Central European Journal of Urology

ORIGINAL PAPER

FUNCTIONAL UROLOGY

# Preliminary outcomes of the European multicentre experience with the ZSI 375 artificial urinary sphincter for treatment of stress urinary incontinence in men

Ireneusz Ostrowski[1], Tomasz Golabek[2], Janusz Ciechan[1], Emil Śledź[1], Mikolaj Przydacz[2], Wojciech Dyś[1], Mariusz Blewniewski[3], Burkhard von Heyden[4], Tobias Pottek[5], Frank Neugart[6], Giuseppe Carrieri[7], Oscar Selvaggio[7], Francesco Iori[8], Manuel Fernández Arjona[9], Steve Foley[10], Bob Yang[10], Christophe Llorens[11], Waldemar Różanski[3], Piotr L. Chłosta[2]

[1]*Department of Urology and Urological Oncology, Regional Specialistic Hospital, Puławy, Poland*
[2]*Department of Urology, Jagiellonian University, Medical College, Cracow, Poland*
[3]*Department of General, Oncological and Functional Urology, II Clinic of Urology, Łódź, Poland*
[4]*Urology Practice, Gaildorf, Germany*
[5]*Department of Reconstructive Urology, Vivantes Urban Hospital, Berlin, Germany*
[6]*Department of Urology, Baden-Baden, Germany*
[7]*Department of Urology, Ospedali Riuniti, Foggia, Italy*
[8]*Department of Urology, University Hospital Policlinic Umberto I, Rome, Italy*
[9]*Department of Urology, Hospital de Henares, Madrit, Spain*
[10]*Department of Urology, Reading, United Kingdom*
[11]*Department of Urology, Reims, France*

Citation: Ostrowski I, Golabek T, Ciechan J, et al. Preliminary outcomes of the European multicentre experience with the ZSI 375 artificial urinary sphincter for treatment of stress urinary incontinence in men. Cent European J Urol. 2019; 72: 263-269.

Article history
Submitted: March 27, 2019
Accepted: July 12, 2019
Published online: July 12, 2019

Corresponding author
Ireneusz Ostrowski
Department of Urology and Urological Oncology
Regional Specialistic Hospital
1 Bema Street
24-100 Puławy, Poland
phone: +48 81 450 21 96
irekostrowski@op.pl

**Introduction** The ZSI 375 is a new artificial urinary sphincter utilised in men suffering from stress urinary incontinence (SUI). We present the first European multicentre study on the effectiveness of ZSI 375.

**Material and methods** This study was conducted in a retrospective, non-randomized format in centres across Europe. Between May 2009 and December 2014, ZSI 375 was fitted in 109 SUI patients following radical prostatectomy, transurethral resection of prostate (TURP), rectal surgery and high intensity focused ultrasound (HIFU). Patients with history of pelvic radiotherapy or previous surgical treatment for incontinence or stricture were excluded from the series. Follow-up was completed by December 2016. The key outcome measures included overall improvement and complication rates.

**Results** A total of 109 patients in 10 European centres were recruited and had the ZSI 375 device implanted. The average patient age was 72 years old. The indication for the majority of patients was incontinence following radical prostatectomy (100/109 patients, 91.74%). On average, patients were incontinent for 48.6 months prior to treatment. All patients used ≥4 pads daily at baseline and thus were classified as suffering from 'severe incontinence'. The average follow-up until the final visit was 43 months. The pad usage decreased to 0.84 on average by the last visit. There were no reported cases of device infection. A total of 9 patients had urethral cuff erosion (8.25%),which was the most common complication in this series. A further 3 men (2.75%) experienced mechanical failure requiring subsequent device reimplantation. The implantation of the ZSI 375 device was considered successful in 92.66% of patients.

