University Medical Center Hamburg-Eppendorf
Department of Urology

The Artificial Urinary Sphincter in Complex Situations

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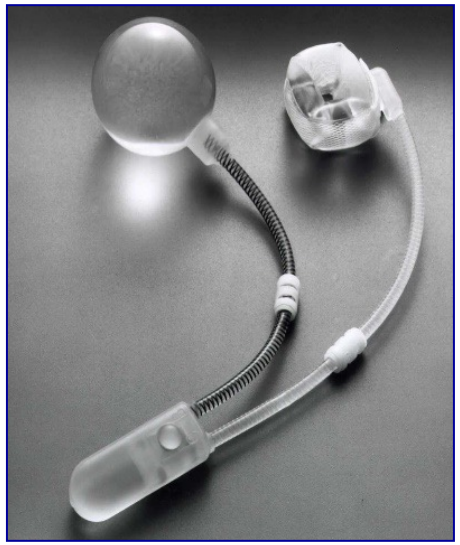
Artificial Urinary Sphincter



- Most predictable successfull surgery in pts. with severe incontinence, after external beam radiation, after prior sling or AUS implantation
- It has the largest body of evidence reporting long-term success
- The success rates and high patient´s satisfaction outweigh the need for revisions

LE 2, grade of recommendation B

Averbeck et al., Report from the 6th International Consultation on Incontinence, Neurourol Urodyn 2019

Systematic Review: pooled analysis

Outcome	Results % (range)
Infection / erosion	8.5 (3.3-27.8)
Mechanical failure	6.2 (2.0-13.8)
Urethral atrophy	7.9 (1.9-28.6)
Reintervention	26.0 (14.8-44.8)
Social continent (≤1pad/24h)	79.0 (60.9-100)
Completely dry (0pad)	43.5 (4.3-85.7)

Van der Aa et al. Eur Urol 2013

Metaanalysis and systematic review (after RPX)

dry rate	52 %
Social dry rate	82 %

Li et al, PLOS ONE 2023

AMS Data Base

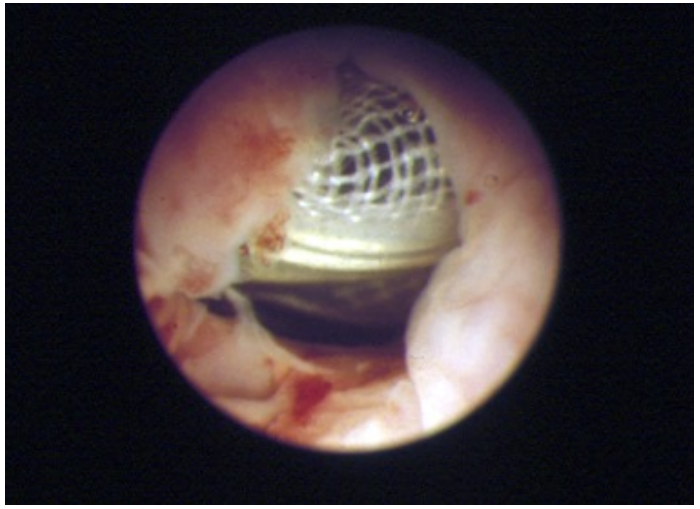
27096 implants in the US 1972-2015

82.6% perfomed by low volume implanters (<5/year)

76.8% perineal approach

32.2% penoscrotal approach

8.2% tandem cuff



Postoperative Complications:

4% cuff erosion

3.8% fluid loss

2.4% subcuff atrophy

1.8% device infection

0.2% PRB herniation

21.1% explantation and /or revision

52.0% explantation only

37.7% revision only

10.2% explantation + revision

Yafi et al. J. Urol 197: 759-765, 2017

AMS Data Base

Device Survival: Kaplan –Meier explantation free device survival rates:

87.1% 5 years

78.3% 10 years

Penoscrotal approach / tandem cuff:

Higher rates of device infection, cuff erosion and fluid loss

Low volume surgeon:

Higher cuff erosion rates

Multivariate analysis:

Younger age, penoscrotal approach, tandem cuff associated with device explantation and revision but not surgeon volume

Yafi et al. J. Urol 197: 759-765, 2017

Artificial Urinary Sphincter

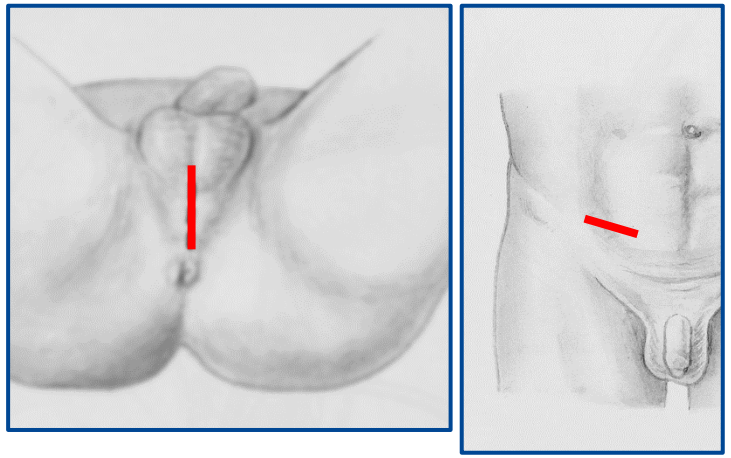
What are the results in complex situations?

- Influence of comorbidities
- St. p. irradiation
- St. P. urethroplasty
- Reimplantations
- Transcorporal cuff

Our Operative Technique

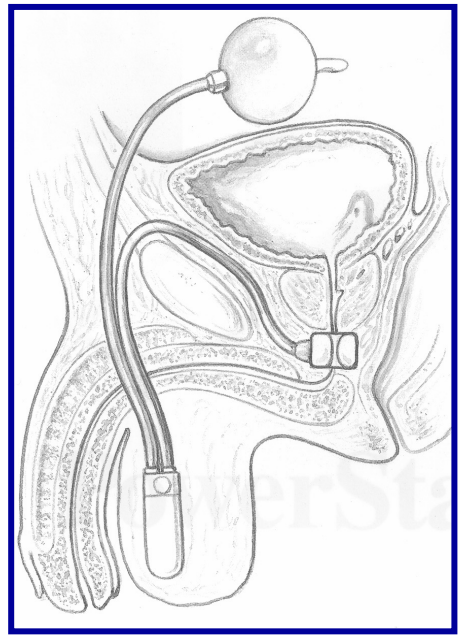
Incision

- perineal
- Suprainguinal
- penoscrotal approach



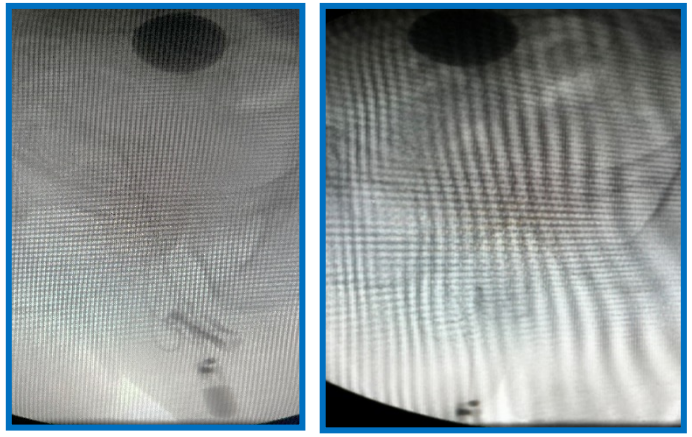
Positioning:

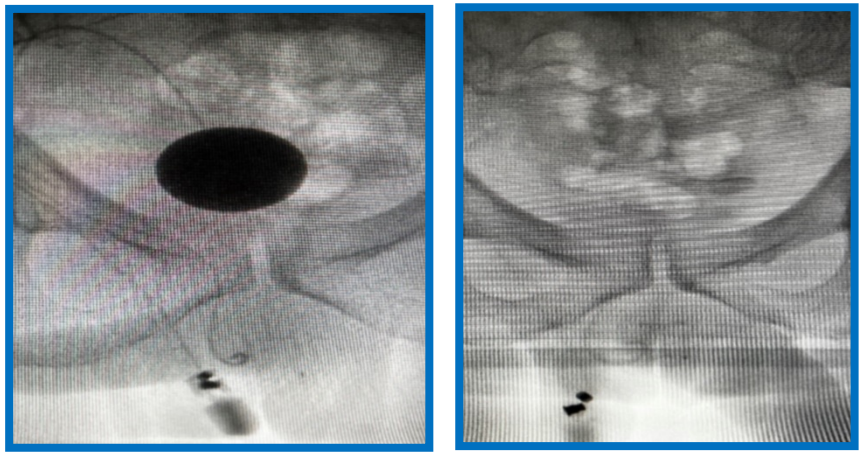
- balloon intraperitoneal behind rectus muscle
- Pressure regulating balloon 61-70
- Pump right scrotum



Filling: saline most commonly used

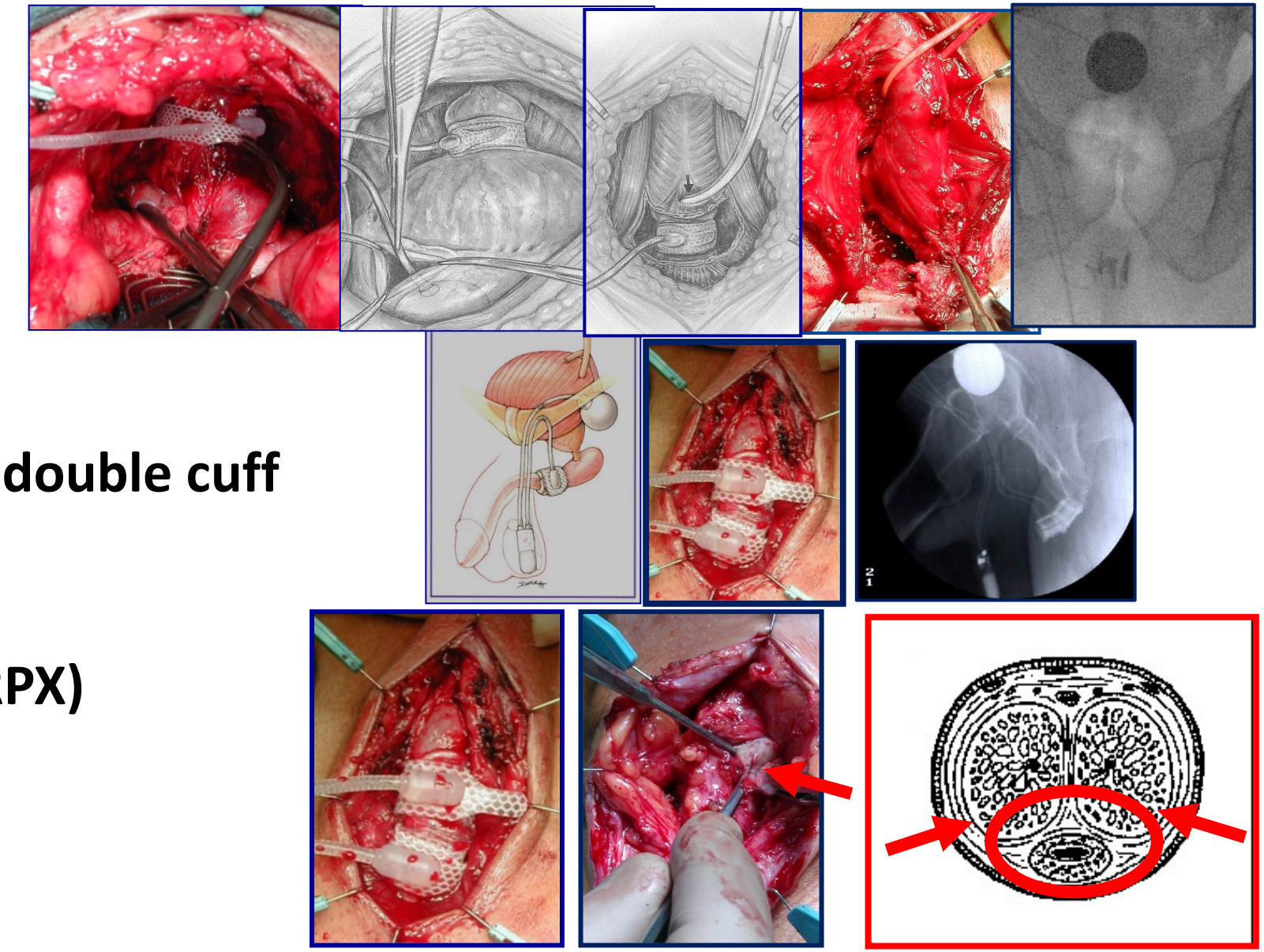
- Ultravist 150
  - Single cuff 22 cc
  - Double cuff 24 cc





