Zephyr Surgical Implants 375 artificial urinary sphincter for male stress urinary incontinence: Short-term outcomes from one centre in Portugal

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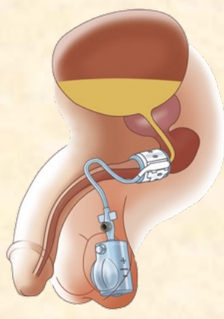


HYPOTHESIS / AIMS OF STUDY

The treatment of choice for patients who have **moderate to severe iatrogenic stress urinary incontinence** is the implantation of an **artificial urinary sphincter** [1]. We analyzed the outcomes of the artificial urinary sphincter (AUS) **Zephyr Surgical Implants (ZSI) 375** implantation for stress urinary incontinence in men, focusing on quality of life assessment (QoL).

STUDY DESIGN / MATERIALS AND METHODS

The ZSI 375 device is a **one-piece device** consisting of an adjustable cuff, molded to fit around the urethra, which is connected by a tube to a pump and a pressure-regulating tank. It has no abdominal reservoir. [2]

The study had a retrospective non-randomized format design. It was conducted in one urological department in Portugal. Between May 2021 and December 2022, **18 consecutive artificial urinary sphincter ZSI 375** were implanted in men with iatrogenic moderate to severe stress urinary incontinence according to **24h pad weight test**. The pre-operative protocol included a 24h pad weight test, cystoscopy and a pressure-flow study. All patients had a previous pelvic floor muscle training program.

The follow up was completed in January 2023. Complications and number of pads used to manage incontinence were recorded. Perioperative complications were categorized according to the Clavien-Dindo classification. The quality of life was assessed based on the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) performed before surgery and in the follow-up after device activation. A qualitative grade of satisfaction was also recorded.

RESULTS / INTERPRETATION OF RESULTS

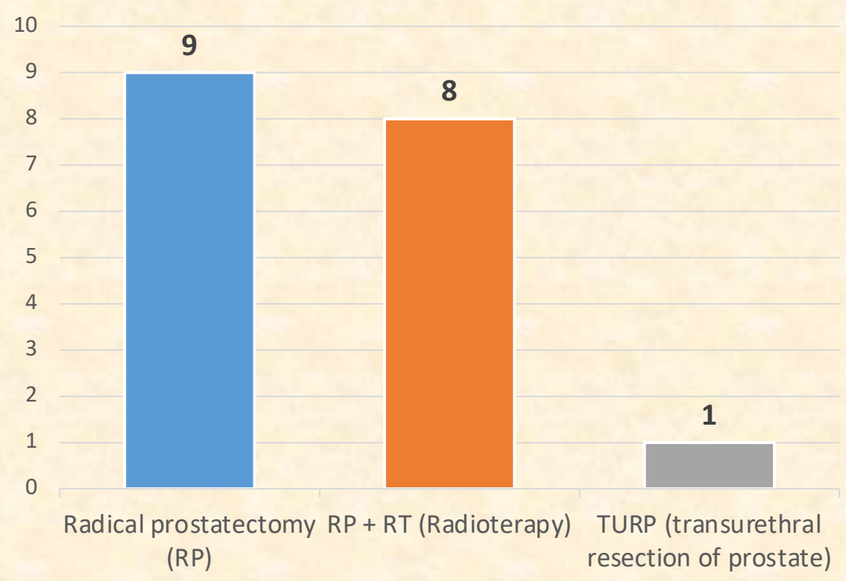
Number of patients	18
Averaged (range) age	71,5 (62-80) Years
Mean (range) follow-up	10 (3-20) Months

Table 1: Sample of the study

24h pad weight test	Number of patients	Percentage
200 – 400 grams	4	**22,2%**
> 400 grams	14	**77,8%**

Table 2: Pre-operative 24h pad weight test

Graphic 1: Causes of urinary incontinence



The mean (range) operative time was **66 (35-90) minutes**, and the mean hospital stay was 1 day with catheter removal on the same day. The device was activated six weeks later by routine.

Perioperatively, **one** patient was classified as grade 2, while **the remaining were classified as grade 0 or 1** in the Clavien-Dindo classification.

Complications	Number of patients	Percentage
Total complications	4	**22,2%**
Erosions of the urethra	2	11,1%
Infections	1	5,6%
Mechanical failure	1	5,6%

Table 3: Complications after surgery

Continence	Number of patients	Percentage
Total continence (0 pads per day)	3	**16,7%**
Social continence (1 pad per day)	9	**50%**
Incontinence (>1 pad per day)	2	**11,1%**
Overall success rate (total and social continence)	1	**66,7%**

Table 4: Continence after surgery

The mean reduction (range) in the ICIQ-SF score was **10,7 (3-21) points** in a scale from 0-21. The grade of satisfaction with the device was **77,7%.**

In this study we report our short-time experience in **18 patients** with an implanted ZSI 375 device. During the median follow-up period of **10 months** the overall success rate (total and social continence) was **66,7%.** The AUS AMS 800 is currently the gold standard therapy of severe SUI in men. However, there are some concerns about it, including **complexity** of the procedure with consequent time consuming, inability to adjust the pressure in the device, or to readjust the cuff in the case of postsurgical urethral atrophy. ZSI 375 is a relatively new device.

With our study we observed the **simplicity** of the surgical procedure with short surgical time even in the early learning curve. One important advantage of this device is the **possibility to adjust the internal pressures via the in situ trans-scrotal applicator, in an office outpatient setting, in order to obtain a better outcome even after surgery.**

The most frequent complication was **urethral erosion** which affected 2 (11,1%) of the patients, a rate comparable to that of AMS 800. One of the 2 patients had previous radiotherapy, a well-known adverse factor for insertion of the sphincter. Mechanical failure resulting in device re-implantation affected 1 (5,5%) patient at the early stage of the study, probably related with the inexperience of the surgeons with the implantation of this new device. This rate is also comparable with the AMS 800 [3]. Our total rate of complications is comparable to other series of ZSI 375 implantations reported. The QoL assessed by ICIQ-SF questionnaire showed a significant improvement. A high grade of satisfaction with the device was also noted, probably due to the simplicity of the device.

CONCLUSIONS

In this short-time follow-up study, the **ZSI 375 AUS was successful in the treatment of moderate to severe male stress urinary incontinence, with a good success rate and an acceptable low rate of complications**. The QoL was assessed using ICIQ-SF with significant improvement demonstrated. The simplicity of the surgical procedure with a short learning curve was also observed. In conclusion the ZSI 375 AUS is a good option for treatment of moderate to severe stress urinary incontinence in men.

REFERENCES

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