**Conclusions** The ZSI 375 is an effective surgical treatment option in men with severe stress urinary incontinence.

Key Words: artificial urinary sphincter ‹› male urinary incontinence ‹› radical prostatectomy ‹› Zephyr Surgical Implants

## INTRODUCTION

Urinary incontinence (UI) affects up to 39% of men and its incidence increases with age [1]. The most common cause of stress urinary incontinence (SUI) in adult men is iatrogenic induced insufficiency of the external urethral sphincter, predominantly as a result of radical treatment for prostate cancer [2]. Stress incontinence, regardless of its aetiology, markedly impairs the quality of life of the affected individuals [3, 4, 6, 10, 11, 12, 23]. Management of persistent incontinence is often challenging. Initial management of male SUI consists of pelvic floor muscle training, biofeedback and electrical stimulation. Should conservative approach fail, the only alternative is surgical interventions [1–4, 6, 9–14, 19–23].

Currently, there have been several competitive products available for operative treatment of male SUI including the artificial urinary sphincter (AUS) AMS 800, which is considered the gold standard in the treatment of stress incontinence in men [4, 6, 14, 23]. Although the AMS 800 has several advantages it has not been updated since 1983. Flaws include complexity of preparation, procedure and connection, and no option to adjust or control the internal pressures in cases of urethral atrophy in years after operation [4, 5, 6, 19–23].

The ZSI 375 (Zephyr Surgical Implants, Geneva, Switzerland) is a new, one-piece artificial urinary sphincter, designed to improve the AUS insertion method. The two-part device composition (cuff and pump connected via kink-resistant tubing) helps ease the difficulty in the implantation process. With the lack of any abdominal reservoir, the risk of inadvertent damage to either the bladder, bowel or other intraperitoneal organs is minimised. Moreover, ZSI 375 contains an adjustable cuff and an adjustable pressure regulator that offers an option to increase the internal pressure of the device in situ in order to achieve better continence control [5, 7, 8, 9].

The ZSI 375 was first implanted in March 2009 and has been used in both Europe and Latin America. However, to date there has only been a limited number of studies on the efficacy of ZSI 375. Hence, the aim of this study was to present the first European multicentre experience with the one-piece ZSI 375 male artificial urinary sphincter in 109 patients.

## MATERIAL AND METHODS

This study was conducted in a retrospective, non-randomised format in 10 centres across Europe. Between May 2009 to December 2014, 109 men with severe stress urinary incontinence had the ZSI 375 device implanted. Follow-up was completed by December 2016. Of these men, 100 (91.7%) was incontinent after radical prostatectomy (RP), 7 (6.4%) after transurethral resection of the prostate (TURP), 1 (0.9%) was incontinent after a rectal surgery with urinary tract injury and 1 (0.9%) following high intensity focused ultrasound (HIFU) treatment. Patients with a history of pelvic radiotherapy or previous surgical treatment for incontinence or stricture were excluded from the series. All men had previously failed rehabilitation by pelvic floor training and electrostimulation. The pre-implantation evaluation comprised a patient's medical history, analysis of voiding diaries (time and voided volumes, number of pads used daily, UI episodes), a clinical examination, cystoscopy and urodynamic assessment. All patients had sterile urine at the time of surgery, and all men who suffered from SUI following radical treatment of prostate cancer had a stable prostate-specific antigen (PSA) level in the preceding year prior to the ZSI 375 implantation. This study was conducted in line with applicable laws and regulations, good clinical practice, and ethical principles, as described in the Helsinki Declaration of 1975, and revised in Tokyo in 2008.

### The ZSI 375 device

The ZSI 375 is an artificial urinary sphincter manufactured from medical grade silicone rubber. It is a one-piece two-part device equipped with an inflatable and adjustable cuff that fits around the urethra and a pressure-regulating tank and a pump that is placed within the scrotum (Figure 1). The size of the pressure-regulating tank and the pump are equivalent to a penile implant pump (41x24.5 mm). The ZSI 375 has two circuits: a hydraulic circuit and a compensation pouch circuit separated by a piston. Spontaneously, the spring pushes the piston up and the piston pushes the saline solution of the hydraulic circuit into the cuff. Before implantation of the deactivated device, the hydraulic circuit is first filled by injecting 4.5 ml saline via the cuff septum. The compensation pouch is then filled with 4.5 ml saline. The urethra itself does not need to be measured before cuff insertion as a 16 Fr calibrate urethra and cuff is adjustable with steps of 2.5 mm increments. After activation of the AUS, the issued pressure in the hydraulic circuit can be increased or decreased to improve patient continence injecting saline solution in the compensation pouch via a septum and trans-scrotal approach. This procedure can be done in the outpatient office setting without the need for any local anaesthesia.

