



# Prospective analysis of artificial urinary sphincter AMS 800 implantation after buccal mucosa graft urethroplasty

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## Abstract

**Objectives** To analyze functional outcomes and complication rates of artificial urinary sphincter (AUS) implantation in patients who had undergone buccal mucosa graft urethroplasty (BMGU) beforehand.

**Patients and methods** This prospectively maintained single-center database comprises data from 236 patients from 2009 to 2015 who underwent AUS implantation. A total of 17 patients after BMGU were available for analysis. Primary endpoints consisted of continence and complication rates. Continence was defined as no use of safety pads, social continence as < 2 pads per day. Stricture recurrence was defined as a decrease in uroflowmetry, a maximum flow rate < 10 ml/s or residual urine volume (> 100 ml). Kaplan–Meier analysis determined explantation-free survival.

**Results** Median follow-up was 24 months (interquartile range [IQR] 6–31 months). Indication for AUS implantation was severe urinary incontinence with a history of radical prostatectomy (RRP) in 8 (47.1%), trauma in 1 (5.9%) and TUR-P in 8 (47.1%) patients. Pelvic irradiation was reported in 13 (76.5%) cases. The median length of buccal mucosa graft for urethroplasty was 4 cm (3–5 cm). A double cuff was implanted in 14 patients (82.4%), 3 patients received a single cuff. Complete and social continence was achieved in 76.5% and 100% of the patients, respectively. There was no significant difference in complications and explantation-free survival (log-rank,  $p = 0.191$ ) between patients who had undergone BMGU before AUS compared to patients with no history of BMGU.

**Conclusions** According to the prospective follow-up data in a homogenous cohort, AUS implantation seems to be a viable, safe and effective therapeutic strategy for incontinence treatment despite previous BMGU.

**Keywords** AMS 800 · Artificial urinary sphincter · Buccal mucosa graft urethroplasty · Reconstructive urology · Postprostatectomy stress urinary incontinence

## Introduction

With increasing numbers of transurethral resections of the prostate as well as radical prostatectomies, male stress urinary incontinence constitutes an increasingly important problem. Although functional outcomes after radical prostatectomy (RP) are improving, incontinence rates of 13.2 up to 36% 1 year after RP and 18.2% after 15 years are

described in the literature [1–3]. Artificial urinary sphincter (AUS) implantation is the current ‘gold standard’ treatment for severe stress urinary incontinence (SUI) [4, 5] with continence rates ranging from 61 up to 100% [5, 6] in high-volume centers. However, contemporary long-term studies describe surgical revision rates of up to 60% [7, 8]. Little is known about risk factors for persisting stress urinary incontinence and complications after the implantation of an artificial urinary sphincter device. Studies have shown that a history of pelvic radiation therapy, previous artificial urinary sphincter implantation or urethroplasty deteriorates outcomes in patients undergoing AUS implantation by comprising urethral tissue [9, 10]. Especially, patients after open urethral surgery are considered to be high-risk patients [10, 11].

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Moreover, most studies have retrospective study designs, lack standardized follow-up data or rely on inconsistent definitions for continence status and complications [6].

Therefore, the aim of our study was to compare functional outcomes in patients with AUS placement with a history of buccal mucosa graft urethroplasty (BMGU) and without prior BMGU. We hypothesized that prior BMGU does not impact functional and complication outcomes after AUS placement.

## Patients and methods

### Patient population

Since January 2009, in accordance with an Institutional Review Board approval, all perioperative and follow-up data of patients undergoing AUS (AMS 800) implantation at the University Medical Centre Hamburg-Eppendorf have been prospectively collected in an AUS database.

The study includes male patients with severe stress urinary incontinence SUI (levels III–IV) examined by pad test and pads used per day as mentioned below. Prior bulbar BMGU was indicated for the treatment of patients with significant bulbar urethral strictures examined by uroflowmetry, residual urine volume and urethrography. Patients with the diagnosis of detrusor overactivity in the mandatory preoperative urodynamic evaluation were not eligible for an AUS implantation.

