A NEW ARTIFICIAL URINARY SPHINCTER (VICTO) WITH CONDITIONAL OCCLUSION FOR STRESS INCONTINENCE: PRELIMINARY CLINICAL RESULTS.

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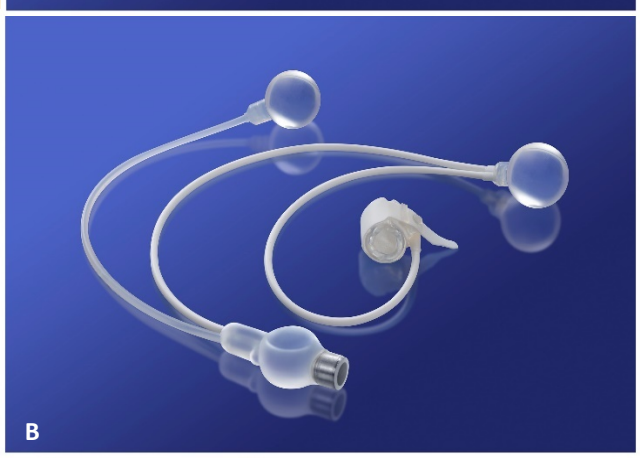
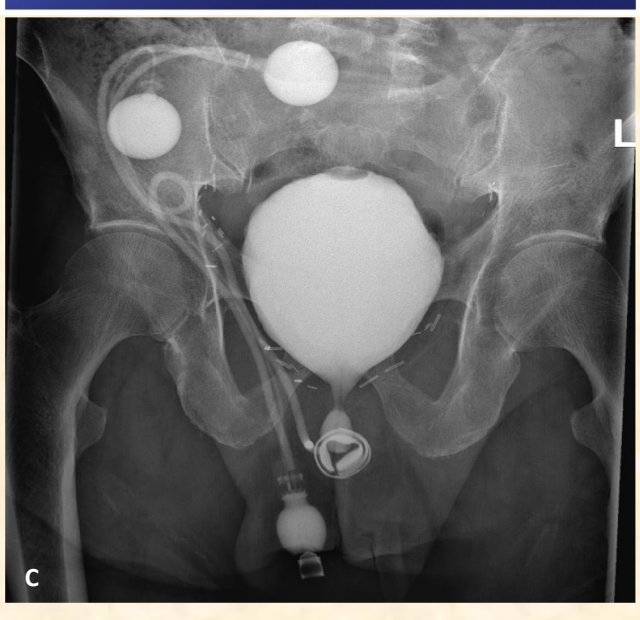
ABSTRACT 103

Figure 1: A- simple VICTO device without stress balloon; B- VICTO PLUS device has small and firm stress balloon, perforation safe titanium port, high volume adjustable pump and new cuff design, C- Plain scan of the lower abdomen and voiding cystourethrogram.





AIM OF THE STUDY

Revisions of the artificial urinary sphincters (AUS) are mostly as the result of urethral erosion and sub cuff atrophy. In addition to general risk factors, this may be attributed to the high occlusion pressures [1].
The aim of the study is to determine the safety and efficacy of a novel AUS.

METHODS

VICTO is an adjustable device with an occluding cuff (OC), a pressure regulating balloon and a self- sealing port for pressure adjustment. VICTO plus has additionally a stress relief balloon (SRB) to transmit transient intraabdominal pressure changes to the OC [2]. The regulating pressure is adjustable in the range 0-100 cmH2O and can be altered at any time after implantation by the injection or removal of fluid.
The VICTO (with or without stress balloon - PROMEDON AUSTRIA) is a artificial urinary sphincter - silicone rubber implant which consists of a pressure regulating balloon with/or without stress relief balloon (for conditional occlusion). Typical urethral cuff and a control pump come as a one piece device ready to use.
From Dec. 2016 to Feb. 2018 the device was implanted in 32 patients (VICTO n=13, VICTO plus n= 19) suffering from stress incontinence after prostate surgery (radical prostatectomy n=29; endoscopic transurethral resection of the prostate n=3). We included the data from 20 patients (VICTO n=9, VICTO plus n= 11) with a mean follow-up time of 8,1 months (range 4-14). We used a telephone questionnaire and/or clinical checks to collect postoperative data as daily pad use and satisfaction rate. Average age at time of implantation was 72.1 (5.6) years. Postoperatively patients underwent between 1 to 5 (IQR=1, M=2) readjustment in order to achieve the final result.

RESULTS

In all 20 cases the device was easily implanted and there were no postoperative complications according to Clavien-Dindo. Pad use per day (p/d) improved from 5.3 (3.4) to 1.7(0.8) p/d. Four of our patients (20%) had one or more prior incontinence operations, all of them had an improvement of at least 50% in p/d. The p/d improvement in patients (n= 6) with a prior irradiation was 73,5%.
In total 10 (50%) patients were socially dry (max 1p/d) after implantation. 6 patients (30%) used 2 p/d and 4 (20%) 3 p/d. Continence improved 61,2% on average. Continence was rated as "excellent" or "good" by 11 patients (55%), 3 patients (15%) rated their continence level as "poor" although the improvement in p/d was over 50%. The satisfaction rate was 100% (n =20), 11 patients (55%) rated their overall satisfaction with the procedure as "excellent", 5 (25%) as "good" and 4 as "satisfactory".

INTEPRETATION OF THE RESULTS

This series represents the very first experience with the device.
Continence results are promising, however they may likely improve with growing experience. 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.

CONCLUSIONS

The device provides adjustability in regulating pressure in situ. Low initial pressure may reduce the need for surgical revision caused by urethral erosion and sub cuff atrophy. Continence rates are promising with 50% dry and zero patients improved by less than 50%. Long term results are currently missing. During the follow up there were no complications resulting in system removal, which emphasizes the remarkable safety of this implant.

REFERENCES

1. **Van der Aa F, Drake MJ, Kasyan GR, Petrolekas A, Cornu JN; Young Academic Urologists Functional Urology Group.** The artificial urinary sphincter after a quarter of a century: a critical systematic review of its use in malenon-neurogenic incontinence. Eur Urol. 2013 Apr;63(4):681-9.
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