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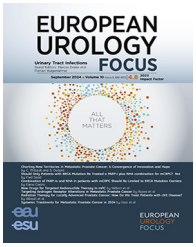

Incontinence

Results at 1 Year from SATURN, A European, Prospective, Multicenter Registry for Male Stress Urinary Incontinence Surgery

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Abstract

Background and objective: The European, prospective, multicenter SATURN registry was developed to analyze surgical devices for male stress urinary incontinence. The primary objective is the cure rate during follow-up.
Methods: Efficacy, complications, patient-reported outcomes, and prognostic factors are being analyzed at various intervals during 10-yr follow-up. The results at 1-yr follow-up are presented here.
Key findings and limitations: The cohort included 1046 patients (mean age 70 yr) from 28 centers in nine countries. The main cause of incontinence was radical prostatectomy (83.5%), followed by radiotherapy (4.5%), endourological procedures (9.7%), neurogenic conditions (1.0%), and trauma (0.2%). Some 19.5% of the patients underwent at least one incontinence procedure before registry inclusion. A baseline pad test was performed in 64% of the patients (mean 525 g, range 3.5–3600), urodynamics in 66%, and cystoscopy in 80%. The main implants used were AMS800 ($n = 684$) and Advance ($n = 210$) devices, followed by Atoms ($n = 63$) Victo/Plus ($n = 33$), ProACT ($n = 30$), and others ($n = 24$). A total of 896 patients had 1-yr follow-up data, of whom 164 completed a 1-yr pad test. Self-reported complete incontinence rates at baseline by device were as follows: Advance, 17%; other slings, 33%; ProACT, 0%; AMS800, 49%; other sphincter prosthesis, 100%; and overall group, 44%. The corresponding 1-yr self-reported continence rates were 73%, 37%, 50%, 76%, 11%, and 68%. Some 32% of the patients were still incontinent. Overall, 132 patients had at least one revision. Among the 110 patients with an artificial urinary sphincter (AUS), 122 revisions were performed, while there were 29 revisions for the 22 patients with a sling or ProACT device. International Consultation on Incontinence Questionnaire Short Form and EuroQol 5-dimensions 5-levels scores improved with all devices.

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Conclusions and clinical implications: AUS implants are used in cases with more severe incontinence and are associated with better outcomes but more revisions than the alternatives. Patients report that every improvement is important. Choices for procedures should be made on the basis of these considerations.

Patient summary: We collected data from 29 urology departments in Europe on surgical treatments for patients who suffer from incontinence during exercise, sneezing, and coughing. Results after 1 year show that an artificial urinary sphincter has the best outcomes overall and for patients with heavy urine loss. However, this surgery also requires more revisions. Patients report that every improvement in continence is important to them.

1. Introduction

Male stress urinary incontinence (SUI) occurs mainly after prostate cancer treatment, but is also associated with other treatments and disorders. SUI has a devastating impact on social functioning and quality of life (QoL). Prevalence varies in the literature, mainly because of differences in the definition used, the techniques for prostatectomy, and follow-up duration after surgery [1].

Treatment of male SUI has evolved from nonsurgical containment devices to implantation of compression devices such as bulking agents, fixed or dynamic slings, and sphincter prostheses [2]. Most studies on implants, including those using the current gold standard, the AMS800 prosthesis, are retrospective. Other limitations include a low number of patients, selection bias, a single-center design, and relatively short follow-up. Heterogeneous and low-quality studies with mostly outdated efficacy outcome criteria make comparisons between studies difficult [3,4]. A randomized controlled trial (RCT) is the gold standard for evidence-based medicine as it can establish an unbiased effect of an intervention. Random assignment of treatment avoids selection bias and outcomes are measured in a controlled fashion. RCTs are indispensable in answering specific questions and have high internal validity. However, RCTs often lack external validity, as results might not mimic real-life situations because of the highly selected patient group and the controlled trial design [5]. The European Section of Female and Functional Urology of the European Association of Urology (EAU) decided to evaluate long-term outcomes of male SUI surgery on the basis of activities that best reflect routine clinical practice. To this end, the group designed a registry, which avoids selection bias and is not hampered by the lack of equipoise that is difficult to preserve in a surgical RCT. A prospective patient registry can provide a real-world view of clinical practices, especially if long-term follow-up and large patient numbers are available [6]. SATURN (Surgery for male incontinence with artificial urinary sphincters and slings) was developed to include every certified implantable device for male SUI for evaluation of efficacy, complications, and impact on QoL. The hypothesis was that different devices will yield different results. The registry protocol has already been published [7] and we present the main 1-yr results here.

