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Secondary Sling Implantation after Failure of Primary Surgical Treatment for Male Stress Urinary Incontinence: A Retrospective Study

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Keywords
Urinary incontinence · Male slings · Salvage surgery

Abstract
Objective: The artificial urinary sphincter (AUS) is the surgical gold standard after previously failed surgical treatment for male urinary stress incontinence. The evidence for a male sling as salvage treatment is poor, but there is a proportion of patients that refuse implantation of an AUS or have a relative contraindication. The goal of our retrospective study was an analysis of outcome and complications of patients with a secondary sling after previously failed surgery for stress urinary incontinence (SUI). ***Materials and Methods:*** Data on 186 patients who had a prior incontinence surgery were extracted from the DOMINO database. 139 patients (74.7%) received an AUS and 41 patients (22.0%) who had received a secondary sling system between 2010 and 2012 after previously failed surgery for male urinary incontinence could be identified and were further analyzed. ***Results:*** Eight patients (19.5%) received a secondary repositioning sling and 33 patients (80.5%) received a secondary adjustable sling system. A prior surgery for urethral stricture was performed in 4 patients (9.8%). No major intraoperative complications were reported. A simultaneous explantation was performed in 12 patients (29.3%). The mean number of pad reductions was 4.93 ($p = 0.026$). No intraoperative complications and no postoperative surgical revisions were reported. The mean follow-up of the patient cohort with a secondary sling was 16 months. ***Conclusion:*** We provide the largest co-

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hort of male patients up to date with a secondary sling after primary failure of surgery for male SUI. Although the procedure is a rarely performed surgery and without a high level of evidence, a secondary adjustable male sling system might be a feasible option in selected patients with acceptable complication rates, whereas a valuable outcome regarding continence rates cannot be sufficiently supplied by our data.

Introduction

The optimal treatment of male patients who fail primary sling surgery for stress urinary incontinence (SUI) is controversial and mainly based on experts' opinions. Although most surgeons would favor the implantation of an artificial urinary sphincter (AUS), there is a percentage of patients with previously failed surgery for SUI that refuse to undergo implantation of an AUS or show contraindications like manual or cognitive impairment. Hence, the relevant guidelines do not offer solid recommendations due to very limited available studies for this situation affecting up to 20% of patients after primary sling implantation [1].

The goal of our retrospective study was a multi-institutional retrospective analysis of postoperative results and complications of patients with previously failed surgery for SUI that underwent a secondary implantation of a male sling device as an individual surgical attempt.

The AUS (AMS 800; Boston Scientific, Marlborough, MA, USA) remains the surgical gold standard in men with severe and recurrent SUI. Postoperative continence rates of the AUS are high with success rates of ~80% – defined as a maximum of 1 pad per day. However, revision rates are reported up to 25% due to infection or urethral atrophy and erosion [2–4]. Nevertheless, most surgeons would favor an AUS after prior incontinence surgery or urethral surgery, due to the lack of data supporting another sling implantation in these patients as well as due to the different modes of action. Maurer et al. [5] just recently published a series of prospectively evaluated patient that underwent implantation of an AUS after prior buccal mucosa graft urethroplasty and could show satisfying results and low complication rates in these patients. Ajay et al. [6] recently published a study that included 61 patients that were retrospectively evaluated and underwent a second surgery for urinary incontinence after previously failed sling implantation. The overall treatment failure was high with 55% (16 of 29) in the group of patients who received a secondary transobturator sling versus 6% (2 of 32) in the group of patients with salvage AUS implantation [6].