Our Strategy: Cuff Location

- Bladder neck
  - neurogenic, females
- Membranous urethra
  - our favorite location
- Bulbar urethra
  - single cuff
    option for redos after double cuff
  - distal double cuff
    after radiation;
    after reanatomosis (RPX)
  - transcorporal cuff
    last option, salvage



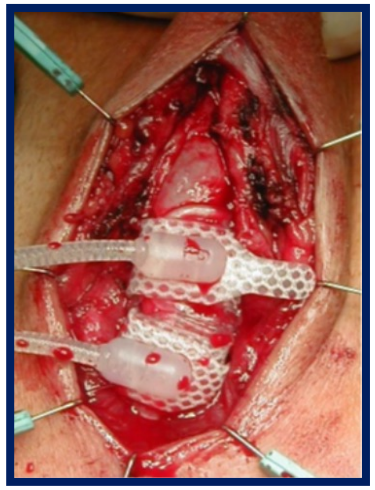
Comorbidities: Single / Doublecuff

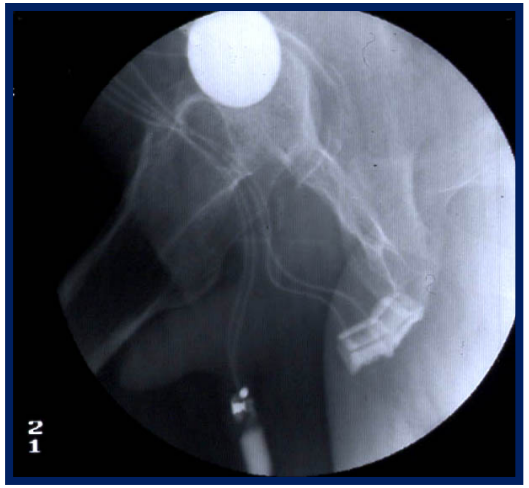
208 implantations, 4,5 year period, 11 pts lost to FU: 197 remaining