### Surgical procedure

The period between the urethroplasty with buccal mucosa graft and the AUS implantation was at least 3 months. The initial BMGUs had been performed in a standardized one-stage bulbar ventral onlay technique [14]. The perioperative management was based on an institutional standardized protocol; each patient received perioperative, i.e., antibiotic therapy (cephalosporin and gentamicin). The AMS 800 AUS system was implanted by high-volume surgeons in a standardized way [12, 13]. Patients were placed in lithotomy position and a midline perineal incision was used to isolate the bulbar urethra. Cuff size and placement were chosen depending on the localization of the buccal mucosal graft [13]. New cuffs were implanted under consideration of a sufficient surgical safety margin to the site of the former BMGU. Single cuffs (SCs) were placed as proximally as possible. Double cuffs (DCs) were placed around the distal bulbar urethra. If a further distal placement was required due to a compromised proximal and bulbar urethra, a transcorsporal SC approach was applied. The AMS 800 system was deactivated after the procedure and a 12-F transurethral catheter was placed and left in situ for 3 days after surgery. Post-void residual

urine measurements after catheter removal and radiological baseline studies were performed. The AUS activation took place 6 weeks after implantation.

### Follow-up

Follow-up was performed according to our institutional protocol. All patients were readmitted to our hospital 6 weeks after AUS implantation. After radiological control of sphincter device position, AUS was activated under stationary conditions and the patients are trained to use the scrotal pump. Functional outcome was objectified by the stress pad test, uroflowmetry, post-void urine measurement, and clinical examination. For follow-up, patients were invited to return to our hospital at 6 and 24 months after surgery, and every 2 years thereafter.

### Study endpoint

The primary endpoint of the study was the continence rate after AMS 800 implantation. The level of SUI was assessed by the 1-h stress pad test (urine loss in g) with standardized activities and the number of pads used per day. Objective and social continence was defined as the use of 0 pads/day and < 2 pads/day, respectively. Subjective continence was defined as self-reported continence.

The secondary endpoint was the assessment of complication rates, using the Clavien–Dindo classification.

### Statistical analyses

For statistical analyses, associations between categorical variables were assessed using the Chi-square test. Differences in variables with continuous distribution were assessed using the Mann–Whitney U and the Kruskal–Wallis tests. Explantation-free rates were compared using Kaplan–Meier curves and the log-rank test. Firth’s penalized Cox regression analyses were performed to analyze proportional hazard ratios for AUS explantation. All tests were performed two-sided and a  $p < 0.05$  was considered to be statistically significant. Statistical tests were performed with SPSS® 20 (SPSS Inc., IBM Corp., Armonk, NY, USA) and R version 3.5.1 (The R foundation).

## Results

### Patient characteristics

Data of 236 patients out of 248 patients in the prospective AUS database from 2009 to 2015 were available for analysis. 17 patients underwent AUS implantation after BMGU. Of these, 8 (47.1%) patients had a history of radical

prostatectomy (RRP), 1 (5.9%) patient suffered from a trauma, 8 (47.1%) patients had undergone TUR-P. Pelvic irradiation therapy was reported in 13 (76.5%) of the cases. 5 (29.4%) patients were diabetics. The median length of buccal mucosa graft urethroplasty was 4 cm (IQR 3–5 cm). A distal bulbar double cuff was implanted in 14 patients (82.4%), whereas only 3 patients received a bulbar or transcorporal single cuff for incontinence therapy. Standard cuff size used was 4.5 cm.

Overall, patients who received single-cuff AUS (SC) did not show significantly different baseline preoperative clinical characteristics compared to those who received a double-cuff device (DC) (Table 2).

