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FUNCTIONAL UROLOGY

Four-year follow-up on a Zephyr Surgical Implants 375 artificial urinary sphincter for male urinary incontinence from one urological centre in Poland

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Introduction The treatment of choice for patients who have iatrogenic urinary incontinence is the implantation of an artificial urinary sphincter. We performed a prospective study on the outcomes of men undergoing artificial urinary sphincter (AUS) implantation (ZSI 375; Zephyr Surgical Implants, Geneva, Switzerland).

Material and methods Patients with moderate-to-severe stress incontinence urinary were included. The ZSI 375 device is a one-piece device with a cuff and a pump unit. Patients underwent a perineal incision for cuff insertion and an inguinal incision for the pump unit to be placed in the scrotum. Complications and number of pads used to manage incontinence were recorded. Perioperative complications were categorized according to the Clavien-Dindo classification. Pain connected with implantation of AUS was assessed with the visual analogue scale (VAS).

Results Between July 2013 and June 2017, 50 patients underwent ZSI 375 device insertion in the Department of Urology and Urological Oncology in Puławy, Poland. The follow-up stopped at the end of September 2017. The median (range) follow-up was 21.04 (1–50) months. No patient experienced bladder hyperactivity. Complications leading to a revision or permanent device removal arose in 12 patients (erosion = 9, infection = 0, mechanical failure = 3). Social continence (0 or 1 pad/day) was achieved in 29/50 patients (58%). An improvement (50% less pads/day) was achieved in 15/50 patients (30%). A failure was seen in 6/50 patients (12%). Perioperatively, all patients were classified as grade I in the Clavien-Dindo classification. Mean value of pain intensity in VAS was 0.82.

Conclusions The ZSI 375 device is safe, effective and the follow-up period was long enough to identify all potential complications.

Key Words: artificial urinary sphincter ‹› radical prostatectomy ‹› male urinary incontinence ‹› Zephyr Surgical Implants 375

INTRODUCTION

The artificial urinary sphincter (AUS) was first introduced in 1973 for the treatment of male stress urinary incontinence and became the treatment of choice for male urinary incontinence [1, 2, 3]. AUS insertion remains a complex procedure with a risk of complications such as erosion, infection and mechanical failure.

Throughout the years, there have been improvements in AUS quality, with the idea of double cuffs and new surgical approaches with improved outcomes and decreased complications [3–8].

With experience and 10.5% of urethral erosion, the double cuff is currently not recommended for first AUS insertion [9, 10, 11].

Recently, minocycline and rifampin (IZ) coated devices, were introduced to decrease the AUS

infection rate, but without any significant success [12].
Revision rates attributable to mechanical failure still range from 8 to 45% [3, 13, 14, 15].
The quality of the sphincter's preparation, connection of components and surgeon's experience during the procedure are the key factors for success as the learning curve is long.
Most of the sphincter insertions are carried out by occasional operators (1 to 3 procedures per year). Less than 10% of AUS insertions are performed by surgeons with experience of at least 100 procedures in the USA [16]. The risk of revision surgery increases from 13 to 24% [17].
ZSI 375 (Zephyr Surgical Implants, Geneva, Switzerland) was designed to facilitate AUS insertion (Figure 1). The cuff is adjustable around the urethra (Figure 2) and pre-connected. The pressure can be increased to improve the patient's continence. It has no abdominal reservoir so as to reduce the operating time and to avoid abdominal incision and dissection in scarred retroperitoneum [18, 19, 26].
The aim of the present study was to analyse the safety and efficacy of ZSI 375 in 50 incontinent male patients with a follow-up period from July 2013 to September 2017.

MATERIAL AND METHODS

Patients

We performed a prospective analysis of patients who underwent ZSI 375 placement in one urological centre in Poland from July 2013 to June 2017. Patients were followed up to September 2017. Our urological team (two surgeons) inserted the ZSI 375 artificial urinary sphincter during their learning curve period. Indication for ZSI 375 insertion was for moderate stress urinary incontinence (2 to 3 pads/day) and severe stress incontinence (4 and more pads/day). All patients had failed previous rehabilitation by pelvic floor training and electrostimulation. The preoperative evaluation included patient history, pad use, a physical examination, and cystoscopy looking for stenosis, urine analysis and urodynamic testing to exclude an overactive bladder.

