

Distal Double Cuff Vs Transcorporal Cuff as Salvage Options—A Prospective Analysis of Different Artificial Urinary Sphincter (AMS 800) Implantation Sites



Valentin Maurer, Roland Dahlem, Clemens M. Rosenbaum, Philipp Gild, Malte W. Vetterlein, Victor Schüttfort, Christian P. Meyer, Silke Riechardt, Margit Fisch, Phillip Marks¹, and Tim A. Ludwig¹

OBJECTIVE	To analyze functional outcomes and complication rates of distal double cuffs (DC) or transcorporal cuffs (TC) as salvage approaches in high-risk patients, since there is an ongoing debate about optimal cuff-placement in a salvage setting (SV). Existing studies analyzing DC or TC are controversial with respect to functional outcomes and complication rates. Studies directly comparing both approaches in SV are scarce.
METHODS AND PATIENTS	Prospective data collection was performed since 2009. DC/TC were applied according to a standardized protocol in SV. Salvage DC was chosen in case of a membranous single cuff explantation due to erosion or infection. TC were implanted after bulbar urethroplasty or DC explantation. Activation was performed 6 weeks postoperatively. Further follow-up was scheduled 6/24 months postoperatively and every 2 years thereafter. Primary/secondary endpoints were continence/complication rates.
RESULTS	In total, 71 high-risk patients were available for analysis (58 DC, 13 TC). Median age was 70 years. Median follow-up was 24 months. Objective/social continence were 88%/94% in the DC and 72%/100% in the TC cohort, respectively ($P = .37/P = 1$). Overall, there were no significant differences with respect to infections, erosions, mechanical failure, and explantation rates. The times of explantation-free survival were similar in Kaplan-Meier analysis (Log-rank 0.399).
CONCLUSION	Complication and continence rates were not significantly different between both cohorts. Hence, a DC in SV can be considered as equally safe and effective. A sequential implantation (first DC, second TC) may be a viable approach to extend overall AUS incontinence therapy. UROLOGY 133: 234–239, 2019. © 2019 Elsevier Inc.

Male stress urinary incontinence (SUI) is a dreaded complication after local treatment of prostate cancer and benign prostatic hyperplasia. Incontinence rates ranging from about 20% up to 36% 1 year after radical prostatectomy are described in the literature.^{1,2} According to the current guidelines,

artificial urinary sphincter (AUS) implantation constitutes the gold standard in the surgical treatment of SUI.^{3,4} As with all prosthetics, the implantation of an AUS may be associated with certain adverse events, such as erosion, mechanical failure, infection, all of which lead to revision surgery or to the explantation of the device.^{5,6} The risk of a device explantation is particularly high in patients suffering from microangiopathy, ie, patients with diabetes mellitus, coronary artery disease, a history of pelvic radiation, and urethral or incontinence surgery.^{7,8}

Despite the fact that studies analyzing reimplant cases have shown a 4-fold higher risk for cuff explantation compared to primary cases⁸ and that half of the patients with an AUS device will require additional surgeries at a median time of 2 years after reimplantation,⁶ there is limited evidence concerning salvage AUS device implantation in high-risk patients. This begs the question whether

¹ Philip Marks and Tim A. Ludwig contributed equally.

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From the Department of Urology, University Medical Center Hamburg-Eppendorf, Hamburg, Germany

Address correspondence to: Valentin Maurer, M.D., Department of Urology, University Medical Center Hamburg-Eppendorf, Martinistrasse 52, Hamburg 20246, Germany. E-mail: Valentin.maurer@gmail.com

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there is a superior surgical technique or a surgical algorithm which allows surgeons to improve and maximize the longevity of surgical treatment options for high-risk patients suffering from severe SUI.

Studies aiming to analyze the transcorporal cuffs (TC) compared to the double cuffs (DC) approach are scarce, many have retrospective study designs, lack standardized follow-up (FU) data or rely on inconsistent definitions for continence status and complications.⁹

Therefore, our aim was to analyze the complication rates and functional outcome of the DC compared to the TC approach in order to evaluate the idea of a sequential therapeutic approach for high-risk patients.

PATIENTS AND METHODS

Patient Population

Since January 2009, in accordance with an Institutional Review Board approval, all perioperative and FU data of patients undergoing AUS implantation (AMS 800) at our institution have been prospectively collected in an AUS database. We included male patients with SUI level III-IV according to international continence society at the initial AUS implantation. Patients with detrusor overactivity or insufficient compliance apparent during first 300 mL of bladder filling at preoperative urodynamic cystomanometry or those who were candidates for male sling implants (mild SUI and no history of radiation therapy) were excluded prior to analyses. Moreover, patients with insufficient manual dexterity in the preoperative evaluation were excluded.

