World Journal of Urology (2019) 37:899–906
https://doi.org/10.1007/s00345-018-2448-7

ORIGINAL ARTICLE

Survival of the artificial urinary sphincter in a changing patient profile

M. J. te Dorsthorst[1] · M. J. van der Doelen[1] · F. Farag[1] · F. M. J. Martens[1] · J. P. F. A. Heesakkers[1]

Received: 10 May 2018 / Accepted: 12 August 2018 / Published online: 28 August 2018

Abstract

Purpose To examine the functional survival of the artificial urinary sphincter (AUS) AMS800 in a changing patient population. Because of increasing experience and dexterity of the operating team, we hypothesize that patients with known risk factors nowadays have a better survival of their prosthesis. However, due to a change to a more complex case mix, overall results appear to be worse.

Materials and methods All men who underwent implantation of an AUS between 2001 and 2016 because of urethral sphincter deficiency were retrospectively analyzed. Patients were divided in groups based on date of surgery and number of patients: 2001–2009 (G1), 2010–2013 (G2), 2014–2016 (G3). Baseline characteristics and additional therapies prior to implantation were analyzed in all groups. Risk factors for failure only in G1 and G2. Revision or explantation of the AUS was used as endpoint. Kaplan–Meier analysis was used to calculate survival of the device.

Results A total of 129 patients (mean age 72 ± 9 years) underwent 129 primary implants, and 11 secondary implants. Median follow-up was 5.74 years in G1, 3.26 years G2 and 1.54 years G3. Approximately 25% of the patients in G1 had received adjuvant therapy for prostate cancer and 14% underwent previous surgery for incontinence. In G2, 51 and 55% underwent adjuvant therapy for prostate cancer and previous surgery for incontinence, respectively, G3 was comparable. The overall 50% survival improved in patients with radiotherapy and previous incontinence surgery in G2 as compared to G1.

Conclusions Despite the more complex patient population, the survival of the AUS did not decrease. In some patient categories, the AUS functional survival is even still improving over the past few years.

Keywords Artificial urinary sphincter · Stress urinary incontinence · Male · Surgery of implant · Non-neurogenic

Introduction

The results of male stress urinary incontinence (SUI) surgery have continued to improve after the artificial urinary sphincter (AUS) was first introduced by Scott et al. in 1972 [1]. The AUS underwent several improvements and nowadays has a success rate of about 88% for improving post-prostatectomy incontinence, of whom 73% achieve total continence [2]. It is considered the gold standard for treating non-neurogenic male SUI [3, 4].

Our department has experience with the AUS since 1977. Over the past years, we observed a change in patient profiles with respect to earlier treatments for SUI and additional treatments for prostate cancer. We also saw a change in functional survival of the AUS. We were questioning ourselves why in certain patient groups the AUS survival had decreased. Potential risk factors for revision and failure are additional therapy for prostate cancer, previous urethral surgery for incontinence, diabetes mellitus and neurogenic etiology [5].

The surgical team including urologist and scrub nurses has been the same for 15 years and the safety procedures on the operation room have developed to more severe rules with strict adherence to protocols. Therefore, we expected better results during recent years. To have more insight, we analyzed our AUS series and tried to define causes that could influence the functional survival of the AUS.

✉ M. J. te Dorsthorst
mj.tedorsthorst@gmail.com

[1] Radboud University Medical Center, Nijmegen, The Netherlands

Materials and methods

All men who underwent implantation of an AMS800™ AUS (Boston Scientific Corporation USA) between January 2001 and October 2016 because of sphincter deficiency were retrospectively evaluated. Patients were put in three groups based on the date of surgery: 2001–2009 (G1), 2010–2013 (G2) and 2014–October 2016 (G3). Baseline criteria, additional therapy for prostate cancer and for incontinence or for urethral problems, survival of the AUS and comorbidities were extracted from patient files. Risk factors for failure of the AUS were analyzed in G1 and G2 separately. Risk factors for shortening of the survival of the AUS are listed in Table 1 [5]. Both G1 and G2 had almost similarly number of patients. The revision-free survival period could only be calculated for G1 and G2, because of the smaller sample size of G3 and the shorter period of follow-up. Statistical analysis was performed using SPSS 22.0 (SPSS, Chicago, IL). Kaplan–Meier curves were used to estimate the survival of the device. Revision or explantation of the AUS was used as survival endpoint. For all survival curves, the 50% survival time of the AUS in each group was determined. This study was approved by the local medical ethics review committee. The principles of the Helsinki Declaration were followed.

