Long-term device survival after a first implantation of AMS800 TM for stress urinary incontinence: Comparison between men and women

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ABSTRACT (283 words)

Purpose: Artificial urinary sphincter is the reference treatment for stress urinary incontinence in men, but it remains rarely used in women. This study aimed to compare long-term device survival between women and men, after the first implantation of an AMS 800™ artificial urinary sphincter (Boston Scientific, USA) for the treatment of a non-neurogenic stress urinary incontinence.

Materials and methods: This retrospective cohort study included all patients with non-neurogenic stress urinary incontinence who underwent surgery in a large-volume university hospital between 2000 and 2013. The primary outcome was the overall survival of the device, defined as the absence of any repeated surgery (revision or explantation) during follow-up. Men and women were matched 3:1 according to age and year of implantation. Differences were analyzed using a Cox model accounting for matching and applying time intervals because hazards were not proportional over time. Sensitivity analyzes were performed, excluding firstly population with history of radiotherapy and secondly population with more than one previous surgery for urinary incontinence.

Results: A total of 107 women were matched to 316 men. Median follow-up was 6.0 years (Q1-Q3 1.8 – 9.4): 7.0 years (Q1-Q3 3.1 – 10.3) for women and 5.1 years (Q1-Q3 1.3 – 9.1) for men. During the follow-up, 56 patients had an explantation of the device: 44 men (13.9%) and 12 women (11.2%) and 113 had a revision: 85 men (26.9%) and 28 women (26.1%). Men have a significantly higher risk of explantation or revision than women between 6 months and 8 years after implantation (HR 2.12 (1.29-3.48)). Before 6 months and after 8 years, there were not significant differences. Both sensitivity analyses found consistent results.

Conclusions: This study suggests that device survival seems better in women after the first 6 months.

KEY WORDS (5)

Artificial urinary sphincter

Men

Women

Survival

Stress urinary incontinence

Introduction

The first artificial urinary sphincters (AUS) were implanted in 1973 by F. Scott (1). Ten years later, after design modification and improvement, current AUS have been introduced (2). Nowadays, the AMS 800™ AUS (Boston Scientific, Marlborough, Massachusetts, MA, USA) is the mostly used device to treat severe stress urinary incontinence (SUI) in men (3-5).

Worldwide, AUS is the gold standard treatment for post prostatectomy incontinence (6-7). In Europe, it is also used in women to treat intrinsic sphincter deficiency due to reduced urethral/bladder outlet resistance (8). European guidelines recommend AUS in women when UI is not corrected by clinical support maneuvers or previous support surgery (9-10).

In both men and women, studies and reviews show an objective reduction of leaking with a significant improvement of quality of life at the mid and long term, despite occurrence of possible complications (11-15). The main complications reported are infections, urethral erosions, and dysfunction of the device. In men, long-term survival studies report revision rates for mechanical failure from 2 to 14%, explantation rates for infection or erosion from 3 to 28% and reintervention rates for any reason from 15 to 45% (7). For women, the largest systematic review reports revisions rates from 6 to 44% and explantation rates from 2 to 27% (14). Thus, according to the literature, complication rates seem in the same range in men and women, even if studies directly comparing AUS performance in men and women are limited (16).

The use of AUS for both incontinent men and women in our large-volume center provides the opportunity to compare AUS performance between both sexes.

The aim of our study is to compare AMS 800™ long-term survival after a first implantation for non-neurogenic stress UI in men and women.

Materials and Methods

1) Study design and population

This study is a retrospective single-center study, led on a cohort of consecutive patients with a first implantation of an AMS 800™ artificial urinary sphincter (Boston Scientific, Marlborough, Massachusetts, MA, USA) between January 2000 and December 2013 for the

treatment of SUI. Patients less than 18 years old at the time of implantation and AUS placement for urinary incontinence secondary to neurogenic bladder were excluded.

2) Description of the procedure

The implantation process of the AUS was standardized as recommended by the operating room manual edited by the manufacturer (3). Only experimented surgeons (more than 10 procedures) underwent the procedure.

For men, the cuff was placed around the bulbous urethra using the perineal approach.

For women, the cuff was placed around the bladder neck thanks to a suprapubic incision.

The device system was left deactivated for four to six weeks following implantation.

3) Data collection

The following data were collected from the medical file of each patient:

- Clinical characteristics: sex and age of the patient at implantation, etiology of urinary incontinence, history of previous incontinence surgery and radiotherapy.
- Intervention characteristics: date of intervention, size of the cuff and pressure regulation balloon.
- Outcomes: revision or explantation including the date. Outcomes data were extracted from follow-up visits in the medical file and from our internal AUS registry. We also contact our patients via phone or mail to update patient and device outcomes when needed.

