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Argus-T Adjustable Male Sling: The Influence of Surgical Technique on Complications and Short-Term Efficacy

Erik Bastiaan Cornel

Department of Urology, Ziekenhuis Groep Twente Hengelo, Hengelo, The Netherlands

Key Words
Male sling · Post-radical prostatectomy incontinence · Single incision · Stress urinary incontinence · Transobturator sling suspension

Abstract
Objectives: The study aims to investigate and evaluate the influence of 2 different methods of implantation of the Argus transobturator (Argus-T) adjustable male sling on complication rate and short-term efficacy. ***Methods:*** A prospective mono-center evaluation was conducted on consecutive patients treated for persistent post-radical prostatectomy incontinence. Thirty-six patients were implanted with the Argus-T adjustable male sling – 18 by inguinal-perineal incision (IPI) and 18 by single-perineal incision (SPI). Measurements included 24-hour frequency volume micturition list, 24-hour pad test, 24-hour pad count, Visual Analogue Scale for continence and satisfaction, flowmetry and residual voided urine. ***Results:*** Cure rate for IPI and SPI at 1, 6 and 12 months was 67, 75, 62% and 59, 63, 63%, respectively (no statistically significant difference). Although more clinically significant complications were seen in the IPI group, a statistical significant difference was observed only for wound infection between the IPI and the SPI groups (33 vs. 0%, p = 0.019). ***Conclusions:*** The Argus-T male sling SPI suspension operation is a minimally invasive and safe procedure for the management of male postoperative stress incontinence which is highly appreciated by the patients.

Introduction

The artificial urinary sphincter (AUS) is still considered the gold standard to treat post-prostatectomy incontinence (PPI), but several new techniques have been introduced during the past decade to treat PPI [1–3]. In practice, more sling procedures are performed than AUS implantations. Kumar et al. [4] showed in 2009 that many patients seeking surgical correction for PPI prefer treatment with a non-mechanical device, avoiding the change of malfunction and misuse.

There is, however, still a paucity of knowledge about real efficacy and complication rates of those new non-mechanical devices. It is difficult to compare current literature because definitions of inclusion and exclusion criteria are inadequate, definition of success is unclear and complication reports lack standardization [5]. To complicate matters even more, several male slings can be implanted in different ways and knowledge about the influence of different surgical approaches on efficacy and

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Erik Bastiaan Cornel, MD, PhD, FEBU, Urologist
Department of Urology
Ziekenhuis Groep Twente Hengelo
PO Box 546, NL–7550 AM Hengelo (The Netherlands)
E-Mail e.cornel@zgt.nl

complication rates is unknown. This study evaluates the efficacy and complications of the Argus transobturator (Argus-T) male sling. It also investigates the influence of implantation technique of the Argus-T adjustable male sling on complication rates and short-term efficacy.

Material and Methods

Patient Population

Between January 2012 and September 2014, 36 men (mean age 69.4 years, SD 7.2) received an adjustable transobturator male sling suspension (Argus-T Male Sling, Promedon, Argentina) as primary therapy for postoperative urinary incontinence in this single-center prospective clinical study.

Inclusion criteria were persistent stress incontinence for >12 months after radical prostatectomy and residual sphincter function by voluntarily contraction of the sphincter mechanism, which was observed by ureteroscopy. Exclusion criteria were radical prostatectomy <12 months, no pelvic floor physiotherapy post surgery, transurethral resection of prostate or green light laser transurethral surgery, past or current neurological disorder (e.g., neurogenic bladder, multiple sclerosis, Parkinson's disease), and postoperative radiotherapy.

Preoperatively, all patients received the following work-up: frequency volume micturition list, 24-hour pad test administered twice (as earlier described), flowmetry and residual urine measurement [6]. All patients underwent an ureteroscopy and a cystoscopy excluding those with urethral stricture, bladder neck stenosis and intravesical pathology for surgery. Moreover, during ureteroscopy all candidates had to demonstrate residual sphincter function by voluntarily contraction of the sphincter mechanism.

The Visual Analogue Scale (VAS) measured the severity of PPI for continence and satisfaction (VAS 0–100) as well as 24-hour pad test administered twice.

Informed consent was obtained for all patients and since the male sling operation had been standard in our hospital since 2007, only approval for retrospective evaluation was obtained by the hospital board.