2. Patients and methods

SATURN is a prospective, multicenter registry (observational cohort) in several European countries. The study is registered on ClinicalTrials.gov (NCT02757274). Data are reported here in accordance with the STROBE statement as much as possible [8,9].

The study was designed to include 1000 male patients with SUI who underwent surgery with follow-up of 10 yr. From January 2017 to May 2022, 1046 consecutive patients were included. Ethical approval was obtained in all participating centers, and informed consent was obtained from each patient.

2.1. Statistical analysis

The primary endpoint was the rate of cure, defined as urinary continence with the use of 0–1 security pads. The cure rate was assessed over the course of the study, both for the entire cohort and for each device. Statistical analyses (SPSS v28.0.1.0) were carried out to identify variables correlated with incontinence/continence or revisions for each device, using the *frequencies*, *descriptives*, and *explore* options in SPSS.

3. Results

3.1. Baseline characteristics

Twenty-eight centers in nine European countries enrolled 1090 men from January 2017 to May 2022, of whom 1046 were eligible for inclusion. The study flowchart is shown in Figure 1 and baseline demographics are listed in Table 1. We excluded 37 patients because of invalid surgery ($n = 7$) and 30 whose surgery was after the inclusion closure date. The main causes of SUI were radical prostatectomy (873 cases) and radiotherapy (47 cases), followed by treatment for bladder outlet obstruction, bladder neck sclerosis, or urethral stricture (101 cases), and other factors, including neurogenic disease or trauma (25 cases). Previous prostate treatments were prostatectomy alone in 640 patients, radiotherapy alone in 23 patients, and both radiotherapy and prostatectomy in 290 patients, while 93 patients had not undergone either prostatectomy or radiotherapy. A total of 842 patients (80.5%) had no previous surgical incontinence procedure,