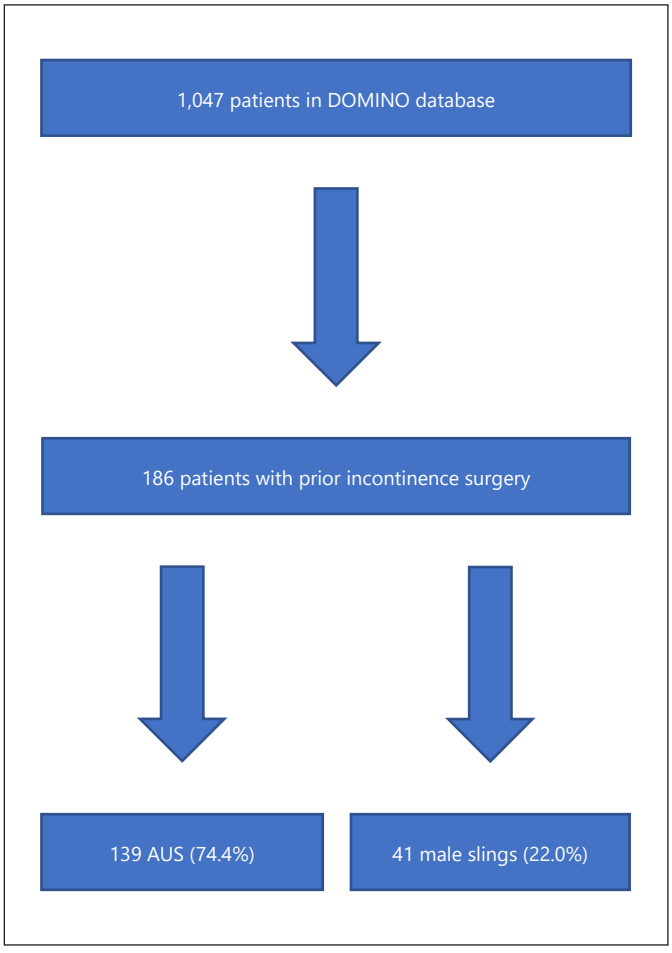

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Fig. 1. Flowchart of patient selection. AUS, artificial urinary sphincter.

Angulo et al. [7] evaluated the efficacy and safety of the ATOMS adjustable male sling system (A.M.I., Feldkirch, Austria) after previously failed surgery for urinary incontinence. Thirty patients were included in the study. The median 24-h pad test decreased from 435 to 10 mL, after adjustment, the pad count was reduced from 4 to 0, and 83.3% of patients declared to be satisfied. After a follow-up of 24 months, only 1 system was removed due to inefficacy. No patient reported persistent urinary retention. The authors concluded that adjustable male sling systems might be a feasible option in patients after previously failed therapy, but highlighted the need for more data [7]. To date, there is a lack of data regarding the efficacy and complication rates of sling implantation in men with previously failed surgery for urinary incontinence.