**Figure 1.** *Artificial urinary sphincter ZSI 375.*

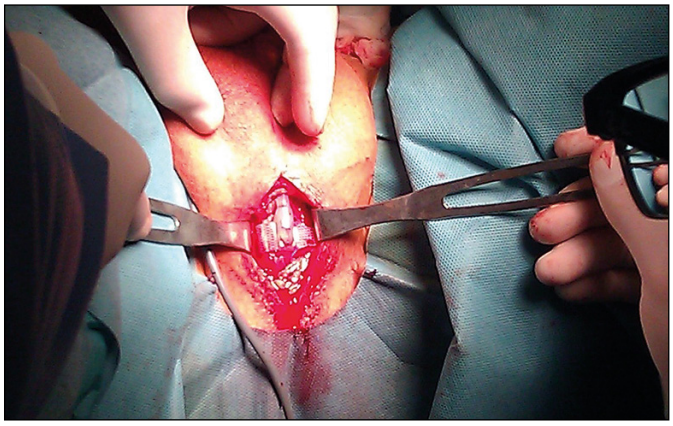

**Figure 2.** *The cuff of the ZSI 375 placed around the urethra via the perineal incision.*

## Surgical technique

Insertion of the ZSI 375 is performed under general or regional anaesthesia. A 16 Fr Foley catheter is inserted to guide urethral dissection. Patients were placed in the lithotomy position and a traditional surgical technique was used consisting of a perineal incision for cuff placement and inguinal incision for pump unit scrotal placement in all the cases (Figure 2). A 12 Fr Foley catheter was inserted at the final stage of the procedure and removed usually after 24 hours. Patients were discharged home as soon as they could urinate spontaneously. After 8 weeks, the ZSI 375 device was activated in an outpatient setting. During the procedure, the sphincter closure pressure had the following ranges: from 60 to 70, from 70 to 80 or from 90 to 100 $cmH_2O$. The internal pressures could be increased postoperatively with the device in situ by trans-scrotal injection of saline into the pouch; 1 ml saline increased pressure by approximately 10 (range 8–12) $cmH_2O$.

## Assessment of postoperative continence

Patient follow-up assessments after initial recruitment was at the time of AUS insertion, at AUS activation 8 weeks from surgery, and at follow-up visit at 3, 6, 12, and 24 months after the procedure and then annually thereafter. The assessment included a clinical examination, urinalysis, bladder ultrasonography to evaluate residual urine volume, flow rate measurements, as well as assessing incontinence severity via the patient reported mean number of pads used per day in their diary completed in the 7 days prior to their follow-up visit.

Each patient was also assessed individually on whether there was a need to adjust the pressures within the ZSI 375 device. Adjustments depended on the severity of the leakage after implantation, and the greater the urine loss, the larger the adjustment volume required. The amount of residual urine volume and maximum urine flow less than 10 ml per second determined the maximum amount of adjustment volume that could be inserted.

Social continence was defined as the need of 0 to 1 pad per day (with total continence: 0 pads per day), and incontinence defined as the use of more than 1 pad per day (light incontinence: 2 pads per day, moderate incontinence: 3 pads per day, severe incontinence: 4 and more pads per day). Patients were considered 'cured' of their incontinence if they used no pads or used up to 1 pad per day for security reasons only or 'improved' if they used both less than 2 pads per day and 50% fewer pads than at baseline. Otherwise they were defined as 'not improved'. Treatment success was considered as both the 'cured' and the 'improved' group following activation of the ZSI 375 device.

## Statistical analysis

Statistical analyses were performed using the statistical package SPSS for Windows (version 19; SPSS, Chicago, IL, USA). Data were expressed as mean ± standard deviation (SD) values. All statistical tests were two-sided, and a p value $<0.05$ was considered statistically significant.