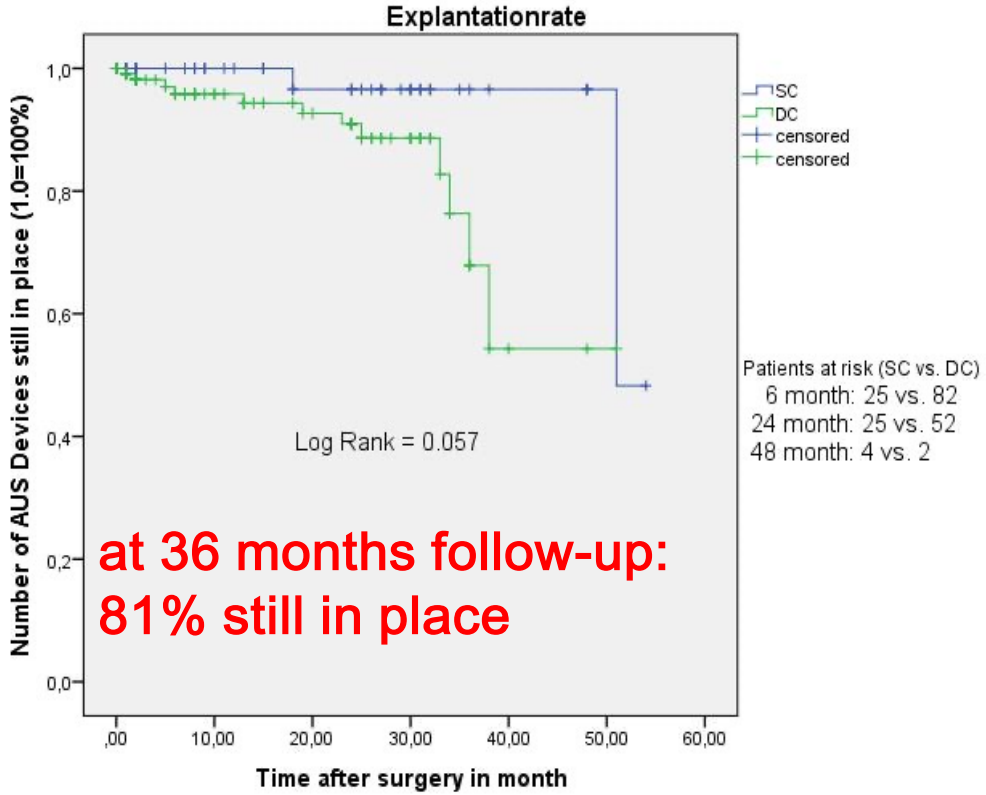
age: 70 (IQR9); ASA: 2 (IQR1); FU: 16.3 (IQR 24.25) m

Cuff Placement:

distal bulbar double cuff	64.2%
membraneous	30.1%
bladder neck	2.8%
transcorporal	2.8%







at 36 months follow-up:
81% still in place

Continence	objective	subjective
double cuff	86.6%	90.2%
single cuff	69.1%	76.4%

Comorbidities: Single vs. Dcuff

Risk Factor Analysis:

Continence	p value	HR	lower CI	upper CI
single compared to double cuff	0.016	1.6	1.09	2.34
detrusor overactivity	0.001	2.64	1.65	4.25
Explantation				
Age	0.012	1.1	1.02	1.19
ASA	0.496	1.35	0.572	3.167
diabetes mellitus	0.83	0.79	0.10	6.19
anticoagulant therapy	0.011	4.54	1.41	14.65
double cuff compared to single cuff	0.076	3.97	0.867	18.18

- DC significantly higher continence rates: 86.6% vs 69.1% (p=0.016)
- tendency of higher complication rate for DC: 15.5% vs 8.3%
- age, anticoagulant therapy riks factors for explantation

Irradiation

Since 2009 prospective database, 248 pts included, 2009 – 2015: n=155 distal double cuff, n=74 after irradiation, Follow-up: median 24 mo (IQR 7.25 - 36), no difference between the two collectives: age, ASA, comorbidities, median urine loss, prior surgeries

Complications	**Overall**	**History of Rx**	**no Rx**	**p-value**
Patients, n (%)	155 (100)	74 (47.7)	81 (52.3)	-
Infection (%)	7 (4.5)	5 (6.8)	2 (2.5)	0.260
Arrosion (%)	23 (14.8)	13 (17.6)	10 (12.3)	0.377
Explantation (%)	35 (22.6)	19 (25.7)	16 (19.8)	0.443
Mechanical Failure (%)	6 (3.9)	1 (1.4)	5 (6.2)	0.212

Continence	**Overall**	**History of Rx**	**no Rx**	**p-value**
Patients, n (%)	155 (100)	74 (47.7)	81 (52.3)	-
Objective continence (%)	120 (77.4)	57 (77)	63 (77.8)	0.691
Subjective continence (%)	127 (81.9)	63 (85.1)	64 (79)	0.666
Social continence(%)	134 (86.5)	66 (89.2)	68 (84)	0.804

