A New Artificial Urinary Sphincter (VICTO) with Conditional Occlusion for male Stress Incontinence: preliminary clinical results

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OBJECTIVES

The artificial urinary sphincter (AUS) is the standard treatment of male stress urinary incontinence (SUI) and has the longest efficacy record. However, revision rates are reported in up to a third of the cases. Revision and explanation rates due to urethral atrophy and cuff erosion vary considerably among published studies[1,2]. In addition to general risk factors, this may be attributed to high occlusion pressures.

METHODS

VICTO is a single unit pre-connected adjustable device with an occluding cuff (OC), a pressure regulating balloon (PRB) and a scrotal pump with a self-sealing port for pressure adjustment (Fig.1). VICTO⁺ additionally has a preperitoneal placed stress relief balloon (SRB) to transmit transient intraabdominal pressure changes to the OC (Fig. 2)[3].The regulating pressure is adjustable in the range 0-100 cmH_2O and can be altered at any time after implantation by injection or removal of fluid.
In the time between 12/2016 and 11/2018 the device was indicated in 52 patients suffering from SUI. We included the data from 46 patients (VICTO *n*=20, VICTO⁺ *n*=26) with a mean follow-up time of 9.8 months (range 1.2-21.1). Patients with more than 2 prior incontinence surgeries were excluded (*n*=3) and 3 systems were not activated at the time of the data collection. We used a standardized questionnaire to collect postoperative data as pad per day usage (p/d) and satisfaction rate. Average age at time of implantation was 69.6 (± 9.5) years. There were between 0 to 5 (IQR=1, *M*=2) readjustment needed to achieve a sufficient result.

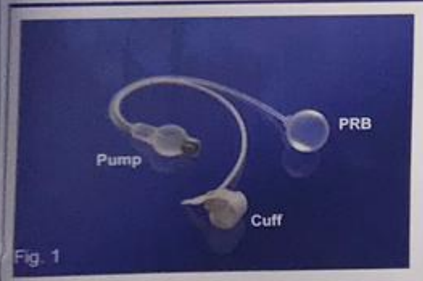

Fig. 1

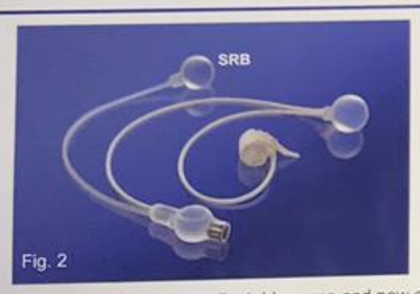

Fig. 2

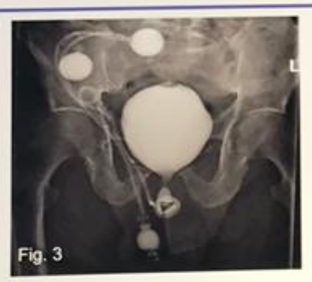
Fig. 3

Fig.1. VICTO device with PRB; perforation safe titanium port, high volume adjustable pump and new cuff design
Fig.2. VICTO⁺ device additionally has a small and firm stress balloon
Fig. 3. Plain scan of the lower abdomen and voiding cystourethrogram with a VICTO⁺ device

RESULTS

In all cases the device was easily implanted without any intraoperative complications. Three patients with persistent incontinence required revisions (smaller OC *n*=2, new pump *n*=1) due to learning curve. The pad per day usage improved from 6.6 (±3.4) to 1.5 (±1) and the continence rate (max. 1p/d) was 59,6%, which is comparable to the long term results of Mayo Clinic (59%)[4]. The overall satisfaction was 87,2% and 91,5% would undergo the same operation again. Only 5 patients had an improvement less than 50%, all of them are not fully activated yet and may improve more with future adjustments.

CONCLUSIONS

The device provides adjustability in regulating pressure in situ. In our cohort of 46 patients, 90% had at least an improvement of 50% (*M*=75) and we have reached socially dry status (max 1 p/d) in 60%. These short results are promising and challenge prior AUS series. Adjusting the system pressure to the lowest level providing continence may reduce the long-term rate of erosions and “subcuff atrophy”, however such data are not yet available.

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