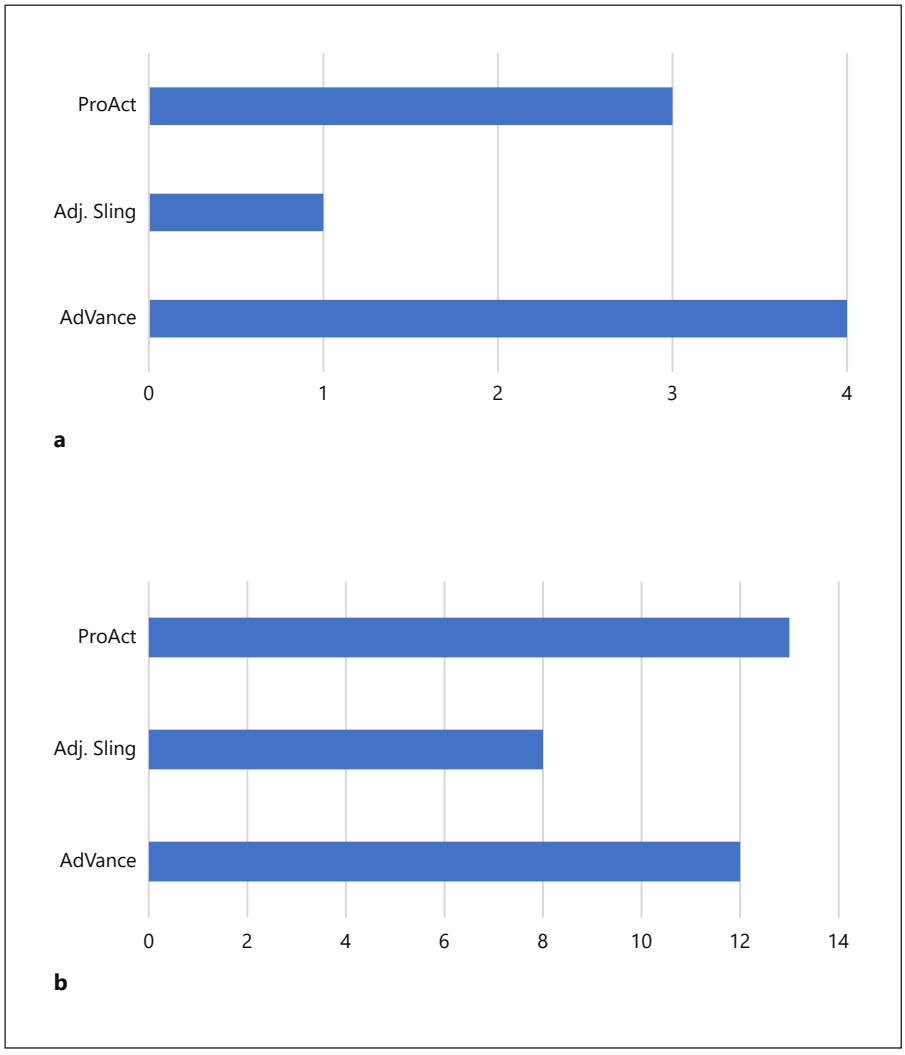

Fig. 2. a Prior surgery in patients receiving repositioning slings (AdVance/AdVance XP). **b** Prior surgery in patients receiving adjustable slings (ATOMS/ARGUS).

Materials and Methods

The "Debates on Male Incontinence" (DOMINO) working group intends to provide evidence with the help of a robust "real-life" database with patients from 18 urological continence centers of very different patient volume from Central Europe. In total, 1,047 male patients that underwent surgery due to SUI between 2010 and 2012 were included in a retrospective database. Of these patients, information of all patients with sling implantation due to an unsatisfactory postoperative continence status after prior surgery for urinary incontinence was extracted and postoperative continence status was assessed with standardized questionnaires.

The study was performed according to the Helsinki Declaration and approved by the local Ethics Committee of the Medical University Frankfurt (Johann-Wolfgang Goethe University, Frankfurt am Main, Germany; number: 442/13). After ethical approval of the study, written informed consent was obtained from all patients participating in prospective evaluation of quality of life. Due to the retrospective nature of the study, patient selection was not standardized. All patients were assessed in an ambulatory clinical visit prior to surgery.

All statistical analyses were performed with IBM SPSS Statistics 25.0 (IBM Co., Armonk, NY, USA). A p value ≤0.05 was considered statistically significant. For statistical analysis, Wilcoxon and ANOVA tests were used.

Results

Data on 186 patients that had a prior incontinence surgery and underwent a secondary surgery were extracted from the DOMINO database (Fig. 1). 139 patients (74.7%) received an AUS, and 41 patients (22.0%) could be identified that received a secondary sling system after a previously unsuccessful implantation of a male sling or ProACT balloon system and were further analyzed. Eight patients (19.5%) received a repositioning suburethral sling,

Table 1. Preoperative continence status

	N	Min.	Max.	Mean	SD
Pads per day	31	1	20	5.65	3.45
24-h pad test	16	100	3,500	611.44	421.64

and 33 patients (80.5%) received an adjustable sling system. A detailed overview of the prior incontinence systems is provided in Figure 2. The mean age of the patient cohort was 78.8 years (65–91), and the mean follow-up was 16 months (min.–max.: 2–42).

Prior surgeries responsible for urinary incontinence were radical prostatectomy in 90.2% of cases (37/41) and TUR-P in 9.8% of cases (4/41). No patient had a known neurological disease. A prior surgery for a urethral stricture was performed in 4 patients (9.8%). Five patients (12.2%) had preoperative urge symptoms. Five patients (12.2%) had a prior radiation therapy. In preoperative assessment, 12 patients (29.3%) underwent urodynamic testing with 3 patients (7.3%) showing a terminal detrusor overactivity, and 24 patients (58.5%) patients underwent preoperative cystoscopy with 2 patients (4.9%) showing a relative stricture that could be passed with the cystoscope. Table 1 gives an overview of preoperative continence status.

The mean duration of surgery was 72 min (min.–max.: 35.0–145.0). No intraoperative complications and no postoperative surgical revisions were reported. A simultaneous explantation was performed in 12 patients (29.3%), whereas in patients with prior AdVance sling (n = 16), only 1 sling system (6.3%) was explanted and in 15 patients a dissection of 1 sling arm was performed.

