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FOUR YEARS EXPERIENCE WITH THE FLOWSECURE ARTIFICIAL URINARY SPHINCTER. PROBLEMS AND SOLUTIONS.

Hypothesis / aims of study

Despite the fact that the AMS-800 artificial urinary sphincter (AUS) has shown good long term clinical results, a surgical revision rate of over 30% has been reported. A number of these revisions are secondary to reappearance of incontinence following urethral atrophy. Others are the result of complications including erosion, mechanical failure and infection. The novel FlowSecure AUS with conditional occlusion was designed to address these problems and preliminary clinical results were published in 2006 by Proffesor Craggs group (Figure 1). Our objectives were to confirm whether surgical technique, management of patients and results were reproducible.

Study design, materials and methods

From Octuber 2000 to date,100 patients with stress urinary incontinence (SUI) of various aetiologies underwent bulbar urethra (96) or bladder neck (4) implantation of a FlowSecure AUS. All patient had tried conservative methods, 59 patients had undergone unsuccessful procedures for SUI (suburethral mesh, bulking agents, Proact and AMS-800) and 9 patiens had undergone previous pelvic radiotherapy. At implantation, the device was left at atmospheric pressure in all cases. Patients attended for initial pressurisation 2-4 weeks after surgery and they were recolled at two week periods for a repeat pressurisation procedure when required. Pressurisation was conducted by injecting normal saline trough the self sealing port of the prosthesis in order to increase or decrease system pressure depending on individual clinical needs.

Results

The procedure took an average of 38-47 minutes. Mean inpatient stay was 4.3 days. 53 patients had postoperative self-limited scrotal haematoma. Intial pressurisation required a mean volume of 3.7 ml. Further pressurisation was needed in 97 patients requiring a mean additional volume of 4.3 ml. Overall, 3 pressurisations procedures were requiered for recognition of socially satisfactory continence in 89 patients. Implants had to be removed in 28 patients due to early infection (8), late infection secondary to pressurisation (5), perforation of the pump at pressurisation (9) and mechanical failure (6).

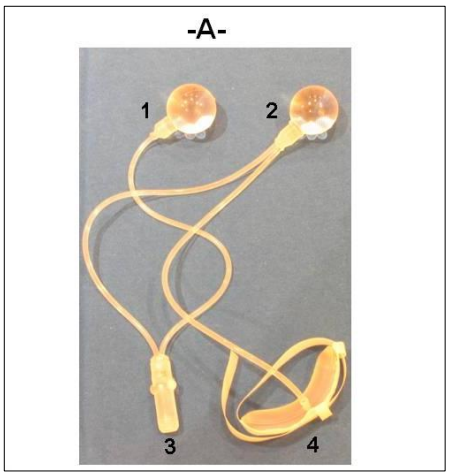
Interpretation of results

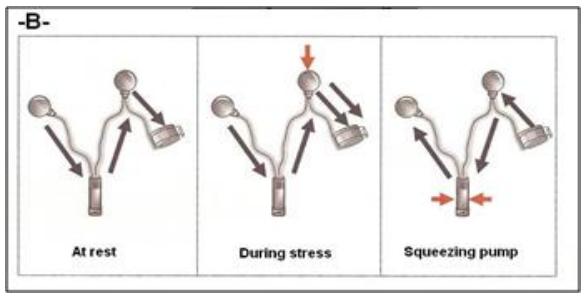
The FlowSecure AUS is an easily implantable prosthesis which allows for adjustability when needed. Though it has been designed for bulbar urethra, the implant can also be placed around the bladder neck. Satisfactory continence rates can be achieved operating at a lower pressure than the AMS-800 and this fact is even more relevant in patients needing intermittent catheterisation. We have had no erosions but we have identified increased risk for system infection and pump puncturing during the pressurisation procedure as well as mechanical failures due to the manufacturing proccess. A revision of the mechanical system has been performed and the pump has been redesigned to prevent punctures in the future

Concluding message

Though short term results look promising, long term results are needed to confirm that the design changes performed in the FlowSecure device is an alternative to the AMS-800 AUS.

Figure 1. The novel FlowSecure artificial sphincter components: (1) Pressure-regulating balloon, (2) Stress relief balloon, (3) pump and (4) urethral cuff





Functioning of the device: At resting periods the pressure regulating balloon keeps the bulbar urethra closed at low pressures. When intra-abdominal pressure raises the stress relief balloon provides additional pressure to maintain continence. The cuff is deflated by squeezing the pump enabling micturition.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**This is a follow up study on patients after insertion of an approved device for use in the E.C.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**