Surgical Technique

Two different ways of transobturator implantation of the Argus are compared: inguinal-perineal incision (IPI) and single-perineal incision (SPI). The inguinal-perineal route is recommended by the manufacturer. The SPI route for Argus-T was developed based on other single incision techniques for the male sling. One hour preoperatively all patients received 1 g cefazolin intravenously. After general or loco-regional anesthesia, patients were placed in lithotomy position and carefully shaved, disinfected and draped. All patients were catheterized transurethrally with a 16-Fr Foley catheter. Bladders were emptied and retrograde leak point pressure (LPP) was measured preoperatively as described by Bochove-Overgaauw and Schrier [7].

The surgical technique for the IPI was performed as described and visualized by Promedon on their website. In short, a 4 cm median perineal incision was made 1 cm cranial of the anus with the patient in dorsal lithotomy position. After dissecting the subcutaneous fatty tissue, the musculus bulbospongiosum was reached and the top of the triangle between corpus spongiosum and corpus cavernosum was identified. One centimeter below and lateral to the insertion of the adductor longus tendon, the medial border of the obturator foramen was searched with a needle on both sides. After identifying the medial border, a 5-mm small inguinal skin incision was made and the needle was guided to the finger tip of the urologist, which was in the top of the triangle between corpus spongiosum and corpus cavernosum. After tacking the column of the Argus-T, the column was pulled to the inguinal area left and right. The silicone cushion of the Argus-T was positioned around the bulbar urethra, and a silicone ring was placed on both sides over the cone columns and positioned on the fascia musculus obturatorius interna and externa. The tension was adjusted to achieve an increase in retrograde LPP of 10–20 cm H_2O [7]. The silicone columns were then tunneled subcutaneously cranial in the inguinal region. The perineal incision was closed in layers. The transurethral catheter was left in situ for 12–24 h. After catheter removal and a successful trial of voiding (urinate volume and post-void residual were measured), patients were discharged and advised to refrain from strenuous activity for 4 weeks.

Due to the high complication rate, but with continence results that satisfied patients, it was decided to change the transobturator implantation method after 18 patients. Only the implantation technique was slightly altered, although both are implanted transobturator, but the indications and treating urologist were identical. The surgical technique for the SPI group differed from the IPI group in several ways: perineal incision 7 cm instead of 4 cm, no inguinal incision, the lower arch of the os pubis was reached through the bigger perineal incision moving the skin upward to get access to the fascia of the musculus obturatorius interna and externa, and the columns were shortened after final position instead of tunneling subcutaneously (fig. 1).

Follow-Up

Follow-up evaluation at 1, 6 and 12 months postoperatively and yearly thereafter included VAS for continence and bother, flowmetry and residual urine measurement, 2 times 24-hour frequency volume charts and 2 times 24-hour pad test to objectively assess the effect of the Argus-T male sling operation.

Definitions Used

The following definitions were used:

Cured: Patients were classified as cured of their post-radical prostatectomy incontinence when there was 0–2 g urine loss in 24-hour pad test and no pad use at all [5, 8].

Improved was defined as >50% reduction of urine loss in 24-hour pad test.

Failed was defined as all others, including those lost to follow-up and those of whom the Argus-T was removed due to pain or infection.

Success: All cured and improved patients.

Statistical Analysis

Normally distributed variables were presented as mean with SD, non-normally distributed variables were presented as median with interquartile range and categorical variables were presented as number with corresponding percentage.

To test differences in the patient baseline characteristics and follow-up data between the 2 groups, we used independent t tests for normally distributed variables, Mann–Whitney U tests for non-normally distributed variables and chi-square tests or Fisher's exact tests for categorical variables. Friedman tests were performed to analyze whether there was a change over time in the