Surgical Procedure

At our institution, the surgical approach as well as the perioperative management is based on an institutional standardized protocol established by Professor Schreiter.^{10,11} A DC-approach as a salvage option is chosen in case of a status after membranous SC explantation due to erosion or infection. Moreover, a DC is implanted if patients have a history of a proximal bulbar urethroplasty. A TC approach is applied in patients with a history of DC explantation or if patients have a history of a distal bulbar urethroplasty. Patients receive perioperative IV antibiotic therapy (ceftriaxone and gentamicin). The AUSs are implanted by 2 high-volume surgeons.

For the DC approach, patients were placed in lithotomy position and a midline perineal incision was used to isolate the bulbar urethra. Cuffs were placed around the bulbar urethra.¹⁰ An appropriate cuff was placed after circumference measurement. The median cuff size applied was 4.5 cm. The pump and the balloon were filled with contrast agent (Imeron 300) and implanted in the scrotum and abdomen. Contrast agent was used, as it allows to check the correct AUS filling postoperatively. 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. Postvoid residual urine measurements after catheter removal and radiological baseline studies were performed. The AUS activation was performed 6 weeks after implantation under inpatient conditions in order to ensure a sufficient device handling by the patient.

For the TC approach, patients were placed in lithotomy position. A midline perineal incision was performed with a subsequent dissection in order to expose the urethra and adjacent lying corpora cavernosa. The urethra was prepared without

excessive mobilization. Cuff placement was 2-3 cm distally to the original cuff location. Two longitudinal incisions were made into the tunica albuginea of both corpora cavernosa, lateral to the urethra. In order to create a tunnel inside the corpora cavernosa, a blunt dissection was performed between the 2 corporal incisions. Cuff placement was performed after circumference measurement. The median cuff size applied was 4.5 cm. The pump and the balloon were implanted in the scrotum and abdomen in line with the DC approach.

Follow-Up

FU was performed according to our institutional protocol. All patients were readmitted to our hospital 6 weeks after the AMS 800 implantation. After radiological imaging control of sphincter device position, the AMS 800 was activated in an inpatient setting and the patients were trained to apply the scrotal pump. Functional outcome was objectified by the stress pad-test, uroflowmetry, postvoid urine measurement, and clinical examination. Furthermore, a standardized, nonvalidated questionnaire covering clinical event reporting as well as self stated continence (including Incontinence Quality of Life, International Consultation of Incontinence Questionnaire—Short Form) was administered. For FU, patients were advised to return to our hospital at 6 and 24 months after surgery, and thereafter every 2 years.

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 hour stress pad-test (urine loss in grams) and the number of pads used per day. Objective or social continence was defined as the use of 0 pads/day or ≤ 2 pads/day, respectively. Subjective continence was defined as self-reported continence as experienced by the patients.

The secondary endpoint was the assessment of complication rates, with a particular focus on Clavien III complications (infection, mechanical failure, and explantation). The explantation-free survival was defined as patients without any need of explantation of the AUS during FU.

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 test. The probability of explantation-free survival was compared using Kaplan-Meier curves and the Log-rank test between characteristic groups. Firth's penalized Cox regression analyses were performed to analyze proportional hazard ratios for AUS explantation. All tests were performed 2-sided and a $P < .05$ was considered to be statistically significant. Statistical tests were performed with SPSS 20 (SPSS Inc., IBM Corp., Armonk, NY and R version 3.5.1 (The R foundation).

RESULTS

Patient Characteristics

Patient characteristics are summarized in Table 1. Overall, 71 patients were analyzed. The median age at surgery was 70 years. There was no significant difference regarding age ($P = .144$). Patients receiving a TC cuff showed significantly higher median urine loss (DC 85 g, IQR 44-137 g vs TC 233 g, IQR 129-351 g; $P = .008$) compared to those with a DC. There was no significant difference regarding pad usage. The cohorts did not differ