Table 1 Risk factors associated with shortening of survival of AUS

Risk factors for shortening of the AUS survival
Neurogenic etiology
Adjuvant therapies and/or pre-AMS urethral stricture
Diabetes mellitus
Previous urethral surgery for incontinence

Results

From January 2001 to October 2016, a total number of 129 patients (age 72 ± 9 years) underwent 308 procedures: 129 times a primary implant was done, 11 times a secondary implant after earlier removal was performed, and 168 times a revisions of one or more components of the AUS was done. The median follow-up was 5.74 years in the group 2001–2009, 3.26 years in the group 2010–2013. All patients were followed until explantation/revision or 30th January 2017. There was an increase in number of patients with known risk factors for shortening of the revision-free survival period of the AUS besides diabetes mellitus and patients with strictures preoperative. 25% of the patients in G1 had had received additional therapy for prostate cancer and 14% underwent previous surgery for incontinence. In G2, 51 and 55% underwent additional therapy for prostate cancer and previous surgery for incontinence, respectively. In G3, 45% underwent additional therapy for prostate cancer and 45% had had previous urethral surgery. Baseline,

Table 3 Additional therapies before placement of AUS in both patient groups

	2001–2009 $n=57$ (%)	2010–2013 $n=54$ (%)	2014–2016 $n=29$ (%)
Adjuvant therapies	25	52	45
Radiotherapy	17.5	29.6	27.6
Chemotherapy	1.8	1.9	–
Hormonal therapy	5.3	16.7	17.2
Cryotherapy	–	3.7	–
Previous incontinence surgery	14	55	45
Sling	7	33.3	34.5
Flowsecure	–	5.6	–
ProAct	7	7.4	3.4
Multiple	–	9.3	6.9
Endoscopic urethrotomy	16	17	10

Table 2 Baseline characteristics for patients in different group

	2001–2009	2010–2013	2014–2016
Number of implanted AUS	57	51	29
Age	76	75	68
Median follow-up in years	5.74	3.26	1.54
Etiology of incontinence			
RRP	78.9%	75.9%	86.2%
TURP	14.0%	16.7	10.3%
Neurogenic	5.3%	3.7%	3.4%
Others	1.8%	3.7%	–
Diabetes mellitus	17.5%	16.7%	17.2%
Preoperative urethral stricture surgery	15.8%	16.7%	10.3%

demographic characteristics and additional treatments are listed in Tables 2 and 3.

The revision-free estimated overall survival of the AUS in G1 and G2 ($n=111$) was 5.46 years (Fig. 1a). The 50% revision-free survival of G1 ($n=57$) and G2 ($n=54$) separately (Fig. 1b) was 5.61 and 5.19 years, respectively. G3 ($n=29$) was not included because of a smaller sample size and a shorter period of follow-up.

Subsequently revision-free survival was determined in patients with risk factors for shortening of the survival of the AUS in G1 and G2. The revision-free survival in all patients with preoperative an urethral stricture in G1 ($n=9$) was 2.64 versus 1.28 years in G2 ($n=9$) (Fig. 2a, $p=0.939$). The 50% survival of the AUS in G1 ($n=10$) in patients with diabetes mellitus was 3.02 years in contrast to 2.32 years in G2 ($n=9$). p value is 0.535.

Survival of the AUS in patients with previous incontinence surgery was also assessed (Fig. 3a). Patients who underwent placement of a sling, Flowsecure and/or ProAct were included. In G2 ($n=30$), we found an 50% survival of 2.89 versus 1.106 years in G1 ($n=8$), p value is 0.411. Analysis between the different types of previous incontinence surgery could not be done because of small sample size (Sling; G1 $n=4$ and G2 $n=18$).

Likewise, the survival of the AUS in patients with adjuvant anticancer therapy (Fig. 3b) was calculated. In G1

