craig Comiter
14:30	15:00	Bone-Anchored Male sling in the management of PPI:	Ajay Singla
15:00	15:30	Role of ProAct in Post-prostatectomy incontinence:	Ervin Kocjancic
15:30	16:00	Break	
16:00	16:30	Artificial Urinary Sphincter, The Gold standard:	Sender Herschorn
16:30	17:00	New on the Horizon- Male TOT system, Virtue Male Sling:	Jacques Corcos
17:00	17:15	Q&A and Case Presentation:	All

Aims of course/workshop

This course is designed to give the specialist an understanding of pathophysiology of this particular problem in men. Its evaluation and management in detail will be discussed. This course in particular will focus on newer treatment modalities in the treatment of post-prostatectomy incontinence especially bone anchored male sling, TOT male sling and ProAct. Details of the steps of the surgical procedures and the outcome will be reviewed by world renowned experts.

Educational Objectives

1. To discuss the prevalence and pathophysiology of post-prostatectomy incontinence in men.
2. To describe the pre-operative office evaluation.
3. To familiarise the audience with bone-anchored male sling, including its surgical technique outcome in detail.
4. To compare bone anchored male sling with the other alternative options for treating male stress urinary incontinence including collagen implant, as well as artificial urinary sphincter.
5. To provide overview of other alternative therapies for post-prostatectomy incontinence including TOT, ProAct.
6. To discuss the role of AUS-the gold standard.
7. To discuss how to manage a patient with recurrent SUI

Male Stress Incontinence: evaluation & non-surgical therapy

Craig Comiter, M.D.
Stanford University Medical Center

Classification

- Sphincter related
  - Post-operative
    - Post-prostatectomy for cancer
    - Post-prostatectomy for benign disease
    - TURP and radiation for cancer
    - Post-cystectomy and neobladder
  - Post-traumatic
    - After membranous urethral reconstruction
    - Pelvic floor trauma
    - Persistent pediatric incontinence
    - Exstrophy and epispadias
- Bladder related
  - Refractory detrusor overactivity incontinence
  - Small fibrotic bladder
- Fistulae

Herschorn: 4th International Consultation on Incontinence

Incidence of PPInc

- Incontinence after TURP
  - 1.2% AUA cooperative study (Mebust 1992)
  - Probably less with newer thermal therapies
- Radical prostatectomy
  - Physician assessment, single institution series 5-8%
  - Almost every patient questionnaire study >7-8% use pads, most much higher

Author	# pts.	Age	Def 1 dry	Def 2 Occ leak/no pad	Def 3 ≤ 1 pad	Surgery
Kielb	90	59.6	76%		99%	RRP
Sebesta	675	<65	43.7%	69.2%	82.2%	RRP
Lepor	92	58.7	44.6%		94.6%	RRP
Olsson	115	65.2	56.8%	78.4%	100%	LRP
Madalinska	107	62.6	33%	65%		RRP
Deliveliotis	149	66.5		92.6%		RRP
Harris	508	65.8		96%		RRP
Maffezzini	300	65.5		88.8%		RRP
Hoffman	83			74.7%	88%	RRP +/- Rx
Ruiz-Deya	200	63			93%	RRP
Augustin	368	63.3			87.5%	RRP
Rassweiler	219	65			89.9%	RRP
	219	64			90.3%	LRP

Prevalence of PPSUI

- Most of these patients are managed with collection devices
- Huge untreated prevalence of disease
  - Patients not informed
  - Treatment options too morbid
  - Treatment options inadequately effective
  - Loss of confidence in medical system
- Great opportunity for new technology

Impact of PPInc

- Incontinence closely linked to loss QoL
  - Severity of UI correlates with bother
  - Medicare survey > ½ rate medium/big problem
- Greater effect than impotence
- But, not all men who leak will elect further treatment. Most large cohort studies indicate that between 6% and 9% of patients undergo subsequent surgical treatment for PPI following prostate cancer surgery.

» Penson et al; J Urol 2005; 173: 1701; Begg et al: NEJM 2002; 346: 1138; Steineck et al: NEJM 2002; 347: 790; Stanford et al: *JAMA 2000;* 283: 354

Literature Search

Post-Prostatectomy Incontinence

- Leach and Yun (1992 then 1996)
  - 56% detrusor overactivity
  - 82% sphincteric dysfunction
  - Only 40% pure sphincter dysfunction
- More recent UDS data:
  - ISD alone in > 2/3
  - DO, poor C, DUA in < 10%
- However, sphincter and bladder dysfunction can coexist in at least one third of incontinent patients.
  - Herschorn, et al: Neurourol Urodyn. 2010;29(1):179-90.

Argument

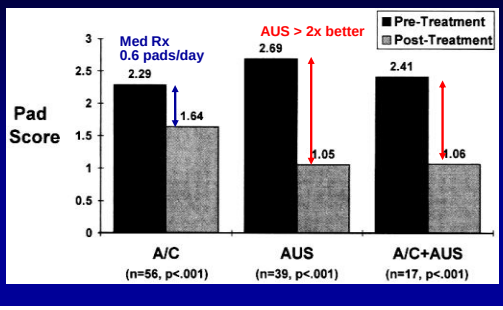
"In our large series most men with prostatectomy incontinence did not have genuine stress incontinence alone. Thus, urodynamic studies are critical, not only to define cause of incontinence but to direct effective therapy."

Leach GE, Trockman B, Wong A, et. al.
J Urol. 1996 Apr;155(4):1256-9.

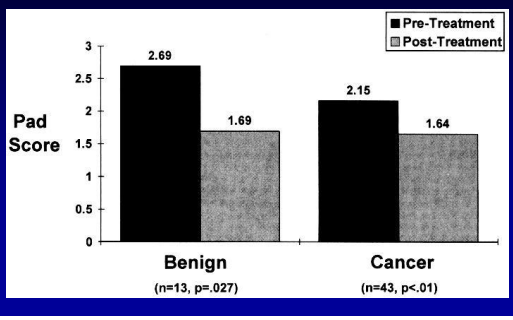
Medical Treatment PPInc

	No. Pts.	No. Anticholinergic Therapy (%)	No. Artificial Urinary Sphincter (%)	No. Anticholinergic Therapy and Artificial Urinary Sphincter (%)
Radical retropubic prostatectomy	102	48 (47)	35 (34)	19 (19)
Radical perineal prostatectomy	6	3 (50)	2 (40)	1 (17)
Transurethral resection of prostate	23	14 (61)	6 (26)	3 (13)
Open surgery	5	3 (60)	2 (40)	

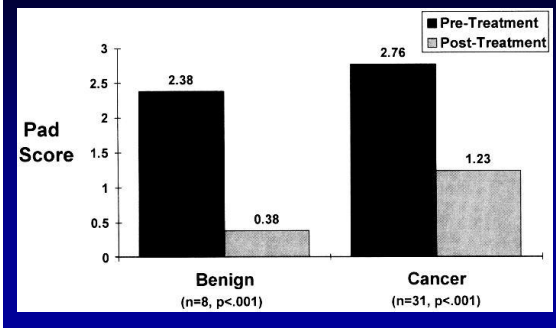
Comparative Effects of Therapy



Anticholinergics for PPInc



AUS for PPInc



The Bottom Line

- Success comes with treatment of the sphincter dysfunction:
  - Chao and Mayo 1995
  - Gudziak et. al. 1996
  - Desautel et. al. 1997
  - Ficazzola and Nitti 1998
  - Winters et. al. 1998
  - Groutz et. al. 2000

PP Inc Prospective Evaluation 01

- 63 consecutive RRP patients with UDS 1 week pre-op and 2 months post-op
- Pre-op 25% DO, 19% BOO
- 32% incontinent at 2 months
  - 29% SUI vs. 3% DO

Majoros et. al. NeuroUrol & UDS 25:2-7 (2006)

PP Inc Prospective Evaluation 01

- Almost all PPInc is SUI
- Pre-op factors:
  - DO not predictive
  - MUCP not predictive