Table 1. Clinical characteristics in patients treated by AUS implantation

	Overall	DC	TC	P Value
Patients, n (%)	71 (100)	58 (100)	13 (100)	–
Median age at surgery, y (IQR)	70 (67-74)	70.0 (66-74)	73 (70-78)	.144
Median preoperative urine loss				
Stress pad-test, g (IQR)	121 (55-160)	85 (44-137)	232.5 (129-351)	.008
Number of pads used/d (IQR)	7 (6-9)	7 (6-8.8)	8 (5.5-12)	.16
Median ASA classification (IQR)	2 (2-3)	2 (2-3)	2 (2-3)	.973
Comorbidities/previous surgeries, n (%)				
Diabetes mellitus	9 (13)	6 (11)	2 (15)	.387
Anticoagulant therapy	29 (41)	21 (38)	7 (54)	.376
Surgeries prior SUI, n (%)				
Radical prostatectomy	60 (85)	51 (88)	10 (77)	.228
TURP	8 (11)	5 (8.8)	2 (15)	.353
Radical cystectomy	2 (2.8)	1 (1.8)	1 (7.7)	.388
Trauma	1 (1.4)	1 (1.8)	0 (-)	1
Neurological disease	0 (0)	0 (0)	0 (-)	–
Surgeries prior AMS implantation, n (%)				
surgical therapy for urethral Stricture	26 (37)	17 (30)	7 (54)	.774
Open surgical therapy for SUI	71 (93)	58 (100)	8 (62)	.136
History of external pelvic irradiation, n (%)	28 (39)	74 (48)	7 (54)	.065
Median AUS operation time, min (IQR)	57 (52-66)	55.5 (51-65)	62 (57-72)	.083

$p = 0.008$ (very significant).

significantly in terms of ASA classification and with respect to relevant comorbidities (ie, diabetes mellitus, anticoagulant therapy). Overall, RP, TURP-prostate, and radical cystectomy were performed in 85%, 11%, and 2.8% of the cases, respectively ($P = .228$; $P = .353$; $P = .388$). In total, 39% of the patients had a history of pelvic radiation, which was not significantly different between both cohorts ($P = .065$). There was no significant difference regarding operation time ($P = .083$).

Complication Rate and Functional Outcome

Data (Table 2) on postoperative complications show that overall Clavien III complications, ie, infections and erosions appeared in 2.8% and 13% of the cases respectively, leading to an overall explantation rate of 16%. Overall, 1.4% of the patients suffered from mechanical failure. There were no statistically significant differences between both cohorts regarding postoperative infections, erosions, explantation, or mechanical failure.

Objective, subjective, and social continence rates after 24 months median FU (6.5-36 m) were assessed including only those patients with the AUS device still in place at the time of data collection (Table 3). In this case, overall objective,

subjective, and social continence for both cohorts were 83%, 88%, and 94%, respectively ($P = .369$; $P = .572$; $P = 1$). In either case, there was no significant difference between both cohorts.

According to the Kaplan-Meier analysis (Fig. 1), 30 months after implantation, 80% of the DC-AUSs were still in place compared to 100% in the TC cohort, which was not significantly different (Log-rank $P = .399$).

In the Kaplan-Meier estimate, the calculated median durability of the AUS was 58 months (50-66 m, confidence interval [CI] 95%) in the DC cohort compared to 34 months (23-45 m, CI 95%) in the TC cohort. The difference of the calculated median durability of the AUSs is not statistically significant (Log-rank, $P = .399$). The median explantation-free time in the TC-cohort was 40 months.

DISCUSSION

There is limited evidence concerning salvage AUS device implantation in high-risk patients with a compromised urethra. Lai et al have shown in a retrospective analysis

Table 2. Complications

	Overall	DC	TC	HR	95% CI	P Value
Patients, n (%)	71 (100)	58 (100)	13 (100)			–
Infection (%)	2 (2.8)	2 (3.4)	0 (-)	1.2	0.0, 10	.89
Erosion (%)	9 (13)	7 (12)	2 (15)	3.2	0.7, 9.9	.21
Explantation (%)	11 (16)	9 (16)	2 (15)	1.3	0.4, 4.2	.64
Mechanical failure (%)	1 (1.4)	1 (1.7)	0 (-)	2.7	0.0, 25	.56

Table 3. Functional outcome (all patients with devices still in place)

	Overall	DC	TC	P Value
Patients, n (%)	60 (100)	49 (100)	11 (100)	–
Objective continence (%)	50 (83)	42 (88)	8 (72)	.369
Subjective continence (%)	53 (88)	42 (88)	11 (100)	.572
Social continence (%)	56 (94)	45 (93)	11 (100)	1