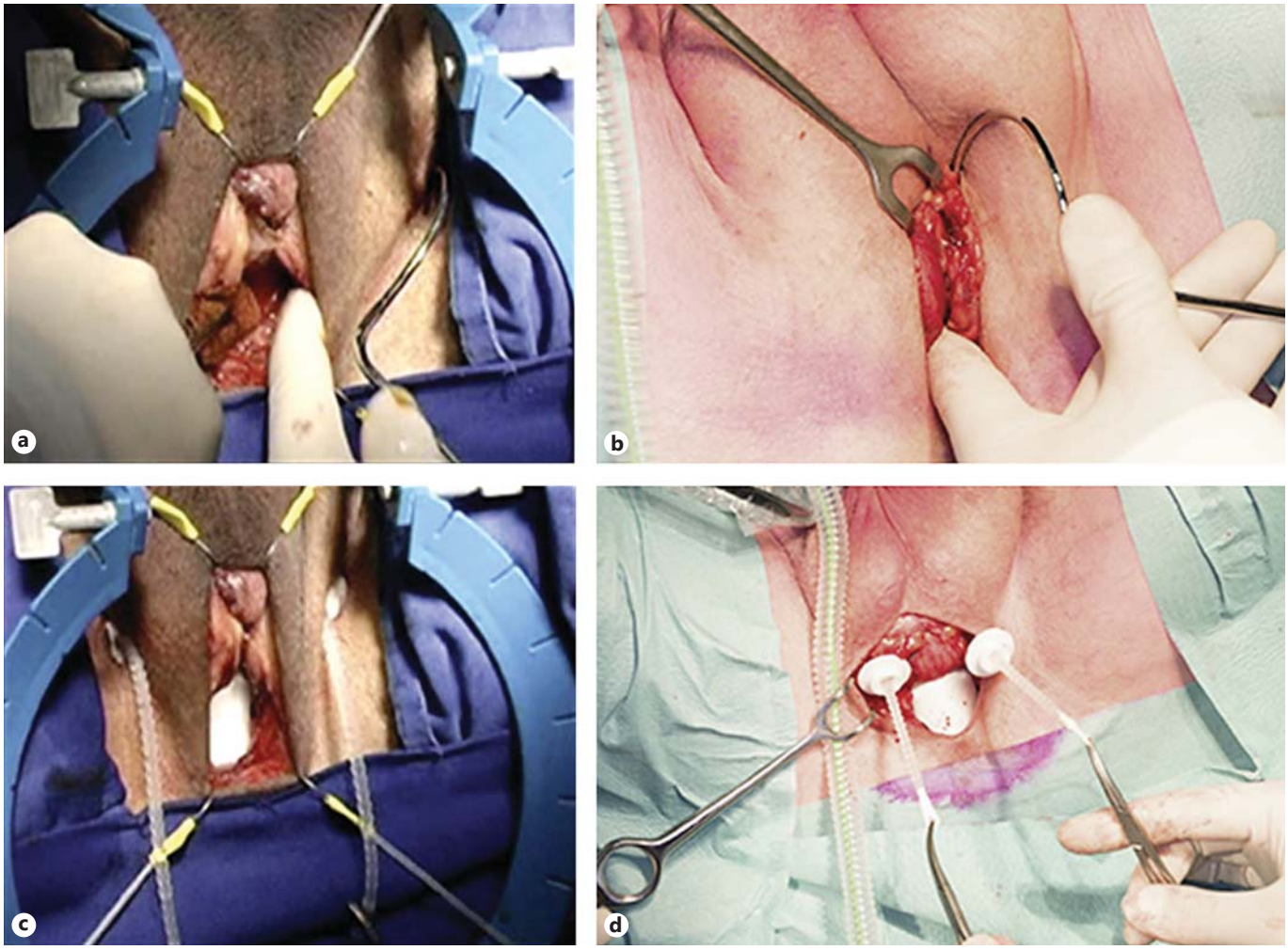

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Fig. 1. a Needle insertion Argus-T: fingertip in the top of the triangle between corpus spongiosum and corpus cavernosum and needle introduction through groin skin incision. **b** Final position Argus-T: the silicone cushion of the Argus-T was positioned around the bulbar urethra and columns with fixation rings through groin incision in place. **c** Needle insertion Argus-T single incision: fingertip in the top of the triangle between corpus spongiosum and corpus cavernosum and needle introduction through same groin incision. **d** Final position Argus-T single incision: the silicone cushion of the Argus-T was positioned around the bulbar urethra and columns with fixation rings through same perineal incision in place.

VAS incontinence score. Wilcoxon signed rank tests with Holm–Bonferroni correction were used to test differences between the baseline VAS scores and the VAS scores after 4 weeks, 6 and 12 months. The level of significance was set at a p value <0.05.

Statistical analyses were performed using the statistical software package SPSS 22.0 (SPSS Inc., Chicago, Ill., USA).