# RESULTS

A total of 109 patients with the mean age of 72.01 (SD 7,03; range 55–85) had a ZSI 375 artificial

urinary sphincter device inserted at 10 European centres. No patients included in the study had detrusor overactivity or urethral or vesico-urethral anastomotic narrowing, radiotherapy history or urethral previous surgical procedure to treat incontinence or stricture. The mean period of incontinence was 48.6 (range 11–132) months preoperatively, and 91% of patients had incontinence over 1 year before ZSI 375 implantation. All patients in this studies cohort had severe incontinence and used ≥4 pads a day at baseline. The most frequent indication for applying an AUS was incontinence resulting from radical laparoscopic or open prostatectomy (100/109 patients, 91.74%). The other causes of incontinence included transurethral resection of the prostate (TURP), high intensity focused ultrasound (HIFU) and rectal surgery. Peri- and postoperative clinical data of the entire cohort are presented in Table 1. Comparison of the pre- and postoperative clinical factors between the success and failure groups are listed in Table 2. Table 3 splits the success and failure groups in regard to underlying aetiology of disease.

The mean operative time was 94 minutes (SD: 17 min; range 60–150 min). Uneventful implantation was performed in 88 patients (80.73%). No patients reported experiencing any bladder overactivity, chronic urinary retention, scrotal discomfort caused by the pump size or any other adverse events following the sphincter activation. A total of 12 patients (11.01%) experienced complications after surgery. There was no case of infection reported, but in 9 (8.25%) cases urethral erosion was identified and it occurred on average at 13.5 months. Mechanical failure (leakage of saline solution) resulting in re-implanting the sphincter occurred in 3 patients (2.75%). These three cases of saline solution leakage (hydraulic circuit liquid) were likely caused by an injury that occurred during the surgery or the application of silicone armed tubbing connecting the urethral cuff with the pump with an embedded pressure-regulating tank placed within the scrotum. Overall, the device had to be explanted in the patients with urethral erosion and exchanged (revision) in the patient with mechanical failure. Two erosions occurred at the pressure of 60–70 $cmH_2O$, five at the pressure of 90–100 $cmH_2O$ and only two erosions developed with a higher closure pressure. Table 4 presents complications connected with inserting the ZSI 375 with regards to the aetiology of urinary incontinence.

Before the ZSI 375 AUS implantation, all patients used ≥4 pads per day (severe incontinence). By the mean follow-up of 43.06 months (SD 14.63; range 24–78), daily pad usage decreased significantly from ≥4 to 0.84 (±0.64) pads per day at the last visit with 21 (19.27%) total continence, 71 (65.14%) social continence, 9 (8.25%) improvement and 8 (7.34%) failures (≥4 pads per day). All patients with the initial sphincter closure pressure of 60–70 $cmH_2O$ needed further pressure increase by the in situ trans-scrotal injection of 2 ml saline (8 patients) into the compensation pouch. With sphincter closure pressure of 90–100 $cmH_2O$, 75 patients (68.81%) had social continence on device activation, and 17 patients (15.59%) needed further pressure increase by injec-

**Table 1.** *Continence rates before and after device implantation*

| | Pads used per day before implantation, n (%) | Pads used per day after implantation n (%) |
|---|---|---|
| None | 0 | 21 (19.27) |
| 1 | 0 | 71 (65.14) |
| 2 | 0 | 8 (7.34) |
| 3 | 0 | 1 (0.91) |
| ≥4 | 109 | 8 (7.34) |
| Cured (0.1 pad), n (%) | 0 | 92 (84.40) |
| Improvement, n (%) | 0 | 9 (8.25) |
| Failure, n (%) | 0 | 8 (7.34) |

n – number of patients

**Table 2.** *Comparison of the pre- and postoperative clinical factors between the success and failure groups*

| | Success group n = 101 | Failure group n = 8 | p value |
|---|---|---|---|
| Age (years) | 71.96 | 72.75 | p = 0.74 |
| Mean number of pads used per day pre-op | ≥4 | ≥4 | p = 0.88 |
| Follow-up duration (months) | 43.25 | 40.75 | p = 0.68 |
| Mean number of pads used per day post-op | 0.82 | ≥4 | p = 0.000001 |

n – number of patients; pre-op – preoperatively; post-op – postoperatively

**Table 3.** *Comparison of aetiology of stress incontinence in both success and failure group*

| | Cause of incontinence n, (%) | | |
|---|---|---|---|
| Aetiology | Success group | Failure group | Total |
| RP | 92 | 8 | 100 |
| TURP | 7 | 0 | 7 |
| Rectal surgery | 1 | 0 | 1 |
| HIFU | 1 | 0 | 1 |

n – number of patients; pre-op – preoperatively; post-op – postoperatively; RP – radical prostatectomy; TURP – transurethral resection of the prostate; HIFU – high intensity focused ultrasound