However, comparing patients with or without a BMGU prior to the AUS implantation, significant differences are to be seen with respect to comorbidities (Table 1). Patients with a history of BMGU suffered more often from Diabetes mellitus ( $p=0.032$ ). Moreover, 76.5% of the patients with prior BMGU had received a pelvic radiation therapy, compared to 31.5% of the comparative Group (Comp Group) ( $p=0.001$ ). Finally, significant differences are seen with respect to surgeries prior to SUI. In the BMGU group, 47.1% of the patients had a history of RRP or TUR-P each. By contrast, in the comparative group, 79.9% ( $p=0.04$ ) and 13.7% ( $p=0.02$ ) had a history of RRP and TUR-P, respectively. Patient clinical characteristics are summarized in Tables 1 and 2.

## Complication rates and functional outcomes

Median follow-up was 24 months (IQR 6–31). The median follow-up in the different subgroups, i.e., AUS without BMGU, AUS with BMGU, single cuffs and double cuffs (Tables 2, 3, 4) were 24 months (IQR 7.25–36), 24 months (IQR 6–31.5), 6 months (IQR 2–6) and 26 months (IQR 10.5–33.75), respectively.

Data (Tables 3, 4) on postoperative Clavien III complications show that in the BMGU, erosions appeared in ( $n=2$ ) 11.8% of the cases. There were no significant differences with respect to erosions. Infections were present in ( $n=2$ ) 11.8% of the cases as well. However, the risk of infections observed in patients with a history of BMGU was significantly increased compared to the BMGU-naïve group (hazard ratio (HR) 6.4; 95% CI [1.1–26.4],  $p=0.04$ ). Nevertheless, there was no significantly increased risk for explantation (HR 2.7; 95% CI [0.96–6.08],  $p=0.06$ ).

There were no significant differences observed between SC and DC. Assessing uroflowmetry and post-voiding residual urine, no measurable failure of BMGU was seen. Uroflowmetry showed a median Qmax of 18 ml/s (12–50 ml/s) 6 months and 30 ml/s (13–50 ml/s) 24 months after BMGU and AUS implantation. There was no patient with a worsened uroflowmetry result. After BMGU and AUS implantation, no secondary interventions were performed because of urethral strictures.

**Table 1** Clinical characteristics in patients treated by implantation of AUS according to BMGU

	BMGU	No BMGU	<i>p</i> value*
Patients, <i>n</i> (%)	<i>n</i> = 17 (100)	<i>n</i> = 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, <i>n</i> (%)			
Diabetes mellitus	5 (29.4)	22 (10)	<b>0.032</b>
Anticoagulant therapy	6 (35.3)	83 (37.9)	0.526
Surgeries prior SUI, <i>n</i> (%)			
Radical prostatectomy	8 (47.1)	175 (79.9)	<b>0.04</b>
TUR-P	8 (47.1)	30 (13.7)	<b>0.02</b>
Trauma	1 (5.9)	5 (2.3)	0.365
Pelvic radiation therapy, <i>n</i> (%)	13 (76.5)	69 (31.5)	<b>0.001</b>
Surgeries prior AUS implantation, <i>n</i> (%)			
Open surgical therapy for SUI	4 (23.5)	65 (29.7)	0.401
Length of Buccal mucosa graft, cm (IQR)	4 (3–5)	–	–
Median AUS operation time minutes (IQR)	62.5 (51–68)	58 (51–68)	0.307

BMGU buccal mucosa graft urethroplasty, *Comp Grp* comparison group, *IQR* interquartile range, *TUR-P* transurethral resection of the prostate, *AUS* artificial urinary sphincter