Results

In total 36 males, mean age 69.4 years (SD 7.2), were implanted with an Argus-T male sling. Eighteen patients, mean age 67.1 years (SD 8.5), were implanted according to the instructions of Promedon: IPI group and 18 men, mean age 71.6 (SD 5.1) were implanted with only 1 perineal incision: SPI group (no significant difference; table 1). All but 5 patients could be evaluated for the whole study period. One patient in the IPI group died 3 months postoperatively due to a metastasized lung cancer, diagnosed 10 weeks after sling implantation. The available follow-up data of this patient were included in the analyses (i.e., 4-week outcomes and occurrence of complications).

In 3 patients of the IPI group, the Argus-T was explanted due to infection at 10, 11 and 34 weeks postop-

Table 1. Patient characteristics

	Total (n = 36)	IPI group (n = 18)	SPI group (n = 18)	p value
Preoperative				
Age, years, mean (SD)	69.4 (7.2)	67.1 (8.5)	71.6 (5.1)	0.06
Incontinence duration, years, median (IQR)	1.8 (1.3–3.9)	2.2 (1.3–4.1)	1.6 (1.2–3.9)	0.70
Urine loss, median (IQR)	206.0 (57.3–434.0)	122.5 (34.0–288.5)	250.0 (172.5–520.0)	0.05
VAS incontinence, median (IQR)	67.5 (39.0–80.0)	56.0 (12.5–74.8)	70.5 (48.3–81.0)	0.14
Peroperative				
Increase LPP, mean (SD)	16.1 (5.3)	14.2 (3.9)	17.8 (5.9)	0.04

Table 2. PAD success and failure

	Total (n = 36)	IPI group (n = 18)	SPI group (n = 18)	p value*
After 4 weeks				
Success	35 (97.2)	18 (100.0)	17 (94.4)	1.00
Dry (0/1/2)/>50% improvement	22/13	12/6	10/7	
Failure	1 (2.8)	–	1 (5.6)	
After 6 months				
Success	28 (80.0)	12 (70.6)	16 (88.9)	0.23
Dry (0/1/2)/>50% improvement	19/9	9/3	10/6	
Failure	7 (20.0)	5 (29.4)	2 (11.1)	
After 12 months				
Success	29 (82.9)	13 (76.5)	16 (88.9)	0.40
Dry (0/1/2)/>50% improvement	18/11	8/5	10/6	
Failure	6 (17.1)	4 (23.5)	2 (11.1)	

Values are presented as numbers and n (%). * Percentage of success in group 1 vs. 2.

eratively and in the SPI group 1 patient was explanted 7 months after implantation.

Results based on 24-hour pad test are summarized in table 2. Cure rate for IPI group at 1, 6 and 12 months was 67, 75 and 62%, respectively. For the SPI group, cure rate at 1, 6 and 12 months was 59, 63 and 63%, respectively (no statistical significant difference).

The result of the Argus-T male sling operation stratified by pad use, urine loss per day (preoperatively and after 1, 6 and 12 months follow-up) and operation technique (IPI or SPI) is listed in table 3. Table 4 shows the patient incontinence and satisfaction scores based on VAS. There was a statistically significant change in the VAS incontinence score over time for the total population ($p < 0.001$), IPI group ($p = 0.04$) and SPI group ($p < 0.001$). The VAS scores after 4 weeks, 6 and 12 months were statistically significantly lower compared to baseline in the total population (all p values <0.001), IPI group ($p = 0.02$, $p = 0.03$ and $p = 0.003$, respectively) and SPI group (all p values <0.001). All patients were very satisfied about their outcome (table 4). The flowmetry and residual post-voided urine was not changed pre- and postoperatively and did not differ for either implantation method.

Complications

Postoperative revision procedures and short-term and long-term complications were recorded. All complications mentioned by type and categorized by the Clavien–Dindo classification are listed in table 5.

Although more clinical significant complications were seen in the IPI group, which was the reason to change the operation procedure, statistical significant differences between the IPI- and SPI-treated patients were only observed for the wound infection complications (Clavien–Dindo 2).

Discussion

This prospective study analyses the efficacy and complications of placement of an adjustable transobturator male sling with 2 different implantation techniques.

Outcomes of incontinence operations like the male sling operation can be measured in several ways: complications and functional outcomes. There was a significant difference for wound infection between the IPI and SPI group in complication rate according to the Clavien–Dindo classification. In the SPI group, significant fewer wound infections occurred. It is most likely that the silicone columns are the risk factor; they give some tension under the skin which could impair wound healing and thus cause infection. The results of this study suggest that the implantation route for the Argus-T matters; there is a significant decrease of clinically significant complications and although the number of patients is limited, a statistical significant difference for wound infections was also seen. This is in my opinion the first male sling study addressing the importance of implantation technique.