Majoros et. al. NeuroUrol & UDS 25:2-7 (2006)

PP Inc Prospective Evaluation 02

- 49 consecutive RRP patients with UDS 1 week pre-op and 1 & 8 month post-op
- Pre-op 55% DO, 57% BOO
- Transient increase in hypocontractility and poor compliance at 1 month
- Strong correlation between ISD (32%) and DO (60%) at 8 months (but most DO was present pre-op)

Giannontoni et. al.: J Urol 171:1563-66, 2004

PPInc Evaluation: Goals

- Confirm and quantify severity of SUI
- Rule out significant DO component
- Confirm normal voiding dynamics
- Rule out BNC, evaluate sphincter fibrosis

Tools for Patient Evaluation

- Bladder diary
- Pad testing
- Urodynamics
  - Filling Cystometry
  - Uroflow-PVR vs. pressure-flow
  - VLPP
- Cystoscopy

Confirm & Quantify SUI

- Abdominal/valsalva leak pressure
- Pad testing

UDS for Male SUI

- Correlation of ALPP, MUCP, RLPP
- All studies gave similar mean values
  - RLPP 48.0 ± 13.5cm H_2O
  - MUCP 52.0 ± 21.1cm H_2O
  - ALPP 49.4 ± 24.4cm H_2O
- Correlation to ALPP 0.75-0.80

Only ALPP demonstrates SUI

Comiter. Urology 62:75-8, 2003

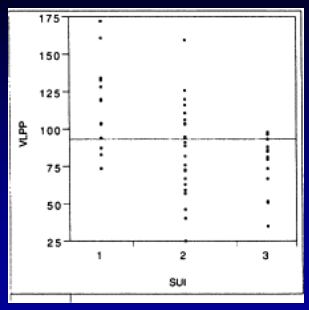
Leak Pressure in PPInc

- ALPP not standardized
- General agreement that urethral catheter should be removed in men
  - Many men don't leak with catheter in
  - LPP 70cm H_2O with urethral cath, 56cm with rectal only[1], 86cm vs. 67cm in another[2]
- ALPP correlates poorly with severity of incontinence[2]

[1]Flood. J Urol 156:1737 (1996)

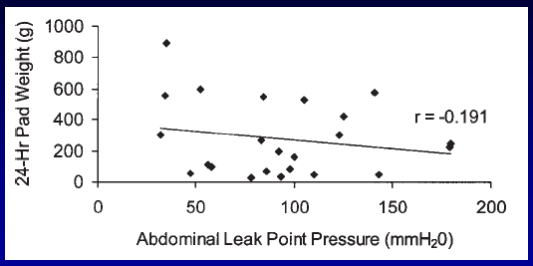
[2]Twiss. NU & UDS 24:207-210 (2005)

Leak Pressure vs. SUI Grade



Ficazzola & Nitti. J Urol 160:1317-1320 (1998)

Leak Pressure vs. Pad Weight

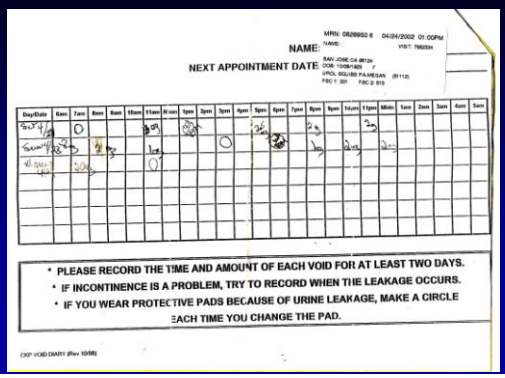


Twiss. NU & UDS 24:207-210 (2005)

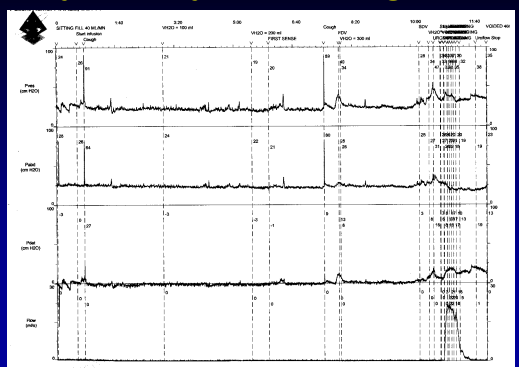
Evaluate Storage Function

- Bladder diary
- Filling cystometry
- Primarily useful in counseling patients, identifying severe bladder dysfunction
- Avoid UDS with indwelling catheter

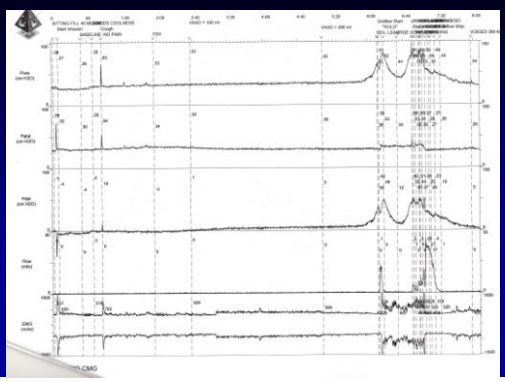
Bladder diary



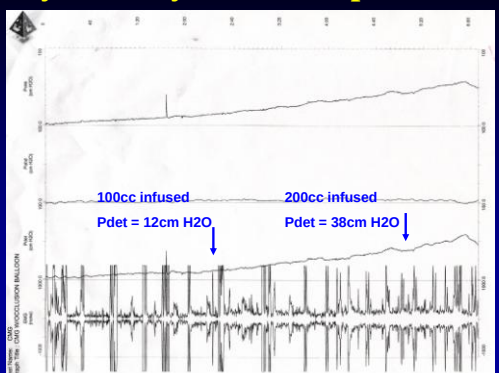
Cystometry—Good Prognosis



Cystometry—Intermediate Prognosis



Cystometry: Non-compliant fill

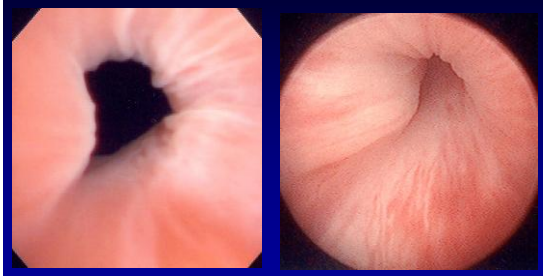


Evaluate Voiding Function

- History, flow, PVR usually adequate
- Pressure-flow studies done on as needed basis
- Normal bladder contractility necessary if sling is being considered

Expect normal voiding with SUI, be concerned about low and erratic flows

Sphincter Assessment



Ideal Result

Basic Treatment of PPInc

- Pelvic floor rehabilitation
  - PFMT
  - Biofeedback
  - Other (E-stim, magnetic stim, etc.)
- Medical Therapy
  - OAB
  - SUI
- Injection therapy
- Compression devices

Pelvic Floor Muscle Training

Pelvic Floor Muscle Training

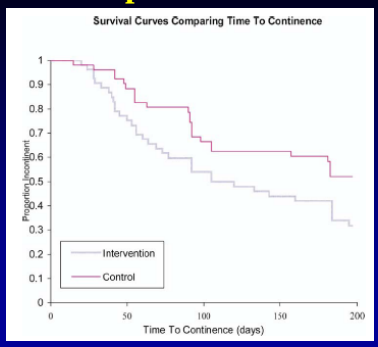
- Variables to consider:
  - Pre-op or Post-op
  - If post-op, when initiated
  - Routine teaching or biofeedback assisted
  - Number of sessions
  - Improved overall continence or faster return to continence

Pre-op PFPT for RRP

- 200 patients contacted
- 125 men age 53 to 68 enrolled
- Randomized to receive
  - One session biofeedback assisted training plus home exercises
  - Routine post-op instructions

