

# Medium-Term Outcomes of the VICTO Adjustable Artificial Urinary Sphincter: A Brazilian Real-World Multicentre Study

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## Research Article

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# Abstract

## Background

Artificial urinary sphincter (AUS) is the established treatment for moderate-to-severe male stress urinary incontinence (SUI). Available AUS present design challenges that can compromise their long-term effectiveness, including urethral atrophy and erosion. The VICTO (Promedon, Argentina) addresses these issues through percutaneous postoperative adjustment, allowing pressure to be set at the lowest effective level; yet real-world evidence remains limited. This study reports medium-term safety and effectiveness outcomes from referral centres in Brazil.

## Methods

Retrospective multicentre cohort study of 50 patients who received VICTO for SUI and attended at least their first annual revision (median follow-up: 16.5 months, IQR 14.8–27.3). Primary outcome: social continence (0–1 pad/day) at follow-up. Secondary outcomes: dry rate (0 pads/day), improvement ( $\geq 50\%$  pad reduction), complications (Clavien–Dindo), and patient-reported satisfaction (VAS 1–10). Predictors of treatment failure were explored by regression.

## Results

Social continence was achieved in 72.0% of patients (36/50; 95%CI 57.5–83.8%); the dry rate was 40.0% (20/50; 95%CI 26.4–54.8%). Overall improvement was 87.8% (43/49; 95%CI 75.2–95.7%). Postoperative complications occurred in 22.0% (11/50; 95%CI 11.5–35.9%) of patients. Among these, Clavien-Dindo Grade  $\geq$  II events were one Grade II and three explantations (6.0%; 95%CI 1.3–16.5%, Grade IIIb). No device infection was observed. Patient reported satisfaction was 77.6% (VAS 7–10). No baseline or implant-related factor reached statistical significance as a predictor of treatment failure.

## Conclusions

VICTO demonstrated safety and effectiveness outcomes comparable with the gold standard. These findings contribute, to our knowledge, the first published evidence on this device from Latin American settings.

## Trial registration:

The study protocol was approved by the Research Ethics Committee of the Irmandade da Santa Casa de Misericórdia de São Paulo (coordinating centre) through Plataforma Brasil (CAAE 75768022.1.0000.5479; opinion no. 6,641,906; 7 February 2024).

## Background

Artificial urinary sphincter (AUS) implantation is the established surgical treatment for moderate-to-severe stress urinary incontinence (SUI) in men with failed conservative management [1, 2]. The most common indication is post-prostatectomy SUI, affecting 10–16% patients following radical prostatectomy (RP) [3]. Since RP is a common treatment for prostate cancer, its prevalence increases along with the global burden of this disease, with 1.47 million cases diagnosed in 2022, increasing 2.9 million annually by 2040 [4, 5].

Several AUS devices are currently available, of which the AMS 800 (Boston Scientific, USA) remains the global gold standard with over 250,000 devices implanted [2]. Its main limitation is the inability to modify occlusive cuff pressure after implantation without surgical revision [6]. Alternative devices have addressed this challenge: the Zephyr ZSI 375 allows postoperative pressure adjustment via a scrotal compensation pouch; the Rigicon ContiReflex® incorporates a mechanism that responds to intra-abdominal pressure changes; and devices such as the UroActive™ and ARTUS offer wireless cuff control [2, 7, 8]. However, across all available AUS, urethral atrophy, erosion, infection, and mechanical failure remain clinically significant complications, with high rates of reintervention [2, 9, 10].

In this context, the VICTO (Promedon, Cordoba, Argentina) includes a self-sealing scrotal port that allows percutaneous pressure adjustment in an outpatient setting, without reoperation [9]. Since its introduction in 2016, cohorts of 17–116 patients and follow-up periods of 15–36 months have reported dry rates of 51–76%, social continence rates of 70–94% [1, 9, 11]. Urethral erosion rates are 0–6%, device infection 1–5%, and mechanical failure 1–6%, with an overall device failure rate of up to 14% [1, 9, 11]. Patient-reported satisfaction ranges from 70% to 92% [1, 11].

However, Latin-American evidence on VICTO remains limited. Here we report outcomes from Brazilian centres, contributing, to our knowledge, the first peer-reviewed evidence on this device from a Latin American setting.