Most studies published so far used pad count per day as an objective outcome measure [9]. Zero or 1 pad per day or 50% decrease in pad use per day has been used to define success [1]. Although this seems to be an objective outcome measure, there are several major drawbacks. Recently, Tsui et al. [8] demonstrated that pad count per day is a very poor measure of severity of urinary incontinence.

Dylewski et al. [10] also showed that the correlation of grams urine loss per day versus actual pads per day is poor. Moreover, Wallerstedt et al. [11] demonstrated that patients using only a safety pad had 5 times higher risk of bother than those using no pads after radical prostatectomy. Patient perceived effectiveness is also lower than the pad count as objective outcome measure [12]. One can therefore conclude that the decrease in pad usage per day is an unreliable outcome measure for success of incontinence operations. Although the ICS and experts in the field recommend the 24-hour pad test to evaluate of PPI and as a tool to evaluate surgical therapy for PPI, this is still not adopted by medical device manufactures, researches and editors of medical journals [13]. In the current study, the definition used to describe continence post-RRP was used: <2 g urine loss a day, since this imitates the normal situation of a non-stress incontinent male [6]. When this definition of cure is applied, the overall results are different from those achieved by looking at patient satisfaction or by using the definition of social continence: 0–1 pad use a day. As mentioned before, not only objective measurements like the 24-hour pad test, but also patient perceived effectiveness is of importance. Therefore, similar to an earlier study, a VAS with 0–100 scale for scoring incontinence bother and satisfaction of the operation result was used [6]. The transobturator approach appears to perform slightly better than implanting

Table 3. PAD number and size

	Total (n = 36)	IPI group (n = 18)	SPI group (n = 18)
Preoperative			
Number			
0	–	–	–
1–2	14 (42.4)	9 (60.0)	5 (27.8)
3–4	16 (48.5)	5 (33.3)	11 (61.1)
5–6	2 (6.1)	1 (6.7)	1 (5.6)
>6	1 (3.0)	–	1 (5.6)
Size			
Small	3 (9.1)	3 (20.0)	–
Middle	23 (69.7)	10 (66.7)	13 (72.2)
Large	7 (21.2)	2 (13.3)	5 (27.8)
After 4 weeks			
Number			
0	17 (56.7)	7 (58.3)	10 (55.6)
1–2	9 (30.0)	4 (33.3)	5 (27.8)
3–4	2 (6.7)	1 (8.3)	1 (5.6)
5–6	2 (6.7)	–	2 (11.1)
>6	–	–	–
Size			
Small	4 (30.8)	2 (40.0)	2 (25.0)
Middle	9 (69.2)	3 (60.0)	6 (75.0)
Large	–	–	–
After 6 months			
Number			
0	15 (51.7)	6 (54.5)	9 (50.0)
1–2	11 (37.9)	5 (45.5)	6 (33.3)
3–4	2 (6.9)	–	2 (11.1)
5–6	–	–	–
>6	1 (3.4)	–	1 (5.6)
Size			
Small	8 (57.1)	4 (80.0)	4 (44.4)
Middle	6 (42.9)	1 (20.0)	5 (55.6)
Large	–	–	–
After 12 months			
Number			
0	14 (48.3)	6 (50.0)	8 (47.1)
1–2	13 (44.8)	6 (50.0)	7 (41.2)
3–4	1 (3.4)	–	1 (5.9)
5–6	–	–	–
>6	1 (3.4)	–	1 (5.9)
Size			
Small	8 (53.3)	3 (50.0)	5 (55.6)
Middle	7 (46.7)	3 (50.0)	4 (44.4)
Large	–	–	–

Values are presented as number (%).