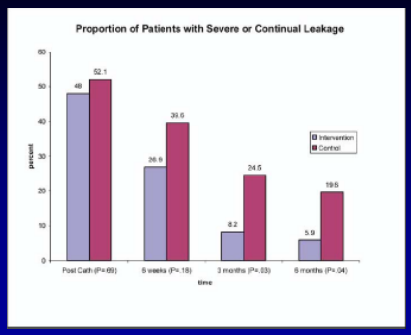
Burgio et. al.: J Urol 175:196-201, 2006

Pre-op PFPT for RRP



Burgio et. al.: J Urol 175:196-201, 2006

Pre-op PFPT for RRP



Burgio et. al.: J Urol 175:196-201, 2006

Pre-op PFPT for RRP

- Conclusions:
  - Pre-op PT hastens return of continence
  - Pre-op PT reduces severity of post-prostatectomy incontinence

Burgio et. al.: J Urol 175:196-201, 2006

Post-op Physiotherapy RCT

- 102 men with RRP, stratified and randomized after catheter removal
- Treatment group received individual weekly therapy—PFMT, bio, stim
- Placebo group instruction and sham electrotherapy only
- Treatment for one year or continence

Van Kampen: Lancet 2000;355:98-102

Post-op Physiotherapy RCT

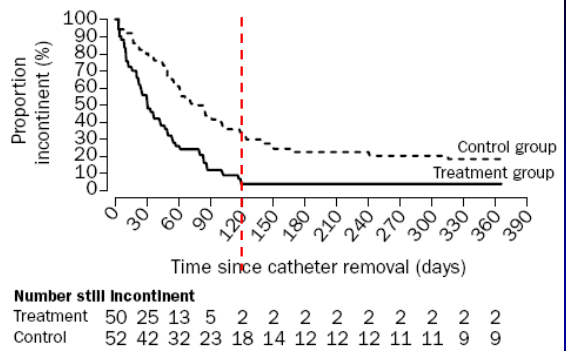
- Continence defined as <2gm urine loss on 1hr & 24hr pad test, no leak x 3 day
- Power to detect 25% difference

Van Kampen: Lancet 2000;355:98-102

Post-op Physiotherapy RCT

- Number of treatments:
  - Treatment group = 8 (1-50)
  - Placebo group = 16 (2-47)
- 12 month continence rates
  - Treatment group 48/50 (96%)
  - Placebo group 43/52 (86%)
- Only one patient in each group >100gm/24hr urine loss

Van Kampen: Lancet 2000;355:98-102



Pad test results over time

Time since catheter removal	Urine loss on 24 h pad test (g)	
	Treatment group	Control group
1 day	416	440
1 week	206	330
1 month	88	166
2 months	30	82
3 months	13	26
4 months	8	13
5 months	9	6
6 months	5	3
12 months	8	3

PPInc Therapy: 3 arm RCT

- 139 men, incontinent at catheter removal after RRP
  - PFME instructions only
  - Instructions + EStim BID (anal electrode)
  - Instructions + Stim + Biofeedback
- Continence
  - 0 or 1 pad per day
  - <1gm urine loss on 20 min test

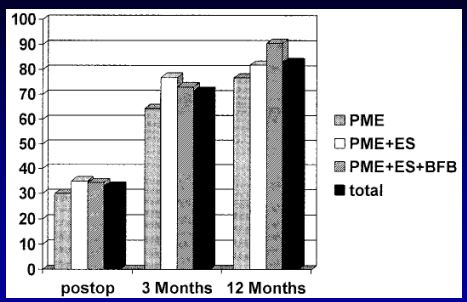
Wille: J Urol 2003;170:490-493

PPInc Therapy: 3 arm RCT

- No differences between treatment groups at either 3 or 12 months
- Compliance with therapy drops off dramatically after two months (>90% to 50-60%)

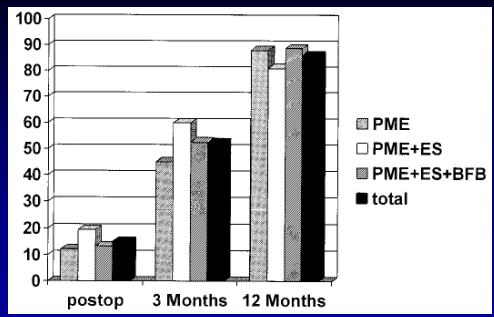
Wille: J Urol 2003;170:490-493

Results: Pad test



Wille: J Urol 2003;170:490-493

Results: Subjective continence



Wille: J Urol 2003;170:490-493

Early Intensive PT after RRP

- 107 incontinent at cath removal
- Treatment group received digital feedback and E Stim if needed, up to one year
- Home exercises 3 x 15 daily
- Dry < 2gms on pad test

Manassero et. al.: NU & UDS 2007

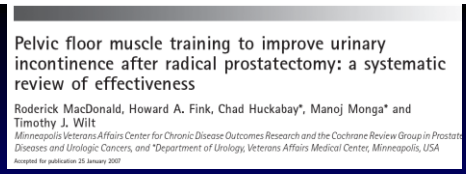
Early Intensive PT after RRP

- Clear treatment effect seen throughout
  - Percentage of incontinent patients
  - 1 month: 83.3 vs. 97.5
  - 3 months: 53.7 vs. 77.5
  - 6 months: 33.3 vs. 60
  - 12 months: 16.6 vs. 52.5

Manassero et. al.: NU & UDS 2007

Conclusions

- Training with biofeedback before RRP may improve outcomes
- Therapy for incontinent men after RRP may speed return of continence
- We don't have the ability to select the patients who need intervention



Pelvic floor muscle training to improve urinary incontinence after radical prostatectomy: a systematic review of effectiveness

Roderick MacDonald, Howard A. Fink, Chad Huckabay*, Manoj Monga* and Timothy J. Wilt

Minneapolis Veterans Affairs Center for Chronic Disease Outcomes Research and the Cochrane Review Group in Prostatic Diseases and Urologic Cancers, and *Department of Urology, Veterans Affairs Medical Center, Minneapolis, USA

Accepted for publication 25 January 2007

- PFMT +/- biofeedback does NOT speed return to continence more than no PFMT
- There is inadequate information to assess effectiveness of electrical or magnetic stimulation

BJU Int 100(2007):76-81

What about a pill?

Medical Therapy of Male SUI

- Literature review
- 9 papers on α-agonists, β2 agonists, SRIs
- Poor quality, level 4 evidence

Tsakaris et. al. Eur Urol 53(2008):53-59

PPInc Medical Therapy--β2 agonists

- Clenbuteral, selective ß-2 agonist
- Not FDA approved for human use
- 14 men with UI after RRP
- At one month 9/14 (64%) were markedly improved
- 5 patients severe incontinence failed

Noguchi: Int J Urol 1997 Sep;4(5):480-3.

PPInc Medical Therapy--SRIs

- 20 patients, no controls
- 3 weeks SUI despite PFMT
- Duloxetine 40mg BID
- 7 patients 0-1 pad, mean decrease 50%
- 6 patients severe side effects

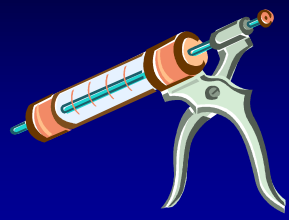
Schlenker: Eur Urol 2006;49(6):1075-8

PPInc Medical Therapy--β2 agonists

- RCT 112 patients with SUI 10 days after catheter removal
- PFMT vs. PFMT + Duloxetine 40mg BID
- At 16 weeks more dry with Duloxetine (p = 0.007), reversed when med stopped
- 15.2% adverse events with Duloxetine

Filacamo et. al.: Eur Urol 51(2007), 1559-1564

How about a needle?



Is There a Role for Injections?

- Essentially all data with bovine collagen
  - "Success" 36-69%
  - Less than 20% get dry
  - Reinjections indefinitely over time
- Multiple injections required
- Antegrade technique proposed. . . died

Long-term collagen results

- 322 ♂ one center, mean f/u 40 months
- Mean injections 4.4 ± 2.1
- 44% response, pad use 5.12 to 3.0
- Mean duration response 6.3 ± 8.1
- 17% dry, mean duration 11.1 ± 8.9 months (mean collagen 29.3cc)
- 1.5% got worse

Westney OL et. al.: J Urol 174(2005):994-997

What Might Be Done?