## Methods

### Study design

This multicentre, retrospective cohort study conducted at four referral urology centres in São Paulo, Brazil. The protocol was approved by the institutional ethics committees and registered on Plataforma Brasil. A waiver of informed consent was granted under CIOMS 2016 guidelines [12]. Data were collected retrospectively from the medical records of eligible patients at the centres; VICTO implantations were performed between May 2022 and October 2024.

### Participants and eligibility criteria

Eligible participants were adult male with stress urinary incontinence (SUI) who received VICTO at the participating centres, had completed at least the initial annual follow-up assessment (scheduled 12 months after implantation), and had complete medical records. Completion of the first annual (12-month) follow-up assessment was an eligibility requirement, so patients without it were not included. When questionnaire data were missing from the record, patients were contacted to complete them.

### Outcomes

The primary outcome was social continence at follow-up (0–1 absorbent pad per day). Secondary outcomes were the dry rate, defined as complete continence with 0 pads per day [13], improvement ( $\geq 50\%$  reduction in pad use from baseline), device-related parameters at implantation and activation (cuff size, activation volume, and final volume after adjustments), and patient-reported quality of life assessed using a visual analogue scale (VAS). Safety outcomes included intraoperative and postoperative complications, classified according to the Clavien–Dindo system [14].

### Device description and surgical technique

The VICTO AUS comprises a urethral cuff, a pressure-regulating balloon (PRB), and a scrotal control pump. The PRB provides variable urethral compression without a fixed pressure setting. Cuff sizes range from 3.7 to 5.5 cm.

All procedures were performed under general or spinal anaesthesia in dorsal lithotomy position. Through a perineal midline incision, the bulbar urethra was circumferentially dissected and the cuff positioned posteriorly. Cuff size was selected intraoperatively from urethral apposition using the manufacturer's sizing tape.

Through a separate lower abdominal incision, the PRB was placed intraperitoneally and secured with a purse-string suture, with the control pump placed in a dependent scrotal pouch. The device was filled with 13 mL of sterile saline solution before implantation. Activation was an outpatient office procedure performed a median of 5 weeks after implantation, by percutaneous injection of saline into the pump port. When continence was not achieved, volume was adjusted at subsequent visits, up to an occlusive pressure of 90–100 cmH<sub>2</sub>O.

### Data analysis

Three main analyses and three exploratory analyses were performed, assessing:

1. **(Main)** Baseline and perioperative data.
2. **(Main)** Continence outcomes (social continence, dry rate, improvement) at follow-up, with daily pad use compared between baseline and follow-up.
3. **(Main)** Complications and patient satisfaction at follow-up.
4. **(Exploratory)** Unadjusted associations of all baseline variables with treatment failure.
5. **(Exploratory)** An adjusted model of baseline risk factors for treatment failure.
6. **(Exploratory)** Implant-related factors (cuff placement and size), activation parameters (volume and timing), and follow-up duration association with outcomes.

Treatment failure was defined as failure to achieve social continence at last follow-up. The events-per-variable (EPV) was limited by 14 events; all regression analyses are therefore exploratory

For analysis 5, three predictors were selected a priori for their established association with AUS failure: previous pelvic radiotherapy [15, 16], previous urethral stenosis [17] and previous surgery for urinary incontinence [18]. Univariable results from analysis 4 were not used for variable selection. A pre-fitting feasibility check showed complete separation for previous incontinence surgery (no failures among 8 exposed patients), and a single failure event for previous urethral stenosis. The three-predictor model was therefore not estimable. A model for previous radiotherapy was adjusted for baseline incontinence severity, the remaining predictors are reported as proportions.

For analysis 6, associations were assessed with univariable models and then adjusted for baseline severity as confounder, consistent with analysis 5 and within the EPV limit.

Two patients had missing data (one baseline pad count, one satisfaction score) and were excluded from the corresponding analyses (n = 49); all other analyses used the full cohort (n = 50). No formal sample-size calculation was performed; all consecutive eligible patients treated at the participating centres were included, so the analysable sample size was determined by the number meeting the inclusion criteria.

## Statistical methods

Confidence intervals for proportions used the Clopper–Pearson exact method. The paired pre–post pad-use comparison used the Wilcoxon signed-rank test, with median change reported as the Hodges–Lehmann estimate (95% CI).