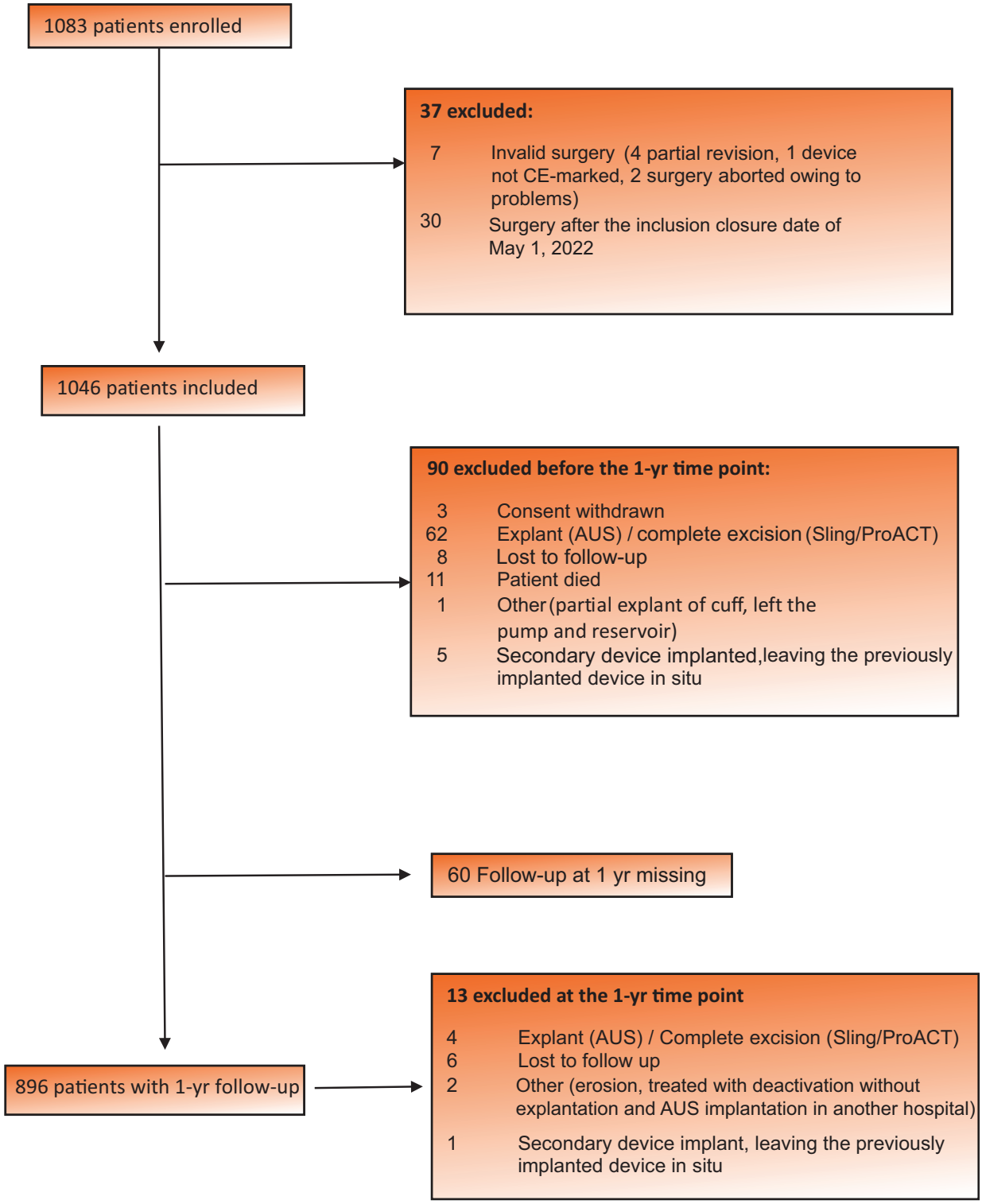

Fig. 1 – Study flowchart. AUS = artificial urinary sphincter.

while 151 (14.4%) had one and 53 had two or more interventions before inclusion. Preoperative urodynamics was performed in 690 patients, revealing a diagnosis of pure stress incontinence in 75% and mixed incontinence in 24%. No urodynamic diagnosis was available for 26 patients. A hypocontractile bladder was seen in 0.5% of cases, and one patient had pure urodynamic detrusor overactivity. Cystoscopy was performed in 80% of cases before surgery. A 24-h pad test was performed by 672 patients. The mean pad weight was 525 g (range 3.5–3600).

Table 1 – Characteristics of the 1046 patients at baseline

Parameter	Result
Mean age, yr (SD)	69.6 (7.7)
Median age, yr (range)	71.0 (19–88)
Mean BMI, kg/m^2 (SD)	27.6 (3.8)
Median BMI, kg/m^2 (range)	27.1 (18.1–49.7)
Mean age-adjusted CCI (SD)	4.7 (1.8)
Median age-adjusted CCI (range)	5.0 (0–14)
Diabetes mellitus (%)	16.9
Anticoagulant use (%)	
None	69.1
Vitamin K inhibitor	2.4
Platelet inhibitor	19.7
Low-molecular-weight heparin	0.7
Direct oral anticoagulant	6.9
Other	1.2
Previous stricture treatment (%)	16.5
Previous SUI surgical treatments (%)	
None (n = 842)	80.5
1 (n = 151)	14.4
2–3	4.5
>3	0.6
Main cause of SUI (%)	
Prostatectomy (n = 873)	83.5
Radiotherapy (n = 47)	4.5
Other treatment (n = 101) [a]	9.7
Neurogenic (n = 10)	1.0
Trauma (n = 2)	0.2
Other (n = 13)	1.2
Preoperative UDS investigation (%)	66.0
Preoperative cystoscopy (%)	79.7
Preoperative UTI screening (%)	68.5
24-h pad weight test (%)	64.2
ICIQ-UI short form (%)	92.3
EQ-5D-5L health questionnaire (%)	91.6

BMI = body mass index; CCI = Charlson comorbidity index; SD = standard deviation; SUI = stress urinary incontinence; UDS = urodynamics; UTI = urinary tract infection.
[a] Including treatment for bladder outlet obstruction, bladder neck sclerosis, or urethral stricture.