**Table 4.** *ZSI 375 implantation-related complications by aetiology of urinary incontinence*

| Aetiology of incontinence | Number of patients n, (%) | Infections n, (%) | Urethral erosions n, (%) | Mechanical complications n, (%) |
|---|---|---|---|---|
| RP | 100 (91.7) | 0 | 9 (8.25) | 2 (1.83) |
| TURP | 7 (6.4) | 0 | 0 | 1 (0.91) |
| Rectal surgery | 1 (0.9) | 0 | 0 | 0 |
| HIFU | 1 (0.9) | 0 | 0 | 0 |
| Total | 109 (100) | 0 | 9 (8.25) | 3 (2.75) |

n – number of patients; RP – radical prostatectomy; TURP – transurethral resection of the prostate; HIFU – high intensity focused ultrasound

tion of 1 ml (11 men) or 2 ml saline (6 patients) into the compensation pouch. According to postoperative reductions in the number of pads used per day, 92 patients (84.40%) were considered cured (social continence including total continence), and an additional 9 patients (8.25%) had improved by the time of the last visit. The ZSI 375 AUS system was considered successful (i.e. cured or had improved) in 92.66% of patients reducing daily pad usage from ≥4 to 1.06 (±0.59). The success rates between the 10 unaffiliated centres were: C1: 100%, C3: 80%, C4: 93.55%, C5: 93.75%, C6: 83.33%, C7: 100%, C8: 100%, C9: 100%, C10:100%, C11: 94.44%.

Analysis of the demographic and clinical variables in both success and failure groups did not show any statistically significant differences with regards to the mean age of the patients, preoperative pad usage and duration of post-implantation follow-up period.

## DISCUSSION

Although artificial urinary sphincter AMS 800 is currently regarded as the gold standard therapy for severe stress urinary incontinence in men, there are issues associated with the AMS 800, including complexity of the implantation procedure, inability to adjust the internal device pressure and inability to adjust the pressure cuffs at any time post implantation in cases of postsurgical urethral atrophy or urinary retention / poor flow [4, 18–23]. The ZSI 375 artificial urinary sphincter aims to address and improve on the deficiencies of the AMS 800 [5, 7, 8, 9]. In this current study, we present the first large-scale European multicentre experience in 109 patients with the ZSI 375 device. A high success rate was found. During the mean follow-up period of 43.06 months, the overall success rate was 92.66%. After the same time of follow-up, 84.40% of patients were considered as presenting social continence (0 to 1 pad per day) and 8.25% of men improved, with only 7.34% of patients failing treatment with the ZSI 375. We also demonstrated that upon achieving total continence with the ZSI 375 device, the effectiveness was maintained, with 95.41% of patients being continent after 12 months and 93.58% continent after 24 months. Previous studies concerning the outcomes of ZSI 375 have demonstrated short-term results ranging from 87% to 94.2% in continence rates [5, 7, 8, 9]. Our total continence rate can be compared to that reported for AMS 800 in a 24-month follow-up period of ≤ 90% [4, 6, 21, 22, 23]. Interestingly, centres reporting high success rates with the AMS 800 are in general centres of excellence with large volumes of cases and therefore do not necessary reflect those achieved in centres with a smaller caseload and less experience with the device implantation. In the present study, the implantations of the ZSI 375 were performed by surgeons with a wide range of experience, yet all, on average, achieved high success rates, suggesting the simplicity of the ZSI 375 implantation technique and a potentially shorter learning curve with the implantation procedure when compared with the AMS 800.

This study excluded patient with a history of preoperative pelvic irradiation therapy. There has been reports on the AMS 800 which noted continence rates are affected by previous radiation [13–23]. However, a recent literature review has not confirmed such a connection regarding AUS implantation [6].