Unadjusted and adjusted associations with treatment failure used Firth's penalised logistic regression, which reduces small-sample bias and addresses separation. All adjusted models included baseline incontinence severity (baseline pads/day) as a confounder. Multicollinearity was assessed by the variance inflation factor and adjusted-model fit by Nagelkerke's R<sup>2</sup>.

Activation variables and follow-up duration were assessed by Kendall's  $\tau$ , except follow-up duration versus treatment failure (Wilcoxon rank-sum test, median [IQR] by outcome group). Adjusted count-outcome analyses used quasi-Poisson regression to account for mild overdispersion with F-test inference, adjusted for baseline severity. A two-sided  $p < 0.05$  was considered significant. As all regression analyses were exploratory, no adjustment for multiple comparisons was applied, and all p-values and CIs are descriptive. Analyses were performed in R version 4.5.2.

## Results

### 1. Baseline and perioperative characteristics

The cohort included 50 patients with at least a completed first annual follow-up (median follow-up 16.5 months (IQR 14.8–27.3). All screened patients were included.

Baseline characteristics are summarized in Table 1. The median age was 69.5 years (IQR 64.0–73.3). 44% (22/50) had prior radiotherapy, with radical prostatectomy being the primary cause of incontinence.

Intraoperative and postoperative data are presented in Table 2. No intraoperative complications occurred, and 90% (45/50) of implants were placed intraperitoneally, following standard procedure. The rationale for extraperitoneal implantation was not recorded. The median time to activation was 5 weeks (IQR 5.0–6.0), with a volume of 4.0 ml (IQR 4.0–5.0). After a median of 2 readjustments (IQR 0.0–2.0), the final median volume was 20.0 ml (IQR 18.0–23.0).

Moreover, 34 patients (68.0%) had not reached the maximum volume (22 mL). Of these, 4 patients had not yet met the cure criteria, meaning they could still receive additional volume.

Table 1: Baseline demographic and clinical characteristics of patients undergoing VICTO implantation (N=50).

| N = 50*                                                 |                  |         |
|---------------------------------------------------------|------------------|---------|
| <b>Baseline data</b>                                    |                  |         |
| <b>Age, years, median (IQR)</b>                         | 69.5 (64.0–73.3) |         |
| <b>BMI, kg/m<sup>2</sup>, median (IQR)</b>              | 26.8 (24.1–28.8) |         |
| <b>Previous smoking habit, n (%)</b>                    | 9                | (18.0%) |
| <b>Previous diabetes, n (%)</b>                         | 14               | (28.0%) |
| <b>Previous neuropathic disease, n (%)</b>              | 1                | (2.0%)  |
| <b>Previous radiotherapy, n (%)</b>                     | 22               | (44.0%) |
| <b>Previous surgery for urinary incontinence, n (%)</b> | 8                | (16.0%) |
| <b>Previous urethral stenosis, n (%)</b>                | 11               | (22.0%) |
| <b>Previous overactive bladder, n (%)</b>               | 14               | (28.0%) |
| <b>Previous hormonal block therapy, n (%)</b>           | 7                | (14.0%) |
| <b>Causes for urinary incontinence, n (%):</b>          |                  |         |
| Radical Prostatectomy                                   | 46               | (92.0%) |
| Radiotherapy                                            | 1                | (2.0%)  |
| Transurethral resection of the prostate                 | 1                | (2.0%)  |
| Pelvic trauma                                           | 1                | (2.0%)  |
| Laser vaporization                                      | 1                | (2.0%)  |

\* No missing data were observed.

Table 2: Summary of intraoperative and postoperative data.