Device preparation and implantation

The ZSI 375 is a one-piece AUS made up of a cuff connected by a kink-resistant tubing to a pump unit (Figure 1). The adjustable cuff is moulded in a curve to avoid folding. It is placed around the urethra, the pump unit (pressure-regulating tank and pump) is placed in the scrotum, in the subdartos pouch

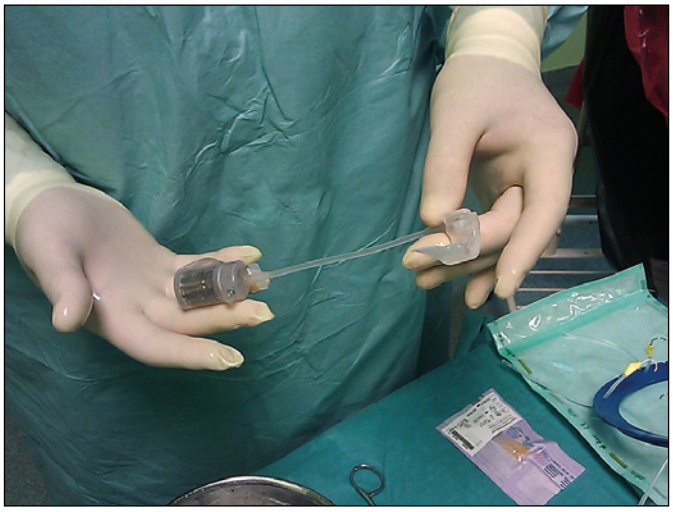

Figure 1. *The artificial urinary sphincter ZSI 375 (Zephyr Surgical Implants).*

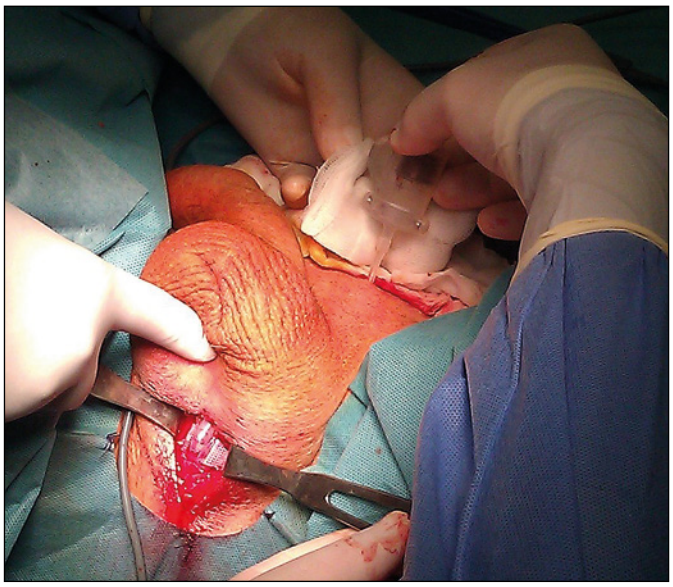

Figure 2. *The implantation of the ZSI 375 (Zephyr Surgical Implants).*

(Figure 2). After activation, the pressure in the hydraulic circuit can be increased or decreased to improve the patient's continence.
Two versions of the sphincter manufactured by Zephyr Surgical Implants (Geneva, Switzerland) are available: a version (ZSI 375) which is initially provided dry and must be filled with a saline solution before insertion and a pre-filled version (ZSI 375 PF) ready to be implanted.
The sphincters used in this prospective study were the first ZSI 375 version and the latest a pre-filled version ZSI 375 PF. The first version has to be prepared before insertion: the sphincter must be filled

with a saline solution and air bubbles removed. The second is already prepared before implantation.
The implantation procedure was carried out under general or regional anaesthesia with patients in the lithotomy position.
A 16 Ch Foley catheter was placed for guidance in all patients.
For all patients, a traditional surgical technique was used consisting of a perineal incision for cuff placement and inguinal incision for scrotal placement of the pump unit. After the procedure, a 12 Ch Foley catheter was inserted into the bladder. On average, it was maintained for 2.4 days (1–4 days). Patients were discharged after catheter removal and after they could void. The postoperative patients stayed in the ward for 4.5 days (3–6 days). The device was activated eight weeks later.