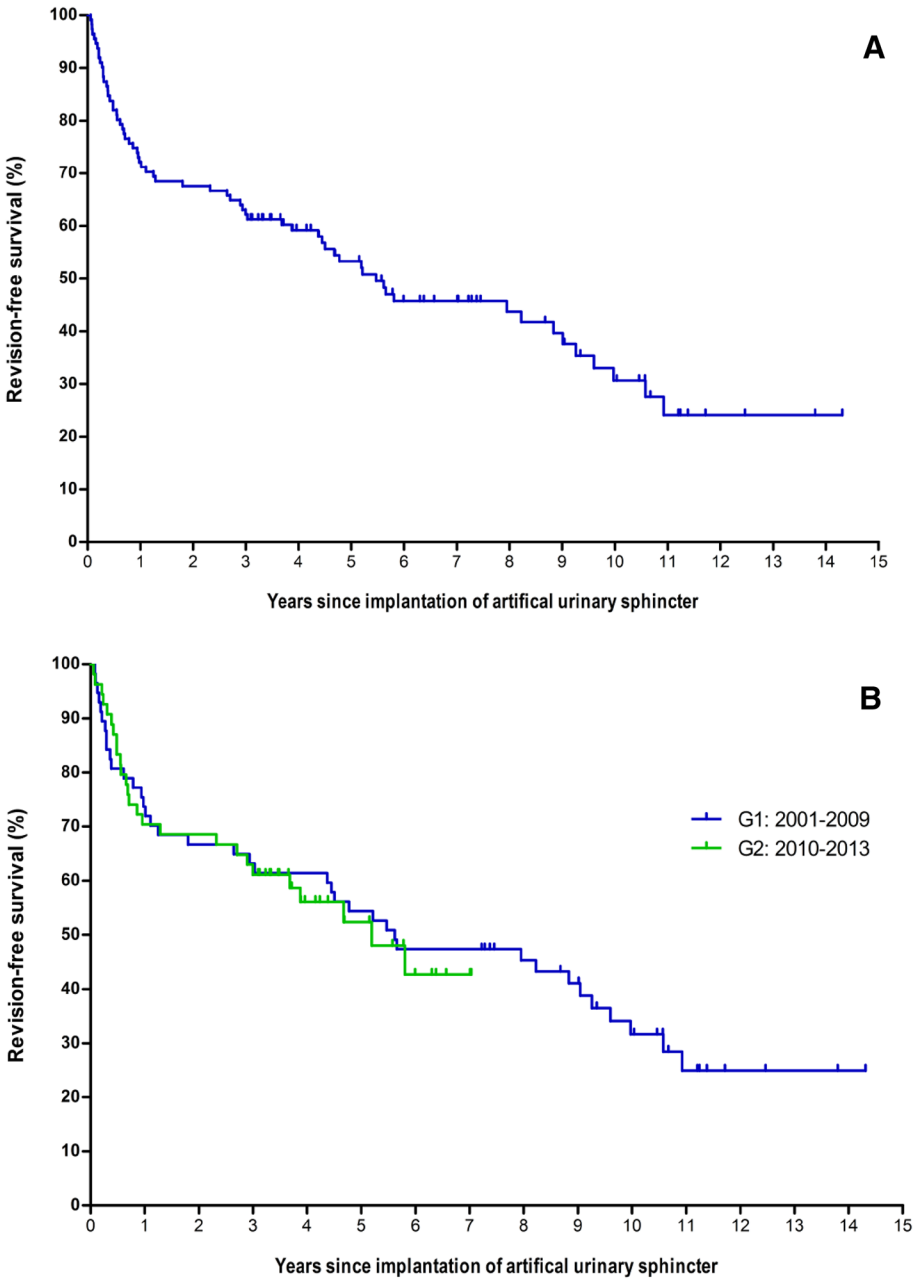


Fig. 1 **a** Revision-free estimated survival of AUS in G1 and G2 ($n=111$). **b** Revision-free estimated survival of AUS in G1 ($n=57$) and G2 ($n=54$)

