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FLOWSECURE ARTIFICIAL URINARY SPHINCTER: CLINICAL EXPERIENCE, MANAGEMENT AND RESULTS.

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 [1]. Our objectives were to confirm whether surgical technique, management of patients and results were reproducible.

Study design, materials and methods
The FlowSecure AUS is a one piece pre-filled silicone device comprising a (1) pressure regulating balloon, (2) a stress relief reservoir for conditional occlusion, (3) a single wrap-around cuff adjustable in the range 4-7 cm and (4) a control pump with a self sealing port for injection of additional fluid to adjust pressure. 17 patients were implanted with the new AUS from October 2006 to date at our institution. Bulbar urethra cuffs were implanted in 16 male patients with stress incontinence secondary to radical prostatectomy (14), retropubic prostatectomy for BPH (1) and orthotopic ileal bladder (1). 5 patients had failed previous surgery for incontinence and 3 patients had previous history of pelvic radiotherapy. One Spina Bifida female patient was also implanted in the bladder neck.

Results
Mean operative time was 57 minutes (39-97). There were no intra-operative complications, though one AUS was punctured when suturing the cuff and needed intra-operative replacement. At implantation, a mean volume of 9.3 cc (6-10.2) was required to be withdrawn from the system in order to leave the device depressurised during the immediate post-operative period. Urethral catheter was removed 2.5 days (1-4) post implantation and mean inpatient hospital stay was 4 days (3-7). Post-operative complications included scrotal oedema/haematoma in 6 patients and pump malposition in 1 patient who needed surgical revision and intra-operative repositioning. Initial device pressurisation was performed 2 weeks post-implantation and subsequent pressurisations were performed at weekly intervals if needed. A mean total volume of 6 cc (3-6) was necessary to inject in 3 (2-4) subsequent weekly punctures in order to reduce daily use of 6-8 pads before the AUS was implanted to 0-1 pads once the pressurisation process concluded.

Interpretation of results
The FlowSecure AUS can be used for bulbar urethra and bladder neck. The surgical technique is easy to learn and associated with little handling, reducing risk of infection and potential assembly errors. The association of a pressure regulating balloon and a stress relief reservoir allows the cuff occluding pressure to be set at a low range, reducing risk for atrophy and erosion. The latter is especially relevant in patients needing intermittent catheterisation. The system can be individually adjusted to clinical needs in order to achieve satisfactory continence rates. Surgical procedure, management and results are reproducible.

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

References
[1] Eur Urol. 2006 Sep;50(3):574-80.

Specify source of funding or grant	**There was no funding or grant**
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 eithics committee approval because	**FlowSecure artificial urinary sphincter has the E.C. mark and therefore is approved por clinical use.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**