Follow-up after implantation

Urine analysis and bladder ultrasonography were conducted to evaluate the residual urine volume, and flow rate measurements were performed after sphincter activation at 1, 3, 6 months after activation and every year up to September 2017.
Patients recorded the number of pads used per day in a 7-day diary before their visits. Total continence was at 0 pads (i.e. completely dry), social continence was at a daily use of 1 pad. Incontinence was given by a daily use of >1 pad.
Success was defined as social continence (0 to 1 pad per day) and an improvement as a decrease in daily pad use (more than a 50% reduction; usually 2 pads per day).
All the patients established their level of pain using the visual analogue scale (VAS) one month after activation of the device. The perioperative complications were classified with Clavien-Dindo questionnaires.

RESULTS

Patient characteristics

From July 2013 to June 2017, 50 patients underwent implantation of a ZSI 375 device in one centre in Poland and were followed up until September 2017. The mean (range) age was 65.5 (24–78) years, with moderate stress incontinence (n = 8) and severe stress urinary incontinence (n = 42). Incontinence was secondary to radical prostatectomy (RP, n = 26), radiotherapy (n = 2), RP and radiotherapy (n = 12), transurethral resection of prostate (TURP, n = 6), rectal surgery with urinary tract injury (n = 1), pelvic injury (n = 1) and neurological disorder (n = 2) (Table 1).

Table 1. *The aetiology of the incontinence and complications*

Aetiology of incontinence	Infections n (%)	Urethral erosions n (%)	Mechanical complications n (%)
RP (26 patients)	0	4 (15)	2 (8)
RT (2 patients)	0	1 (50)	0
RP+RT (12 patients)	0	2 (17)	0
TURP (6 patients)	0	1 (17)	1 (17)
Rectal surgery (1 patients)	0	0	0
Neurogenic disorder (2 patients)	0	0	0
Pelvic trauma (1 patient)	0	1 (100)	0
Total (50 patients)	0	9 (18)	3 (6)

RP – radical prostatectomy; RT – radiotherapy; TURP – transurethral resection of prostate

The mean hospital stay was 4.8 days and the median (range) follow-up was 21.04 (1–50) months.

Complications

Implantation and recovery were uneventful in 48/50 patients (96%). Perioperatively, all patients were classified as grade I in the Clavien-Dindo classification. Pain related to the presence of artificial urethral sphincter ZSI 375 were assessed with the use of VAS. In the pain intensity scale from 0 to 10 patients assessed their ailments as ranging from 0 to 4. Mean pain intensity value in VAS was 0.82. Thirty-five patients (70%) did not feel any pain resulting from the presence of the artificial sphincter. Pain occurred much more frequently in the group of patients with urethral erosion (7/9 patients). No patient experienced bladder hyperactivity after device activation.
Complications leading to revision or permanent device removal arose in 12/50 patients (24%). The recorded complications were urethral erosion (n = 9), infection (n = 0) and mechanical failure (n = 3).
All patients with urethral erosion underwent permanent removal of the artificial sphincter.
The three patients presenting with mechanical failure all had revision and reimplantation surgery which resulted in social continence maintaining to this day.

Efficacy

Before device implantation, all patients used ≥3 pads for incontinence.
Social continence was achieved in 29/50 patients (58%); continence improved from "4 or more pads" to 2 pads per day in 15/50 patients (30%) (Table 2). Persistent incontinence without complication and with sphincter functioning properly occurred in 6/50 patient (12%).

Table 2. *The results of the implantations of the ZSI 375 (Zephyr Surgical Implants)*

	Before implantation	12 months after implantation	24 months after implantation	36 months after implantation
Patients, n	50	32	19	15
Pads used/ day, n (%)				
None	0	1 (3)	1 (6)	1 (6.6)
1	0	18 (56)	5 (26)	4 (26.7)
2	0	9 (28)	5 (26)	4 (26.7)
3	7 (14)	0 (0)	3 (16)	4 (26.7)
>= 4	43 (86)	4 (13)	5 (26)	2 (13.3)
Social continence 0,1 pad, n (%)	0	19 (59)	6 (32)	5 (33.3)
Improvement, n (%)	0	10 (31)	9 (47)	6 (40)
Success, n (%)	0	29 (91)	15 (79)	11 (73.3)
Failure, n (%)	0	3 (9)	4 (21)	4 (26.7)

DISCUSSION

The present study has some limitations: the patients included in the study underwent radiotherapy treatment or previous AMS 800 AUS (American Medical Systems, Minnetonka, MN, USA) surgery in the past, the patients were operated during surgeons' ZSI 375's learning curve and assessment of continence was based on pad numbers and not on pad weight.