\*Calculated by Mann–Whitney U test, Fishers exact test

**Table 2** Clinical characteristics of patients with BMGU prior to AUS implantation according to AUS position

	Overall	SC	DC	<i>p</i> value*
Patients, <i>n</i> (%)	<i>n</i> = 17 (100.0)	<i>n</i> = 3 (17.6)	<i>n</i> = 14 (82.4)	–
Median age at surgery, years (IQR)	70.0 (67.0–74)	72.0 (63.0–72.0)	70.0 (67.0–74.0)	0.536
Median urine loss				
Stress pad test, g (IQR)	119 (73–137.5)	125 (125–125)	99.5 (69.5–142.25)	0.580
Number of pads used/day (IQR)	7 (4.75–8.5)	15 (15–15)	6 (4.5–7.5)	0.189
Median ASA classification (IQR)	2 (2–3)	2 (2–2)	2 (2–3)	0.847
Comorbidities/previous surgeries, <i>n</i> (%)				
Diabetes mellitus	5 (29.4)	1 (33.3)	4 (28.6)	0.676
Anticoagulant therapy	6 (35.3)	1 (33.3)	5 (35.7)	0.728
Surgeries prior SUI, <i>n</i> (%)				
Radical prostatectomy	8 (47.1)	2 (66.7)	6 (42.9)	0.453
TUR-P	8 (47.1)	1 (33.3)	7 (50)	0.547
Trauma	1 (5.9)	0 (–)	1 (7.1)	0.824
Pelvic radiation therapy, <i>n</i> (%)	13 (76.5)	3 (100)	10 (71.4)	0.421
Surgeries prior AUS implantation, <i>n</i> (%)				
Open surgical therapy for SUI	4 (23.5)	2 (66.7)	2 (14.3)	0.121
Length of Buccal mucosa graft, cm (IQR)	4 (3–5)	3 (3–3)	4 (2.75–5)	0.506
Median AUS operation time minutes (IQR)	62.5 (51–68)	58 (58–62)	63 (50–67.5)	0.313

SC single cuff (AUS), DC double cuff (AUS), IQR interquartile range, TUR-P transurethral resection of the prostate, AUS artificial urinary sphincter

\*Calculated by Mann–Whitney U, Fishers exact test

**Table 3** Comparison of complication rates (Clavien–Dindo Grade  $\geq 3$ ) in patients with AUS implantation with or without history of BMGU

Patients, <i>n</i> (%)	BMGU, <i>n</i> = 17 (100.0)	Comp Grp, <i>n</i> = 219 (100)	HR	95% CI	<i>p</i> value*
Infection (%)	2 (11.8)	6 (2.7)	6.4	1.1, 26.4	<b>0.04</b>
Erosion (%)	2 (11.8)	23 (10.5)	1.9	0.4, 6.1	0.36
Explantation (%)	4 (23.6)	36 (16.4)	2.7	0.96, 6.08	0.06
Mechanical failure (%)	0 (–)	8 (3.7)	1.0	0.0, 9.0	0.96

BMGU buccal mucosa graft urethroplasty, Comp Grp comparison group

\*Calculated with Firth's penalized cox proportional hazard analysis

**Table 4** Complication rates in patients with single or double cuff AUS implantation after BMGU

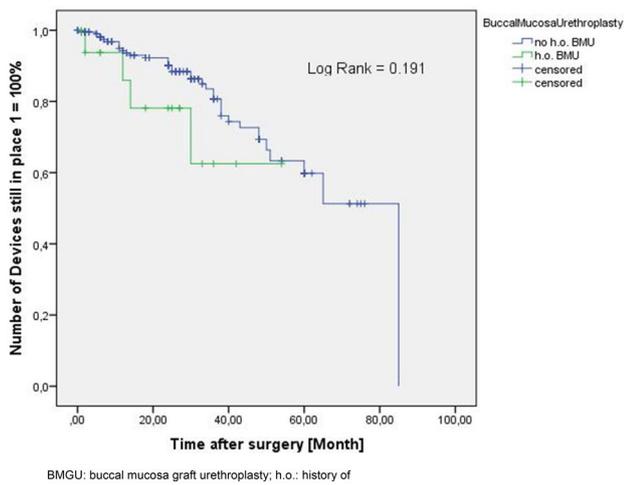
Patients, <i>n</i> (%)	Overall, <i>n</i> = 17 (100.0)	SC, <i>n</i> = 3 (17.6)	DC, <i>n</i> = 14 (82.4)	HR	95% CI	<i>p</i> value*
Infection (%)	2 (11.8)	0 (–)	2 (14.3)	0.3	0.01, 39.8	0.481
Erosion (%)	2 (11.8)	0 (–)	2 (14.3)	0.8	0.06, 117.7	0.911
Explantation (%)	4 (23.6)	0 (–)	4 (28.6)	1.0	0.09, 136.4	0.998
Mechanical failure (%)	0 (–)	0 (–)	0 (–)	–	–	–