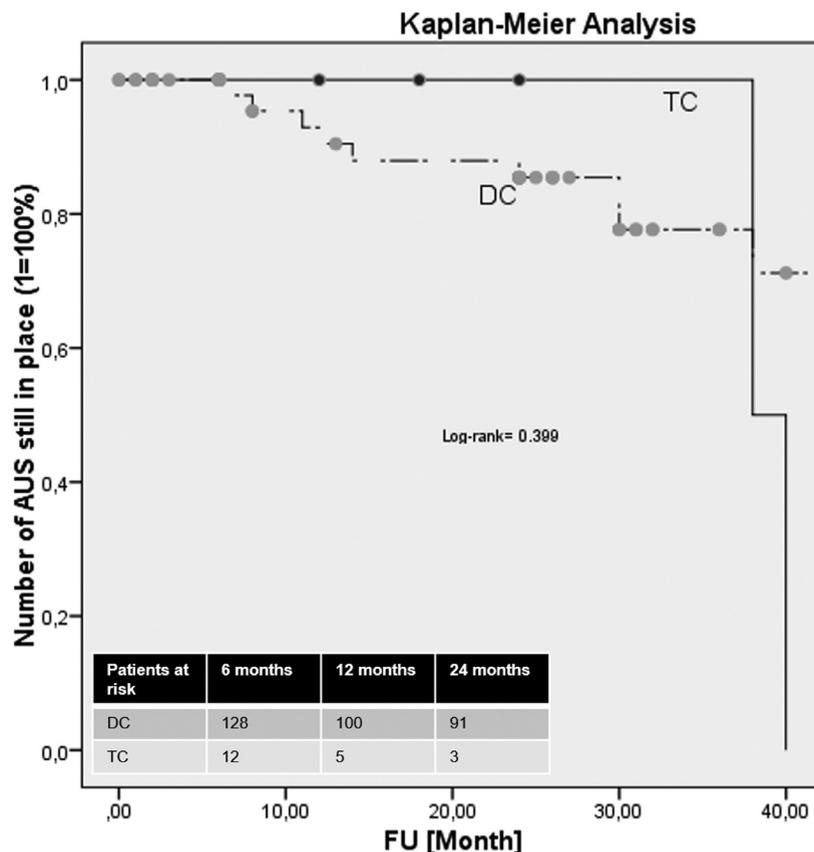


Figure 1. Kaplan-Meier estimates of explantation-free survival after AUS implantation, DC (grey, dotted) vs TC (black, line); patients at risk.

that AUS reimplantation cases have a 4-fold higher risk for future cuff erosion and subsequent explantation compared to primary cases.⁸ This is also supported by Wang et al who analyzed long-term outcomes after primary failures of AUS implantation. According to their analysis, more than half of patients with an AUS device will require additional procedures at a median time of 2 years after reimplantation.⁶ The aspect of a higher risk of failure in reimplantation cases begs the question whether there is a superior surgical technique or a surgical algorithm, which allows surgeons to improve and maximize the longevity of surgical treatment options in high-risk patients.

The need to elevate the urethra off the corporal bodies in the standard AUS approach is often regarded as a major drawback in compromised urethras as it may lead to direct urethral injury and further urethral devascularization.⁷ Guralnick et al outline that the TC technique offers significant advantages in cases of revisions, as it protects the urethra from the aforementioned intraoperative dissection injury. The authors argue that it decreases the risk of erosion because the urethra is buttressed at its vulnerable location. Furthermore, advantages are seen with respect to better cuff sizing and a superior functional outcome (84%, reporting 0-1 pads/d; no explantations at 17 months) compared to the DC salvage technique.¹² Some authors therefore promote the TC placement as an effective salvage or even primary incontinence treatment for high-risk

patients.^{13,14} It is argued that the TC cuff placement constitutes a useful alternative for challenging cases of male SUI after failure of previous surgical treatment, urethral atrophy or erosion (17 TC, 47% free of stress incontinence symptoms and pad use, 29% 1 pad daily, 23% 2 to 3 pads daily; 18% explantations due to infections, 24% revision for cuff replacement).¹⁵ Mock et al further support the thesis, that TC should be reserved for complex high-risk cases. Their analysis showed that the proportion of patients free of AUS explantation decreases as the number of risk factors is rising. At 35 months, explantation-free survival was 100% for those with 0-1 urethral risk factors and 52% for those with ≥ 2 risk factors (Log-rank test, $P = .02$).¹⁶ In a multi-institutional prospective study by Brant et al, high-risk men who underwent TC placement reported rates of explantation which were lower than those of the overall cohort (11% vs 13%; $P = .42$). Interestingly, the same study revealed that high-risk men who received a 3.5 cm SC were at a considerably higher risk of explantation than those who had received larger cuffs (27% vs 13%; $P = .04$), which allowed the authors to conclude that TC placement may be superior to placement of a 3.5 cm cuff in the compromised smaller urethra.⁷

Nevertheless, there is an ongoing debate about the technique to be applied in high-risk patients. Moser et al analyzed the outcomes of 34 patients after eroded cuff reimplantation in a multicenter retrospective analysis.