**N = 50\***

|                                                                    |      |             |
|--------------------------------------------------------------------|------|-------------|
| <b>Intraoperative data</b>                                         |      |             |
| <b>Intraoperative complications, n (%)</b>                         | 0    | (0.0%)      |
| <b>Device placement, n (%):</b>                                    |      |             |
| Intraperitoneal                                                    | 45   | (90.0%)     |
| Extraperitoneal                                                    | 5    | (10.0%)     |
| <b>Device size, n (%):</b>                                         |      |             |
| 3.7                                                                | 13   | (26.0%)     |
| 4                                                                  | 22   | (44.0%)     |
| 4.5                                                                | 13   | (26.0%)     |
| 5                                                                  | 2    | (4.0%)      |
| <b>Postoperative data</b>                                          |      |             |
| <b>Time from surgery to device activation, weeks, median (IQR)</b> | 5.0  | (5.0-6.0)   |
| <b>Initial volume injected for activation, ml, median (IQR)</b>    | 4.0  | (4.0-5.0)   |
| <b>Final volume after adjustment/s, ml, median (IQR)</b>           | 20.0 | (18.0-23.0) |
| <b>Number of patients with final volume &lt;22 ml, n (%)</b>       | 34   | (68.0%)     |
| <b>Number of readjustments needed, n (%):</b>                      |      |             |
| 0                                                                  | 17   | (34.0%)     |
| 1                                                                  | 7    | (14.0%)     |
| 2                                                                  | 15   | (30.0%)     |
| 3                                                                  | 6    | (12.0%)     |
| >4                                                                 | 5    | (10.0%)     |

\* No missing data were observed.

## 2. Continence and improvement rates

At follow-up, social continence rate (0–1 pad/day) was 72.0% (36/50; 95% CI 57.5%–83.8%), including a dry rate of 40.0% (20/50; 95% CI 26.4%–54.8%) (Table 3). Pad use decreased from median 5 (IQR 4–6) preoperatively to 1 (IQR 0–2) at follow-up (Wilcoxon signed-rank test:  $p < 0.0001$ , median change (Hodges-Lehmann estimate) –4 pads, 95% CI –4.5 to –3.5).

87.8% of patients (43/49; 95% CI 75.2%–95.7%) achieved  $\geq 50\%$  reduction in pad use at follow-up (Figure 1). Any improvement occurred in 48/49 patients (98.0%); with one patient unchanged and none worse.

Table 3: Distribution of daily pad use before and after VICTO implantation, and primary and secondary continence outcomes (N=50).

|                                                                 | Number of patients (N=50) <sup>1</sup> |         |              |         |                     | Median [Min - Max] |              | Median Change <sup>3</sup> (95%CI) | p-value <sup>4</sup> |
|-----------------------------------------------------------------|----------------------------------------|---------|--------------|---------|---------------------|--------------------|--------------|------------------------------------|----------------------|
|                                                                 | Preoperative                           |         | At follow-up |         |                     | Preoperative       | At follow-up |                                    |                      |
|                                                                 |                                        |         | n (%)        |         | 95% CI <sup>2</sup> |                    |              |                                    |                      |
| Pads per day, n(%)                                              |                                        |         |              |         |                     | 5 (4–6)            | 1 (0–2)      | -4 (-3.5 to- 4.5)                  | <0.0001              |
| 0                                                               | 0                                      | (0.0%)  | 20           | (40.0%) | 26.4%–54.8%         |                    |              |                                    |                      |
| 1                                                               | 0                                      | (0.0%)  | 16           | (32.0%) |                     |                    |              |                                    |                      |
| 2-3                                                             | 5                                      | (10.0%) | 10           | (20.0%) |                     |                    |              |                                    |                      |
| 4                                                               | 16                                     | (32.0%) | 3            | (6.0%)  |                     |                    |              |                                    |                      |
| 5                                                               | 9                                      | (18.0%) | 1            | (2.0%)  |                     |                    |              |                                    |                      |
| 6                                                               | 12                                     | (24.0%) | 0            | (0.0%)  |                     |                    |              |                                    |                      |
| ≥7                                                              | 7                                      | (14.0%) | 0            | (0.0%)  |                     |                    |              |                                    |                      |
| Patients achieving social continence (use of 0–1 pad/day), n(%) | 0                                      | (0.0%)  | 36           | (72.0%) | 57.5%–83.8%         |                    |              |                                    |                      |

<sup>1</sup> Missing data: Preoperative, n = 1 (2.0%); follow-up, n = 0 (0.0%).

<sup>2</sup> Derived from Clopper-Pearson Exact method.

<sup>3</sup> Hodges–Lehmann estimate derived from Wilcoxon signed-rank test with continuity correction.

<sup>4</sup> p value derived from Wilcoxon signed-rank test with continuity correction.

### 3. Complications and patient satisfaction at follow-up

Postoperative complications occurred in 22.0% (11/50; 95%CI 11.5%–35.9%) (Table 4).