Irradiation

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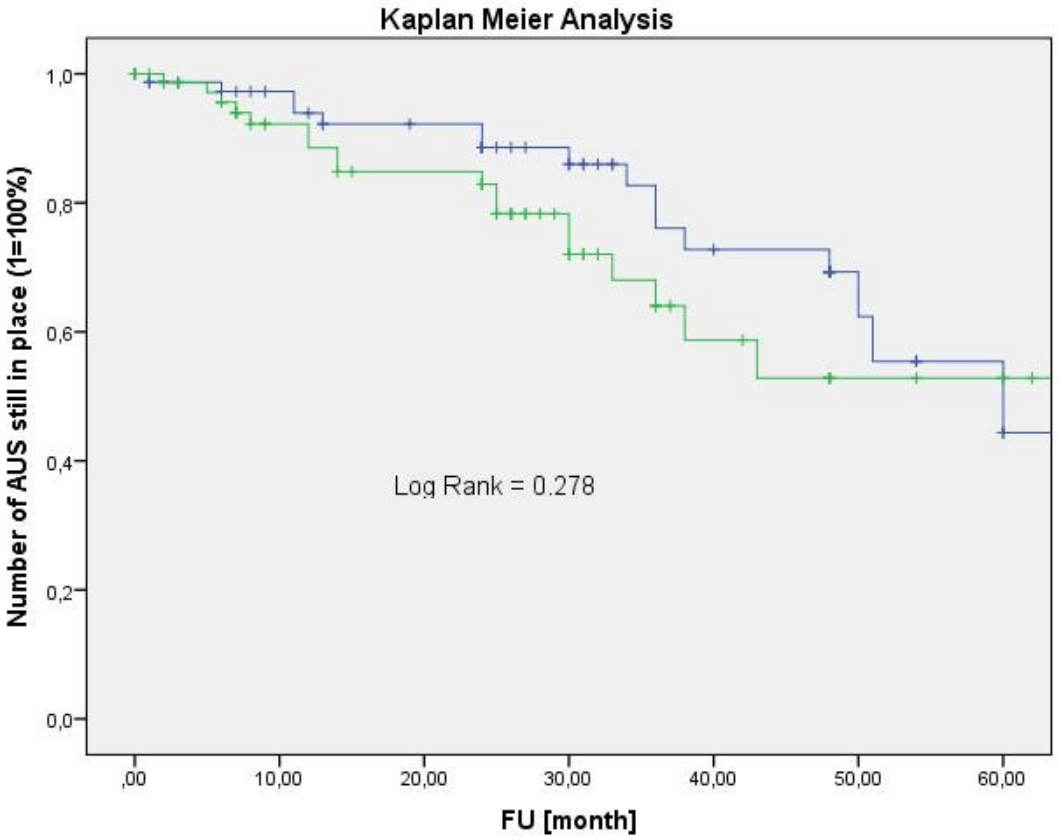
Explantation rate: DC vs. DC st. p.. radiation



- **No significant differences: continence, complications, explantation rates**

  Maurer et al, BJU Int 124:1040-1046, 2019

- **No differences concerning outcome**

  Sathianathen et al. BJUI 2014; Jhavar et al. Clin Genitourin Cancer 2017

- **Signif. higher revision rate after irradiation**

  Manunta et al. BJUI 2000; Brant et al. Urology 2014

- **Signif. lower continence rate after irradiation**

  Guillaumier et al. Urol Ann 2017

Previous Urethroplasty

Since 2009 prospective database, 248 pts included, 2009 – 2015:

n=236, n=17 urethroplasty with buccal mucosa, Follow-up: median 24 mo (IQR 6 - 31)