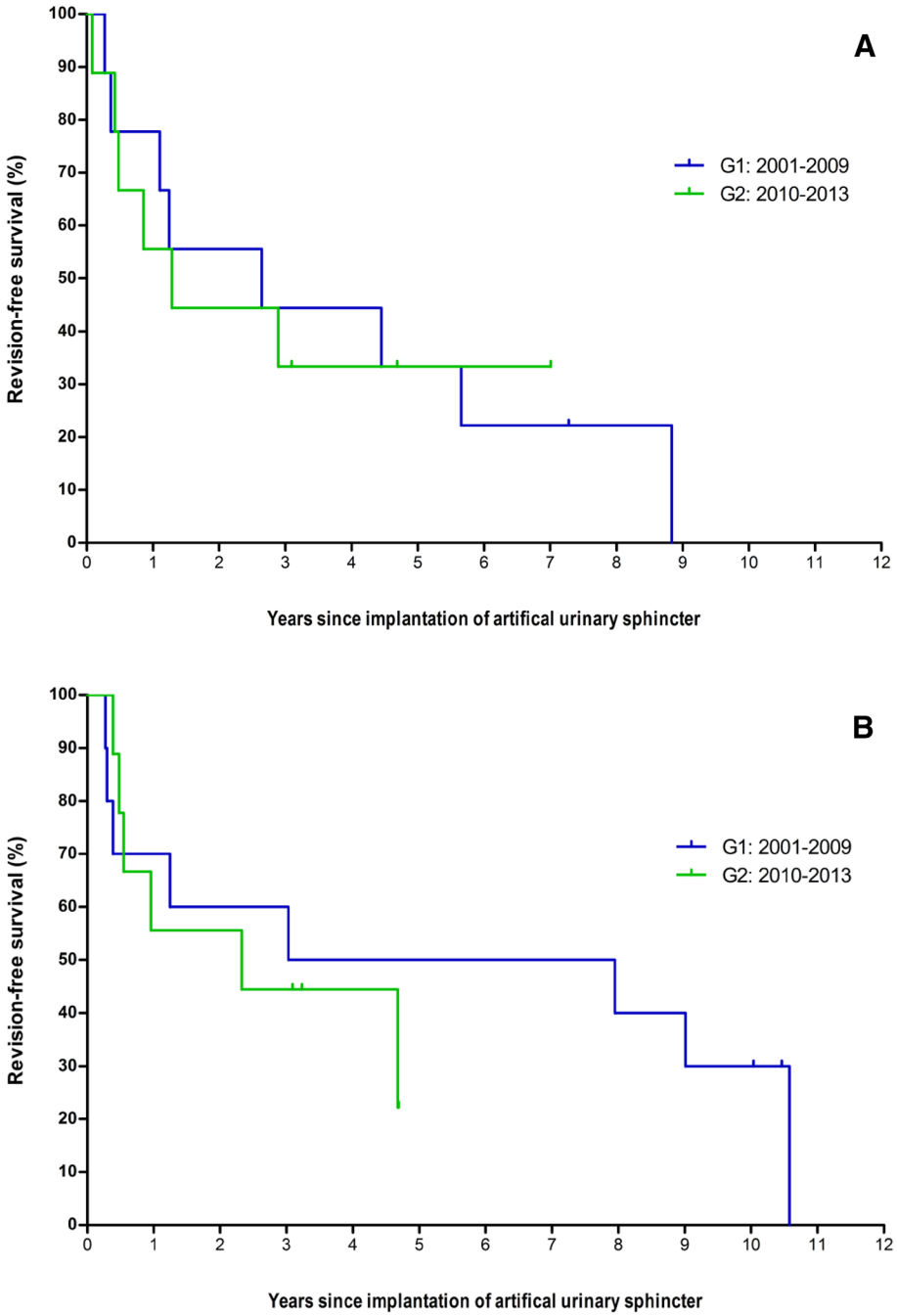
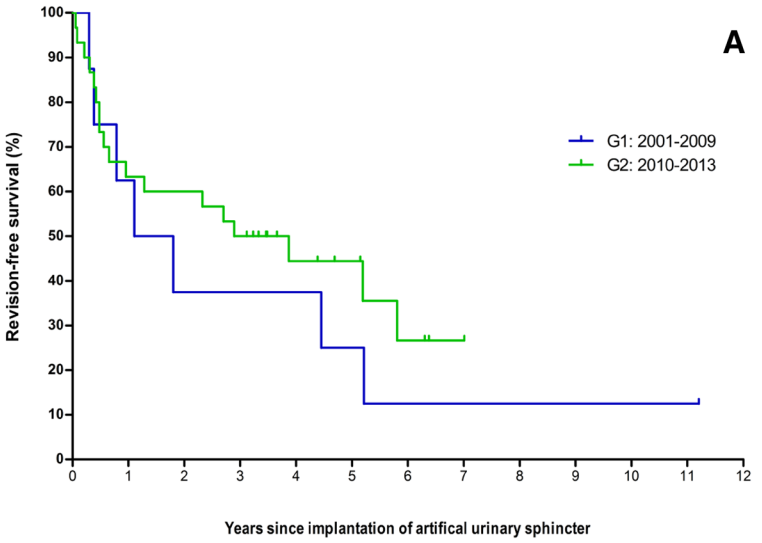
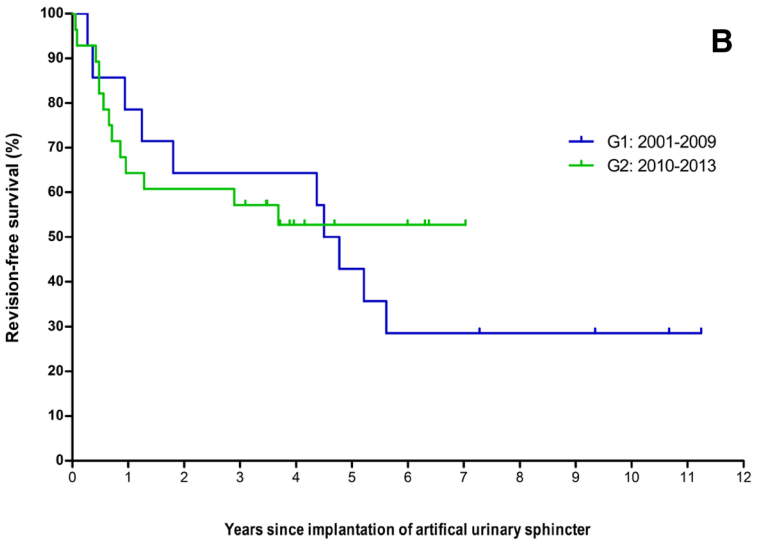