- Newer materials:
  - Silicone particles (Macroplastique)
  - Calcium Hydroxylapatite (Coaptite)
  - Cross linked hyaluronic acid (Deflux)
  - Stem cells
- Improved needle

Macroplastique vs. AUS

- 45 patients (not total incontinence) after RRP, TURP, TVP randomized
- 21 minimal incontinence (Group 1)
- 24 total incontinence (Group 2)
- No detrusor overactivity
- Minimum follow-up 6 months

Imamoglu MA, Tuygun C, Bakirtas H, Yigitbasi O, Kiper A
Eur Urol. 2005 Feb;47(2):209-13

Macroplastique vs. AUS

- Minimal group
  - ≤ 2 pads/day
  - 100gms total urine loss
  - QoL ≤ 30
- Average Macroplastique 5-7.5cc
- Up to two injection procedures under spinal or general

Imamoglu MA, Tuygun C, Bakirtas H, Yigitbasi O, Kiper A
Eur Urol. 2005 Feb;47(2):209-13

Macroplastique vs. AUS

- Group I
  - 10 patients—8 dry, 1 improved, 1 fail
  - 11 AUS—10 dry, 1 improved
- Group II
  - 13 injections—3 dry, 5 improved, 3 fail
  - 11 AUS—8 dry, 2 improved, 1 fail

Imamoglu MA, Tuygun C, Bakirtas H, Yigitbasi O, Kiper A
Eur Urol. 2005 Feb;47(2):209-13

Macroplastique vs. AUS

- Group I Macroplastique results
  - Pads 1.52 reduced to 0.34
  - Daily pad weight 84 reduced to 20gms
- Both $p < 0.001$

Imamoglu MA, Tuygun C, Bakirtas H, Yigitbasi O, Kiper A
Eur Urol. 2005 Feb;47(2):209-13

Macroplastique in Male SUI

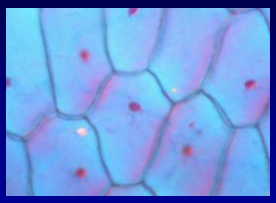
- 50 consecutive male patients
- 46 RRP, no detrusor overactivity
- Mean 1-hour pad test 48gms
- 1 to 4 treatments
- 30 dry, 12 improved, 8 no change
- No follow-up detailed

Kylmala T, Tainio H, Raitanen M, Tammela TL
J Endourol. 2003 Mar;17(2):113-5

Summary

- Injection therapy only for highly selected patients:
  - SUI mild (I use <100gms)
  - No detrusor overactivity
  - Sphincter looks supple on cystoscopy
  - No XRT, bladder neck procedures/scar
- Small chance of worsening incontinence (2-5%)

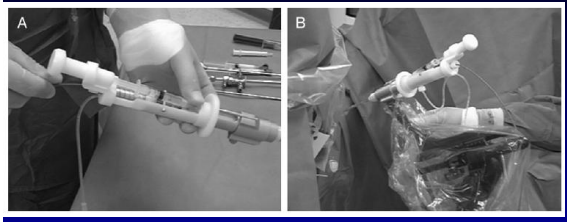
The Future

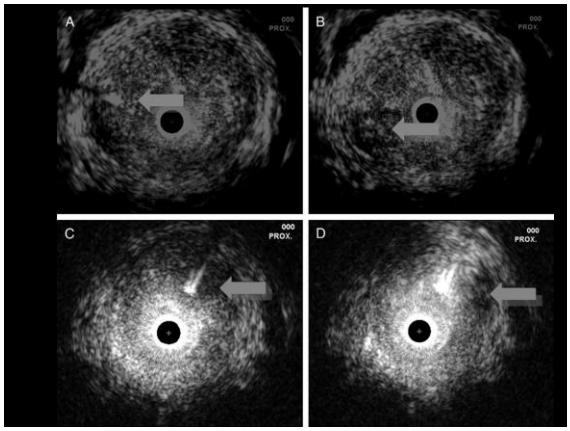


Stem Cell Injections

- Autologous myoblasts and fibroblasts harvested from bicep biopsy
- 63 men injected from 1/04 to 12/05
- All injections performed with U/S
- Outcome measured at one year

Mitterberger et. al.: J Urol 179(2008):226-231





Myoblast/Fibroblast results

- 41/63 dry (no pads) and 17 improved
- Incontinence scores decreased from 6 to 1 (based on pad test, diary, questionnaire)
- None worse, no retention beyond 24 hours

Compression Devices

- Comparison of Cunningham clamp, C3, and U-Tex penile compression devices
- 12 men used each in four hour pad test:
  - Cunningham 17.1gms
  - C3 32.3gms
  - U-Tex 53.3gms
- Cunningham reduced penile blood flow

Moore KN et. al.
Urology 63:150-154, 2004

The Minimally Invasive Procedure for Male Stress Urinary Incontinence-The Male Sling

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And Voiding Dysfunction
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Objectives

1) To familiarize the audience with bone anchored male sling, including its' technique, indications, and the outcome.
2) To discuss the pre-operative evaluation prior to the procedure.
3) To discuss the surgical technique in more detail and post-operative instructions.
4) To discuss various published literature and the surgical outcome in more detail.
5) To compare bone anchored male sling with the other alternative options for treating male stress urinary incontinence including collagen implant, as well as artificial urinary sphincter.
6) To provide the algorithm and the various guidelines to treat patients with extrinsic sphincter deficiency.

Procedure

Bone anchored male sling has been a recent addition in the management of post prostatectomy incontinence. The cause of urinary incontinence following radical prostatectomy is extrinsic sphincter deficiency which leads to stress urinary incontinence in men. Initial management of stress urinary incontinence is usually conservative, consisting of kegel exercises and use of pads. When these measure fail, various treatment options have been used, including collagen, implantation of artificial urinary sphincter. Recently sling procedures have been developed either using vascular graft material under the bulbas urethra or a bone anchored male sling using synthetic prolene mesh. The bone anchored sling is placed perennially and six titanium five millimeter screws are used. A sling is made of either polypropylene silicone mesh alone or as a composite graft using a four by seven dermis patch. Tension can be applied by either retrograde urethral pressure profilometery keeping the pressure around 60-70 cm. of water and/or by a cough test. The sling is tied after confirming there is no leakage intra operatively. There have been a number of publications over the years regarding the surgical outcome as well as patient satisfaction. These have been published in various peer review journals. All these articles have clearly shown a continence rate around 70% in short as well as intermediate follow up. Similarly, a patent satisfaction rate of 70% was also found with this particular procedure. It has been learned that this particular procedure provide high satisfaction and high continence rates in patients with mild to moderate incontinence and has a good urethral closure function and a high failure rate has been seen in patients who have severe urinary incontinence or poor urethral closure functions. Even in further comparison with collagen implant which has been recommended for patients with mild incontinence, the male sling certainly provides a much better result as compared to collagen injections, 76% versus 29% respectively. Also the collagen injections are needed in more than one occasion and only provide some improvement, if any. Literature found on collagen

implant has clearly shown the poor efficacy of collagen implant in men as compared with collagen injections in women. It appears that bone anchored male sling is a better option as compared to the collagen injection for mild to moderate urinary incontinence.

Advantages of Male Sling include:

1) It provides instantaneous results to the patient as in the case of the artificial urinary sphincter; there is a need for deactivation of the device for four to six weeks.
2) It also provides a more physiological voiding for the patient as compared to the artificial sphincter where the patient has to press the pump to be able to void.
3) It has less risk of erosion or infection as compared to an artificial urinary sphincter.
4) It can be used in patients that have limited manual dexterity or patients that have refused or previously failed or removed artificial urinary sphincter.

