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Failure of the AMS 800 artificial sphincter
Why and what to do?

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History

- First used in 1972, first report in 1974
- Deactivation button (1983)
- Narrow backed cuff (1987)
- Kink resistant tubing (colour coded) (1988)
- Quick (and Y) connectors
- Inhibizone coating (2001)

Since 1972

Scott et al. J Urol 1974;110:1125-9

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AMS 800 is the best solution...

- ...for **moderate to severe** stress urinary incontinence
- ...with **good candidate** selection
- ...with **experienced implanters**

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Candidate selection

<ul style="list-style-type: none"> • Dexterity (female>male) • Mental capacity • Moderate to severe incontinence • Lasting at least 6 months 	<ul style="list-style-type: none"> • Adequate bladder capacity • No detrusor overactivity • No urethral stricture disease/BNC/... • Chronic UTI
<ul style="list-style-type: none"> • Show demo device at outpatient clinic 	<ul style="list-style-type: none"> • Micturition diary • Cystoscopy • Urodynamic study • Urinary culture

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Experienced implanters

Risk of reoperation in 5 years after implant by surgeon with:

- 5 prior cases: 24%
- 100 prior cases: 18%
- 200 prior cases: 13%

Sandhu et al. Eur Urol 2011;60(6):1285-90

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AMS 800 is the best solution

- Best level of evidence (2b)
- Higher success rate (83% versus 75% and 71% in Advance and Argus pooled analysis)
 - In a more severely incontinent population
 - Also in irradiated patients
 - Using stricter criteria (i.e. 0-1 pad vs. 50% improvement)
- Long standing clinical experience
 - > 25 years in its current form
 - Expectations and disadvantages well known

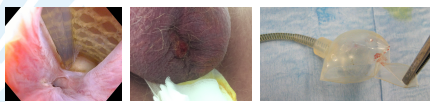
Van Bruwene et al. BJU Int 2015;116(3):330-42
Van der Aa et al. Eur Urol 2013;63(4):681-9

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KEEP CALM AND DO REVISION

But at what price?

- High reoperation rate (26%, 14,8 – 44,8%):
 - Erosion/infection 8,5% (3,3 – 27,8%)
 - Mechanical failure 6,2% (2,0 – 13,8%)
 - Urethral atrophy 7,9% (1,9 – 28,6%)



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Table 2. Complication rates of AUS separated by device

Complication	AMS single cuff	AMS double cuff	Flow secure	Zephyr	Total
Explantation, n (%)	62 (23.4)	36 (16.6)	2 (18.2)	9 (69.2)	109 (21.5)
Infection, n (%)	20 (7.5)	13 (6.0)	0	1 (7.7)	34 (6.7)
De novo-urge, n (%)	27 (10.2)	12 (5.2)	1 (9.1)	2 (15.4)	42 (8.3)
Urethral erosion, n (%)	40 (15.1)	19 (8.8)	1 (9.1)	3 (23.1)	63 (12.5)
Dislocation of the device, n (%)	11 (2.2)	7 (1.4)	0	0	18 (3.6)
Impaired wound healing, n (%)	11 (4.2)	2 (0.9)	0	0	13 (2.6)
Pain, n (%)	18 (6.8)	12 (5.5)	0	2 (15.4)	32 (6.3)
Bleeding, n (%)	16 (6.0)	15 (6.9)	0	0	31 (6.1)
Acute urinary retention, n (%)	32 (12.1)	32 (14.8)	0	2 (15.4)	66 (13)
Mechanical failure, n (%)	10 (3.8)	9 (4.1)	1 (9.1)	3 (23.1)	23 (4.5)

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Complications

- Urethral stricture
- Post- radiotherapy changes
- Persisting incontinence post AUS
- AUS erosion, infection, dysfunction

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Urethral / bladder neck stricture

- No clear guidance
 - Incision with cold knife, laser ?
 - Bladder neck resection ?
 - Open re-anastomosis ?
- Wait long enough before implanting anything
- ‘Highway to Bricker??’



Urethral stricture Radiotherapy Persisting incontinence Erosion/infection

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Anastomotic stricture

- Eltahawy et al
 - Patients with anastomotic strictures and radiotherapy
 - Treated with holmium laser and steroid injection
 - Out of 24 patients, 19 (83%) had an open anastomosis at 24 months
 - 11 got an artificial sphincter of which 3 were explanted (30%)

Eltahawy et al. BJU Int 2008

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Risk Factors for Failure of Male Slings and Artificial Urinary Sphincters: Results from a Large Middle European Cohort Study

Tanja Hilsch^a Alexander Kretschmer^{b,c,d} Frauke Thomsen^a

Urol Int DOI: 10.1159/000449232

Results: A history of pubic irradiation was an independent risk factor for explantation in AUS (p < 0.001) and MS (p = 0.018). Moreover, prior urethral stricture (p = 0.036) and higher ASA-classification (p = 0.039) were positively correlated with explantation in univariate analysis for AUS. Urethral erosion was correlated with prior urethral stricture (p < 0.001) and a history of pelvic irradiation (p < 0.001) in AUS. Furthermore, infection was correlated with additional procedures during SUI surgery in univariate analysis (p = 0.037) in MS.