In the early postoperative phase, 8 patients (19.5%) showed a residual urine volume of ≥30 mL and 2 patients (4.9%) required a temporary transurethral catheterization (complication grade 3a according to Clavien-Dindo Classification [CDC]). Two patients (4.9%) developed an epididymitis and required antibiotic treatment (complication grade 2 according to CDC). No patient reported of de novo urge symptoms, but 2 patients (4.9%) needed to continue anticholinergic medication.

During the follow-up period, no urethral erosions or system defects occurred. In total, 2 patients (4.9%) underwent explantation due to dislocation of the system. Six patients (14.6%) with adjustable sling systems reported of prolonged perineal pain caused by the sling system and permanent use of analgesic medication (complication grade 2 according to CDC), and in 3 patients (7.3%), transection of 1 sling arm was performed due to persistent pain (complication grade 3b according to CDC). 54.5% of patients (18/33) who received an adjustable male sling underwent a readjustment procedure. The mean number of adjustments was 1.39 (min.–max.: 1–3; SD 0.608).

Patients' subjective change in continence was available for 18 patients, whereas 5 patients (27.8%) stated to be completely dry, 7 patients (38.9%) reported an improvement, 5 patients (27.8%) experienced no change, and 1 patient (5.6%) reported a worsening of urinary incontinence symptoms. In patients with repositioning slings (AdVance and AdVance XP), postoperative pad usage was available for 4/8 patients with a mean value of 0.5 pads in 24 h (min.–max.: 0–1). In patients with adjustable sling systems (n = 11/33), the mean postoperative pad usage was 0.7 pads in 24 h. In all patients, the mean postoperative pad usage was reduced significantly compared to the preoperative continence status: −4.9 (p = 0.026).

Patients with secondary AUS implantation showed a better postoperative continence status in comparison. Patients' subjective change in continence was available for 61/139 patients (43.9%), whereas 37 patients (60.7%) stated to be completely dry, 16 patients (26.2%) reported of an improvement, 7 patients (11.5%) experienced no change, and 1 patient (1.6%) reported of a worsening of urinary incontinence symptoms.

Discussion

Only a small proportion of patients with previously failed surgery for urinary incontinence were chosen for a secondary sling implantation in our cohort. In this complex clinical situation, the AUS is favored by most surgeons due to the different modes of action by circumferential compression of the urethra which is thought to be more likely to lead to a successful outcome.

The repositioning male sling (AdVance/AdVanceXP; Boston Scientific) is an established treatment modality in patients with male SUI. Good results could be demonstrated for patients with strictly applied selection criteria and a limited degree of incontinence [8]. Adjustable male slings (e.g., Argus, Promedon, Argentina, or ATOMS, A.M.I., Austria) are another minimally invasive treatment option in male patients with SUI. Several studies could demonstrate satisfying postoperative continence rates, but mostly in patients without prior incontinence surgery and without a high level of evidence in regard to patient selection [9, 10]. Meisterhofer et al. [11] recently summarized available evidence for sling systems in the

treatment of male SUI and concluded that due to the heterogeneity of the data no clear recommendation can be made for certain patient populations and more randomized-controlled trials with clearly defined inclusion criteria are needed.

In patients with previously damaged urethra, some experts might suggest that an adjustable male sling system might be an option due to less constriction to the urethra, but there is no reliable evidence for a sling implantation in these patients. In summary, data on sling usage in these patients are very limited and most of the literature is only evaluating selected patient cohorts. Consequently, there is no guideline recommendation on sling usage in patients undergoing secondary operations due to the low level of evidence [1].