Summary

This is an outpatient procedure and is minimally invasive procedure or certainly less invasive procedure as compared to artificial urinary sphincter. We have also compared our results of male sling with artificial urinary sphincter in a retrospective review and found out that the male sling does provide a comparable results with artificial sphincter in mild to moderate incontinence. Certainly artificial sphincter provides a better result in severe incontinence in comparison with bone anchored male sling.

In Conclusion

The male sling is an effective and safe for the management of stress urinary incontinence. Though, the artificial urinary sphincter continues to be a co extender for the treatment of post prostatectomy incontinence in men, but it should be regarded as an additional tool in the management of male stress urinary incontinence. However, a longer follow-up is necessary to confirm the durability of the novel procedure.

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3. Samli, M, **Ajay Singla**. Absorbable versus Non-absorbable graft: Outcome of Bone Anchored Male Sling for Post-Radical Prostatectomy Incontinence. Journal of Urology, vol. 173, 499-502, 2005
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8. Mark Fisher, Neelesh Aggarwal, **Ajay Singla**. Efficacy of AUS implantation after failed Bone Anchored Male sling for post-prostatectomy incontinence. UROLOGY 70 (5): 942-944, 2007
9.

Post orpeative adjustable procedures for male stress urinary incontinence

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INTRODUCTION:

The incidence of urinary Incontinence after prostate surgery is a grossly under reported problem, with a significant variation between reports. Many men do not seek medical treatment, partially due to the relatively ineffective treatment options available. The Artificial Urinary Sphincter (American Medical Systems) is considered the gold standard of surgical intervention however its global adoption is limited somewhat by the cost, the invasiveness of the technique, and therefore the skill of the surgeon to perform the procedure and manage the complications, as well as the need for patient participation in its management.

Ideal device for male SUI

-Should avoid bladder injury (avoid the retropubic pathway)

-Should create enough tension

-Should be an adjustable system

-Adjustment should be possible at any time

WITHOUT surgical intervention

-Should consist of minimal mechanical parts

(Patient compliance, Durability !)

-Should not dislocate or migrate

-Should avoid erosion of the uretra

Adjustable devices

-Pure Slings:

Argus

MR Remex

-Ballooned Slings:

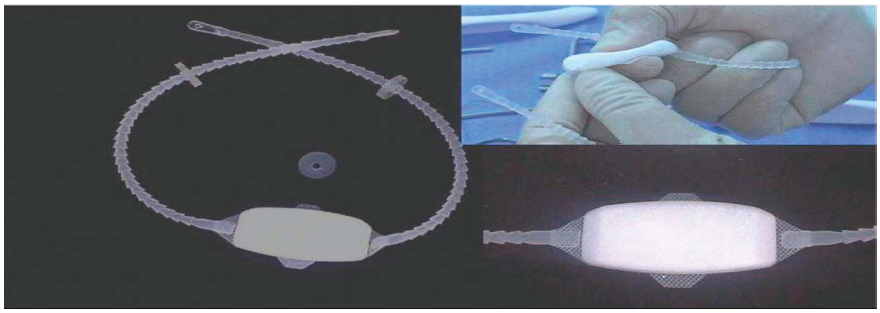
Adjustable Perineal male sling

-Pure Balloons:

ProACT

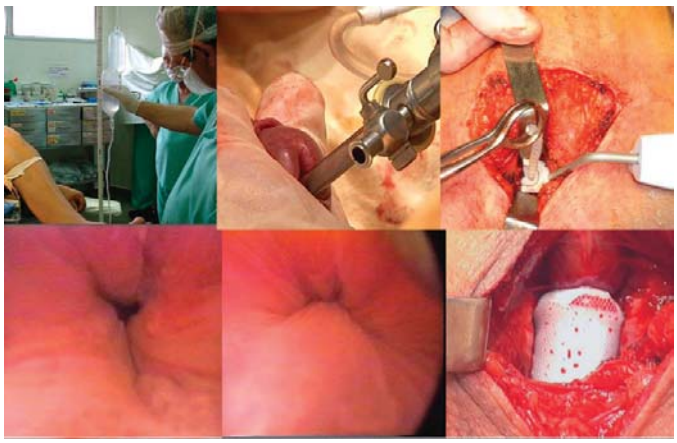
An adjustable male sling for treating urinary incontinence after prostatectomy: a phase III multicentre trial

Romano et al. BJU Int. 2006 Mar;97(3):533-9



The Argus sling components: (1) foam pad; (2) cone columns; and (3) the washers

Adjustment starts by moving the washers with a specially designed 'pusher', up to loosen or down to tighten. It is posiitioned under simultaneous control: urethral coaptation at the desire pressure (45 cmH2O).



Results:

•48 men (mean age 67.7 y, range 52–77)

–Radical prostatectomy (39)
–Simple prostatectomy (9)

•19 wore pads, using a mean (range) of 5 (3–8) pads/day, with weights of 83 g.

•29 used a penile clamp or a condom catheter.
•Cystoscopy and urodynamics were used to determine bladder and sphincteric function (LPP)
–Before surgery the LPP was 23.5 (5–66)
•The ICIQ-SF was used to determine the quality of life
–Before surgery the ICIQ-SF was 19.2 (12–21)

•Follow-up, after 1 and 3 months
•The ICIQ-SF after surgery: 4 (0–21).
•LPP 47.5 (35–55) cmHO
•SUI was cured (dry, no pads) in 35 (73%) patients;
•SUI was improved (≤ pads/day) in 5 (10%).
•Treatment failed in 8 (17%) patients (≥ two pads a day)
•41 (86%) voided at first attempt after removing the Foley catheter;
•7 (15%) patients with acute urinary retention were cured spontaneously after a short period of catheter replacement
•The sling was removed in 3 patients (6%) due to urethral erosion and in 2 (4%) due to infection.

Adjustable Suburethral Sling (Male Remeex System®) in the Treatment of Male Stress Urinary Incontinence

E. Sousea Eur.Urol, Nov 2007

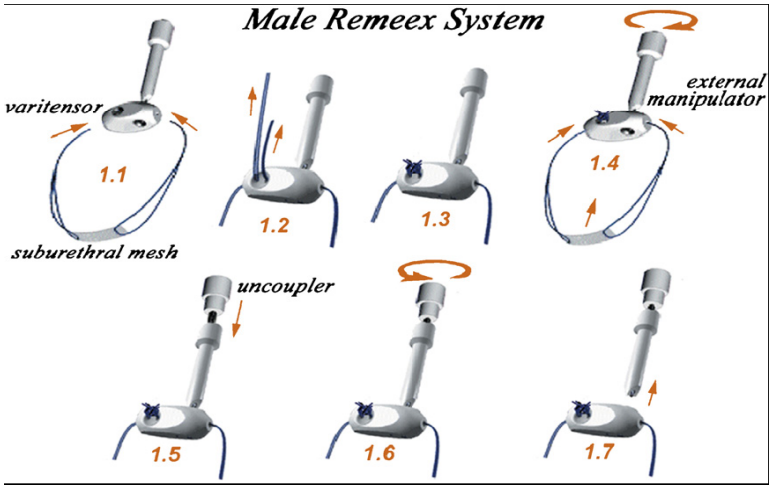
• **MRS consists of:**
• monofilament suburethral polypropilene sling (3- 4 cm) mesh

• suprapubic mechanical regulator (varitensor): a (1x1x2.5 cm) cubic device with an internal never-ending axis to wind the traction threads.