4) Outcome

Our primary outcome is the overall survival of the device, defined by the absence of any repeated surgery (revision or explantation) during the follow-up after surgery. Explantation was performed for erosion or infection, but also sometimes for other causes as patient convenience. Revisions were performed for recurrence of urinary incontinence or a mechanical failure of the device (due to urethral atrophy, pump malpositioning or device dysfunction) and included complete and partial revisions of the device (i.e. revision of only one part of the device).

The secondary outcomes were survival of the device without explantation or revision considered separately.

The last follow-up was determined by the last date we were able to have news of the patient. It was either an office visit or a phone call.

5) Statistical analysis

Our objective was to compare long-term device survival between men and women after a first implantation of AMS800^{TM}. We matched 1:3 women to men on age (+/- 5 years) and year of implantation (+/-3 years). General and intervention characteristics were described by frequencies and percentages for qualitative variables and by mean +/- SD or median (Q1-Q3) as appropriate for quantitative variables. The Kaplan-Meier method was used to describe device survival, from the first implantation to subsequent revision for any reason, device explantation or end of follow-up (date of last visit). Patients without event were censored at the date of the last follow-up. Differences between men and women were analyzed using a Cox model accounting for matching. Because hazards were not proportional over time, we used an analysis by intervals considering three time intervals: short term (ie, within 6 months), medium term (after 6 months to 8 years) and long term (after 8 years). These intervals were fixed at the beginning of statistical analysis by plotting standardized Schoenfeld residuals and were not modified thereafter. Sensitivity analyzes were performed to verify the stability of the results excluding patients with radiotherapy (as it is more frequent in men) and patients with 2 or more previous urinary surgical procedures (as it is more frequent in women). P values < 0.05 were considered to be statistically significant. All analyses were performed using R software (version 3.6.2) (17)(18).

6) Ethics

The study was registered at the Commission Nationale de l'Informatique et des Libertés (CNIL) under the number 20201112133406 and approved by the French urology association ethics committee under number CERU_2021/11. Patients were informed of the potential use of their data for research purpose and of the possibility to refuse the use of their personal data.

Results

1) Study population

There were 1076 consecutive patients with an AUS surgery in our urology department; 514 were excluded: 53 for neurogenic bladder and 461 for repeat AUS surgery. Thereby, 562 patients were eligible for this study: 420 men and 142 women (Appendix). Among them, 316 men have been matched with 107 women for a total of 423 patients (Figure 1).

2) Description of the procedure and patient clinical characteristics

In the matched cohort, mean age at implantation was 67.2 years old (SD 7.37) for men and 66.2 years old for women (Standard deviation SD 8.37). Main indications for AUS implantation were post-prostatectomy incontinence (n= 271, 85.8%) in men, and intrinsic sphincter deficiency incontinence (n= 88, 82.2%) in women. Eighty-seven (27.5%) men had a history of radiotherapy, whereas no women had. Ninety-four women (87.5%) had a previous history of incontinence related-surgery, with 48 women (44.8%) having 2 or more previous surgeries, compared to 44 men (13.9%) (Table 1).

The median cuff size for men was 4.5 cm (Q1-Q3 4.0-4.5), 279 men (88%) had a cuff of 4 or 4.5 cm. The median cuff size for women was 7.0 cm (Q1-Q3 6.5-7.5), 75 women (71%) had a cuff between 7 and 8 cm. For women, only 61-70cmH20 pressure regulation balloon (PRB) was used. For men, PRB used were 61-70 cmH20 in 66% (208/316) and 51-60 cmH2O in 23% (74/316), with missing data in 11% (34/316).

There was no operative mortality. Three women and two men were re-operated before activation for an explantation because of erosion. A man had an early revision. All other devices were activated 4 to 6 weeks after surgery.

3) Outcomes

Median follow up was 6.0 years (Q1-Q3 1.8 – 9.4): 7.0 years (Q1-Q3 3.1 – 10.3) for women and 5.1 years (Q1-Q3 1.3 – 9.1) for men. During the follow-up, 56 patients had an explantation of the device: 44 men (13.9%) and 12 women (11.2%) and 113 had a revision: 85 men (26.9%) and 28 women (26.1%) (Table 2). There was no difference in terms of explantation or revision between women with zero or one previous IU surgery (n=22 events, 37.2%), compared to women with two or more IU surgeries (n =18 events, 37.5%). At the end of the follow up, 57% of men and 60% of women had neither explantation nor revision.