Table 4. VAS scores

	Total (n = 36)	IPI group (n = 18)	SPI group (n = 18)
VAS incontinence			
Pre operative	67.5 (39.0–80.0)	56.0 (12.5–74.8)	70.5 (48.3–81.0)
After 4 weeks	6.0 (0.8–17.3)	7.0 (2.0–11.0)	5.0 (0.0–19.0)
After 6 months	6.0 (2.0–15.0)	12.0 (2.0–20.0)	4.5 (0.0–11.5)
After 12 months	5.5 (0.3–9.8)	5.5 (2.0–9.8)	5.0 (0.0–13.5)
VAS quality of life			
After 4 weeks	93.0 (88.3–98.8)	93.0 (89.0–99.0)	93.0 (85.0–98.5)
After 6 months	94.0 (80.0–99.0)	97.0 (67.5–99.5)	93.5 (80.0–99.3)
After 12 months	91.5 (86.3–98.3)	94.0 (88.0–98.5)	90.0 (83.5–98.5)

Values are presented as median (IQR).

Table 5. Complications

	IPI group (n = 18)	SPI group (n = 18)	p value
Complications (Clavien grade 1 + 2 + 3)			
Complications present	12 (66.7)	12 (66.7)	1.00
Total number, median (IQR)	1.0 (0.0–3.0)	1.0 (0.0–2.0)	0.36
Clavien grade 1			
Complications present	9 (50.0)	12 (66.7)	0.31
Total number, median (IQR)	0.5 (0.0–1.0)	1.0 (0.0–2.0)	0.28
Acute urinary retention	4 (22.2)	3 (16.7)	1.00
Hematoma	1 (5.6)	–	1.00
Insensibility scrotum	–	4 (22.2)	0.10
Perineal pain <6 weeks	2 (11.1)	6 (33.3)	0.23
Perineal pain <6 months	5 (27.8)	4 (22.2)	1.00
Clavien grade 2			
Complications present	6 (33.3)	–	0.02
Total number, median (IQR)	0.0 (0.0–1.0)	0.0 (0.0–0.0)	0.09
Urinary tract infection	1 (5.6)	–	1.00
Wound infection	6 (33.3)	–	0.02
Clavien grade 3			
Complications present	5 (27.8)	1 (5.6)	0.18
Total number, median (IQR)	0.0 (0.0–1.3)	0.0 (0.0–0.0)	0.24
Inguinal wound reclosure	4 (22.2)	–	0.10
Removal sling column	3 (16.7)	–	0.23
Removal sling (infection)	3 (16.7)	1 (5.6)	0.60

Values are presented as number (%), unless stated otherwise.

the suprapubic Argus sling [7]. Finally, all patients were asked at every follow-up moment if they would be willing to undergo the operation again with their current knowledge. At 1-year follow-up, only 2 patients, equally divided over both groups, would refrain from surgery. These results can be seen as an objective and subjective outcome and, therefore, as a true representation of the favorable outcome. Comparison might be difficult due to differences in success definitions used so far by most of the publications dealing with male sling. However, with a 77% 1-year cure and improvement rate for the IPI and 89% cure and improvement rate for the SPI, the results are comparable with current literature [2, 3, 14–18]. Romano et al. [16] and Bauer et al. [15] recently published similar results with the Argus-T with maximum follow-up time of 30 months. Leruth et al. [14] published in 2012

the 2-year follow-up data of the de Leval and Waltregny sling (TOM sling); 49% dry rate and 33 > 50% improvement rate: 82% success rate. The results from this current Argus study and recent Argus-T literature are remarkably similar. The key factor is that in these studies a LPP test was performed during the procedure, as was performed in the current study. Before and after placing the sling at the bulbar urethra, a significant increase in LPP must be achieved. Thus, not only repositioning but also some compression without causing a significant obstructive flow is important.

This study has, of course, several drawbacks. First, this is a non-randomized study. All patients were seeking for a PPI surgical solution and chose for a male sling operation. Since this is a consecutive patient series, the first 18 patients were operated with the IPI and due to the high complication rate changed to the SPI for the following patients. Fortunately, both patient groups have the same base line characteristics and type of incision: IPI or the SPI was the only difference between both groups. Second, this is a single-center series with interventions performed by one urologist. Although it is generally accepted that volume and experience are important for quality control of surgery, these results may be a reflection of the surgical skills of the surgeon. These results are in that case a strong argument to centralize male sling surgery for PPI. Finally, although the follow-up period is limited, all the complications that have occurred thus far are within the first year postoperative period. This suggests that conclusions for complication rates will not change substantially with longer follow-up. Efficacy rates might still change in the future, and therefore, follow-up will be prospectively prolonged to be able to report 5 years data in due time.

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Disclosure Statement

The author has no conflict of interest, including specific financial interests or relationships and affiliations relevant to the subject matter or materials discussed in the manuscript.

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