• two monofilament traction threads

• an external manipulator

• a special screwdriver (the uncoupler)

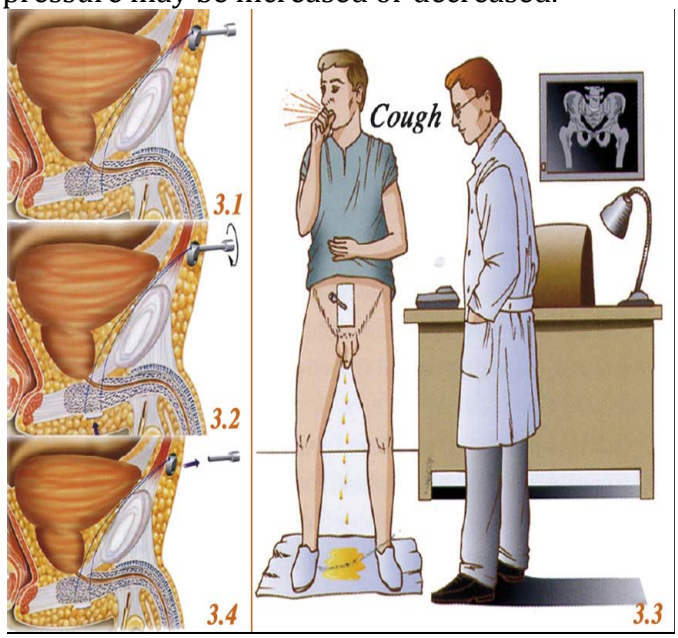


• **MRS function**
• The varitensor allows adjustment of suburethral pressure from outside the body by means of the
Externalmanipulator.

• The uncoupler is used to disconnect and separate the
external manipulator from the varitensor.

• The threads are passed through into the varitensor through two lateral holes and emerge through the central hole at the varitensor midline.

• By rotating the manipulator clockwise or counterclockwise, suburethral pressure may be increased or decreased.



Reulsts:
•51♂: 43 RRP 4 TURP 4 ORP

•9 patients (17.6%) mild incontinence (1–2 pads),

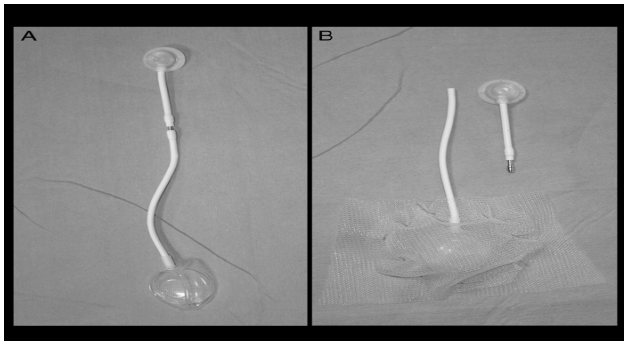
•10 (19.6%) moderate incontinence (3–4 pads),
•32 (62.7%) severe incontinence (5 or more pads).
•44 patients required a second regulation under local anaesthesia between 1 to 4 mo after surgery;
•17 patients required more than one delayed regulation under local anaesthesia;
•33 patients (64.7%)were considered dry
–25 no pads,
–8 only one ‘‘security’’ pad/day
•10 patients (19,6%) showed important improvement
•8 patients (15,7%) remain unchanged

•The average # of pads needed diminished from 4.25 to 1.4 pads per day (f-u 32 mo)
•No patient presented urinary retention during immediate post-op period
•IIQ-7: from 52,8 pre-op to 7,6 post-op

Complications
•1 urethral erosion
•2 infections
•5 bladder perforation
•3 perineal haematomas

A New Device for the Treatment of
Post-Prostatectomy Incontinence: Adjustable Perineal Male Sling Inci K et al, J Urol. 2008 Feb; 179(2):605-9

A,: Tissue expander showing silicone balloon expander, small tube and injection port.
B: Silicone balloon expander in pocket created by suturing 2 polypropylene meshes to each other at center of polypropylene mesh.



•19 consecutive patients with severe incontinence (mean age 67.5 years)
–radical prostatectomy in 10 patients
–TURP in 4
–open prostatectomy in 4
–cystectomy with an orthotopic ileal neobladder in 1
•Seven patients underwent previous surgery for incontinence.

•Average pad use decreased from 10.3 to 2.5 per day.

Surgery

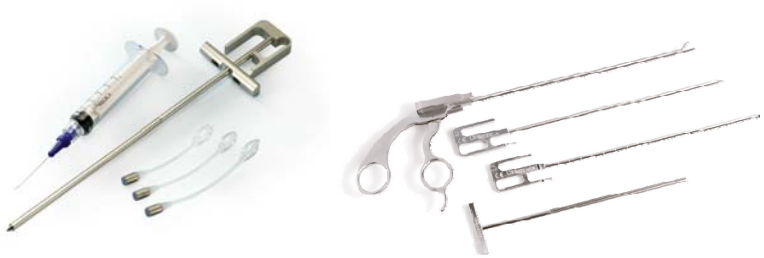
•Lithotomy position.
•Perineal incision was made over the bulbous urethra
•Fatty tissue over the bulbospongiosus muscle was dissected and the medial aspects of the descending pubic ramus were exposed bilaterally
•Three No. 1 polypropylene sutures were inserted into the periosteum of the anteromedial aspect of each ramus

•A round, 3.0 cm in diameter, 10 cc Eurosilicone tissue expander (Laboratoires Eurosilicone, Apt, France) was used as a tissue expander.
•The tissue expander includes a silicone balloon expander, a small tube and a filler dome (injection port) that allows the expander to gradually fill with saline solution.
•A pocket is created to anchor the balloon expander in its position by suturing 2 polypropylene meshes to each other around the filled balloon expander at the center of the 6x6 cm trapezoidal polypropylene mesh.
•The empty silicone balloon expander is inserted into the pocket. It is secured by an additional 2 sutures and the sling is placed over the fatty tissue.

Results

•Mean followup was 17,3 months
–Eight patients (42.1%) were completely dry without any injection
–11 required injection (One adjustment at month 3 after surgery was sufficient in 1 patient, while 10 required 2 or more adjustments)
•The total number of injections was 22
•average number of adjustments was 2 (range 1 to 3)
•average injected saline volume was 6.3 cc
•After implantation 15 men (78.9%) used zero pads daily, 2 men (10.5%) used 1 to 2 and 2 men (10.5%) used 3 or more.
•Average pad use in these patients decreased from 10.3 to 0.6 per day at the end of follow-up.
•Three patients underwent repeat catheterization because of early urinary retention
•2 patients had problems for infections
•No complications related to mesh erosion, de novo voiding dysfunction or mechanical failure occurred.

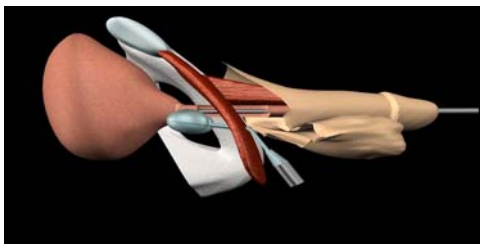
ProACT (Adjustable Balloons)



The ProACT device, developed by Uromedica Inc for the treatment of male stress urinary incontinence is a minimally invasive treatment for this condition, with the unique feature that it is post operatively adjustable if required. It consists of two silicone elastomer balloons placed paraurethrally at the bladder neck in post radical prostatectomy patients or at the level of the membranous urethra in patients who have residual prostatic tissue following benign surgery. Each balloon is attached via a conduit to a titanium port buried in the anterior lateral aspect of the scrotum. Post operative adjustment of the balloon is facilitated by percutaneous injection of the port, a minimum of 4 weeks post operatively, with a 4 week interval between further adjustments. The implant is available in 12 and 14cm length and each balloon can be inflated up to 8cc over time if necessary. The ProACT device can be simply inserted using general, spinal or local anaesthesia as required.

The procedure was performed using similar technique to that reported by Huebner et al. With the patient in lithotomy position, the bladder is emptied and filled with 100 cc of contrast solution. The filling cystoscope is retained to maintain horizontal positioning of the urethra. Two small perineal stab incisions are made on each side of the urethra, to allow passage of the balloons via designated blunt and sharp trocars and outer cannula. The trocar is designed to perforate the pelvic floor and is gently rotated to advance it towards the bladder neck or membranous urethra as appropriate. Image intensification is used to identify the position of the trocar in relation to the urethra and final position. Once in position, the trocar is removed and a tissue expanding device (TED) inserted through the U shaped channel of the cannula. This device dilates only the area where the balloon will be inflated. The choice of device length is generally made based on the patient

anatomical configuration. Prior to insertion, the device is primed to remove all air and is soaked briefly in antibiotic solution. The trocar is removed and the balloon inserted with the assistance of a push wire. Once in position, the balloon is inflated using an isotonic contrast and water mixture using a dedicated non coring 23G needle and syringe. The process is repeated on the contralateral side. A urethrogram should be performed to verify position and a 12 Fr Foley catheter inserted overnight. A superficial pocket is created in the sub dartos fascia of the anterior lateral aspect of the scrotum taking care to ensure that the ports are well separated and able to be accessed easily during post operative adjustments.