AUS artificial urinary sphincter, BMGU buccal mucosa graft urethroplasty, SC single cuff (AUS), DC double cuff (AUS)

\*Calculated with Firth's penalized cox proportional hazard analysis

According to the Kaplan–Meier (Fig. 1) analysis which shows the probability of explantation-free survival in patients without compared to those with a history of urethroplasty, no significant differences between both groups

could be observed (median durability 63.55 month, 95% CI [57.34–69.72] and 43,12 months, 95% CI [31.37–55.87], log-rank,  $p = 0.191$ ). However, it has to be mentioned that



**Fig. 1** Comparative analyses of explantation-free rates in patients with implantation of AUS with or without history of BMGU. *BMGU* buccal mucosa graft urethroplasty, *h.o.* history of

**Table 5** Comparison of continence rates in patients with AUS implantation with or without history of BMGU

	BMGU	Comp Grp	<i>p</i> value*
Patients, <i>n</i> (%)	<i>n</i> = 17 (100.0)	<i>n</i> = 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

*BMGU* buccal mucosa graft urethroplasty, *Comp Grp* comparison group

\*Assessed using the Chi-square test

there is a trend towards a shorter durability in patients with a history of BMGU.

The objective, subjective and social continence rates after 24-month median follow-up in the BMGU were 70.6, 88.2 and 94.1%. There was no significant difference between the SC and the DC group. As Tables 5 and 6 show, these results are not significantly different from those of the BMGU-naïve population.

**Table 6** Continence rates in patients with single- or double-cuff AUS implantation after BMGU

	Overall	SC	DC	<i>p</i> value*
Patients, <i>n</i> (%)	<i>n</i> = 17 (100.0)	<i>n</i> = 3 (17.6)	<i>n</i> = 14 (82.4)	–
Objective continence (%)	12 (70.6)	1 (33.3)	11 (78.6)	0.191
Subjective continence (%)	15 (88.2)	3 (100)	12 (85.7)	0.669
Social continence (%)	16 (94.1)	3 (100)	13 (92.9)	0.824

*AUS* artificial urinary sphincter, *BMGU* buccal mucosa graft urethroplasty, *SC* single cuff (AUS), *DC* double cuff (AUS)

\*Assessed using the Chi-square test

## Discussion

The existing literature investigating the AUS implantation in patients with a history of buccal mucosa graft urethroplasty is scarce and predominantly retrospective [9, 10]. Moreover, some studies are based on non-standardized surgical approaches and non-urethral factors such as diabetes mellitus, known to affect the microvasculature, were not taken into consideration [7, 15]. To our knowledge, this study represents the only and currently largest prospective study of a homogeneous single-center cohort of patients with a buccal mucosa graft urethroplasty prior to AUS implantation. Thus, our study holds new and important findings.

The literature with respect to surgical outcome in high-risk patients is diverse. On the one hand, it is being argued that the AUS is a viable treatment option for severe incontinence even in “fragile urethra”, with early explantation rates as low as 7% [9]. Data of a prospective analysis in a multi-center study with high-risk patients outlined that radiation was a significant predictor for subsequent AUS explantation; whereas, a history of urethroplasty did not constitute a significant predictor [11]. Other authors describe higher complications as well as sphincter explantation rates in high-risk patients (i.e., pelvic radiation, urethroplasty, previous AUS explantation), based on the idea of a compromised urethral blood supply [8]. For instance, the retrospective study by McGeedy et al. [10] showed that cases of prior urethroplasty and radiation therapy had a significantly higher risk of failure than non-compromised cases (34 vs. 21%, *p* = 0.02). Moreover, in the literature, it is argued that an increased risk of failure is to be observed after 3.5-cm-cuff implantation, in particular after DC placement but not in case of a transcervical placement [10, 16, 17].