Explantation was required in 6.0% of these patients (3/50; 95%CI 1.3%–16.5%), all Clavien-Dindo Grade 3b: 2 urethral erosions (one complicated by scrotal abscess and enterectomy) and one pump malfunction.

7 complications were Clavien–Dindo Grade 1 (minor device-related interventions, hematuria, pump volume loss, and pump migration) and one Grade 2 (hydrocele managed pharmacologically).

High satisfaction (VAS 7–10) was reported by 77.6% of patients (38/49; 95%CI 63.4%–88.2%) (Table 4). Satisfaction correlated inversely with number of pads used postoperatively (Spearman's  $\rho = -0.58$ ,  $p < 0.001$ ).

Table 4: Postoperative complications classified by Clavien–Dindo grade and patient-reported satisfaction at follow-up.

| N=50 <sup>1</sup>                                 |    |                      |
|---------------------------------------------------|----|----------------------|
| <b>Follow-up data</b>                             |    |                      |
| <b>Explantations,</b>                             | 3  | (6.0%; 1.3%–16.5%)   |
| <i>n (%) 95%CI<sup>2</sup></i>                    |    |                      |
| <b>Complications at follow up,</b>                | 11 | (22.0%; 11.5%–35.9%) |
| <i>n (%) 95%CI<sup>2</sup></i>                    |    |                      |
| Clavien-Dindo Classification, <i>n (%)</i>        |    |                      |
| 1                                                 | 7  | (14.0%)              |
| 2                                                 | 1  | (2.0%)               |
| 3                                                 | 0  | (0.0%)               |
| 3a                                                | 0  | (0.0%)               |
| 3b                                                | 3  | (6.0%)               |
| <b>Patient satisfaction, [1-10], <i>n (%)</i></b> |    |                      |
| Low (1–3)                                         | 6  | (12.0%)              |
| Medium (4–6)                                      | 5  | (10.0%)              |
| High (7-8)                                        | 16 | (32.0%)              |
| Very High (9-10)                                  | 22 | (44.0%)              |

<sup>1</sup> No missing data were observed.

<sup>2</sup> Derived from Clopper-Pearson Exact method.

## 1. Exploratory analysis of baseline variables

No baseline variable was significantly associated with treatment failure (Table 5.A). Smoking showed the largest point estimate for failure odds, yet with a wide confidence interval reflecting the small number of smokers. Higher baseline pad use and higher BMI also showed association trends with greater failure odds. The baseline models showed modest explanatory power.

## 2. Exploratory adjusted analysis of baseline risk factors

Of the three predictors specified a priori, only previous radiotherapy could be modelled. It was not significantly associated with treatment failure when adjusting for baseline severity (OR 0.49, 95% CI 0.12–1.74; *p* = 0.276). Treatment failure was observed in 1 patient with previous urethral stenosis, and absent in patients with prior incontinence surgery (Table 5.B).

## 3. Exploratory analysis of implant, activation, and follow-up factors

No implant-related factor was associated with treatment failure (Table 5.C). Extraperitoneal placement and larger cuff sizes trended toward higher failure, yet none reached significance. Neither activation volume nor time to activation was associated with postoperative pad use or number of readjustments (Table 5.D). Follow-up duration was unrelated to treatment failure or pad use and did not differ between patients who did and did not achieve social continence (median 18.0 vs 15.0 months; *p* = 0.334), suggesting stable outcomes within the observation period (Table 5.E).

Table 5: Association of baseline, implant-related, and postoperative factors with treatment outcomes. OR, odds ratio; RR, rate ratio; CI, confidence interval;  $\tau$ , Kendall's rank correlation coefficient.

