Adjustable artificial sphincter VICTO in the treatment of urinary incontinence: early results in a cohort of high-risk cases in a prospective single center study

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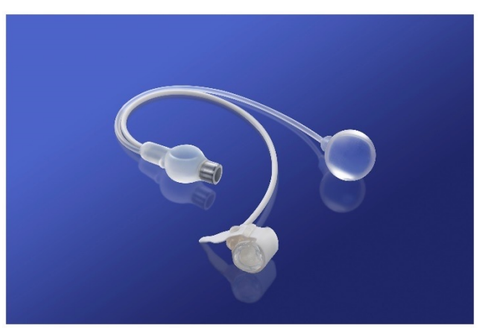
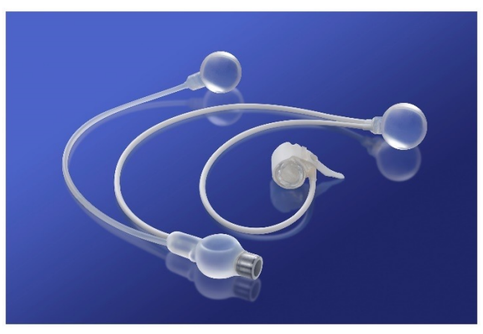
Introduction

Victo is an artificial urinary sphincter (AUS), consisting of three parts which are preconnected. A pressure regulating balloon, a control pump, and a cuff. Victo⁺ is offering an additional, stress regulating balloon, in case of short-term increase of abdominal pressure such as coughing, additional fluid is provided by the stress regulating balloon to the cuff in order to increase temporarily the system pressure. Additionally, both systems offer the possibility of postoperative adjustment of the device pressure.

The objective of the present study is to test the efficiency and practicality of VICTO and VICTO⁺ in the control of stress urinary incontinence and to evaluate the short- and long-term complications.



Victo system with Single balloon configuration and easy pressure adjustment



Victo⁺ with double balloon configuration

- Stress Relief Balloon added to provide conditional occlusion of the cuff under abdominal pressure increases
- Operating pressure to be set at a lower level

Methods

A total of 30 patients were included between January 2020 and December 2021, the trial is still ongoing and estimated end of the clinical trial is May 2025.

43,3% of the patients in this cohort has undergone prior procedures for stress urinary incontinence (SUI): sling n=4, ProACT balloons n=4, AMS 800=1, 3 patients had multiple prior SUI surgeries. 40% of the patients had undergone secondary irradiation therapy (RT) after prostatectomy. Additionally, 9 patients had undergone procedures for bladder neck pathologies or urethral strictures (UTI, TW n=7, end-to-end anastomosis n=2).

All patients underwent artificial urethral sphincter (AUS) implant “VICTO” according to established technique.

The mean age was 71,4 years, 40% of the patients had systemic arterial hypertension and 24% diabetes mellitus. Functional urinary outcomes were assessed according to daily pad use and a standardized questionnaire. Data were collected as part of the follow up care of these patients.

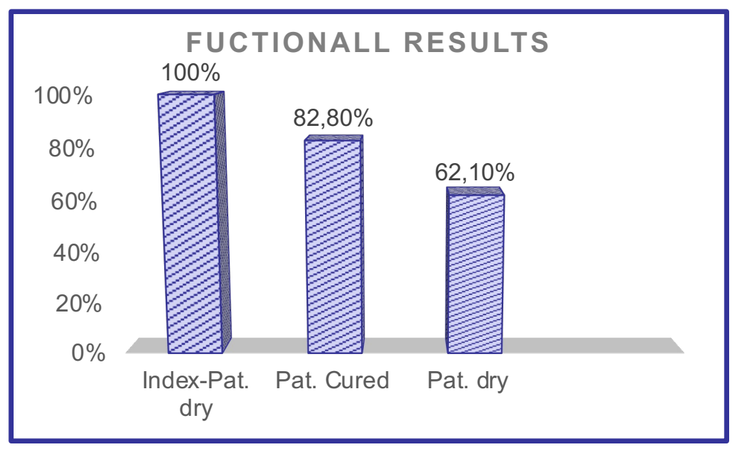
Table 1: Baseline characteristics

N=30	n (%)
History of pelvic irradiation	12 (40)
History of surgical treatment of SUI proACT balloons Male sling AUS multiple SUI surgeries	13 (43,3) 4 4 1 3
Procedures for bladder neck pathologies	9 (30)

Results

The reduction in number of pads compared between baseline and Follow-Up was significant (p<0,001). Cure of urinary incontinence was defined as using either 0 or 1 pad/day. All the index patients (no prior surgery, no previous irradiation) in this cohort (n=5) were cured. In total 62,1% (n=18) of the patients reported to be dry and were cured by definition. Additionally, 20,7% (n=6) patients reported improvement of ≥ 50 % according the PGI-I (Patients Global Impression of Improvement).

Further surgery has been performed in a total of 8/29 (27,6%) patient. One patient required the change of the pump due to malfunction and one patient required relocation of the pump due to facilitate the handling. Explanation of the device has been performed in four patients, the reasons were persistence of incontinence (n=2; 6,8%) infection and erosion (n=2; 6,8%). One of the infections occurred after traumatic catheterization without deactivation of the device which caused urethral erosion and consequently infection and explantation of the device. Both patients with erosion had previous pelvic irradiation. One explantation was reported at day 2 after implantation, the presumable cause of explantation was unrecognized intra-operative urethral injury and consequently urethral erosion and was excluded from the study.



Interpretation of results

Importantly, taking to account the current evidence on the impact of RT on the AUS outcome, the patient population in the current trial might not be only at increased risk for repeated surgery and explantation but also for increased risk of incontinence persistence, thus, decreased treatment success. In this complex group with mostly high-risk patients, all men with uncomplicated SUI (no previous surgeries and no history of irradiation) were cured after device implantation and the overall treatment success was 83% according PGI-I and 62% according to p/d. There is evidence, that prior SUI surgeries and RT might have a negative impact on success rates. These risk factors must be considered for interpretation of the current results.

Conclusions

Despite the above average number of patients with risk factors for failure in this cohort, the results of the current trial are consistent with the evidence in literature and confirm the effectiveness of this new adjustable AUS for treatment of male SUI.