The quality of ZSI 375 has improved over the last five years. The reinforced hydraulic circuit of ZSI 375 PF (pre-filled) has been available since March 2015 and the resulting decrease in operating time should also reduce infection and mechanical failure rates.

A better management of pressure increase after activation should help to decrease urethral erosion.

Two surgeons from one urological centre included their patients in the study and from their own experience in terms of the procedure, the present series of implantations, complications and revision rates are similar to the AMS 800 [20, 21, 22]. In spite of the fact that patient observation time includes the period when operators acquire experience in connection with the learning curve, the obtained results are comparable to the data from literature concerning the artificial urethral sphincter AMS 800.

In our study, efficacy results are similar for social continence, as evaluated by pad use, which was achieved in 29/50 patients (58%). Continence was improved in a further 15/50 patients (30%). Data from the Food and Drug Administration in the USA give a 73% total continence rate for the AMS 800 and an 88% improvement rate [23].

The abdominal approach for reservoir placement can be difficult, especially after robotic surgery and laparoscopy leading to a new approach for the reservoir [24]. A pre-connected device with the absence of an abdominal reservoir simplified the procedure, reducing operating time and risk of infection.

Our median follow-up of 21.04 (1–50) months was long enough to establish the safety and efficacy of the ZSI 375 device and to identify all potential complications. The reported mean time of complication onset for AUS is 19.8 months for erosion, 29.6 months for atrophy, and 68.9 months for mechanical complications [25].

Erosion risk and rate must be discussed and accepted by the patient. From the nine patients presenting erosion, three patients had previous radiotherapy. Radiotherapy is a very well-known adverse factor for insertion of the sphincter. In other publications urethral erosion ranges from 2% to 17% of patients [20, 21, 22, 25, 26].

Infection did not occur in this study. Postoperative wound infection is one of the most common complications. According to Staerman et al., it can occur in 8.3% of patients, which is comparable to or better than that of AMS 800, Flow Secure or other systems used to treat incontinence in men [4, 5, 12, 15, 20, 21, 22, 26].

Three patients had mechanical failures. In all cases of mechanical failure, a new sphincter was implanted with social continence maintained to this day. In the literature, mechanical complications are found in about 10% of artificial urethral sphincter implantation cases [22, 26–28].

A suspicion of one spontaneous reactivation occurred at the same time AMS withdrew its sphincter AMS 800 from the worldwide market because of spontaneous activation in many pumps. Zephyr Surgical Implants have added a security system, which locks the

sphincter in a safer deactivated position to avoid this kind of complication.
The armed tubing was reinforced in 2011 to avoid kinking, thus making the tubing resistant to breakage. Usually, surgeons are not fond of preparing the AUS, filling the components with a saline solution and removing air bubbles. One sphincter required revision surgery because of a hydraulic circuit leakage of an unknown cause. The ZSI 375 now comes pre-filled, ready to be implanted and the hydraulic circuit is reinforced to reduce the risk of long-term leakage.

CONCLUSIONS

The present study has some limitations: the patients included in the study underwent radiotherapy treatment or previous AMS 800 AUS surgery in the past, the patients were operated during surgeons' ZSI 375's learning curve and assessment of continence was based on pad numbers and not on pad weight.
Nevertheless, the results of this version of ZSI 375 are similar to AMS 800. This is revealed by comparing our results to the results achieved by other authors presented in the quoted literature.
The quality of ZSI 375 has improved over the last five years. The reinforced hydraulic circuit of ZSI 375 PF (pre-filled) has been available since March 2015 and has reduced the operating time.
The ZSI 375 device is safe, effective and the follow-up was long enough to identify all potential complications.

CONFLICTS OF INTEREST

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

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