| Unadjusted                                     |                      |                                                                                                                     |        | Adjusted for baseline severity   |       |
|------------------------------------------------|----------------------|---------------------------------------------------------------------------------------------------------------------|--------|----------------------------------|-------|
| Predictor                                      | Outcome              | Estimate (95% CI)                                                                                                   | p      | Estimate (95% CI)                | p     |
| A. Univariable association of baseline factors |                      |                                                                                                                     |        |                                  |       |
| Age                                            | Treatment failure    | OR 0.97 (0.90–1.04)                                                                                                 | 0.334  |                                  |       |
| BMI                                            |                      | OR 1.13 (0.96–1.35)                                                                                                 | 0.147  |                                  |       |
| Preoperative pads per day (baseline severity)  |                      | OR 1.35 (0.94–2.01)                                                                                                 | 0.101  |                                  |       |
| Previous diabetes                              |                      | OR 0.39 (0.07–1.60)                                                                                                 | 0.201  |                                  |       |
| Previous surgery for urinary incontinence      |                      | OR 0.12 (0.00–1.05)                                                                                                 | 0.056  |                                  |       |
| Previous urethral stenosis                     |                      | OR 0.28 (0.03–1.40)                                                                                                 | 0.13   |                                  |       |
| Previous overactive bladder                    |                      | OR 0.67 (0.15–2.54)                                                                                                 | 0.571  |                                  |       |
| Previous hormonal block therapy                |                      | OR 1.15 (0.19–5.52)                                                                                                 | 0.871  |                                  |       |
| Previous smoking habit                         |                      | OR 2.45 (0.56–10.42)                                                                                                | 0.224  |                                  |       |
| B. Baseline risk factors*                      |                      |                                                                                                                     |        |                                  |       |
| Previous radiotherapy                          | Treatment failure    | OR 0.43 (0.11–1.48)                                                                                                 | 0.183  | OR 0.49 (0.12–1.74)              | 0.276 |
| Previous urethral stenosis                     |                      | Proportions: Failure in 1/11 (9.1%, 95%CI 0.2–41.3%) with prior stenosis vs 13/39 without (33.3%, 95%CI 19.1–50.2%) |        |                                  |       |
| Previous surgery for urinary incontinence      |                      | Proportions: Failure in 0/8 (0%, 95%CI 0.0–36.9%) with prior surgery vs 14/42 without (33.3%, 95%CI 19.6–49.5%)     |        |                                  |       |
| C. Implant-related factors                     |                      |                                                                                                                     |        |                                  |       |
| Device placement (extra- vs intraperitoneal)   | Treatment failure    | OR 1.86 (0.28–10.80)                                                                                                | 0.495  | OR 1.65 (0.24–9.87)              | 0.587 |
| Device size (reference: 3.7 cm)                |                      |                                                                                                                     |        |                                  |       |
| 4.0 cm                                         |                      | OR 2.38 (0.51–14.72)                                                                                                | 0.279  | OR 1.99 (0.40–12.48)             | 0.406 |
| ≥4.5 cm                                        |                      | OR 2.41 (0.46–15.88)                                                                                                | 0.302  | OR 2.29 (0.43–15.30)             | 0.335 |
| D. Activation factors                          |                      |                                                                                                                     |        |                                  |       |
| Activation volume                              | Pad use at follow-up | τ = 0.094                                                                                                           | 0.457  | RR 0.99 (0.71–1.29) <sup>†</sup> | 0.959 |
|                                                | Readjustments        | τ = 0.004                                                                                                           | 0.973  | RR 0.91 (0.63–1.20) <sup>†</sup> | 0.541 |
| Time to activation                             | Pad use at follow-up | τ = -0.113                                                                                                          | 0.350  | RR 0.90 (0.70–1.13) <sup>†</sup> | 0.385 |
|                                                | Readjustments        | τ = -0.190                                                                                                          | 0.110  | RR 1.00 (0.79–1.25) <sup>†</sup> | 0.979 |
| E. Follow-up duration                          |                      |                                                                                                                     |        |                                  |       |
| Follow-up duration                             | Treatment failure    | Median (IQR)*: Success 18.0 months (15.0–26.5) vs Failure 15.0 months (13.2–28.8)                                   | 0.334* | OR 1.00 (0.94–1.06)              | 0.954 |

| Predictor | Outcome              | Unadjusted        |       | Adjusted for baseline severity   |       |
|-----------|----------------------|-------------------|-------|----------------------------------|-------|
|           |                      | Estimate (95% CI) | p     | Estimate (95% CI)                | p     |
|           | Pad use at follow-up | $\tau = -0.142$   | 0.204 | RR 0.99 (0.96–1.02) <sup>†</sup> | 0.529 |

\* *Mann-Whitney rank-sum test.*

<sup>†</sup> *Quasi-Poisson, adjusted for baseline pads per day. All other adjusted models: Firth's penalised logistic regression; models pseudo-R<sup>2</sup>=0.087-0.114.*

## Discussion

This cohort achieved social continence in 72.0% (95%CI 57.5–83.8%), a dry rate of 40.0% (95%CI 26.4–54.8%), and improvement in 87.8% of patients at a median follow-up of 16.5 months. These findings are consistent with published VICTO social continence rates ranges of 70%–94% and improvement rates of 81%–88% [1, 9, 11].