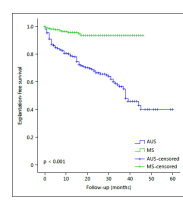


Fig. 1. Explantation-free survival of AUS and MS estimated by the Kaplan-Meier method.

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Neurology and Urodynamics 29:179-190 (2010)

TABLE V. Results of the Artificial Urinary Sphincter in Post-Radical Prostatectomy Incontinence

Refs.	No. of patients	Follow-up (years)	Q-1 pad/day (%)
Montague ¹⁰	66	3.2	75
Perez and Webster ¹⁷	69	3.7	85
Martins and Boyd ¹⁶	28	2	85
Reichers and Hershovici ¹⁴	30	3	87
Mottet et al. ¹⁰¹	96	1	86
Majid et al. ¹⁰²	51	7.7	59
Kijiri et al. ¹⁰³	27	3	81
Hsieh et al. ¹⁰⁴	56	7.2	80
Trigo-Rodriguez et al. ¹⁰⁵	60	4.5	90
Kim et al. ¹⁰⁶	124	6.8	82
Lai et al. ¹⁰⁷	218	3.1	69
Goldwasser et al. ¹⁰⁸	42	1.2	82

80.3%

TABLE VI. The Artificial Sphincter for Incontinence After Radiotherapy

Refs.	Number of patients	Revision rate after radiotherapy	Continence (%)
Martins and Boyd ¹⁶	34/81	38% for whole group	88
Wang and Haddley ¹¹¹	16	25% (infection and erosion - 12.5%)	87
Perez and Webster ¹⁷	13/75	53%	83
Goldman et al. ¹¹²	15/56	22%	90
Ellert and Rappel ¹¹³	46/153	22%	90
Mamata et al. ¹¹⁴	15/72	53% (infection and erosion - 20%)	73
Combs and Rocco ¹¹⁵	58/96	25% (similar to a non-radiated control group)	64
Lai et al. ¹⁰⁷	60/136	20% versus 32% for non-radiated group	69

76%

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Implantation of Artificial Urinary Sphincter in Patients With Post-Prostatectomy Incontinence, and Preoperative Overactive Bladder and Mixed Symptoms

H. Henry Lai* and Timothy B. Boonet

THE JOURNAL OF UROLOGY® Vol. 185, 2254-2259, June 2011

Pre-operative OAB did not negatively impact the overall continence after AUS

- De novo OAB 23%
- Patients with pre-operative mixed incontinence continue to have OAB
- Capacity of <200cc is risk factor for OAB
- Anticholinergics need to be continued
- Presence of urodynamic DO or radiotherapy were not predictive

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Artificial Urinary Sphincter Revision: The Role of Ultrasound

Benjamin M. Brucker, Abdullah Demirtas, Eva Fong, Chris Kelly, and Victor W. Nitli

Figure 5. Ultrasound measurements of a full (22.09 mL) and empty (0.00 mL) pressurizing balloon. (Color version available online.)

UROLOGY 82: 1424-1429, 2013.

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Urethral atrophy after implantation of an artificial urinary sphincter: fact or fiction?

Simon Buaeia, Stella L. Ivaz, Anastasia Frost, Daniela E. Andrich and Anthony R. Mundy

BJU Int 2016, 117: 649-676

Material failure to generate pressure at long-term Encapsulation of cuff AND urethra

Downsizing cuff
Higher pressure balloon
Double cuff
Transcorporeal cuff

Not always necessary

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Erosion/encapsulation/failure

Urethral stricture Radiotherapy Persisting incontinence Erosion/infection

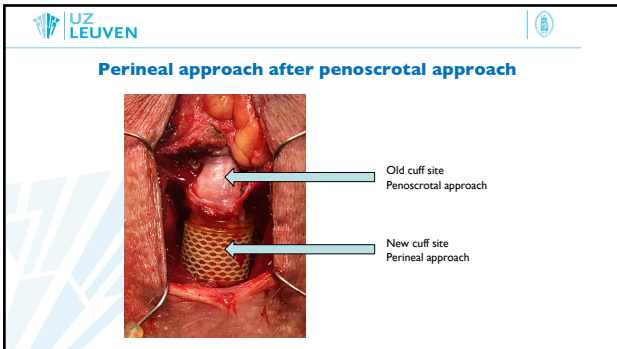
A Multicenter Study on the Perineal Versus Penoscrotal Approach for Implantation of an Artificial Urinary Sphincter: Cuff Size and Control of Male Stress Urinary Incontinence

Gerard D. Henry,† Stephen M. Graham,‡ Robert J. Cornell,‡ Mario A. Cleves,‡ Caroline J. Simmons,‡ Ioannis Vakilopoulos‡ and Brian Flynn‡

Conclusions: There appears to be a higher completely dry rate with fewer subsequent tandem cuff additions with the perineal approach compared to the penoscrotal approach. This disparity may be explained by a more proximal artificial urinary sphincter cuff placement in the perineal group as evidenced by a larger cuff size.