In our study, the short-term complication rate was comparable or better than that achieved with AMS 800 [4, 9, 13, 14, 16–23]. Half of all explantations took place within the first 5 months after surgery, the remainder occurred within 10 months following device implantation. No revision/explantation was performed in the second year of follow-up. The infection rate was nil in our series, compared to infection rates for the AMS 800 device which range from 1% to 8% [4, 13–23].

The complication most frequently reported in the present study was erosion, which affected 9 (8.25%) patients. All cases of urethral erosion occurred in patients with prostatectomy as the aetiology for their incontinence. Our urethral erosion rate is comparable to that of AMS 800 [4, 9, 13–23]. As urethral erosions in our study occurred on average after 13.5 months and all cases appeared at least 3 months after the device implantation, it is likely that the circumferential compression of the urethra may interfere with venous blood flow and thus predispose to urethral atrophy and erosion, rather than unrecognized injury to the urethra during the operation being the underlying cause. It should be noted that the increase in sphincter closure pressure did not lead to a greater risk of erosions in our series

as erosion can occur with all ranges of pressure. Despite this, it is important to note the increase of sphincter pressure must be used with care and could be a cause of increase of erosion rates during the surgeon's learning curve.

Mechanical failure resulting in device re-implantation affected 3 patients (2.75%) at the early stage of the study. It likely reflects the relative inexperience of surgeons performing an implantation procedure, as there were no cases of mechanical failure after the first 4 cases performed by any given surgeon. The rate of mechanical failure of ZSI 375 in our series is comparable with that of AMS 800 in contemporary series data [4, 9, 13–23].

This European multicentre experience with the ZSI 375 sphincter implantation has several limitations in the design and outcome analysis of this study that could be improved in future research. Future studies could incorporate a prospective randomised process as well as incorporate patient satisfaction questionnaires into the follow-up phase. We excluded patients with any pelvis radiotherapy history or previous surgical treatment for incontinence from our study, which do form a proportion of men presenting with stress urinary incontinence. Moreover, the relatively short mean follow-up period may not be adequate in determining the possible subsequent long-term complications, in particular urethral atrophy and mechanical complications. This is especially prudent as the mean time to AUS complications has been reported to range between 29.6 and 68.9 months [22]. We do, however, believe that our follow-up time period was long enough to establish the safety and efficacy of the ZSI 375 device. Finally, this present study is limited in its evaluation of incontinence via the number of pads only, whereas the weight of pad itself would also be an accurate marker for incontinence, though it is relatively more difficult for the patients to accurately measure this themselves.

In conclusion, this study suggests that the ZSI 375 AUS was successful in treating severe urinary incontinence in men, achieving a high success rate and acceptably low complication rate. The ability to adjust the internal pressures within the device via the in situ trans-scrotal applicator in an office outpatient setting makes the ZSI 375 an attractive option for men with severe urinary incontinence with the potential ability to deal with subsequent urethral atrophy or worsening incontinence, or alternatively, decrease pressures in cases of retention or poor flow.

### CONFLICTS OF INTEREST

Christophe Llorens is a shareholder of ZSI.

Ireneusz Ostrowski has performed one surgical support for Zephyr in Serbia.