Fig. 2 **a** Revision-free estimated survival of AUS in all patients with preoperative urethral stricture defined in G1 ($n=9$) and G2 ($n=9$). **b** Revision-free estimated survival of AUS in all patients with diabetes mellitus defined in G1 ($n=10$) and G2 ($n=9$)

($n=14$), the 50% survival for patients with adjuvant cancer treatment was 4.5 years. However, in G2 ($n=28$), the 50% survival period has not yet been reached ($p=0.726$). Figure 3c shows the survival of patients with adjuvant radiotherapy only. They did not receive any other additional cancer therapy such as chemotherapy or hormonal therapy. In G1 ($n=10$), the 50% survival is 1.80 years, in G2 ($n=16$) the 50% survival period has not yet been reached, but already improved compared to G1 ($p=0.160$). As well as in the group of previous incontinence surgery, further subdivision apart from radiotherapy was not done, because of small sample size (i.e., chemotherapy, hormonal therapy and cryo therapy).

Finally, we determined the revision-free estimated survival of the artificial urinary sphincter. The survival of the AUS was higher if risk factors were excluded. Known risk factors for shortening survival of the AUS are anticancer treatment (i.e., radiotherapy, chemotherapy), previous urethral surgery (i.e., sling), neurogenic etiology and diabetes mellitus (5). G1 and G2 were compared and there was no negative difference in survival for G2 ($n=7$). In G2 the





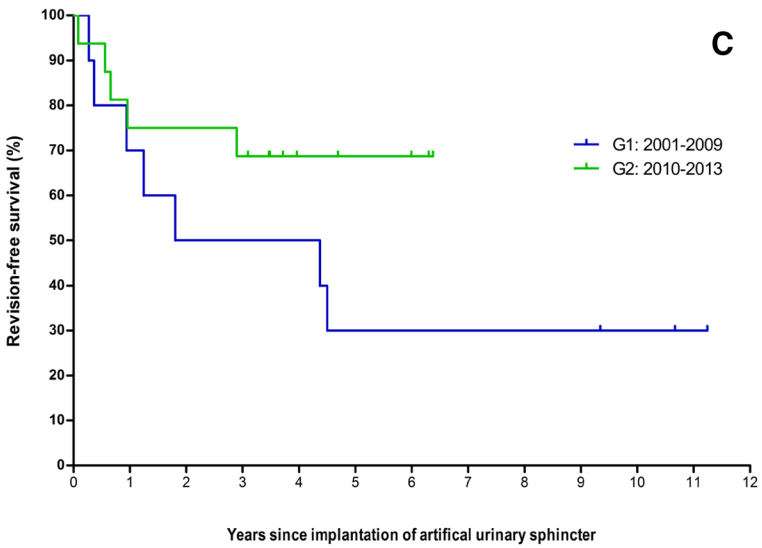


Fig. 3 **a** Revision-free estimated survival of AUS in all patients with previous incontinence surgery in G1 ($n=8$) and G2 ($n=30$). **b** Revision-free estimated survival of AUS in all patients with adjuvant anti-cancer treatment in G1 ($n=14$) and G2 ($n=28$). Figure 3 **c** Revision-free estimated survival of AUS in all patients with adjuvant radiotherapy only in G1 ($n=10$) and G2 ($n=16$)

50% survival has not yet been reached, in G1($n=29$) this is 8.83 years (Fig. 4).

Discussion

Rates of incontinence after surgery for benign diseases are similar across the various treatment modalities, but were slightly higher after open prostatectomy for benign disease, ranging from 0 to 8.4% according to international consultation on incontinence [6]. The incidence of incontinence after radical prostatectomy for malign disease has been a source of controversy because reported rates varied greatly from 0.8 to 87% [7–13].

