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Early experiences with the adjustable artificial urinary sphincter Zephyr ZSI 375 Version 1.0 and 2.0

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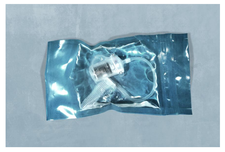
Introduction & Objectives:

To evaluate the outcomes of an artificial urinary sphincter implantation, the ZSI 375 device in male patients with stress urinary incontinence at seven unrelated centres in Europe. The primary outcome was continence. The secondary outcomes included: improvement and complication rates.

Zephyr ZSI 375 Version 1.0

Zephyr ZSI 375 Version 2.0
reinforced buttons



Zephyr ZSI 375 Version 3.0
pre-filled

Zephyr ZSI 375 Version 4.0
1st implantation
21.02.2017
Hamburg

Material & Methods:

It is a retrospective, non-randomised, multicentre study from January 2012 to December 2014, with 106 consecutive men with moderate to severe SUI. The patients were followed up until November 2015. All men had failed previous rehabilitation by pelvic floor training and electrostimulation. This study was carried out in agreement with applicable laws and regulations, good clinical practice, and ethical principles, as described in the Declaration of Helsinki in 1975, and revised in Tokyo in 2008.

- 106 patients with the mean age of 71.56 years (8.9; 26-85).
- The mean (range) period of incontinence: 48.6 (11-132) months,
- 91% were incontinent > 1 year before implantation.
- Among the total patient population:
- The mean number of urinary pads used daily was 4.22
- 96 patients (90.6%) were considered to have had a severe incontinence, with a daily pad usage ≥4 at baseline.
- The mean (SD; range) operative time was 54 (30-150) min.
- Uneventful implantation was performed in 82 patients (77.3%).
- No patient experienced bladder overactivity, chronic urinary retention, or any other adverse effect following the device activation.

Results:

- Postoperative complications occurred in 24 patients (22.6%):
- Infection: 2 cases (1.8%),
- one at the site of mesh implantation and the other in the perineal area leading the explantation of the device. All infections occurred early in
- the series.
- Postoperative erosion of the urethra:
- 19 cases (17.9%) and it occurred at the mean time of 13.5 months.
- Mechanical failure (saline leakage) with resultant device re-implantation
- 3 patients (2.8%). due to intraoperative injury of a silicone tube that connects a urethral cuff with a pump.
- The device had to be explanted in 24 patients (22.6%).
- The ZSI 375 implantation-related complications by etiology of urinary incontinence are presented in the table below:

. ZSI 375 implantation-related complications by etiology of urinary incontinence

Actiology of incontinence	Infections n,(%)	Urethral erosions n, (%)	Mechanical complications n, (%)
RP	1 (50.0)	11 (57.9)	2 (66.7)
RT	0	4 (21.1)	0
RP+RT	0	2 (10.5)	0
TURP	0	0	1 (33.3)
RC	1 (50.0)	1 (5.25)	0
Pelvic trauma	0	1 (5.25)	0
Total	2 (1.8)	19 (17.9)	3 (2.8)

Key: n=number of patients; RP=radical prostatectomy; RT=radiotherapy; TURP=transurethral resection of the prostate; RC=radical cystectomy

Conclusions:

AMS 800 is currently considered the gold standard: it has several drawbacks including:
•complexity of the procedure,
•significant cost,
•no option to adjust the issued pressure of the device,
•inability to re-adjust the cuff in case of postoperative urethral atrophy.

- In effort to improve the disadvantages of AMS 800, the ZSI 375 artificial urinary sphincter has recently been developed.
- As ZSI 375 is a relatively new device, only a handful of studies have explored its safety and efficacy in incontinent male patients

European multicentre experience in 106 patients with ZSI 375.
•Largest series of the ZSI 375 implantations
•Longest follow-up period available,
•high success rate.

- During the mean follow-up period of 24 months the overall success rate was 91.8%. After the same follow-up time:
- 83.6% of patients were considered dry
- 8.2% of men improved,
- 8.2% of patients who failed the treatment.
- total continence achieved with the ZSI 375 device was stable over 24 months.
- Previous studies regarding the ZSI 375 outcomes have shown excellent short-term results, which ranged from 87% to 94.2% 5,7,8.
- Our total continence rate is comparable with the reported continence rate for AMS 800 in a 24-month follow-up period of ≤ 90%

Vivantes