		BMGU	no BMGU	p-value*
Patients, n (%)		n=17 (100)	n=219 (100)	-
Median age at surgery years (IQR)		70.0 (67.0-74)	70.0 (65.0-74.0)	0.82
Median urine loss				
	Stress pad test, g (IQR)	119 (73-137.5)	108 (55.5-144)	0.357
	Number of pads used/day (IQR)	7 (4.75-8.5)	7 (5-8)	0.803
Median ASA classification (IQR)		2 (2-3)	2 (2-3)	0.285
Comorbidities/previous surgeries, n (%)				
	Diabetes mellitus	5 (29.4)	22 (10)	**0.032**
	Anticoagulant therapy	6 (35.3)	83 (37.9)	0.526
Surgeries prior SUI, n (%)				
	Radical prostatectomy	8 (47.1)	175 (79.9)	**0.04**
	TUR-P	8 (47.1)	30 (13.7)	**0.02**
	Trauma	1 (5.9)	5 (2.3)	0.365
Pelvic radiation therapy, n (%)		13 (76.5)	69 (31.5)	**0.001**
Surgeries prior AUS implantation, n (%)				
	Open surgical therapy for SUI	4 (23.5)	65 (29.7)	0.401
Length of Buccalmucosagraft	cm (IQR)	4 (3-5)	-	-
Median AUS operation time minutes (IQR)		62.5 (51-68)	58 (51-68)	0.307

Previous Urethroplasty

Since 2009 prospective database, 248 pts included, 2009 – 2015:

n=236, n=17 urethroplasty with buccal mucosa, Follow-up: median 24 mo (IQR 6 - 31)

Complications urethroplasty + AMS 800 vs. AMS 800

	BMGU	Comp Grp	p-value*
Patients, n (%)	n=17 (100.0)	n=219 (100)	-
Infection (%)	2 (11.8)	6 (2.7)	0.106
Arrosion (%)	2 (11.8)	23 (10.5)	0.559
Explantation (%)	4 (23.6)	36 (16.4)	0.320
Mechanical Failure (%)	0 (-)	8 (3.7)	0.545

Continence rates urethroplasty + AMS 800 vs. AMS 800

	BMGU	Comp Grp	p-value*
Patients, n (%)	n=17 (100.0)	n=219 (100)	-
Objective continence (%)	12 (70.6)	163 (75.8)	0.409
Subjective continence (%)	15 (88.2)	176 (81.5)	0.377
Social continence(%)	16 (94.1)	187 (87)	0.344

Previous Urethroplasty

Since 2009 prospective database, 248 pts included, 2009 – 2015:

n=236, n=17 urethroplasty with buccal mucosa, Follow-up: median 24 mo (IQR 6 - 31)

- **No significant differences: continence, complications, explantation rates**

  Maurer et al, World J Urol 37: 647-653, 2019

- **Prospective multicenter study: urethroplasty is no significant risk factor for higher complication rate**

  Brant et al, J Urol 2014

- **Urthroplasty is a significant risk factor for a negative outcome (complication and explantation rate)**

  McGeady et al, J Urol 2014

Primary, Secondary & Repeat Implantation

Since 2009 prospective database, 248 pts included, 2009 – 2015: n=235, Median FU

n=165 (70.2%) primary implantation	24 (7-36) months
n= 46 (19.6%) secondary implantation (AUS after any other type of incontinence surgery)	25.5 (7.75-36) months
n= 24 (10.2%) repeat implantation (AUS reimplantation)	14 (7-27) months

- No significant differences in complication rates
- Three-year explantation free survival rates:
  - 82.3% primary
  - 81.5% secondary
  - 78.6% repeat
- Signif. higher continence rates after secondary AUS implantation

Rosenbaum et al, World J Urol 2289 - 2294, 2020

Primary, Secondary & Repeat Implantation

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n=165 (70.2%) primary implantation — **24 (7-36) months**

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(AUS after any other type of incontinence surgery)

n= 24 (10.2%) repeat implantation (AUS reimplantation) — **14 (7-27) months**

Continence rates AMS 800

	Primary Aus (58.2% DC)	Repeat AUS (62.5%DC)	Secondary AUS (91.3% DC)	p-value prim vs sec.
Patients, n (%)	165 (100)	24 (100)	46 (100)	
Objective continence (%)	118 (71.5)	15 (62.5)	41 (89.1)	**0.016**
Subjective continence (%)	128 (77.6)	19 (79.2)	43 (93.5)	**0.014**
Social continence(%)	137 (83)	21 (87.5)	44 (95.7)	**0.037**