Treatment for SUI starts with first-line conservative treatments; these include pelvic floor muscle training with or without biofeedback, electrical stimulation, lifestyle adjustments and external penile compression [13]. In patients with persistent SUI after conservative treatment surgery is recommended. At present, AUS is the gold standard for surgical treatment of persistent moderate and severe SUI [3, 4].

Although the AUS is the gold standard for SUI in men, it is not perfect. Limitations of the AUS are the requirement of manual dexterity to operate the device, experienced surgeons, a pre-set geometry in the cuff diameter and the inability to alter the cuff pressure and to correct for delayed tissue atrophy without further surgery [14, 15]. In the past decade, several minimal invasive treatment options for SUI have been developed, because of these limitations of the AUS.

Over the years, the number of therapies for prostate cancer has increased. These therapies include more aggressive local therapy and early combinatory therapy in patients with high-risk metastatic hormone-sensitive prostate cancer. Mostly because of implementation of new guidelines based on research for early additional therapies in patients with prostate cancer, for example, implementation of STAMPEDE [16] or early radiotherapy [17]. These implementations will result in a more diverse patient population in future.

Data were analyzed because we experienced an increase in revisions after AUS implantation over the past few years in our center. We expected the opposite and wondered what the cause of the increase in revisions was. Our team had gained more experience, operating room (OR) routine to prevent surgical infections had become more strict over the years and operative technique stayed the same. Hence, we analyzed the change in patient profile over time. Known risk factors for AUS survival shortening are radiotherapy, prior explantation for infection/erosion, prior urethroplasty, prior sling, prior tandem cuff, post implantation urinary retention, history of bladder neck contractures/procedures, and history of Urolume stent placement [18]. We found a decreasing trend in the number of patients who did not have any risk factors for shortening survival of the AUS. In G1, there were 29 patients without any risk factors for shortening of the survival, compared to seven patients in G2. Though there was no significant difference in survival in G2 comparing to G1 or vice versa, which means the AUS survival of patients without risk factors has not changed over the past few years. However, we found an increase in patients with previous incontinence surgery and/or adjuvant prostate cancer therapy. This is in line with the trend that shows when patients present with incontinence because of treatment for prostate cancer,

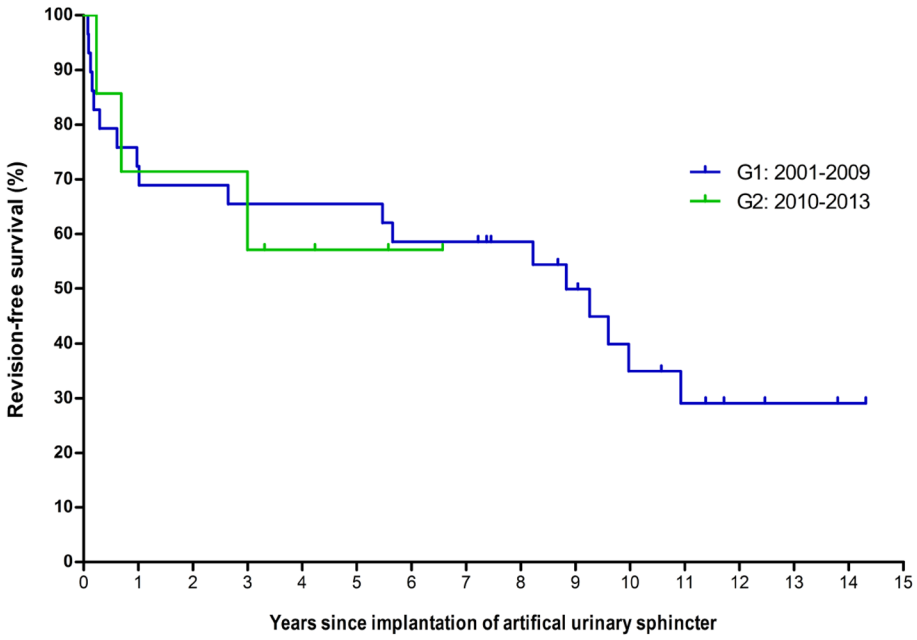


Fig. 4 Revision-free estimated survival of AUS after correction for risk factors

they often had multiple additional treatments for prostate cancer and/or for the complications of the prostate cancer treatments. Patients might have undergone several additional treatments after radical prostatectomy (i.e., cryotherapy, radiotherapy, hormonal deprivation therapy) and there are several options for correcting urinary incontinence caused by radical prostatectomy (i.e., Sling, Pro Act Balloon or Flowsecure). Altogether, patients nowadays are more complex based on their medical history (previous cancer therapy, previous incontinence surgery, DM).