Results from different published series:

Huebner
67% dryness rate
Immediate post op. continence (5/117)
Mean No. of adjustments (3 (1 – 15)
Final mean volume 3.5mls (1 – 10)
Immediate post op retention 7/117

Mean Follow-up 13 months. (3 – 54)

•Pad usage decreased from:
6 pre op (1 – 24)
2 @ 3 months (1 – 15)
1 @ 6 months (0 – 6)

•IQoL improved from:
34.7 @ baseline
64.8 @12 months
66.3 @ 24 months

Trigo-Rocha
25 patients

Mean follow –up 22.4 months (range 6 – 48)
Balloon adjustments 4.6 (range 1 – 7)
Final volume 3.5 (2.0 – 7) all within first 6 months

Pad Count

Mean 4.76 @ baseline to a
Mean 1.83 @ last follow up ($p < 0.05$)

IQOL

63.04 @ baseline to
82.59 @ last follow up ($p < 0.05$)

VLPP

48.76 cm H2O @ baseline
84.1 cm H2O @ last follow - up

Overall

15/25 (65%) dry (0 to 1 pad/day)
3/25 (13%) some improvement
5/25 (25%) unchanged

Complications
1 post op. retention

4 (17.3%) revisions due to:
–1 migration
–1 bladder perforation
–1 device failure
–1port erosion

2 (8%) pts denovo detrusor overactivity treated with anticholinergics

Kocjancic

•N = 160
•Age = 67 (27-82)
•Time since initial surgery = 3.6+/- 3.2 yrs.
•Cause of incontinence :

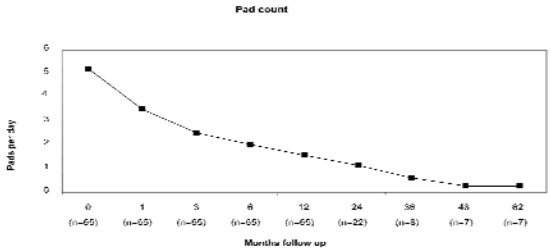
- RRP	141
- TURP	10
- OPEN PROSTATECTOMY	4
- NEUROLOGIC BLADDER	2
- CYSTECTOMY	3

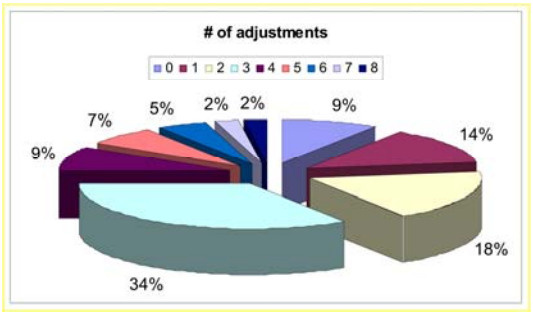
Follow up : 19 months (12-48)

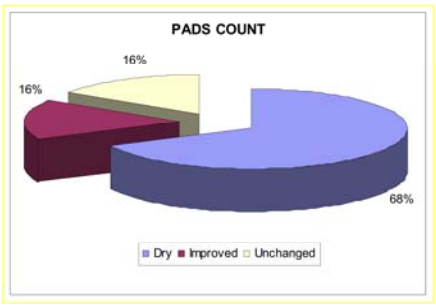
Procedural time: 18 minutes (14-35)

Postop adjustments: 3 +/- 1.9 (0 – 8)

Final balloon volume: 4.5cc +/- 1.7 (1-9cc)







Intraoperative perforation (bladder) (4.6%)
Intraoperative perforation (urethra) (4.6%)
Infection : (1.5%)
Erosion : (3.0%)
Balloon deflation : (3.0%)
Balloon migration : (3.0%)

10 FAILED PATIENTS
- 1 INFECTION
- 2 EROSIONS
- 1 DEFLATION
- 1 INCORRECT POSITIONING
1 MIGRATION
4 UNRELATED TO ANY DETECTABLE PROBLEM

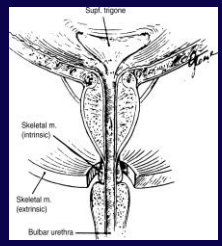
The artificial sphincter for post-radical prostatectomy incontinence

Sender Herschorn, MD, FRCSC
Division of Urology

University of Toronto

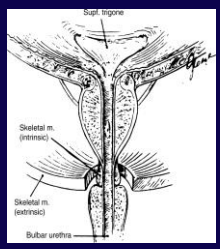
Mechanisms of Continence

- **Quiescent bladder**
- **Proximal Sphincter**
  - internal sphincter - loop of detrusor muscle surrounding the anterior portion of the bladder neck
  - urethral mucosal layer surrounded by vascular plexus with fibroelastic and muscular tissue



Mechanisms of Continence

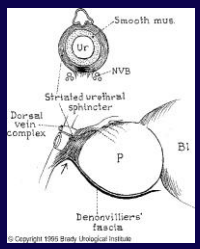
- **Distal sphincter mechanism**
  - Striated external urethral sphincter (rhabdosphincter)
  - Smooth muscle component
  - Pelvic diaphragm
  - Ligaments



Mechanisms of Continence

Distal sphincter mechanism

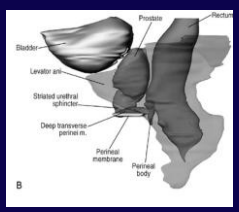
A. Striated external urethral sphincter (rhabdosphincter)
  - surrounds the membranous urethra, extends from perineal membrane to distal prostate
  - at prostate apex circular fibres surround urethra and thin posteriorly to insert into fibrous raphe
  - distally the fibres do not meet posteriorly, omega shape (fan out laterally)



Mechanisms of Continence

Distal sphincter mechanism

A. Striated external urethral sphincter (rhabdosphincter)
  - posterior portion inserts into perineal body
  - consists of slow-twitch fatigue resistant fibres
  - innervated by pudendal nerve and a branch of sacral plexus that runs on pelvic surface of levators



Lateral view of levator ani, pelvic diaphragm and pelvic viscera

Brooks JD, Chao W-M, Kerr J: J Urol 1998;159:869–870.

Investigations prior to surgery

- History and physical examination
- Urinalysis
- Post void residual urine
  - Frequency/volume chart
  - Pad test
  - Serum creatinine if renal disease suspected

A to C

Investigations prior to surgery

Further evaluation

- Cystourethroscopy: urethral integrity, sphincter appearance, stricture, bladder pathology
- Imaging: cystourethrography, KUB, ultrasound

B, C

Investigations prior to surgery

Urodynamics

Sphincter weakness

- Valsalva leak point pressure
  - standardized in women, catheter may obstruct a stricture
  - retrograde test (perfusion sphincterometry) with AUS, sling
- Sphincter electromyography for suspected neuropathy

Detrusor function

- Multichannel, video, pressure/flow

Investigations prior to surgery

Urodynamics

- 2 retrospective studies showing no predictive value of UD findings on outcome after AUS
  - Thiel at al. *Urology* 2007;69:315-9
  - Trigo Rocha et al. *Urology* 2008; 71:85-9
- Urodynamic evaluation to characterize the underlying physiopathology is useful to perform prior to invasive therapy

B

Definition of post-RP continence

1. Total control without any pad or leakage
2. No pad a day but few drops of urine
3. One or 0 pad per day

Post-RP continence

9 - 48%

Author	No. Pts.	Age	Continence at 12 mo			Procedure
			Def 1	Def 2	Def 3	
Harris	508	66		96		PP
Maffezzini	300	66		89		RP
Hoffman	83			75	88	RP+/-RT
Ruiz-Deya	200	63			93	PP
Augustin	368	63			88	RP
Rassweiler	219	65			89	RP
	219	64			90	Lap RP