Rosenbaum et al, World J Urol 2289 - 2294, 2020

Transcorporal Cuff

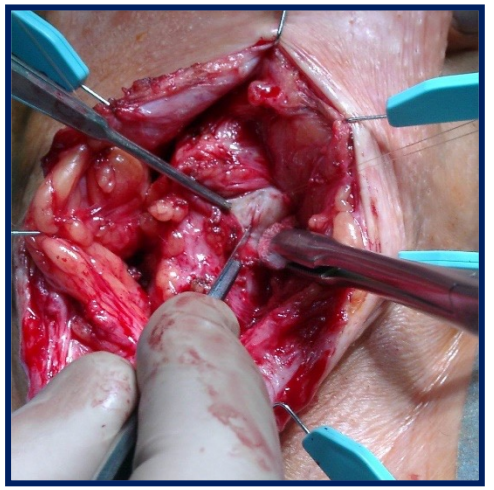
Transcorporal Cuff with closure of corporal bodies

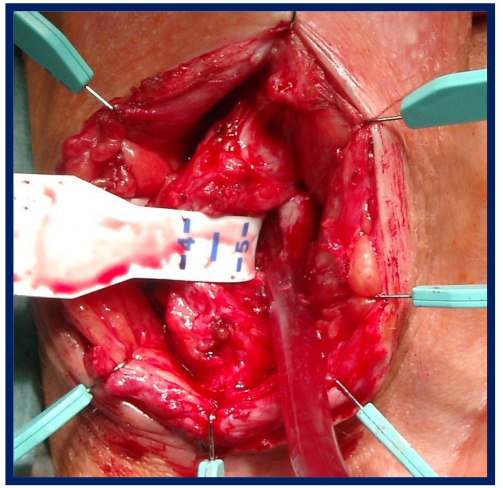
N= 39, median age 72 yrs, median Follow-up 27months

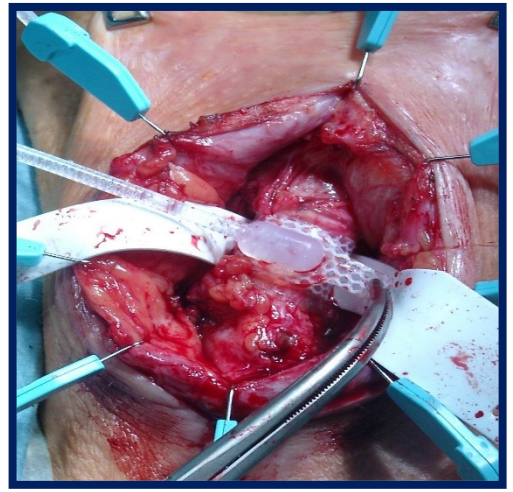
61.5% radiation

41% urethral surgery

96% after distal double cuff







Mean explantation free survival: 83 months

Continence:

- **Objective 54.5%**
- **Subjective 69.7%**
- **Social 78.8%**

Maurer et al, Frontiers in Surgery 9: Article 918011, 2022

Summary

- The artificial urinary sphincter remains the gold standard for treatment of male SUI
- DC has significant higher continence rate but tendency to higher complication rates
- Age and anticoagulant therapy are rik factors for explantation
- No significant differences concerning continence, complications and explantation rates in irradiated vs. nonirradiated patients in our series
- Comparable results concerning continence, complications and explantation rates in patients after urethroplasty with buccal mucosa in our series
- Comparable complication and explantation rates after primary, secondary and repeat implantation; secondary implantation: bettter continence rates in our series
- Transcorporal cuff: mean explant. free survival: 83 months,
  Continence: objective 54.5%, subjective 69.7%

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Thank You