Despite the change in patient population, as described above, we observed an improvement of revision-free period in some groups with risk factors. For instance, radiotherapy is a risk factor for shortening survival of the AUS. Radiotherapy targeted at the prostate invariably induces urethral changes, alters bladder wall structure and detrusor function [19, 20]. Nevertheless, we observed improvement in survival of the AUS over the past few years after adjuvant radiotherapy. This is in accordance to the outcomes of a retrospective review of Gomha and Boone [21]. Jhaver et al. also concluded radiotherapy does not alter the functionality (incontinence rates) and outcomes (rate of sphincter revision, erosion, infection and removal) [22]. On the contrary, Guillaumier et al. found significant differences in the radiation group. In their series, the continence rate was 56% in contrary to 89% who did not had radiotherapy after prostatectomy [23]. We demonstrated functional survival is improving over the years in patients with prior radiotherapy (Fig. 3).

Ziegelman et al. described that patients who underwent a male urethral sling for the treatment of SUI prior to primary AUS placement had no significant difference in overall 3-year survival than those patients without a prior sling procedure [24]. Our study shows a significant improvement of the survival-free period in G2 after previous incontinence surgery. Most of the patients who underwent incontinence therapy before implantation of an AUS received a sling prior to an AUS. This means the outcome in patients undergoing AUS placement after prior sling implantation is still a viable option.

This analysis has shown that the patient population is changing over the past few years. We observed a more complex patient population due to more diverse additional therapies for prostate cancer and previous incontinence therapy. However, the revision-free period was not affected in patients without risk factors. In addition, we identified that implantation of an AUS adjuvant radiotherapy and previous incontinence surgery has better outcomes nowadays. On the other hand, we found that patients who underwent multiple incontinence surgeries prior to implantation of an AUS have shorter AUS survival. Unfortunately not in every one urodynamics were done and the existence of smoking was not assessed as well as an objective measure of incontinence severity. This could have provided a better clarification of the outcome.

This study is, to the best of our knowledge, unique because of the longitudinal character. We did not use any time-points for follow-up. For that reason we can compare the groups over a longer time of follow-up. Conclusions for the clinical setting are: patients with prior incontinence surgery or radiotherapy could expect an improved revision-free survival comparing to a couple of years ago. However, when patient did have more treatments for incontinence prior to implantation of the AUS, we still expect a shorter revision-free overall survival. This is valuable information for the counseling of patients prior to implantation of an AUS.

The limitations of this study are the retrospective character, the single-surgeon cohort and the small number patients in the subgroups. Therefore, prospective, longer term, higher volume and possibly multi-institutional studies are warranted. The ongoing Saturn study from the European Association of Urology (EAU) Research Foundation is a very good step to achieve this [25].

Conclusion

Despite the changing patient population, where patients do have a more complex medical history, the survival of the artificial urinary sphincter is not decreasing. After correction for risk factors there is a stable revision-free survival period since 2001. In some patient categories (previous radiotherapy or a male sling), the AUS function survival is even still improving over the past few years.

Author contributions MJD data collection or management, data analysis, manuscript writing/editing. MJD manuscript writing/editing, data analysis. FF data collection or management. FMJM manuscript writing/editing. JPFAH protocol/project development.

Compliance with ethical standards

Conflict of interest None declared.

Research involving human participants and/or animals The study was approved by the ethical committee of RadboudUMC.

Informed consent Informed consent was obtained from all patients.

References

1. Scott FB, Bradley WE, Timm GW (2002) Treatment of urinary incontinence by an implantable prosthetic urinary sphincter. 1974. J Urol 167:1125
2. Hajivassilou CA (1999) A review of the complications and results of the implantation of the AMS artificial urinary sphincter. Eur Urol 35:36–44