Men have a significantly higher risk of explantation or revision of the device than women between 6 months and 8 years (HR 2.12 (1.29-3.48), p=0. 00274). There was no statistically difference within the 6 first months (HR 1.51 (0.49-4.65), p=0.47) and after 8 years (HR 0.78 (0.43-1.40), p=0.39) (Figure 2). Both sensitivity analyses, without patients with radiotherapy and without patients operated for more than one surgery, found consistent results.

Concerning explantations, there were 4 explantations in women (3.7%) compared to 8 in men (2.5%) during the first six months, with no significant higher risk in term of survival (HR 0.70 (0.21-2.41), p=0.58). Between 6 months and 8 years, there was a higher risk of explantation in men (HR 4.52 (1.35-15.09), p=0.0142). There was no significant difference after 8 years (HR 0.37 (0.09-1.48), p=0.16).

Concerning revisions, women have a significantly lower risk of revision than men in the short term with no revision during the first six months versus 13 revisions in men (HR 1,47 x 10^7 (7,61 x 10^6 – 2,83 x 10^7), p <0.001). There was no significant difference between six months and 8 years (HR 1,43 (0,83-2,48), p=0,20) and after 8 years (HR 0,98 (0,49-1,97), p=0,95).

Discussion

This study was intended to compare long-term artificial urinary sphincter survival between men and women implanted with a first AUS for a non-neurogenic SUI. We found a significantly lower rate of explantation or revision at the mid term (6 months – 8 years) for women while there was no significant difference during the short and long-term follow-up between men and women. Both sensitivity analyses, without patients with radiotherapy and without patients operated for more than one surgery, found consistent results. To our knowledge, this is the largest cohort focusing on device survival with a long-term follow-up to date.

In contrast to what is usually thought, AUS device seems to have a better long-term survival in women than in men, which is consistent with the study by Petero and al. published in 2006 (16). However, our study has some limits. One important limit shared with other studies comparing AUS survival between men and women is that the two populations are not

comparable because of different surgical procedures and different medical histories. We matched men and women on age and year of implantation to make these populations more comparable and also conducted sensitivity analyzes based on the main differences between the two populations related to risk factors of complications in AUS surgery. Another limit in our study is the lack of information about anastomosis strictures history. As all the urologists in the department did not systematically require a specific cystoscopy, it was not possible to report it objectively. We also miss data about general comorbidities and quality of life. Indeed, this was a retrospective study and data on immediate satisfaction after implantation or quality of life during the follow-up were not available for many patients.

AUS long-term complications rate reported in the literature seems in the same range in men and women. Van der Aa and al. (7) reported, a revision rate for mechanical failure from 2 to 14% and for urethral atrophy from 2 to 30%. Also, he reported an explantation rate for infection or erosion from 3 to 28% and a reintervention rate for any reason from 15 to 45% in men. For women, Reus and al. (14) found revisions rates from 6 to 44% and explantation rates from 2 to 27%.

The good AUS survival in women can be explained by several factors. First, the cuff is larger in women because implanted around bladder neck whereas the device is implanted around bulbous urethra in men. Moreover, the intra-abdominal bladder neck position of the cuff in women allows a transmission of abdominal pressure on the cuff. That position seems to be associated with a better efficiency of the device and thereby less revision for recurrence of urinary incontinence (19). Finally, contrary to women's condition, bulbous urethra in men is more thin and vulnerable to trauma (sitting position) compared to the bladder neck that is thicker and intraabdominally protected. These technical factors may explain that there is less erosion and failure in women than in men.

The main reason for the low level of AUS implantation in women in the United States was related to a presumed high rate of explantation and erosion, compared to the easier surgery of pubovaginal slings. Indeed, it seems that there is more explantation in women than in men in the first six months, even if there is no significant difference. But, consistently with the study by Petero and al.(16), long-term survival device seems globally better in women, especially in

the mid-term. In our cohort, the bladder neck dissection challenge reported after past urinary incontinence surgery did not seem to be associated with an increased rate of complications compared to non-operated women. Moreover, contrarily to slings, there is a possibility to remove AUS and to implant a new one in case of failure or patient dissatisfaction. Also, the risk of erosion largely reported in men is low in women thanks to a larger cuff and a thicker urethra. All these elements suggest that the indication of AUS in women may be extended. Finally, as reported by Chartier-Kastler and al., robot assisted laparoscopic surgery will decrease the technical difficulties encountered with the open dissection for deep pelvic surgery (20). We believe that AUS may be a good option even in women with previous multiple pelvic dissections including failed sling procedure.

Conclusion

Our study gives a comprehensive assessment of long-term differences between men and women AUS results It suggests that long-term survival device is better in women at mid-term, despite a slightly higher rate of explantation (not statistically significant) in women in the first 6 months. Both sexes should benefit of this inflatable and active prosthesis for treatment of SUI. Medico-administrative databases may help to provide long-term data in a more exhaustive population of patients.