UROLOGY 2007; 46:1704-1709
THE JOURNAL OF UROLOGY Vol. 182, 2404-2409, November 2009

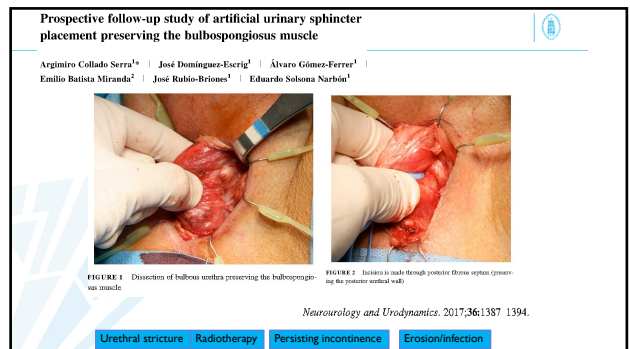
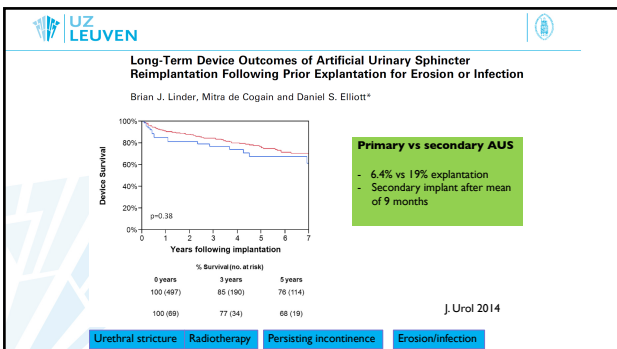
Urethral stricture Radiotherapy Persisting incontinence Erosion/infection



AUS vs sling after eroded sphincter

- TUYGUNG et al Urology 73:1363-7, 2009
 - Sling 25% cure
 - Second AUS 75% cure

Urethral stricture Radiotherapy Persisting incontinence Erosion/infection



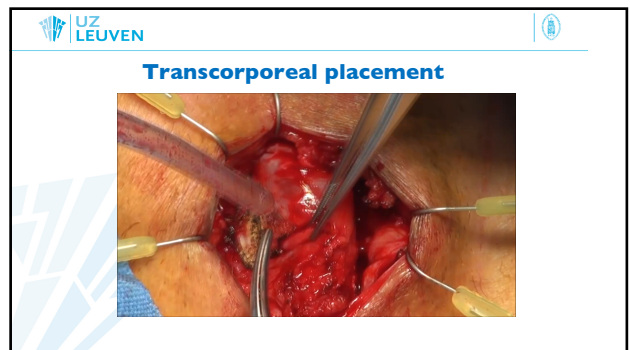
Transcorporeal artificial urinary sphincter implantation as a salvage surgical procedure for challenging cases of male stress urinary incontinence: surgical technique and functional outcomes in a contemporary series

Laura Wiedemann, Jean-Nicolas Cornu, Emile Hoob, Laurence Peyrol, Sébastien Balay, Xavier Cathelineau, * and François Hoob

Reference	Number of Patients	Procedure	Median (range) Incontinence (no. events)	Continence	Device Survival	Complications
Geisler et al (4)	16	transcorporeal cuff placement	0 (0-10)	0 (0 patients)	100% (16)	penile edema 100% (16)
Hall et al (5)	16	transcorporeal cuff placement	16 (0-30)	0 (0 patients)	100% (16)	penile edema 100% (16)
Anderson et al (6)	8	transcorporeal cuff placement	28 (0-28)	0 (0 patients)	100% (8)	penile edema 100% (8)
Hall et al (5)	16	transcorporeal cuff placement	12 (0-18)	0 (0 patients)	100% (16)	penile edema 100% (16)
Lee et al (7)	16	transcorporeal cuff placement	40 (0-40)	0 (0 patients)	100% (16)	penile edema 100% (16)
Meyer and Elbar (8)	18	transcorporeal cuff placement	20 (0-30)	0 (0 patients)	100% (18)	penile edema 100% (18)
Present series	27	transcorporeal cuff placement	20 (0-30)	0 (0 patients)	100% (27)	penile edema 100% (27)

N=27
17 patients dry of whom 13 dry (76%) 59% 0-1 pad/day

BJU Int 2013; 112: 1165-1168



Golden rules

- Infection or erosion: take it out (semi) urgent!
Reimplant later!
- Mechanical failure after ≥ 5 years: total revision.
- "urethral atrophy": think about balloon "fatigue":
change total system?
- Patients satisfaction is linked to continence more
than to number of revisions

Marshall et al. *NeuroUrol Urodyn* 2015;34 (53):5154
Ooms et al. *J Urol* 2001;166 (5):1755-8
Viers et al. *J Urol* 2016;196:828-
83