3. Van Bruwaene S, De Ridder D, van der Aa F (2015) The use of sling vs. sphincter in post-prostatectomy urinary incontinence. BJU Int 116:330–342
4. Bauer RM, Gozzi C, Hubner W et al (2011) Contemporary management of postprostatectomy incontinence. Eur Urol 59:98596
5. Farag F, van der Doelen M, van Breda J, D'Hauwers K, Heesakkers J (2016) Decline in artificial urinary sphincter survival in modern practice—do we treat a different patient? Neurourol Urodyn 9999:1–6
6. Buckley BS, Lapitan MCM, Epidemiology committee of the fourth International Consultation on Incontinence, Paris, 2008 (2010) Prevalence of urinary incontinence in men, women, and children—current evidence: findings of the fourth International Consultation on Incontinence. Urology 76(2):265–270
7. Augustin H, Pummer K, Daghofer F, Habermann H, Primus G, Hubmer G (2002) Patient self-reporting questionnaire on urological morbidity and bother after radical retropubic prostatectomy. Eur Urol 42(2):112–117
8. Burkhard FC, Kessler TM, Fleischmann A, Thalmann GN, Schumacher M, Studer UE (2006) Nerve sparing open radical retropubic prostatectomy–does it have an impact on urinary continence? J Urol 176(1):189–195
9. Haab F, Yamaguchi R, Leach GE (1996) Postprostatectomy incontinence. Urol Clin North Am 23(3):447–457
10. Penson DF, Mc Lerran D, Feng Z, Li L, Albertsen PC, Gilliland FD, Hamilton A, Hoffman RM, Stephenson RA, Potosky AL, Stanford JL (2005) 5-year urinary and sexual outcomes after radical prostatectomy: results from the prostate cancer outcomes study. J Urol 173(5):1701–1705
11. Sacco E, Prayer-Galetti T, Pinto F, Fracalanza S, Betto G, Pagano F, Artibani W (2006) Urinary incontinence after radical prostatectomy: incidence by definition, risk factors and temporal trend in a large series with a long term follow-up. BJU Int 97(1234–124):1
12. Veenema RJ, Gursel EO, Lattimer JK (1977) Radical retropubic prostatectomy for cancer: a 20-year experience. J Urol 117(3):330–331
13. Walsh PC, Jewett HJ (1980) Radical surgery for prostatic cancer. Cancer 45:1906–1911
14. Campbel SE, Glazener CMA, Hunter KF, Cody JD, Moore KN (2012) Conservative management for postprostatectomy urinary incontinence. Cochrane Database Syst Rev 1:CD001843
15. Chung E, Ranaweera M, Cartmill R (2012) Newer and novel artificial urinary sphincters (AUS): the development of alternatives to the current AUS device. BJU Int 110:5–11
16. James ND et al (2016) STAMPEDE investigators. Addition of docetaxel, zoledronic acid, or both to first-line long-term hormone therapy in prostate cancer (STAMPEDE): survival results from an adaptive, multiarm, multistage, platform randomised controlled trial. Lancet 387(10024):1163–1177
17. Shaikh MP, Alite F, WU MJ, Solanki AA, Harkenrider MM (2017) Adjuvant radiotherapy versus wait-and-see strategy for pathologic T3 or margin-positive prostate cancer: a meta-analysis. Am J Clin Oncol 41(8):730–738
18. Mock S, Dmochowski RR, Brown ET, Reynolds WS, Kaufman MR, Milam DF (2015) The impact of urethral risk factors on transcorporal artificial urinary sphincter erosion rates and device survival. J Urol 194(6):1692–1696
19. Martins FE, Boyd SD (1995) Artificial urinary sphincter in patient following major pelvic surgery and/or radiotherapy: are they less favourable candidates? J Urol 153:1188
20. Manunta A, Guille F, Patard JJ et al (2000) Artificial sphincter insertion after radiotherapy: is it worthwhile? BJU Int 85:490
21. Gomha MA, Boone TB (2002) Artificial urinary sphincter in patients with post-prostatectomy incontinence in men who had prior radiotherapy; a risk and outcome analysis. J Urol 167:591–596
22. Jhavar S, Swanson G, Deb N, Littlejohn L, Pruszynski J, Machen G, Milburn P, Bird E (2017) Durability of artificial urinary sphincter with prior radiation therapy. Clin Genitourin Cancer 15(2):e175–e180
23. Guillaumier S, Solomon E, Jenks J, Pakzad M, Hamid R, Ockrim J, Greenwell T (2017) Radiotherapy is associated with reduced continence outcomes following implantation of the artificial urinary sphincter in men with post-radical prostatectomy incontinence. Urol Ann 9(3):253–256
24. Ziegelmann MJ, Linder BJ, Rivera ME, Viers BR, Elliot DS (2016) The impact of prior urethral sling on artificial urinary sphincter outcomes. Can Urol Assoc J 10(11–12):405–409
25. Hamid R. SATURN: prospective registry for patients undergoing surgery for male stress urinary incontinence in multiple European centres. EAU-RF 2016-01