The TC approach appeared not to be a protective maneuver in this analysis. In accordance with our results, differences regarding complications were not to be seen between the TC and the non-TC group ($P = .438$). The TC group was associated with a higher rate of repeat complications in irradiated patients.¹⁷ A retrospective study by Mc Geady et al, analyzing the outcomes of sphincter placement in compromised urethras, showed that tandem cuffs ($n = 3$) had a higher risk of failure compared to patients with a TC placement ($n = 22$). However, these results are limited due to the small population (hazards ratio 4.11; 95% CI 1.1, 16).¹⁸

Only very few studies exist, directly comparing the outcomes of a TC vs a non-TC bulbar approach in case of a fragile urethra. The results of these studies were limited due to small cohorts and partially different surgical approaches (perineal and transscrotal) in the same cohort. The reference groups with respect to complications and functional outcome consisted predominantly of patients with a history of SC implantation.^{7,13,19,17}

To our knowledge, this is the first study with a prospective database comparing the outcome of DC vs TC approach in case of a fragile urethra. Results from our study group have shown that a DC approach to the AUS implantation is a viable and noninferior alternative in high-risk patients with a history of pelvic radiation, buccal mucosa graft urethroplasty, a history of failed continence surgery, or AUS-explantation.²⁰ The argument that a compromised urethral blood supply due to urethral injury entails worse functional and surgical outcomes despite a cuff placement outside of the compromised radiation or surgical area, is not in accordance with our results. By contrast, the distal bulbar placement of an AUS with a DC seems to be an equally viable alternative strategy in case of a compromised urethra. Our results show that, despite the fact that the TC cohort suffered from significantly more urine loss in the stress pad-test (DC 85 g, IQR 44-137 g vs TC 233 g, IQR 129-351 g; $P = .008$), the functional outcome was not inferior to the DC cohort. The rate of erosions (DC 12% vs TC 15%; $P = .21$) and explantations (DC 16% vs TC 15%; $P = .64$) as well as objective, subjective, and social continence (DC 88%, 88%, 94% vs TC 72%, 100%, 100%; $P = .369, .572, 1$) was not significantly different between the 2 cohorts and corresponds to the rates published for high-risk patients.^{12,15} Equally, the erosion and explantation rates for the TC cohort are within the range described in the existing body of literature for high-risk patients.^{7,16}

Based on these results and also considering the higher degree of invasiveness associated with the TC approach, we argue that the AUS with a TC ought to be applied as a salvage option only. According to our Kaplan-Meier analysis, which showed no significant difference in terms of the median estimated durability of the AMS 800 system (Log-rank test, $P = .399$), a sequential approach, ie, DC followed by TC in case of DC failure, would potentially allow for another 40 months of AUS continence therapy. The Kaplan-Meier estimate so far only shows a trend with

respect to a difference in durability. Longer FU as well as randomized prospective studies of a larger volume are required to address this aspect more sufficiently.

Strongpoints of this study are the strict surgical standardization and the standardization of the perioperative management as well as the prospective data collection.

However, when analyzing the data, it ought to be taken into consideration that a major limitation of this study is the small TC cohort ($n = 13$). Larger study cohorts are required to further support our data. Moreover, patients in the TC group had higher urine loss in the preoperative pad-test. This constitutes a bias and might have a detrimental effect with regard to postoperative complications and functional outcome.

CONCLUSION

The distal DC approach as a salvage option is not inferior to the TC approach with respect to complications and functional outcome. Moreover, the probability of explanation-free survival is not significantly different between the analyzed cohorts. Consequently, the implantation of the AUS with a distal DC is a safe and effective means in the treatment of SUI in high-risk patients and constitutes an alternative salvage approach to the currently often favored TC cuff placement. Thus, in order to maximize the duration of an effective incontinence therapy, a sequential approach ought to be pursued, starting with the DC approach which is then followed by the TC approach in case of failure.

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