Tables and Figures

Table 1: Characteristics of men and women after matching 3:1

Characteristics of the matched population		Men (n=316)		Women (n=107)	
		With explantation or revision N= 129	With no explantation or revision N= 187	With explantation or revision N= 40	With no explantation or revision N=67
Age (Mean +/- SD)		66.59 +/- 6.72	67.56 +/- 7.77	64.8 +/- 9	67.11+/- 7.91
Indication (n, %)	Post prostatectomy	106 (82.1)	165 (88.2)	0	0
	Gynecologic intrinsic sphincter deficiency	0	0	30 (75.0)	58 (86.6)
	Post TURP	20 (20.0)	19 (10.2)	0	0
	Post pelvic surgery (without prostatectomy)	2 (1.55)	0	3 (7.5)	2 (2.99)
	Post traumatic	1 (0.78)	2 (1.07)	7 (17.5)	7 (10.5)
	Post radiotherapy	0	1 (0.53)	0	0
Medical history	Radiotherapy	35 (27.1)	52 (27.8)	0	0
	No UI surgery	116 (90.0)	156 (83.4)	7 (17.5)	6 (9.0)
	1 UI surgery	11 (8.5)	25 (13.4)	15 (37.5)	31 (46.3)
	2 or more UI surgery	2 (1.55)	6 (3.2)	18 (45.0)	30 (44.8)
	Slings	2 (1.6)	2 (1.1)	27 (67.5)	44 (65.7)
	Adjustable compressive therapy (ACT)	11 (8.5)	21 (11.2)	4 (6.0)	5 (12.5)
Implantation	Less than 4cm	2 (1.6)	2 (1.07)	-	-
	4 cm	44 (34.1)	76 (40.6)	-	-
	4.5 cm	66 (51.2)	93 (49.7)	-	-
	Up than 4.5	13 (10.1)	12 (6.4)	-	-
	NA	4 (3.1)	4 (2.1)	-	-
Size of cuff (n,%)	Less than 6.5 cm	-	-	5 (12.5)	8 (11.9)
	6.5 cm	-	-	8 (20.0)	8 (11.9)
	7 cm	-	-	13 (32.5)	23 (34.3)
	7.5 cm	-	-	5 (12.5)	13 (19.4)
	8 cm	-	-	9 (22.5)	12 (17.9)
	Up than 8 cm	-	-	0	3 (4.5)

Table 2. Survival of the device without revision or explantation in primary and sensitivity analyses according to the Kaplan-Meier method

	Men			Women		
Primary analysis	N= 316			N = 107		
	n	**%**	IC95%	**n**	**%**	IC95%
Survival without Revision or Explantation						
At 5 years	**246**	71.2%	0.66-0.77	**96**	88.5%	0.82-0.95
At 10 years	**207**	46.9%	0.40-0.55	**80**	60.9%	0.50-0.75
At 15 years	**189**	14.1%	0.07-0.30	**67**	15.6%	0.06-0.40
Survival without Explantation						
At 5 years	**284**	86.1%	0.82-0.91	**102**	95.2%	0.91-0.99
At 10 years	**275**	79.2%	0.73-0.86	**98**	86.1%	0.77-0.96
At 15 years	**272**	71.8%	0.63-0.82	**95**	64.6%	0.43-0.97
Survival without Revision						
At 5 years	**279**	83.1%	0.78-0.88	**101**	92.9%	0.87-0.99
At 10 years	**248**	58.7%	0.51-0.68	**89**	70.0%	0.59-0.84
At 15 years	**233**	19.6%	0.09-0.42	**79**	22.8%	0.10-0.54
Sensitivity analyses						
Exclusion of patients with radiotherapy	N = 230			N = 107		
Survival without Revision or Explantation	**n**	%	IC95%	**n**	%	IC95%
At 5 years	**181**	72.8%	0.66-0.80	**96**	88.5%	0.82-0.95
At 10 years	**154**	49.8%	0.42-0.59	**80**	60.9%	0.50-0.75
At 15 years	**138**	15.1%	0.07-0.33	**67**	15.6%	0.06-0.40
Survival without Explantation						
At 5 years	**214**	90.4%	0.86-0.95	**102**	95.2%	0.91-0.99
At 10 years	**209**	85.5%	0.80-0.92	**98**	86.1%	0.77-0.96
At 15 years	**206**	75.2%	0.64-0.88	**95**	64.6%	0.43-0.97
Survival without Revision						
At 5 years	**197**	80.5%	0.75-0.87	**101**	92.9%	0.87-0.99
At 10 years	**175**	58.4%	0.50-0.68	**89**	70.0%	0.58-0.84
At 15 years	**162**	20.2%	0.09-0.43	**79**	22.8%	0.10-0.54
Exclusion of patients with IU surgery	N = 309			N = 59		
Survival without Revision or Explantation	**n**	%	IC95%	**n**	%	IC95%
At 5 years	**240**	71.0%	0.65-0.77	**53**	88.4%	0.80-0.98
At 10 years	**202**	46.9%	0.40-0.55	**45**	65.6%	0.52-0.83
At 15 years	**184**	14.0%	0.07-0.30	**37**	18.0%	0.06-0.56
Survival without Explantation						
At 5 years	**277**	85.9%	0.81-0.91	**57**	96.6%	0.92-1

