The New ZSI 375 Artificial Urinary Sphincter

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INTRODUCTION

Stress urinary incontinence (SUI) can be a significant morbidity in men, in particular after radical treatments, such as post-prostatectomy. Brantley-Scott artificial urinary sphincters (AUS) are the current standard treatment for moderate and severe SUI (1). ZSI 375 (Zephyr Surgical Implants, Geneva, Switzerland) is a one-piece artificial urinary sphincter (Photo 1) manufactured from medical-grade silicone rubber. This facilitates implantation and minimises mechanical failures. Furthermore, the cuff is curved to reduce the risk of creasing and fracture (photo 2). It is adjustable from 3.75cm to 6cm. The Pump-Unit (Pressure-Regulating Tank + Pump) is placed within the scrotum and connected to the cuff via a kink-resistant tubing. The Pump-Unit size is 40mm in length and 24mm in diameter, equivalent to the size of a penile implant pump. However, as ZSI 375 contains no abdominal reservoir, the operative time is reduced and there is less risk of damage to both bladder and bowel. Sphincter pressures can be adjusted via a trans-scrotal approach to improve continence rates. The insertion of 1ml of saline increases the pressure by 10cmH_2O (8-12cmH_2O).

On voiding the patient presses the bulb shaped pump button. Pressure from the spring refills the cuff via a restriction flow filter over 2 to 3 minutes. This allows the patient to empty their bladder before the urethra is closed again by the cuff.

ZSI 375 is indicated in male patients with moderate to severe SUI due to intrinsic sphincter deficiency. Contraindications include poor manual dexterity, impaired cognitive function, infection, recurrent urethral strictures, small bladder capacity, poor compliance or overactive bladder.

Prior to implantation, three essential assessments are required: urine culture to minimise infection risk, cystoscopy to exclude a urethral or bladder neck stricture, and urodynamic studies to exclude overactive bladder.

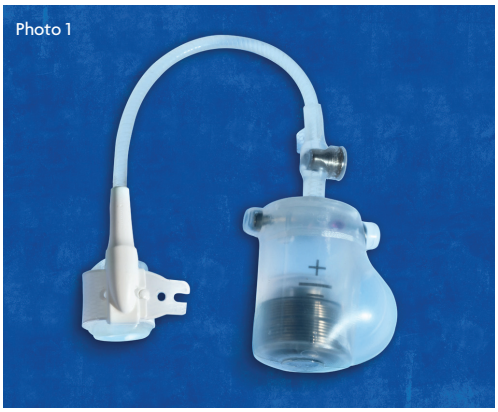
Photo 1

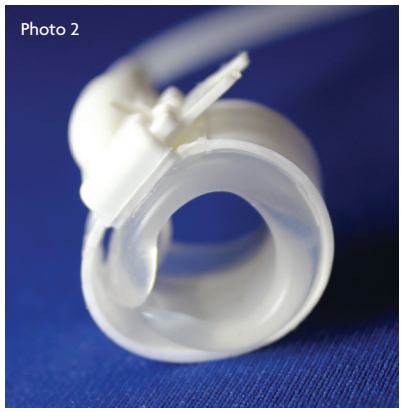
Photo 2

SURGICAL TECHNIQUE

Implantation of the device is performed under general anaesthesia in the lithotomy position with a 16F Foley catheter in the urethra for guidance (2). The urethra is exposed through a perineal incision for adjustable cuff placement and an inguinal incision for Pump-Unit scrotal placement. A 12F Foley catheter is inserted at the end of the procedure and removed 24 hours after the procedure. The patient is discharged the same day or the following day after successfully emptying their bladder spontaneously.

RESULTS

Several published studies are now available online with open access (3-6).

These initials studies range from regional tertiary referral centres and centres of excellence, to centres with less or no previous AUS experience. Outcomes have shown excellent results, which ranged from 87 to 94.2% (5, 7, 8). The outcomes are equivalent to AMS 800 with 88% of patients showing improvement on continence rate from 73% to 90% (9-14).

Serial follow-up studies were of significant duration to report on the safety, efficacy and complication rates of ZSI 375. Short-term complication rates were similar to AMS 800. ZSI 375 infection rate is 2.2-11.11% (2-5) compared to AMS 800 rates, which are 1-8.5% (9, 11, 15-16). Urethral erosion is a documented complication with AUS AMS 800, with rates reported between 7-12% (9, 15, 17). In ZSI 375, with patients from the initial learning curve included in the studies, erosion rates range from 6.7-13.3% (3, 4)

The rate of mechanical failure in the pre-connected ZSI 375 is between 3.4-7.41% (3-5) whereas AMS 800 rate is 6-45% (9, 11, 18-20).

CONCLUSION

These initial studies support ZSI 375 as a safe and effective form of treatment in male patients with stress urinary incontinence.

The introduction of the pre-filled ZSI 375 since 2015 has dramatically reduced operative duration as well as mechanical failure rates.

However, the data is limited due to all studies being retrospective, the inclusion in the data analysis of patients operated on during the 'learning curve' process and the use of a subjective assessment of continence via the number of pads used.

In the future, further experience and better handling of issued pressure adjustment is predicted to further reduce surgical revision rates and urethral erosion.

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