Postoperative continence results in these secondary cases seem inferior compared to patients undergoing primary implantation. Previous studies describe a dry rate of 79.2% in patients undergoing primary procedures for the retropubic Argus sling (Promedon, Cordoba, Argentina) [12], and a dry rate of 61.9% was shown for the Argus-T sling [9] after a follow-up of ~2 years. For the ATOMS sling (A.M.I., Feldkirch, Austria), a complete dry rate of 64% after a follow-up of 31 months was previously published [10]. Our postoperative results show lower continence rates and are more in line with previously published data of a small ATOMS series by Angulo et al. [7] after previously failed treatment with a dry rate of 76.6%. The median pad test decreased from 435 to 10 mL, and the pad count was reduced from 4 to 0 in this study. Lentz et al. [13] published a small series of 29 patients that underwent a secondary AUS implantation. The dry rate was high with 96% and comparable to primary implantation [13]. Also, the study of Ajay et al. [6] is in favor of the AUS. Treatment failures were seen in 55% of patients (16/29) with a secondary sling versus 6% of patients (2/32) with an AUS [6]. After prior sling implantation Ziegelmann et al. [14] could show a trend towards an impaired function of AUS in a cohort of 30 patients compared to 510 patients in the control group without prior sling surgery, but the study failed to show a statistically significant difference in 3-year device survival (70 vs. 85%; $p = 0.21$). In addition, no statistically significant differences in the evaluation of complications like infection, erosion, and urethral atrophy could be shown [14].

The complication rates in our study were low and acceptable. No major complications were reported. This goes in line with previously published studies. Angulo et al. [7] presented a low complication rate of 13.3% after a median follow-up of 24 months in patients with secondary ATOMS implantation, no system was infected and no system led to urethral erosion, and only 3.3% of patients underwent explantation due to inefficacy. In patients with secondary AUS implantation and sling implantation, Lentz et al. [13] reported a low overall complication rate of 6.9%. Baron et al. [15] reported a revision rate of 28% in a small series of patients ($n = 14$) that underwent secondary ProACT balloon implantation.

There are certain limitations to our study. Firstly, our study was a retrospective evaluation with only a limited number of patients and different primary systems. Follow-up was limited, and data on postoperative continence status were incomplete. Nevertheless, our study provides "real-life" data with the largest patient population up to date from a multi-institutional database that aims to evaluate and consequently improve treatment of this complex patient population. In addition, our study is reflecting the current status of surgical treatment of these patients and underlines the urgent need for randomized trials comparing surgical therapeutic options in male incontinence.

In summary, a secondary sling after primary failure of surgery for male SUI is still a rarely performed procedure without a high level of evidence. In selected patients, a secondary male sling system might be a feasible option that can be performed safely with acceptable complications rates, whereas a valuable outcome regarding continence rates cannot be sufficiently supplied by our data and patients should be informed preoperatively of a potentially impaired functional outcome compared to the AUS. More prospective studies are needed for a better understanding of the feasibility of the procedure and selection criteria in these patients.

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Statement of Ethics

The study was performed according to the Helsinki Declaration and approved by the local Ethics Committee of the Medical University Frankfurt (Johann-Wolfgang Goethe University, Frankfurt am Main, Germany; Number: 442/13). This was a retrospective study evaluating perioperative data. Different questionnaires were utilized prospectively. A signed informed consent from the patients participating in the prospective collection of the questionnaires was obtained.

Disclosure Statement

M. Grabbert, A. Kretschmer, R. Kirschner-Hermanns, R. Anding, B. Brehmer, F. Queissert, W. Khoder, C. Gratzke, T. Hofmann, and A. Haferkamp declare no potential conflicts of interest. T. Hüsch is an employee of Promedon GmbH (Kolbermoor, Germany) outside of this study. C.M. Naumann declares lectures, consultancy work, and participation in clinical trials for Coloplast (Humlebæk, Denmark). H. Loertzer declares lectures, consultancy work, and participation in clinical trials for Coloplast (Humlebæk, Denmark). R.M. Bauer declares consultancy work, lectures, and participation in clinical trials for AMS/Boston Scientific (Marlborough, MA, USA), AMI (Feldkirch, Austria), and Promedon (Cordoba, Argentina). W. Huebner declares consultancy work, lectures, and participation in clinical trials for Uromedica (Plymouth, MN, USA) and Promedon (Cordoba, Argentina).

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Author Contributions

M. Grabbert collected and analyzed data and wrote the manuscript. T. Hüsch helped with data analysis as well as data collection. A. Kretschmer, R. Kirschner-Hermanns, R. Anding, B. Brehmer, F. Queissert, H. Loertzer, W. Khoder, C. Gratzke, T. Hofmann, and C.M. Naumann helped with data collection and reviewed the manuscript. W. Huebner, A. Haferkamp, and R.M. Bauer were in charge of the project and supervised the project and reviewed the manuscript.

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