Table 2 – All devices used in the SATURN registry

Device	Number (%)
Advance XP sling	210 (20)
ATOMS sling	63 (6)
Argus sling	12 (11.4)
Remeex sling	1
Virtue sling	7 (0.7)
TILOOP sling	1
ProACT balloon	30 (2.9)
AMS 800 AUS	684 (65)
Victo (plus) AUS	33 (3.2)
ZSI 375 AUS	5 (0.5)
Total	1046

AUS = artificial urinary sphincter.

3.2. Perioperative results

The device types are listed in Table 2. In 684 cases, the patient received an AMS800 sphincter prosthesis, of which 91% were at the bulbous urethra. A cuff size of 4.5 cm was used in 40% and a pressure-regulating balloon of 61–70 cm H_2O in 95%. A total of 210 patients received an Advance-XP male sling implant, 84 (8%) a different sling, 38 (3.6%) a different artificial urinary sphincter (AUS), and 30 a ProACT balloon.

Before or during the procedure listed in the SATURN registry, 151 patients (14%) underwent device explantation, mostly in the AMS800 group. In 42 patients, the previous implant was left in situ and another one was implanted. In 95 cases (63%) the explant was an AMS800 device or one of its components. The main reason for explantation was device malfunction or recurrent or persistent incontinence in 98 patients (65%), and infection and/or erosion in 46 (30%). In addition, devices were explanted because of pain (n = 2), atrophy (n = 2), and unknown reasons (n = 3). The skin-to-skin operative time was 50 min (standard deviation [SD] 24) for Advance-XP, 29 min (SD 10) for ProACT, and 69 min (SD 30) for AMS800. Preoperative antibiotics were administered to 1028 patients (98%), while 874 (84%) received antibiotics after surgery. After surgery, an indwelling catheter was inserted for 977 patients (93%), which remained in situ for <24 h in 559 patients (62%) a transurethral catheter and for 1 d in 56 patients (70%) with a suprapubic catheter. Concomitant procedures were performed in 51 (7%) patients, all in the AMS800 group. These involved a penile prosthesis in 18 cases, another additional procedure in 33 cases, and removal of previous implants or components in 17 cases. There were 41 (4%) intraoperative complications, primarily bladder perforation (n = 12) and bleeding (n = 7). Among 769 patients the mean Visual Analog Scale score (range 0–100) at 1–2 wk after surgery was 20 for perineal pain and 15 for groin pain. These scores were higher in the Atoms (30 and 22; n = 57) and Virtue (36 and 31; n = 5) groups. At 1 yr after surgery, 131 patients still experienced some pain. Postoperative retention requiring catheterization occurred in 86 patients in the Advance (14%), Argus (25%), ProACT (13%), ATOMS (2%), (Victo) 3%, and AMS800 (7%) groups. Scrotal hematoma was noted in 228 patients. Activation-related problems (hematoma, pain, pump migration, or handling difficulties) were experienced by 91 patients (13%).

3.3. Results at 1 yr

A total of 103 patients (10%) excited the study within the first year. The primary reason was device explantation (n = 66), mainly in the AMS800 group (n = 61). Other reasons included consent withdrawal (n = 3), loss to follow-up (n = 14), patient death (n = 11), implantation of a secondary device (n = 6), and other factors (n = 3). Follow-up data at 1 yr were available for 13 of these 103 patients. Overall, 1-yr follow-up data were available for 896 patients.

3.3.1. Continence

Self-reported cure rates by device were as follows: Advance-XP, 73%; other sling, 37%; ProACT, 50%; AMS800, 76%; other AUS, 11%; and overall group, 68%. Some 32% of the patients reported that they remained incontinent. Of the 285 incontinent patients, 164 (58%) performed a 1-yr pad test. Table 3 lists baseline and 1yr pad results, as well as the change in leakage weight from baseline at 1 yr for those who were still incontinent at 1 yr and had test results for both time points. Baseline 24-h pad results did not significantly differ by cause of incontinence, patient age, or body mass index.