Definitions
1: total control 2: few drops, no pad 3: 1 or 0 pads/day

Herschorn et al. 3rd ICI 2005: 1241-1296

Incontinence risk factors

Reported

- Age and co-morbidities
- Nerve sparing
- Bladder neck stenosis
- Stage (possibly related to surgical technique)
- Preoperative bladder and sphincter dysfunction

Unrelated to

- RRP versus PP versus Lap RP versus robotic

Reports entirely from centres of excellence

Interventional treatment for PPI

- Urethral bulking agents
  - Collagen
  - Macroplastique
  - (Ethylene vinyl alcohol (Tegress))
- Artificial sphincter
- Sling

Surgical treatment - AUS

AUS - Post-RP

Author	N	Follow-up (yr)	% 0-1 pads/day
Montague	66	3.2	75
Perez	49	3.7	85
Martins	28*	2	85
Fleshner	30	3	87
Mottet	96	1	80
Klijn	27	5	70
Haab	36	7.2	80
Elliott	160	5.7	79
Madjar	131	7.7	59
Goldwasser	42	1.2	82
Trigo	40	4.5	90
Kim	124	6.8	69
Lai	218	1.2	82

*Adjuvant radiation therapy

Surgical treatment - AUS

- Results summary
  - Treatment of BPH and post RP reported together in many studies
  - 59-90% 0-1 pad/day
  - Long-term results reported
  - Level 2-3 evidence

PPI surgery recommendations

- After a period of conservative management of at least 6-12 months,
  - AUS is the treatment of choice for patients with moderate to severe UI
  - Male slings are an alternative for men with mild to moderate UI
    - RT may be an adverse risk factor
  - Bulking agents are a less effective option for some men with mild to moderate UI.
- B

PPI treatment and age

- Age is not a restriction for surgical treatment of PPI.
- Cognitive impairment and lack of dexterity may be restriction for the AUS and are necessary to determine preoperatively.
- C

AUS after radiotherapy

- Variably higher revision rate than without RT
  - Higher incidence of erosion and infection, urethral atrophy possibly from radiation induced vasculitis
  - Bladder overactivity and BN contractures
- Prolonged +/- intermittent deactivation
- Cuff outside radiation field
- Level 3 evidence
- C

AUS complications

Incontinence
- Alterations in bladder function:
  - neurogenic bladders (3-57%)
- Urethral atrophy (3-9%)
- Mechanical failure (up to 52%)

Erosion and/or infection (0-25%)
- Risk factors - surgery, radiation, catheterization and endoscopy

Rare
- Urethral diverticulum in previous cuff site

Causes of persistent or recurrent incontinence after AUS

- Inadvertent sphincter deactivation
- Mechanical failure (fluid loss)
- Cuff erosion
- Detrusor overactivity
- Urethral atrophy (under the cuff)
- Other mechanical malfunction

Workup

- History
  - Onset and type of UI, preop symptoms, any urethral instrumentation (catheter, cystoscopy)
- Physical
  - Number of cycles needed to collapse pump; if number increased possible atrophy
  - Hard pump suggests deactivation (inadvertent)
  - Signs of infection

Montague. Urology 2001; 58:779-782

Workup

- Imaging
  - Plain films if contrast
  - Ultrasound if saline
- Cystourethroscopy
  - Initially to see if cuff inflated and then re-inflates
  - Signs of erosion
- Videourodynamics
  - Overactivity, compliance, sui
  - Low leak pressure (<balloon pressure)
  - Voiding study

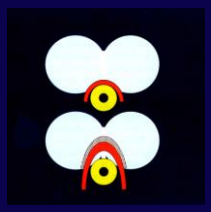
Workup

Montague. Urology 2001; 58:779-782

Treatment of incontinence after AUS implantation

Cause	Treatment
Inadvertent deactivation	Reactivate
Mechanical failure	Replace component or device
Cuff erosion	Remove device
Detrusor overactivity	Anticholinergics
Urethral atrophy	Downsize cuff, add fluid, change reservoir, tandem cuff

Treatment of urethral atrophy



Transcorporal cuff placement

Guralnick et al. J Urol 2002; 167:2075-8

Treatment of urethral atrophy

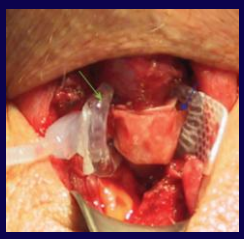
- Tandem cuff placement
  - Cuff added 1 cm distal to original or 2 replaced
  - At least 1 cm gap between cuffs
  - Bulbospongiosus muscle may be used as cushion
- Suspicion of increased erosion with tandem cuffs

Double cuff

Brito et al. J Urol 1993; 149:283-5
O'Connor et al. Urology 2003; 62:723-726
Montague Urology 2000; 55:2-4

Treatment of urethral atrophy

- Surgisis wrap
- 4/5 patients improved after 18 months



Rahman et al BJUI 2005;95:824-826

Prevention of urethral atrophy

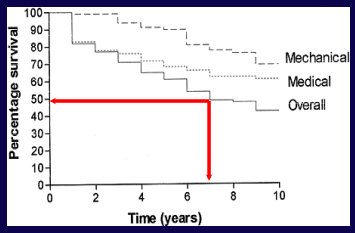
- Nocturnal deactivation
  - Prospective study
  - 61 pts. from Mayo Clinic did nocturnal deactivation versus 41 pts. from Baylor who did not
  - After 40 months at Mayo Clinic 10% developed atrophy-related complication versus 21% after 28 months at Baylor (P>0.05)

Elliott et al. 2001; Urology 57:1051-4

AUS durability

- Simeoni (96): Operational life mean 56 mo (range 3-118)
- 1987: narrow back cuff design change
  - Revision rate - 21% to 12%
- Durability with Kaplan-Meier curve

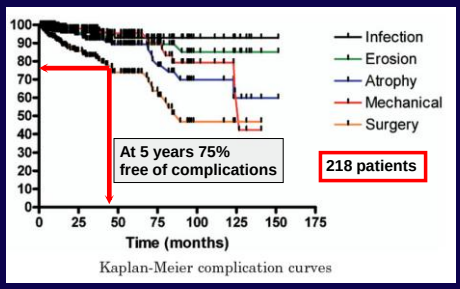
AUS durability



Overall device survival; *Medical* device survival excluding prosthesis failure; *Mechanical* device survival excluding those removed infection or erosion.

Venn et al. J Urol 2000, 164:702

AUS durability and complications



Lai et al J Urol 2007; 177:1021-1025

AUS durability after revision

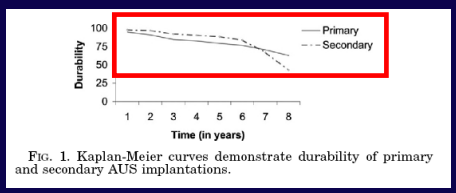
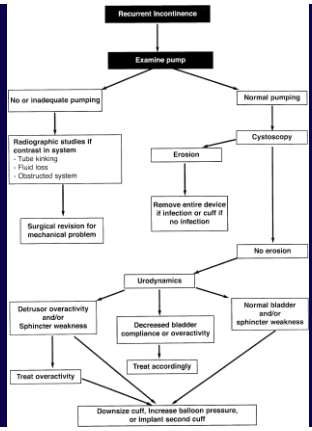


FIG. 1. Kaplan-Meier curves demonstrate durability of primary and secondary AUS implantations.

- 554 men
- 119 with revisions (159 secondary procedures)

Raj et al. J Urol 2005; 173: 1242-1245

AUS Algorithm



Conclusions

- Increasing number of patients with PPI
- Systematic workup
- Good surgical options being developed
- Slings for mild to moderate incontinence
- AUS for moderate to severe incontinence