At 10 years	**269**	79.7%	0.74-0.86	**56**	92.5%	0.84-1
At 15 years	**265**	80.2%	0.60-0.81	**54**	80.2%	0.64-1
Survival without Revision						
At 5 years	**273**	83.1%	0.78-0.88	**55**	91.4%	0.84-1.00
At 10 years	**243**	58.9%	0.51-0.68	**48**	69.8%	0.56-0.87
At 15 years	**228**	19.5%	0.09-0.42	**42**	22.1%	0.07-0.67

Figure 1: Flow diagram showing enrollment and matching of men and women in a study comparing long-term device survival after a first implantation of AMS800™ for stress urinary incontinence. (Adapted from CONSORT)

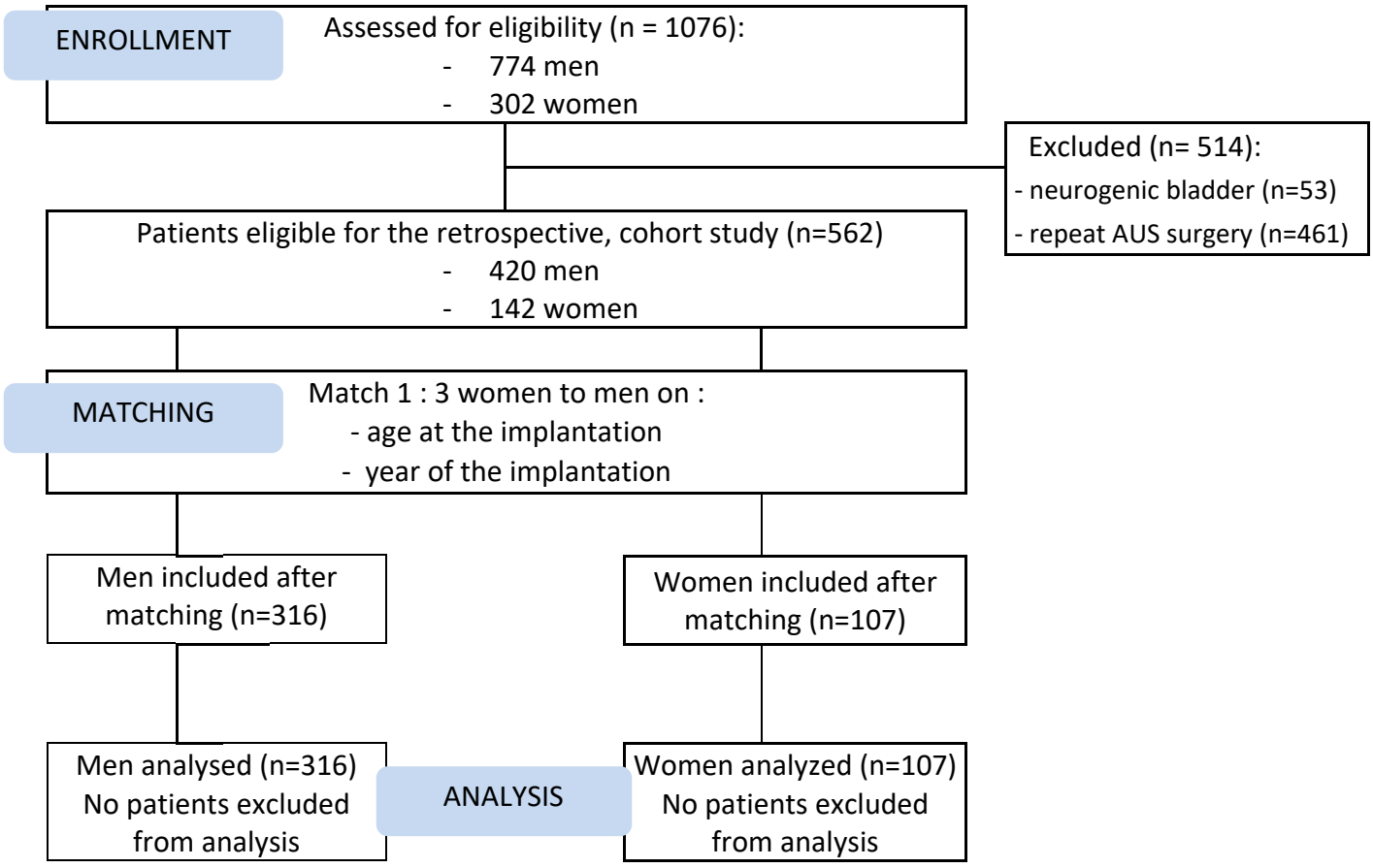
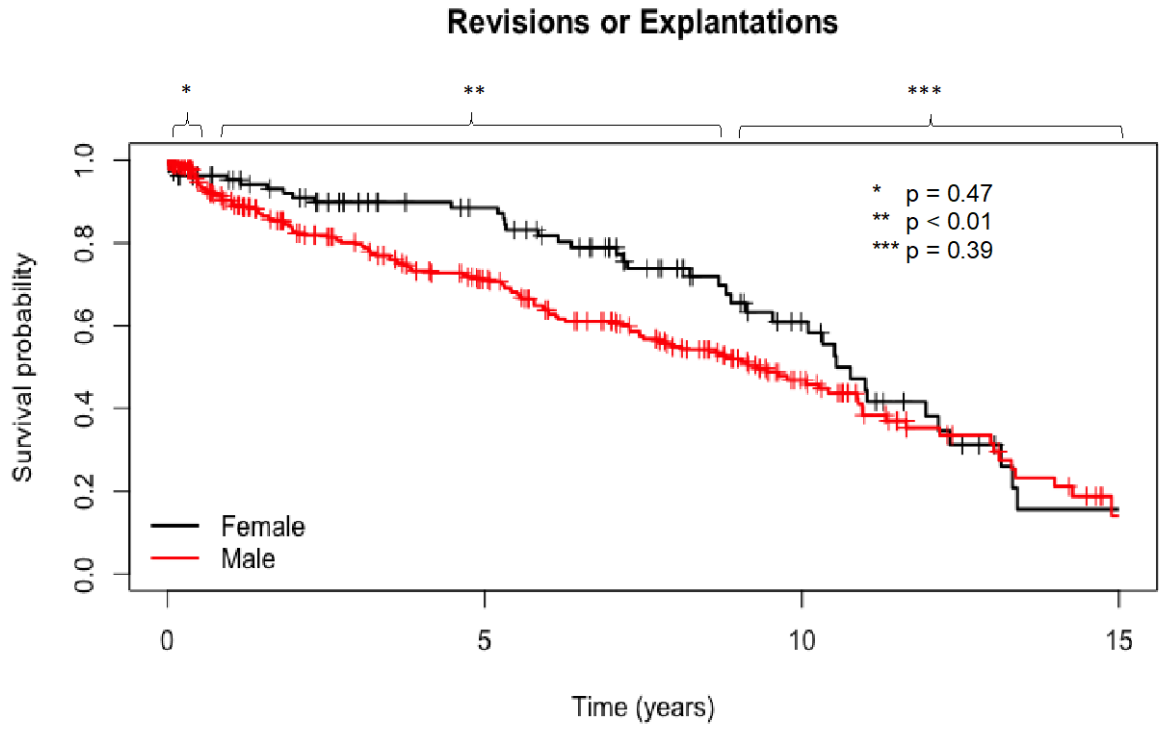
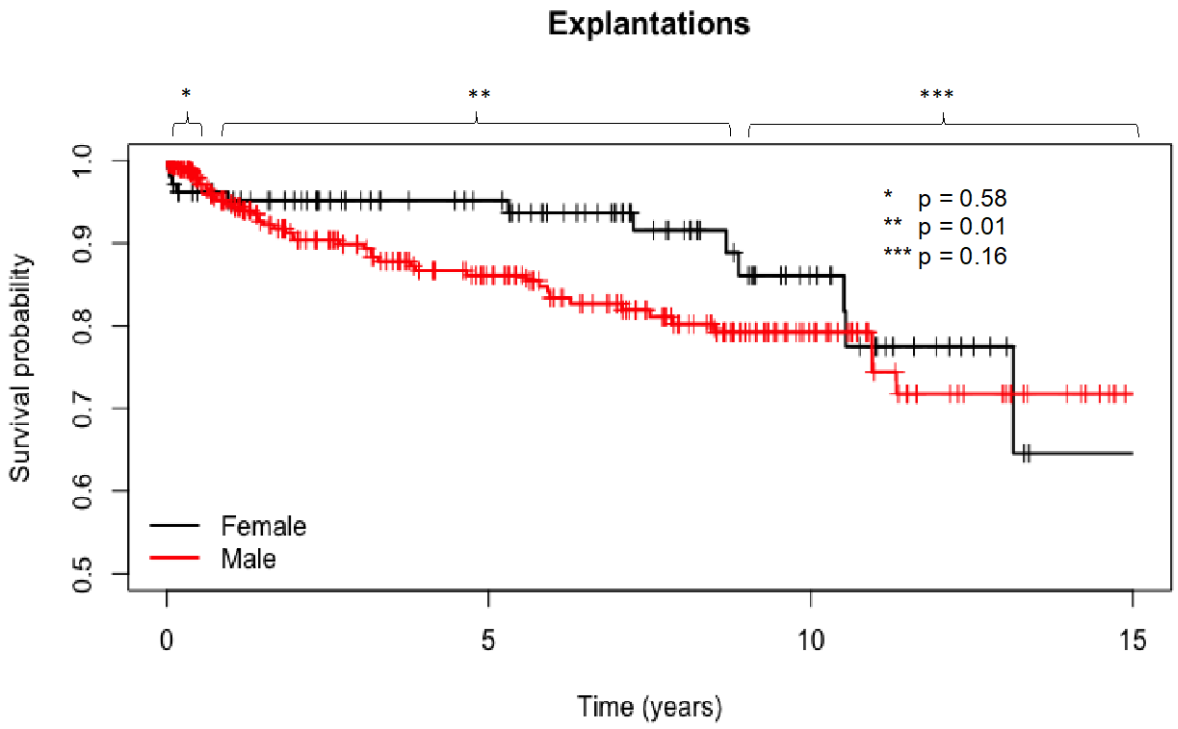