Our above-presented results showed a significantly increased risk of infection for patients with a history of BMGU (HR 6.4; 95% CI [1.1–26.4], *p* = 0.04). The large CI shows that the test is underpowered. However, the aforementioned results could be explained by the difference in the patients’ characteristics, since a history of irradiation and diabetes was observed significantly more often in the BMGU group. This might constitute a selection bias.

Interestingly, the significantly increased risk of infection in the BMGU group was not reflected by a significantly increased explantation rate. Only a trend for an increased risk of device explantation was to be observed in our study (BMGU 23.6% vs. patients without prior BMGU 16.4%, HR 2.7; 95% CI [0.96–6.08],  $p=0.06$ ). From our point of view, this may be explained by the fact that pre-operated tissue was never chosen as the site of implantation during secondary interventions. Cuffs were always placed in regions of virginal urethral tissue to reduce the risk of insufficient blood supply in the operated area. Furthermore, in case of a distal AUS implantation after prior proximal SC explantation, it was our institutional standard to choose a DC approach to reduce physical pressure of the cuffs on the operated tissue. As only patients with a history of a bulbar ventral only were taken into consideration in the BMGU group, this aforementioned approach explains the high rate of DC placement in our study.

Our approach of decision-making is in line with previously published data of our working group which showed success rates of 73.9% in AUS implantation after transperineal reanastomosis, i.e., in cases of severely compromised urethral tissue, with low complication rates of 8.7% [18].

Literature focusing on functional outcomes after AUS implantation in patients with a history of (buccal mucosa) urethroplasty is limited. In most of the abovementioned studies, little detailed information is provided on urethroplasty techniques and continence. However, comparing the results with respect to complete continence only, recent publications showed that adjuvant pelvic radiotherapy entails significantly worse results. Guillaumier et al. [15] show that success rates were 89% in nonirradiated men compared to 56% in irradiated men. By contrast in our study, despite the fact that the BMGU group had a significantly higher proportion of irradiated patients (76.5 vs. 31.6%,  $p=0.001$ ), there was no significant difference in terms of complete continence to be stated (70.6 vs. 75.8%,  $p=0.409$ ). In terms of social continence, defined as <2 pads/day, the results of this study (BMGU 94.1% vs. Comp Group 87%,  $p=0.344$ ) are in line with other publications [7, 19].

The main limitation of this study is the low number of AUS patients with a history of buccal mucosa graft urethroplasty ( $n=17$ ). Unfortunately, the ability to assess results among subgroups is limited due to small sample sizes. Larger study volumes are required to perform more profound statistical analysis. Moreover, the median follow-up was only 2 years (24 months [6–31]). Further follow-up is necessary to determine the longevity of the AMS 800 AUS device in high-risk patients with a history of urethroplasty prior to AUS implantation and to perform subgroup analyses. In addition, a matched pair analysis should be planned for further studies as this could reduce the aforementioned selection bias.

## Conclusions

Patients with a history of BMGU prior to AUS implantation do not show a significantly worse functional outcome. Despite a significantly increased risk of infection observed in the BMGU group, the probability of explantation-free survival is not significantly different from the BMGU-naïve group. Consequently, the implantation of the AMS800 AUS device is a safe and effective means in the treatment of severe incontinence in patients with a history of urethroplasty.

**Author contributions** VM and PM: Data Collection and Analysis, Project Development, Manuscript Writing. RD: Data Collection, Manuscript Editing. CR and CPM: Manuscript Editing. SR and MR: Manuscript Editing. TAL: Data Collection and Analysis, Project Development, Manuscript Editing.

## Compliance with ethical standards

**Conflict of interest** Margit Fisch and Roland Dahlem has served as consultant for Boston Scientific. All other authors declare they have no conflict of interest.

**Ethical approval** All procedures performed in our studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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