Table 3 – Results for 24-h pad tests at BL and 1 yr

Device	Pts	Pad weight after 24 h (g)									
	(*n*)	BL				1 yr				Difference[a]	
		Mean	MD	Range	SD	Mean	MD	Range	SD	Mean (95% CI)	MD
Advance XP	12	246	200	75–600	173	134	90	15–700	188	−111 (−264 to 42)	−94
Atoms	30	503	394	12–1500	397	181	90	7–1000	233	−323 (−445 to −200)	−248
Argus	3	429	450	192–646	228	40	44	25–51	13	−389 (−922 to 143)	−406
Virtue	3	192	237	60–280	117	337	240	150–621	250	145 (−766 to 1055)	3
ProACT	9	253	231	35–608	174	71	25	1–324	106	−182 (−299 to −66)	−144
AMS 800	52	765	682	78–3000	590	68	21	0–500	105	−697 (−866 to −528)	−623
Victo	30	645	525	175–1650	377	164	135	10–450	125	−481 (−602 to −360)	−368
TILOOP	1	–	–	–	–	–	–	–	–	–	–
Overall	140	582	443	12–3000	481	127	59	0–1000	166	−455 (−538 to −373)	−344

BL = baseline; CI = confidence interval; MD = median; Pts = patients; SD = standard deviation
[a] The difference in leakage weight between BL and 1 yr was calculated for patients who were still incontinent at 1 yr and for whom both BL and 1-yr pad test results were available.

3.3.2. *Complications and revisions*

During the first year, 240 postoperative complications were recorded for 169 patients (16%). These complications comprised mechanical failure in 25, urinary retention or inadequate emptying in 45, pain in 33, erosion of the prosthesis in 28, and infection in 60 patients. A revision was performed for 115/240 (48%) complications.

Within the first year, 132 patients (13%) underwent one or more revision. These included 122 revisions in 110 patients with an AUS device, including AUS explantation ($n = 44$), cuff change ($n = 16$), total revision ($n = 19$), and other procedures ($n = 43$), mainly repositioning of parts. Indications for AUS revision included persistent incontinence ($n = 16$), implant complications ($n = 55$), device malfunction ($n = 24$), and other reasons ($n = 27$). There were 29 sling revisions in 22 patients (7%): six slings were transected or removed, nine ATOMS devices had extra fluid inserted, five patients had sling replacement with an AUS, and nine revisions involved other procedures. The indications for sling revision were persistent incontinence ($n = 17$), complications ($n = 8$), and other reasons ($n = 4$).

For 80 patients, 95 concomitant pelvic disorders were reported. There were 84 treatments for other conditions, mainly overactive bladder.

We analyzed AMS800 revision rates in low-, intermediate-, and high-volume centers. The revision rate was lower in low-volume (8%) than in intermediate-volume (18%) and high-volume (17%) centers ($p = 0.048$). Results are listed in Table 4 and Figure 2.

Table 4 – Revision for AMS800 recipients in low-volume (<10 procedures/yr), intermediate-volume (10–25 procedures/yr), and high-volume (>25 procedures/yr) centers

Center category	Revision within 1 yr, *n* (%)		
	Yes	No	Overall
Low-volume	12 (8.1)	137 (91.9)	149 (100)
Intermediate-volume	36 (17.8)	166 (82.2)	202 (100)
High-volume	58 (17.4)	275 (82.6)	333 (100)
Overall	106 (15.5)	578 (84.5)	684 (100)

3.3.3. *Patient-reported outcomes*

Sum scores (scale 0–21) for the International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF) at baseline and 1 yr and the change over time are listed in Table 5. The EuroQol 5-dimensions 5-levels (EQ-5D-5L) scores at baseline and 1 yr revealed an improvement in most groups, except for the Argus, Virtue, and Proact devices, for which the score remained the same or even slightly worsened (Table 6).

4. Discussion

Our data reflect daily practice in experienced European surgical centers. Ten various CE-marked devices were used for implantation. Two were used more than 100 times, while two were used once. This suggests that some devices are used routinely whereas others are still being used in the learning curve, which also reflects routine clinical practice involving both routine procedures and new initiatives to achieve progress. Against a background of ongoing developments, it is striking to see that the AMS800 device, introduced in 1972, is still is the implant most frequently used, showing good results. The AMS800 efficacy has not been challenged, especially for cases with severe incontinence. The flipside of this success is greater revision and complication rates [10]. The AMS800 1-yr cure rate was also the highest (76%), and the leakage weight improved significantly (mean 697 g) in patients who were still incontinent. The MASTER trial also demonstrated that for severe incontinence, the AMS800 is superior to male slings [11]. The pad