Figure 2: Kaplan-Meier curve for survival of the artificial urinary sphincter without revision or explantation



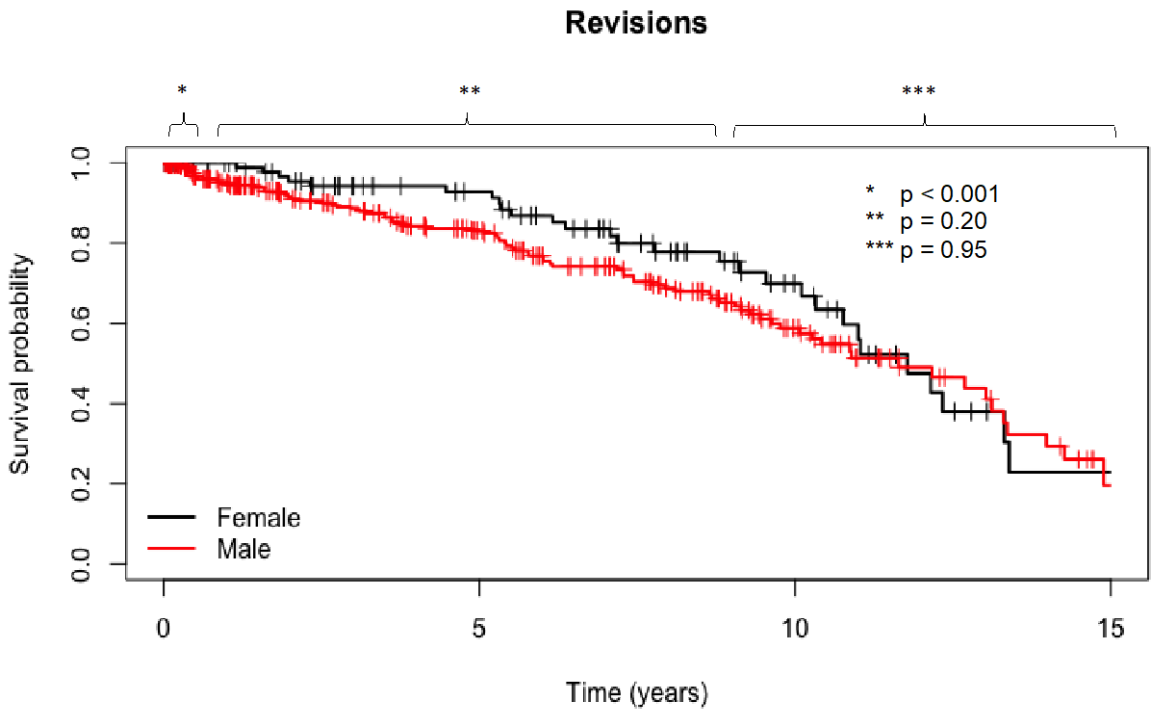
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
F	Nb at risk	107	102	98	97	97	96	91	89	86	82	80	75	72	70	67	67
	Event	5	4	1	0	1	5	2	3	4	2	5	3	2	3	0	0
M	Nb at risk	316	289	271	264	250	246	232	227	217	213	207	200	198	196	191	189
	Event	27	18	7	14	4	14	5	10	4	6	7	2	2	5	2	1