Importantly, given the adjustable nature of the device, some of the patients who did not achieve social continence or a dry state have not yet reached the maximum system volume, suggesting that further adjustments could potentially improve their continence outcomes.

For comparison, the gold-standard device AMS 800 presents pooled social continence rates of approximately 79% [2], with a 60% dry rate and 94% improvement ( $\geq 50\%$  pad weight reduction) in the prospective AUSCO trial [19]. The Zephyr ZSI 375 achieved social continence in 58% and improvement in a further 30% at 21 months in a single-centre series [2]. These comparisons are limited, as outcome definitions and follow-up durations differed substantially across studies, and AUSCO enrolled exclusively high-volume surgeons, limiting generalizability [19]. Other similar devices have limited published efficacy data.

In this cohort, many patients presented risk factors (44% had prior radiotherapy, 22% presented urethral stenosis, and 16% had surgery for SUI), which may account for the dry rate observed.

Postoperative complications occurred in 22.0% of patients, with a device explantation rate of 6.0% (95%CI 1.3%–16.5%). Two cases of urethral erosion (4.0%) and one pump malfunction (2.0%) accounted for all explantations. These rates fall within VICTO reported ranges (erosion 0–6%, infection 1–5%, and mechanical failure 1–6%) [1, 9, 11]. The total complication rate of 22.0% was higher than the 17.6% reported by Giammò et al. [9], though differences in sample size and patient risk profile limit direct comparison.

Moreover, pooled AMS 800 literature reports infection/erosion of 8.5% and mechanical failure of 6.2%, with reoperation up to 26% [13]. In AUSCO, serious adverse events occurred in 15%, device-related events in 8.7%, surgical revisions in 7.8%, and erosion in 1.7% [19].

No device infection was observed in this cohort, aligned with AUSCO outcomes for AMS 800 [19]. Among other devices, the Zephyr ZSI 375 has reported revision/removal rates of up to 24% at 21 months and 57.9% at 24 months [2]. The Rigicon ContiClassic reported 6.9% revision in 116 patients, and the ContiReflex reported no infections or erosions at 18 months in 50 patients, though follow-up remains limited [2].

Patient satisfaction was high (77.6% of patients scoring 7–10 on the VAS), within the 70–92% reported previously [1, 11]; and comparable to the long-term satisfaction for AMS 800 around 90%-92% [2, 19]. However, direct comparison across studies is hindered by differences in measurement instruments.

## Exploratory findings of risk factors and implant-related factors

No significant predictors of treatment failure or postoperative pad use was identified, most likely reflecting the limited number of events. Smoking higher preoperative pad use trended toward worse outcomes, consistent with the known effects of smoking on tissue perfusion and urethral integrity [20], and with risk factors for conventional AUS devices [19, 21]. Conversely, factors usually associated with higher failure, such as previous radiotherapy, urethral stenosis, and incontinence surgery, trended toward lower failure, opposite to expectation. However, all confidence intervals were wide and non-significant.

Of the three risk factors selected a priori, only previous radiotherapy could be modelled in an adjusted analysis. It was not associated with failure, showing a protective direction that likely reflects patient selection at implantation rather than a true protective effect. Moreover, no patient with prior incontinence surgery and only one patient with prior urethral stenosis presented treatment failure.

One potential hypothesis is that postoperative pressure adjustability lets patients with compromised urethral tissue be managed at individually optimised pressures rather than a fixed setting, potentially attenuating the excess risk these conditions carry with non-adjustable devices. This remains speculative since the present data cannot separate such a mechanism from selection bias and would require a larger cohort with direct comparison against a fixed-pressure device. All these findings are hypothesis-generating.

Moreover, neither activation volume nor timing was associated with outcomes or readjustment number, supporting the current activation protocol with a standardized initial and activation volume (13 mL and 4 mL, respectively) followed by a patient-guided adjustment rather than a strict volumetric target.