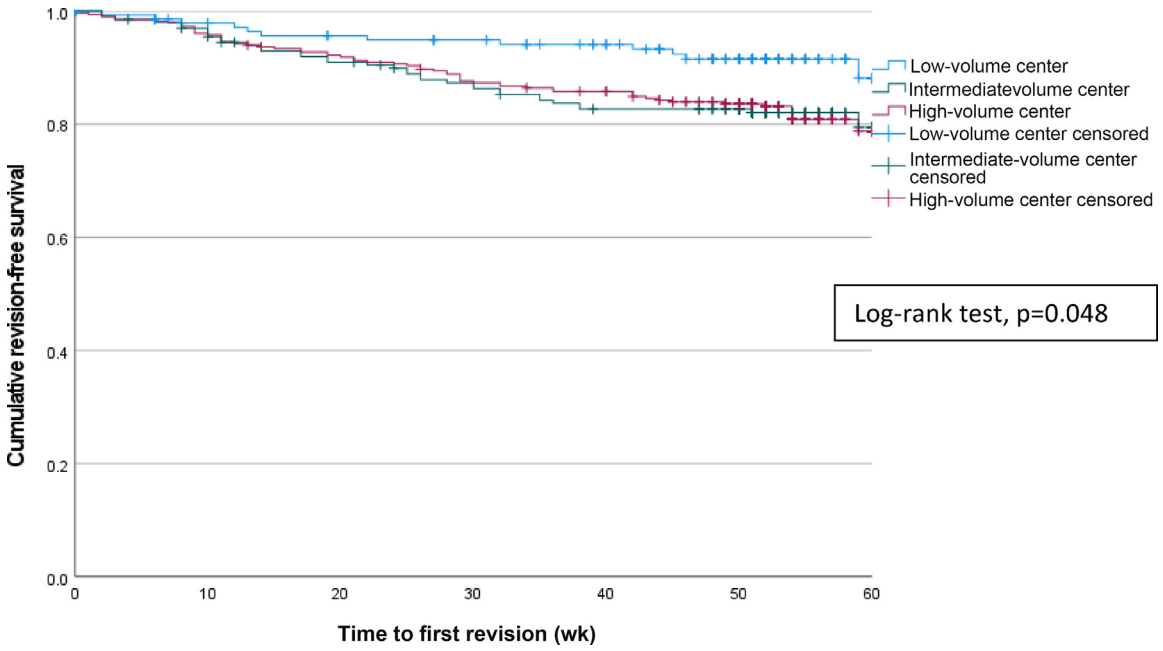

Fig. 2 – Kaplan Meier analysis of time to first revision for AMS800 recipients in low-volume (<10 procedures/yr), intermediate-volume (10–25 procedures/yr). and high-volume (>25 procedures/yr) centers.

Table 5 – ICIQ-UI SF aggregate score for questions 3, 4, and 5 at baseline, and 1-yr follow up[a]

Device[b]	Pts (*n*)	Aggregate ICIQ-UI SF score for questions 3–5							
		Baseline			1 yr			Difference[c]	
		Mean	Median	Range	Mean	Median	Range	Mean	Median
Advance XP	163	15	16	3–21	6	6	0–21	−9	−10
Atoms	44	17	18	11–21	9	10	0–21	−8	−8
Argus	6	17	17	12–19	8	8	4–12	−9	−10
Virtue	5	16	14	14–20	12	9	5–19	−4	−5
ProACT	24	14	14	10–19	6	5	0–16	−8	−9
AMS 800	447	18	18	3–21	6	6	0–21	−11	−12
Victo	30	19	19	15–21	11	11	0–21	−8	−8
ZSI 375	1			16–16			8–8		
TILOOP	1			17–17			20–20		
Overall	721	17	17	3–21	7	6	0–21	−10	−11

ICIQ-UI SF = International Consultation on Incontinence Questionnaire Short Form; Pts = patients.
[a] Questions 3: How often do you leak urine? (score 0–5). Question 4: How much do you usually leak? (score 0–6). Question 5: How much does this interfere with your daily life? (score 0–10).
[b] The Remeex device was excluded from the analysis because of insufficient data.
[c] The difference from baseline to 1 yr was calculated for patients who had scores available at both time points.

test results for patients with slings are also surprising. Although slings are mainly used for moderate SUI, their efficacy is only modest [12]. This is surprising, as patients prefer slings over AUS devices [13].