Figure 3: Kaplan-Meier curve for survival of the artificial urinary sphincter without explantation



		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
F	Nb at risk	107	102	102	102	102	102	101	101	100	98	98	96	96	96	95	95
	Event	5	0	0	0	0	1	0	1	2	0	2	0	0	1	0	0
M	Nb at risk	316	302	292	291	285	284	279	278	275	275	275	273	272	272	272	272
	Event	14	10	1	6	1	5	1	3	0	0	2	1	0	0	0	0

Figure 4: Kaplan-Meier curve for survival of the artificial urinary sphincter without revision.



		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
F	Nb at risk	107	107	103	102	102	101	97	95	93	91	89	86	83	81	79	79
	Event	0	4	1	0	1	4	2	2	2	2	3	3	2	2	0	0
M	Nb at risk	316	303	295	289	281	279	269	265	258	254	248	243	242	240	235	233
	Event	13	8	6	8	2	10	4	7	4	6	5	1	2	5	2	2

Appendix: Characteristics of patients in the initial population before matching 3:1

		Initial Population (n=562)		Matched Population (n = 423)	
		Men	Women	Men	Women
		n = 420	n = 142	n = 316	n = 107
With explantation or revision (n (%))		159 (37.9)	55 (38.7)	129 (40.8)	40 (37.4)
Age (Mean +/- SD)		68.12 +/- 7.5	61.9 +/- 11.2	67.2 +/- 7.4	66.3 +/- 8.4
Indication (n, %)	Post prostatectomy	364 (86.6)	0	271 (85.8)	0
	Gynecologic intrinsic sphincter deficiency	0	114 (80.3)	0	88 (82.2)
	Post TURP	49 (11.7)	0	39 (12.3)	0
	Post pelvic surgery (without prostatectomy)	3 (0.7)	7 (4.9)	2 (0.6)	5 (4.7)
	Post traumatic	3 (0.7)	21 (14.8)	3 (0.9)	14 (13.1)
	Post radiotheapy	1 (0.2)	0	1 (0.3)	0
Medical history (n,%)	Radiotherapy	115 (27.4)	0	87 (27.5)	0
	No UI surgery	367 (87.4)	19 (13.4)	272 (86.1)	13 (12.1)
	1 UI surgery	43 (10.2)	60 (42.3)	36 (11.4)	46 (43.0)
	2 or more UI surgery	10 (2.4)	63 (44.4)	8 (2.5)	48 (44.9)
	Slings	5 (1.2)	93 (65.5)	4 (1.3)	71 (66.4)
	Adjustable compressive therapy (ACT)	37 (8.8)	15 (10.6)	31 (9.8)	9 (8.4)
Implantation Size of cuff (n,%)	Less than 4cm	7 (1.7)	-	4 (1.3)	
	4 cm	160 (38.1)	-	120 (38.0)	
	4.5 cm	210 (50.0)	-	159 (50.3)	
	Up than 4.5	31 (7.4)	-	25 (7.9)	
	NA	12 (2.8)	0	8 (2.5)	0
	Less than 6.5 cm	-	17 (12.0)		13 (12.1)
	6.5 cm	-	25 (17.6)		16 (15.0)
	7 cm	-	44 (31.0)		36 (33.6)
	7.5 cm	-	26 (18.3)		18 (16.8)
	8 cm	-	25 (17.6)		21 (19.6)
	Up than 8 cm	-	5 (3.5)		3 (2.8)

Abbreviations

AUS	Artificial Urinary Sphincter
SUI	Stress Urinary Incontinence
UI	Urinary Incontinence
IFU	Instructions for Use
PRB	Pressure Regulation Balloon
SD	Standard Deviation
HR	Hazard Ratio

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Tables and Figures Legend

Figure 1: Flow diagram showing enrollment and matching of men and women in a study comparing long-term device survival after a first implantation of AMS800™ for stress urinary incontinence. (Adapted from CONSORT)

Figure 2: Kaplan-Meier curve for survival of the artificial urinary sphincter without revision or explantation

Figure 3: Kaplan-Meier curve for survival of the artificial urinary sphincter without explantation

Figure 4: Kaplan-Meier curve for survival of the artificial urinary sphincter without revision

Table 1: Characteristics of men and women after matching 3:1

Table 2. Survival of the device without revision or explantation in primary and sensitivity analyses according to the Kaplan-Meier method

Appendix: Characteristics of patients in the initial population before matching 3:1