## References

1. Bauer RM, Gozzi C, Hübner W, et al. Contemporary management of postprostatectomy incontinence. Eur Urol. 2011; 59: 985-996.
2. Shamliyan TA, Wyman JF, Ping R, Wilt TJ, Kane RL. Male urinary incontinence: prevalence, risk factors, and preventive interventions. Rev Urol. 2009; 11: 145-165.
3. Park HK, Chang S, Palmer MH, Kim I, Choi H. Assessment of the Impact of Male Urinary Incontinence on Health-Related Quality of Life: A Population Based Study. Low Urine Tract Symptoms. 2015; 7:22-26.
4. Ostrowski I, Śledź E, Ciechan J, et al. Current interventional management of male stress urinary incontinence following urological procedures. Cent European J Urol. 2015; 68: 340-347.
5. Vakalopoulos I, Kampantais S, Laskaridis L, Chachopoulos V, Koptsis M, Toutziaris C. New artificial urinary sphincter devices in the treatment of male iatrogenic incontinence. Adv Urol. 2012; 2012: 439372.
6. James MH, McCammon KA. Artificial urinary sphincter for post-prostatectomy incontinence: a review. Int J Urol. 2014; 21: 536-543.
7. Staerman F, G-Llorens C, Leon P, Leclerc Y. ZSI 375 artificial urinary sphincter for male urinary incontinence: a preliminary study. BJU Int. 2013; 111 (4 Pt B): E202-206.
8. Sandul A, Martins FE, Barros P, Lopes TM, Llorens C. The ZSI 375 artificial urinary sphincter: a new device for male urinary incontinence. In Proceedings of the 7th National Congress of Portugese Association of Neurourology and Urogynaecology, Vilamoura, Portugal, November 2010.
9. Ostrowski I, Blewniewski M, Neugart F, et al. Multicentre experience with ZSI 375 artificial urinary sphincter for the treatment of stress urinary incontinence in men. Urologia. 2017; 84: 148-152.
10. Sousa-Escandón A, Cabrera J, Mantovani F, et al. Adjustable suburethral sling (male remeex system) in the treatment of male stress urinary incontinence: a multicentric European study. Eur Urol. 2007; 52: 1473-1479.
11. Leruth J, Waltregny D, de Leval J. The inside-out transobturator male sling for the surgical treatment of stress urinary incontinence after radical prostatectomy: midterm results of a single-center prospective study. Eur Urol. 2012; 61: 608-615.
12. Kim SW, Walsh R, Berger Y, Kim JH. Male Readjustable Sling (MRS) System for Postprostatectomy Incontinence: Experiences of 2 Centers. Urology. 2016; 88: 195-200.
13. Hajivassiliou CA. A review of the complications and results of implantation of the AMS artificial urinary sphincter. Eur Urol. 1999; 35: 36-44.
14. Herschorn S, Bruschini H, Comiter Cet al. Committee of the International Consultation on Incontinence. Surgical treatment of stress incontinence

in men. Neurourol Urodyn. 2010; 29: 179-190.

15. Andreasson A, Fall M, Persson E, Stranne J, Peeker R. High revision rate following artificial urethral sphincter implantation. Scand J Urol. 2014; 48: 544-548.

16. Gousse AE, Madjar S, Lambert MM, Fishman IJ. Artificial urinary sphincter for post-radical prostatectomy urinary incontinence: long-term subjective results. J Urol. 2001; 166: 1755-1758.

17. Trigo Rocha F, Gomes CM, Mitre AI, Arap S, Srougi M. A prospective study evaluating the efficacy of the artificial sphincter AMS 800 for the treatment of post radical prostatectomy urinary incontinence and the correlation between preoperative urodynamic and surgical outcomes. Urology. 2008; 71: 85-89.

18. O'Connor RC, Nanigian DK, Patel BN, Guralnick ML, Ellision LM, Stone AR. Artificial urinary sphincter placement in elderly men. Urology. 2007; 69: 126-128.

19. Clemens JQ, Schuster TG, Konnak JW, McGuire EJ, Faerber GJ. Revision rate after artificial urinary sphincter implantation for incontinence after radical prostatectomy: actuarial analysis. J Urol. 2001; 166: 1372-1375.

20. Petrou SP, Elliott DS, Barrett DM. Artificial urethral sphincter for incontinence. Urology. 2000; 56: 353-359.

21. Elliott DS, Barrett DM. Mayo Clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. J Urol. 1998; 159: 1206-1208.

22. Lai HH, Hsu EI, Teh BS, Butler EB, Boone TB. 13 years of experience with artificial urinary sphincter implantation at Baylor College of Medicine. J Urol. 2007; 177: 1021-1025.

23. Van der Aa F, Drake MJ, Kasyan GR, Petrolekas A, Cornu JN; Young Academic Urologists Functional Urology Group. The artificial urinary sphincter after a quarter of a century: a critical systematic review of its use in male non-neurogenic incontinence. Eur Urol. 2013; 63: 681-689. ■