A total of 204 patients (20%) had received a prior implant, of whom 184 were in the AMS800 group, indicating that this is the most important second-try device.

Complications during surgery occurred in 4% of patients, while 8% experienced postoperative retention, mainly in the sling groups. In total, 132 patients (13%) had at least one revision within 1 yr, which was an AUS implant in 110 cases. This is in line with other studies [14]. Revision surgery was performed for 7% of implanted slings and mainly involved sling transection or secondary implantation of an AMS800 device. This confirms that the AMS800 is effective and frequently used in severe and secondary cases. However, the revision rate for the AMS800 device is high, which should be explained during counseling so that patients have realistic expectations. Surprisingly, the rate of AMS800 revision within 1 yr was lower in low-volume than in high volume centers. The reasons are unclear, as fewer revisions would be expected for high-volume centers. One possibility is that high-volume centers treat patients with greater risk factors, resulting in a greater proportion of detrimental outcomes. A further possibility is the artificial cutoffs used to define low-volume versus high-volume centers.

Regarding For ICIQ-UI-SF and the EQ-5D-5L an improvement is seen in all patients groups for the ICIQ-UI-SF. This change was most pronounced in the AMS800 group. An improvement in EQ-5D-5L score was seen in most groups, except for the Argus, Virtue, and Proact devices. The lack of association between clinically important and objectively

Table 6 – EQ-5D-5L health scores at baseline and 1 yr

Device[a]	Pts	EQ-5D-5L visual analog scale score[b]							
	(*n*)	Baseline			1 yr			Difference[c]	
		Mean	Median	Range	Mean	Median	Range	Mean	Median
Advance XP	140	75	75	8–100	81	83	30–100	6	5
Atoms	41	68	75	30–99	79	80	50–100	11	10
Argus	7	81	80	60–95	76	80	60–90	−5	0
Virtue	2	68	68	60–75	65	65	40–90	−2.5	−2.5
ProACT	25	80	80	65–95	79	80	6–100	0	5
AMS 800	439	73	75	7–100	78	80	10–100	5	2
Victo	30	34	33	10–66	78	80	40–100	44	50
ZSI	1			80–80			85–85		
TILOOP	1			80–80			80–80		
Overall	686	72	75	7–100	79	80	6–100	7	5

EQ-5D-5L = EuroQol 5-dimensions 5-levels; Pts = patients.
[a] The Remeex device was excluded from the analysis because of insufficient data.
[b] Score for the question "How is your health today?", rated from 0 to 100, where 100 represents perfect; the mean score is typically around 80.
[c] The difference from baseline to 1 yr was calculated for patients who had scores available at both time points.

large improvements in 24-h pad results and an equally important change in EQ-5D-5L score highlights that other factors in patient QoL (eg, elevation of prostate-specific antigen) might be important . General health-related questionnaires might therefore not reflect the improvement in continence status in these comorbid patient groups.

Limitations of the SATURN registry include the lack of randomization, prior power calculations, and strict inclusion and exclusion criteria. Thus, it is difficult to make solid scientific comparisons between treatment arms. Second, there are important variations among countries with respect to health insurance systems and reimbursement policies. This means that standard treatments differ between countries and may deviate from the EAU guidelines. A positive aspect of a registry is that external validity and so-called equipoise are maintained [15]. Surgeons have individual preferences for certain procedures and it is difficult to maintain verbal and nonverbal objectivity. Registry results may therefore lead to superior decision-making, especially when large patients numbers are followed over a prolonged period.

5. Conclusions

SATURN is a good reflection of daily clinical practice for the treatment of male stress incontinence. Our initial results show that AUS implants are used in patients with more severe incontinence at baseline and result in better outcome than alternatives. This comes at the cost of a greater number of revision procedures. Patient-reported outcome results demonstrate that patients value an improvement of any level.

Author contributions: John Heesakkers had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Heesakkers, Thiruchelvam, Witjes, Hamid, Van der Aa.
Acquisition of data: Heesakkers, Thiruchelvam, Hamid, Van der Aa, Martens.
Analysis and interpretation of data: Heesakkers, Thiruchelvam, Witjes, Hamid, Van der Aa, Caris, Martens.
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