A non-significant trend toward higher failure with extraperitoneal placement supports intraperitoneal implantation as standard, though limited cases preclude conclusions.

Follow-up duration showed no association with outcomes, suggesting that continence is stable over the medium term, consistent with the sustained pad-weight reductions previously reported at 3 years [1].

## Study limitations

The retrospective design and small sample limit power and preclude definitive conclusions on risk factors. In particular, the regression analysis is limited by the low events per variable and should be considered as exploratory only. The median follow-up of 16.5 months precludes evaluation of late complications such as urethral atrophy or delayed mechanical failure, which typically emerge beyond 2 years. Finally, use of a VAS rather than a validated instrument limits comparability with studies using standardized patient-reported outcomes.

## Conclusion

VICTO implantation showed outcomes consistent with published evidence and with real-world AMS 800 benchmarks. Continence rates were stable over the medium term.

Established risk factors such as previous radiotherapy, urethral stenosis, and incontinence surgery trended toward lower failure. This may reflect either selection at implantation or the effects of device's adjustability, that requires further confirmation. Larger prospective studies with longer follow-up are needed to characterize late complications and predictors of outcome.

## Abbreviations

AUS  
Artificial urinary sphincter  
BMI  
Body mass index  
CI  
Confidence interval  
EPV  
Events per variable  
IQR  
Interquartile range  
OR  
Odds ratio  
PRB  
Pressure-regulating balloon  
RP  
Radical prostatectomy  
RR  
Rate ratio  
SUI

Stress urinary incontinence  
VAS  
Visual analogue scale

## Declarations

## Ethics approval and consent to participate

The study protocol was approved by the Research Ethics Committee of the Irmandade da Santa Casa de Misericórdia de São Paulo (coordinating centre) through Plataforma Brasil (CAAE 75768022.1.0000.5479; opinion no. 6,641,906; 7 February 2024). Given the retrospective design, a waiver of informed consent was granted in accordance with Guideline 10 of the CIOMS 2016 International Ethical Guidelines for Health-Related Research Involving Humans. The study was performed in accordance with the Declaration of Helsinki.

## Consent for publication

Not applicable – the manuscript reports only aggregated data and contains no individually identifiable patient information, images or details.

## Availability of data and materials

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

## Competing interests

All authors declare that they have no competing interests.

## Funding

This was an investigator-initiated study. Costs related to study conduct and data collection were covered by the urology service of each participating centre. Promedon SA (Córdoba, Argentina) funded medical-writing and statistical-analysis support only (see Acknowledgements) and had no role in study design, data collection, or the decision to submit.

## Authors' contributions

TRF: Protocol development, Data management, Manuscript editing, and final approval.

LBR: Data collection, Data analysis, Manuscript drafting, and final approval.

KF: Data collection, Data analysis, Manuscript editing, and final approval.

GVM: Data collection, Data analysis, Manuscript editing, and final approval.

TLGM: Protocol development, Data collection, Data analysis, Manuscript editing, and final approval.

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## Figures

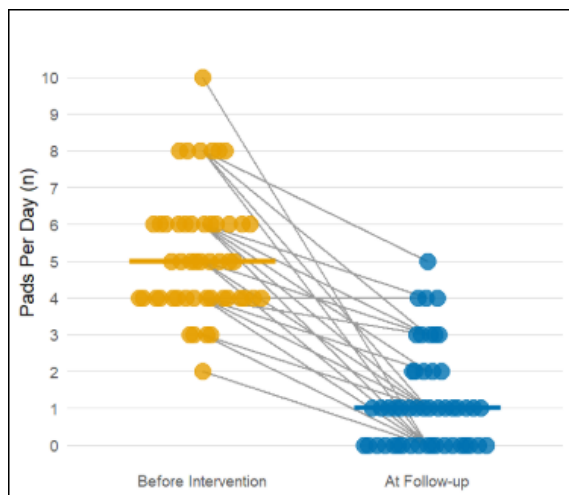


**Figure 1**

Distribution of daily pad use before and after VICTO implantation. Dots represent patients using each number of pads per day at baseline (preoperative) and at follow-up. The median change was -4 pads (95% CI -4.5 to -3.5). One patient with missing baseline pad count was excluded from the improvement rate analysis.